Australian Government

Department of Health
Office of the Gene Technology Regulator

Ms Julia Morris
Committee Secretary
House of Representatives Standing Committee on Agriculture and Industry
PO Box 6021
Parliament House
Canberra ACT 2600

Dear Ms Morris

Submission to the House of Representatives Standing Committee on Agriculture and Industry Inquiry into Agricultural Innovation

I understand that the Standing Committee on Agriculture and Industry has been asked to inquire into and report on the role of technology in increasing agricultural productivity in Australia. The inquiry will have particular regard to:

- improvements in the efficiency of agricultural practices due to new technology, and the scope for further improvements;
- emerging technology relevant to the agricultural sector, in areas including but not limited to telecommunications, remote monitoring and drones, plant genomics, and agricultural chemicals; and
- barriers to the adoption of emerging technology.

I am providing this submission in my capacity as the Gene Technology Regulator (the Regulator), from the perspective of the statutory office holder charged with administering the national scheme for regulating gene technology.

Regulatory role

The object of the gene technology regulatory scheme, as set out in the *Gene Technology Act 2000* (Cth) (GT Act) and corresponding State and Territory laws, is to protect the health and safety of people, and to protect 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).

In addition, the regulatory framework to achieve that objective includes that the scheme should "provide an efficient and effective regulatory system for the application of gene technologies" and that it "operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products". In effect, the regulatory framework provides a predictable, timely pathway to bring GMOs to market that is based on rigorous scientific assessment.

My role as Regulator, supported by the Office of the Gene Technology Regulator, involves the risk assessment, risk management and monitoring of work with GMOs to ensure compliance with the

legislation[1]. In granting licences for work with GMOs, I must be satisfied that any risks to human health and the environment can be managed.

The gene technology scheme has a number of tiers of regulation, from exempting certain dealings with GMOs, through notifiable low risk dealings (NLRDs), to licensing of certain dealing with GMOs, including any involving intentional release of GMOs to the environment. This ensures that the level of regulation is matched to the level of risk.

The scheme is designed to ensure appropriate regulatory coverage but prevent duplication. There are provisions in the legislation that mandate the exchange of advice between regulators of food standards, human therapeutic goods, agricultural and veterinary chemicals, and industrial chemicals.

I must seek advice from Food Standards Australia New Zealand, the Therapeutic Goods Administration, the Australian Pesticides and Veterinary Medicines Authority, and the National Industrial Chemicals Notification and Assessment Scheme for all applications for environmental release of GMOs. These product regulators must also seek my advice in relation to applications involving genetically modified (GM) products.

There are also provisions for expert advice to support risk assessment and mandatory public consultation on applications. I must seek advice from the Environment Minister, the Gene Technology Technical Advisory Committee, the Department of Agriculture and relevant local councils on all environmental releases. Public consultation is also required.

As part of an open and transparent approach to regulation, risk assessments and regulatory processes are made available on the OGTR web page. Additionally, the GMO Record[2] contains information on all GMO approvals by or notified to the Regulator, or specified in an Emergency Dealing Determination. The purpose of the GMO Record is to provide the Australian public with ready access to information about GMO dealings in Australia.

A national scheme

The gene technology regulatory scheme is established under the intergovernmental Gene Technology Agreement (IGA).[3] The scheme is comprised of Commonwealth, State and Territory gene technology laws. In addition to the Commonwealth GT Act, I also administer the State and Territory Acts that are declared to be corresponding to the Commonwealth Act. This enables seamless regulation of gene technology across jurisdictions and ensures consistency of regulatory requirements and clarity for regulated stakeholders. Maintaining corresponding legislation is one of the commitments falling on the States and Territories under the Agreement that is important in ensuring a nationally consistent scheme.

At the inception of the scheme a number of States and Territories had concerns that the introduction of GMOs into agricultural production would cause marketing difficulties for agricultural products from that State or Territory. In recognition of this concern, the Commonwealth, State and Territory Ministers developed the *Gene Technology (Recognition of Designated Areas) Principle 2003*, which allows States and Territories to designate geographical areas for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops for marketing purposes. These laws are sometimes known as GM moratoria.

These laws are not within my regulatory responsibilities, which focus on the health and safety of people and protection of the environment, and not marketing issues. The scope and regulation of these laws is a matter for the States and Territories.

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[1] See www.ogtr.gov.au
[2] Available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmorec-index-1
[3] Available at http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-agreement

Application to Australian agriculture

The effect of the gene technology regulatory scheme is to create a science-based system to assess and regulate the safe development, trialling and commercial release of GM plants and animals that can be used in agriculture (among other sectors). The scheme touches all stages of the research and development pipeline, from proof of concept through to commercial release. The assessment of applications and decisions about licence conditions are based on current available science and a published, well respected Risk Analysis Framework[4] which ensures consistent decision making. The GT Act establishes predictable timeframes for decisions and we maintain an excellent record for meeting those timeframes.

The major and most evident intersection of the GT scheme with agriculture in Australia is with GM crops. Any environmental release of GM crops in Australia, whether for field trials or commercial release, requires my assessment and approval.

A number of GM crops have been approved for commercial scale release, specifically different types of GM cotton and canola. GM cotton now accounts for over 95% of the Australian cotton crop. There is a steady stream of field trials for research and development of a range of GM plants including cotton, canola, wheat, barley, sugarcane and ryegrass, and for a variety of modified traits. There has been an expansion in the type of trait being trialled, from relatively simple herbicide tolerance (so called 'first generation' traits) to efforts to enhance more complex environmental stress responses such as drought and salinity tolerance.

There is also other GM work relevant to agriculture at various stages in the research and development pipeline. This includes early stage development of live GMO veterinary vaccines and GM animals. I have recently approved a commercial GM vaccine for chickens but there have been no environmental releases of GM animals in Australia to date.

When the scheme was established in 2001, public interest and concern was greatest in relation to the environmental release of GMOs, especially GM crops. In the early days of the scheme OGTR received many submissions that did not relate to the protection of people or the environment and therefore were outside the scope of the Gene Technology Regulator's considerations. The number of such submissions has declined, although more broadly gene technology remains a contentious area. In 2003 the consultation process for the early decisions on environmental release of commercial GM canola attracted significant public interest in the form of 727 submissions (DIR 21). In 2014 the consultation process for my most recent decision on the release of a commercial GM canola variety attracted 17 submissions from the public (DIR 127). A recent survey of community attitudes suggests that public awareness of gene technology has declined[5].

Approach to new technologies

One issue that is exercising governments around the world is the application of existing gene technology law to new and emerging technologies. There are a range of new technologies approaching the market, with broad applications in agriculture, which have given rise to international debate around whether they should be regulated as gene technology.

In the context of the GT Act, regulatory coverage is determined by the definitions of 'gene technology' and 'genetically modified organism' which are framed broadly, with exclusions in the Regulations describing things not intended to be regulated. The definitions and exclusions were written prior to the development of a range of new technologies.

Regulating a dynamic industry requires regular review and updating of legislation. Under the IGA the GT scheme is subject to independent five-yearly reviews, with the next due in 2016. The 2006 and 2011 reviews concluded that the scheme is operating efficiently and effectively and that the policy settings remained appropriate.

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[4] Available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/risk-analysis-framework
[5] Available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reports-other

In summary, the national gene technology regulatory scheme provides an efficient and effective system for the application of gene technology in Australia that allows work with the technology while ensuring any risks to people and the environment are appropriately managed. Should the committee require any further information about the administration of the gene technology scheme I would be happy to provide it.

Yours sincerely

Dr Robyn Cleland
Acting Gene Technology Regulator

30 September 2015