

# Proposed Revision of the National Gene Technology Scheme for Australia

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## Abstract

Plant breeding was provided access to wider genetic variation through genetic modification (GM) of crops in the 1980s. This involved transfer of DNA between species, and introduction of new traits into domestic crops. Concerns were raised for the outcomes in food health and in the environment with GM crops, with the spectre of ‘Frankenstein’ foods and fear of the unknown. This led to widespread adoption of GM regulations based on the ‘Precautionary principle’ of safeguarding the risks to health and to the environment, even when scientific evidence was lacking to support these concerns. The Green lobby required GM foods to be safe for consumption, with no ill-effects over the long term and for many generations into the future. GM foods have proven safe for over two decades, and with benefits to crop productivity, pest and disease resistances, improved nutrition and tolerances of extreme climatic stresses. GM includes the new biotechnology of Genome Editing (GE), with targeted and precise changes to gene sites, and inter-specific transfer of genes from poorly accessible Crop Wild Relatives (CRW), for adaptation of crops to climate change. Food and fibre crops need to be exempt from GM regulations.

**Keywords:** Regulation, genetic modification, genome editing, crops, climate change, crop wild relatives

## 1. Introduction

As outlined by Redden [1], Australia’s cultivation of GM crops in 2015 comprised herbicide-tolerant canola 444,000 ha, stacked GM (herbicide-tolerant plus pest resistant) cotton 253,000 ha, and herbicide tolerant only cotton 20,000 ha [2, 3].

With GM cotton pesticides have been substantially reduced, benefiting human safety, adjacent livestock enterprises and the environment, plus improving yields [4–6]. Herbicide resistant canola both controlled weeds and raised yields [5, 7]. These GM crops can be grown with minimum tillage, thereby conserving soil moisture for crop maturation in the low rainfall Southern cropping zone where every mm saved is 20 kg/ha or more grain [8]! Herbicide weed control allows earlier sowing to better match crop growth with seasonal winter rainfall.

South Australia (SA) was the last mainland state to have a moratoria on GM crops [1]), scheduled to 2025 but now lifted as recommended by Anderson [9]. The moratoria cost the canola industry \$33 million over 2004–2018. Australian GM

canola with a 10% yield benefit, suffered no adverse international market advantage compared with non-GM canola except for Japan, which paid an estimated price premium of \$32/tonne (about 7%) for GM free (zero adventitious contamination) canola from Kangaroo Island (KI) in SA [9]. This entailed segregation of non-GM from GM canola in the delivery-chain with identity protocols and codes of practice. The moratoria was kept for KI crops, and the market chain for KI produce will remain segregated.

In Tasmania GM crops have been banned since 2001 [10]. This is supported by the horticulture and honey industries maintain Tasmania's image for pure GM free produce.

## **2. Issues**

### **2.1 Regulation of GM crops in Australia**

The National Gene Technology Scheme (NGTS) in Australia was enabled by the Gene Technology Act 2000. Regulation is administered by the Office of the Gene Technology Regulator (OGTR), to apply a process based 'Precautionary' approach to any kind of directed genetic alteration [1, 11], specifically DNA transfer between species.

The object of the Act for all living organisms is: *'To protect the health and safety of people, and to protect the environment, by identifying risks posed by gene technology, and by managing those risks through regulating 'dealings' with GMOs'.*

OGTR authorises the release of GM crops in coordination with other agencies; Food Safety Australia and New Zealand (FSANZ), the Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, National Industrial Chemical Notification and Assessment Scheme, Department of Agriculture and Water Resources, and Department of the Environment and Energy [11, 12].

CRISPR Genome Editing (GE) is able to alter genetic expression without transfer of new genetic material with the SDN1 procedure, as a more advanced version of GM. OGTR has made a recent incremental change to a 'Principles based' flexible approach, with recognition of the SDN 1 with a product history of low risk [4, 11, 12]. However OGTR risk assessment and oversight remain, plus the regulations of complementary agencies.

SDN 1 genome editing is classified as GM/GE under 'Notifiable Low Risk Dealings' (NLRD) [11, 12]. NLRD products cannot be released to the environment without OGTR approval, and must be compliant with OGTR regulations for transport, storage and disposal, while GM field trials have to be registered and isolated [11]. NLRDs must be approved by the Institutional Biosafety Committee (IBC) and OGTR [11, 12]. Costs apply for administration, risk assessment and management.

OGTR requires that GM/GE crop development must undergo detailed case-by-case assessment of risks to food safety and to the environment, with research and development conducted in contained facilities; this is expensive research [13, 14]. This is based on the 'Precautionary' principle, rather than 'Outcome' based with recognition of benefits to society and the environment.

The science of gene technology is poorly understood publicly, enabling the Green lobby to demonise GM for socio-economic reasons or to challenge details of a scientific study [15, 16], or now to raise fears that SDN 1 GE is GM in disguise, so allowing GM foods to be unlabelled and hidden from the public [17, 18].

The anti-GM lobby is well funded in USA through tax deductions to 'organic' and environmental groups [19, 20]. Anti-GM protesters have destroyed GM field trials in UK and Australia, and with non-scientific health and environmental claims supported risk regulation of GM crops and discouraged developing countries from approving GM crops [18, 19, 21, 22]. Organic certification demands no GM products, so that the organic industry has a large vested interest in denigrating GM.

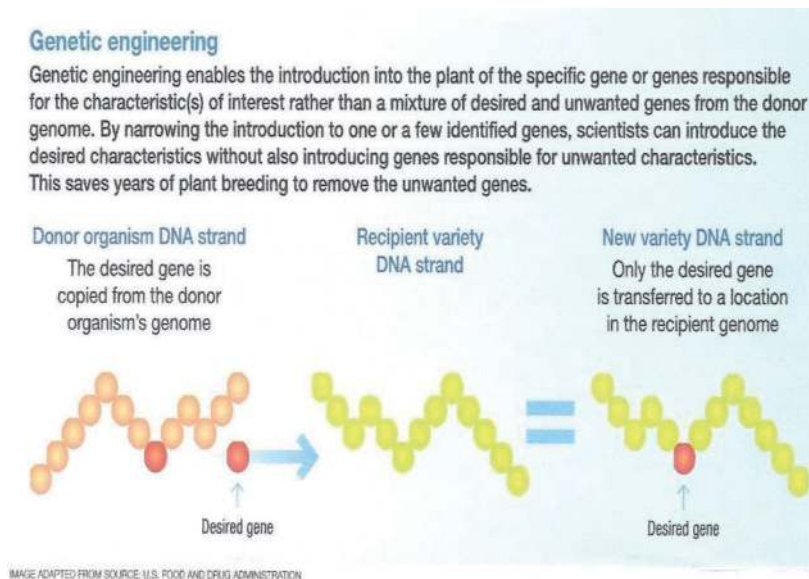
Foods derived from GM crops pose no greater safety risk than from conventional plant breeding [2, 4, 5, 23, 24]. GM food safety has been validated with over 25 years of research by the American Medical Association [25], World Health Organisation [26], The British Royal Society [27], and 500+ independent institutions. GM crops benefit the environment primarily by substantially reducing the use of toxic pesticides/fungicides [28].

## 2.2 Genome editing (GE)

The new GE techniques such as CRISPR enable precise changes to the genome, with cutting of DNA at a specific location, and insertion, deletion, or modification of nucleotides in a gene, and include gene silencing, gene enhancement, and synthetic genes (**Figure 1**) [4, 29, 30].

China has heavily invested in GE with the purchase of Syngenta [31]. Genome editing has been developed for tomato, potato, maize, rice, wheat, sorghum and citrus, and presents a major challenge to GM crop regulators [4]. GE dramatically increases the number of traits which can be modified in crops, in a manner which is far quicker and cheaper than the original GM technology has been able to achieve [30, 32].

Base pair alteration (SDN 1) may be indistinguishable from either a random mutation or what may be achieved by conventional breeding, and is regarded as very low risk for health and the environment [4]. It is unlikely however to replace most uses of GM from before 2010 and already in farmers' fields. The SDN 2 CRISPR procedure involves larger DNA changes with a DNA repair template, while



**Figure 1.**  
Image adapted from source U.S. Food and Drug Administration [29].

SDN 3 enables targeted insertion of foreign DNA, both are still subject to full OGTR regulation.

The CRISPR-Cas9 DNA insertion is displayed in **Figure 2** [29].

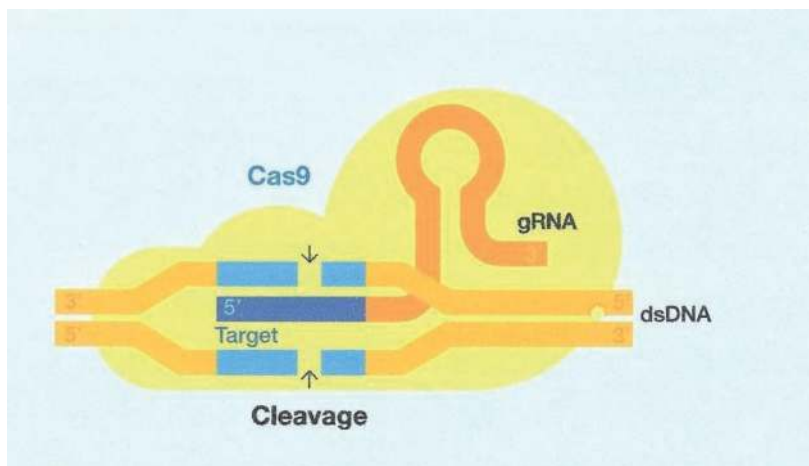
Occurrences of ‘off-target’ changes are very rare in plants and detectable by whole genome sequencing [4]. Mutation breeding has always been exempt from regulations, a precedent for SDN 1 GE.

### 2.3 GM regulation and GE

Policies on GM regulation are evolving with changes in biotechnology, but at different rates and to different extents in various countries. Genome editing targets the introduced traits themselves rather than the technology used to create them, in contrast to the traditional process-triggered GM regulatory system championed by Europeans [13, 33, 34]. EU does not exempt GE from GM regulations [4, 35].

In recent national responses to advances in GE [36]; USA, Norway, Australia, New Zealand, Japan, and Argentina either permit SDN 1 genetic changes, or are considering relaxation of regulation. Lassoued *et al.* [37] reviewed plant breeders on deregulation of GE, who noted increased ease of transformation, gain in precision, and improved opportunity to introduce novel traits from Crop Wild Relatives (CWR) through GE. Public education about GE was seen as necessary, plus opportunity for public participation in legislative processes to relax regulations [38]. New regulatory frameworks have been proposed [39–42], with the latter suggesting a product based approach for regulation of GE crops, especially now that genome sequencing is complete for over 200 plants and under development for over 10,000 genome assemblies.

Agribio Victoria can process 50,000 SNPs at a time, and has sequencing capabilities for reliable detection of interactions between large numbers of different genes. These affect the majority of traits of agricultural interest, and can be a significant complement to the expression of major genes such as ‘blackleg’ resistance in canola [43]. The advances in sequencing and in GE together make possible the targeted transfer of complex abiotic stress tolerance traits from CWR to domestic crops.



**Figure 2.** A Schematic diagram of the Cas9 enzyme (yellow) and the guide RNA (gRNA) that directs the enzyme to cleave double-stranded DNA (dsDNA) at specific sites. Image adapted from source: Marus Walter, Attribution-share alike 4.0 International (CC BY-SA 4.0).

However worldwide acceptance of revised regulations would be needed to achieve international consensus and removal of asynchronous trade barriers [44–46], which are significant barriers to international commercialisation of GM/GE [47, 48].

Future challenges include a warmer more variable climate for which CRW can provide genes for abiotic and biotic stress tolerances [40, 41, 49]. In many cases biotechnology applications can assist introgression of these stress tolerant traits into crops [4]. This would help to address twin challenges to agriculture of climate change and food security for a predicted 10 billion people by 2060 [50].

## **2.4 Climate change and genetic adaptation**

World food security has become severely threatened since the introduction of regulations on gene technology for crops over 20 years ago [1]. Gene technology regulation needs to recognise that crop environments are becoming more variable and challenging. There has been an unprecedented growth in world population by over three-fold in the last 100 years to 7.85 billion today [50], with an equally dramatic 60% rise in the greenhouse gases, especially CO<sub>2</sub> mainly from coal, oil, gas and cement sources of pollution to over 400 ppm [51], resulting in a continual but fluctuating increase in global mean temperature towards 1.5°C above pre-industrial levels since 1900 [51]. On most scenarios this warming will rise above 2°C by 2100, with the lowest emission scenario very unlikely to eventuate, with increasing urbanisation and more energy intensive life styles. Certain trends such as polar warming can set up reinforcing feedback loops for warming: ice melts, permafrost thaws, and desertification. Spikes in high temperature will be from a higher base, and frosts and droughts will be more severe especially upon seed set. Food security will be under threat [30, 49].

Thus a climate crisis for agriculture has intensified since the 1990s, when genetic modification of food and fibre crops raised safety concerns. However GM crops have been shown to be beneficial with improvements in crop and food nutrition, disease and pest resistances, yield productivity, and tolerances of drought, high temperature, frost and salinity [4].

Now in the 2020s there is an urgent need to widen the genetic diversity of food and fibre crops to address the coming challenges of abiotic and biotic crop stresses with Climate Change [30, 41, 49]. GE provides the tools to exploit the largely untapped genetic diversity of CWR, the evolutionary ancestors of crops [17, 30], with precise introgression of genes for abiotic/biotic tolerances (heat, frost, and drought tolerances, salinity, pest and disease resistances). CWR have genetic diversity for adaptation to far more extreme environments than crops were exposed to during domestication over the past 12,000 years, and provide opportunities to transform crop adaptation to Climate Change [17, 52]. However it is an immense challenge to implement GE transformations across all crops; from vegetables, spices, cereals and legumes to root crops and fruits, before the world is stranded with agricultural systems un-adapted to changed environments.

There is a future opportunity cost in not recognising that climate change combined with an unprecedented growth in population creates an urgency to re-adjust GM regulation, to promotion and acceptance of new gene technologies, especially GE [16, 29, 45, 53–55]. NGTS can re-align towards an aspiration of crop adaptation (climate proofing) to climate change [24, 39]. Advances in cropping ingenuity and crop genetics will be essential to produce more food in more hostile environments.

## 2.5 Proposal for a revised NGTS for food and fibre crops only, in Australia

An appropriate tiering of regulation for crops should recognise outcomes of product benefits to farming and the environment, and a long established food safety record.

GM/GE food and fibre crops should be exempt from NGTS regulation [1]. The current NGTS/OGTR over-regulation stifles the opportunity to realise the benefits from CWR for adaptation to climate change, raises costs, and tends to exclude GM/GE research and development from small research organisations. The present costs to market for GM/GE crops are prohibitive [16]. The current NGTS/OGTR regulations are no longer fit for purpose, and NGTS could be changed to exempt food and fibre crops only, but not vaccine and pharmaceutical crops, micro-organisms and animals [1, 11].

A Revised NGTS [1] for food and fibre crops would have a new aim: *‘Genetic improvement of food and fibre crops by application of gene technologies, with recognition of product outcomes of agricultural, health and environmental benefits’*.

This Revised NGTS would greatly reduce operational costs of the plant-centric OGTR and better secure its funding sustainability, without the monitoring, surveillance and compliance activities for GM/GE food and fibre crops.

A restructured OGTR could change from regulating GM food and fibre crops, to play a major role in educating the public on the benefits of new biotechnologies with publications, educational webinars and social media posts [1]. OGTR has the required expertise to explain and illustrate new developments in biotechnology [11, 12]. This could be supported with championing of a Revised NGTS for food security in a more populous world with a changing climate.

## 3. Summary of a proposed revision of NGTS for crops in Australia

OGTR regulations on GM food and fibre crops need to be removed for equivalence with conventionally bred crops. The proposal is for an exemption of GM food and fibre crops from current NGTS regulation, and adoption of a Revised NGTS for sustainability of agriculture under climate change.

As proposed by Redden [1], a Revised NGTS would include:

- Regulations of relevant agencies such as OGTR, FSANZ, and APVMA, to be science based and supportive of GM products.
- Exemption of GM food and fibre crops from NGTS/OGTR legislation, yet still comply with FSANZ standards.
- Deployment of current and new gene technologies for world food security, even as cropping environments become less favourable.
- Research organisations to champion the introgression of genes from CWR into crops for improved productivity, food nutrition, and adaptation to abiotic and biotic stresses.
- An education campaign across primary to tertiary education levels, and social media.
- Risk objections to GM crops and derived foods to be science based, taking into account both medical expertise on health risks and social and environmental benefits.

- Relaxation of regulations for crop GE would facilitate new market entrants for GM crops and broaden the scope of GE across more crops and key traits.
- Individual food choice is retained, but labelling requirements should not be burdensome on GM derived foods.
- International trade barriers to GE produce are removed as other countries also rollback GM regulations on food and fibre crops.
- Co-existence of GM and non-GM crops is manageable in Australia, given existing SA segregation protocols and stack management practices at grain reception points.
- GE also benefits the organics industry, both with genetic resistances to pests and diseases, and tolerances of abiotic stresses.
- Excluded from the proposed Revised NGTS are vaccine, and pharmaceutical crops, micro-organisms and domestic animals.


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