Australian Government
Department of Health
Office of the Gene Technology Regulator

Mr Paul Lindwall and Mr Ken Baxter
Commissioners
Productivity Commission
Inquiry into the Regulation of Agriculture
Locked Bag 2
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Dear Commissioners

Submission to the Productivity Commission Inquiry into the Regulation of Agriculture

Thank you for meeting on 25 February 2016 in relation to the Inquiry into the Regulation of Agriculture. Further to the information supplied at that meeting, I am happy to provide this submission to the inquiry process.

I am providing this submission in my capacity as the acting 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". 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 (OGTR), involves the risk assessment, risk management and monitoring of work with GMOs to ensure compliance with the legislation[1].

[1] See www.ogtr.gov.au

The GT Act establishes a licensing scheme – dealings with GMOs require prior assessment and authorisation by a licence from the Regulator unless otherwise authorised under the Act. In granting licences for work with GMOs, I must be satisfied that any risks to human health and the environment can be managed. All environmental releases of GMOs require assessment and licensing by the Regulator.

However, the Act also provides a tiered framework of authorisations and classifications designed to match the level of regulation to the level of risk. Almost all research and development work with genetically modified plants only requires a notification not a licence, provided it is undertaken in a facility certified by the Regulator as appropriate, for example, work undertaken in glasshouses and laboratories.

The gene technology scheme was designed to be transparent and consultative. For example, risk assessments, regulatory processes and approvals are made available on the OGTR web page. For environmental releases of GMOs, I must seek advice from: the Environment Minister, States and Territories, the Gene Technology Technical Advisory Committee (GTTAC) and prescribed Commonwealth agencies. These agencies include the Department of Agriculture and Water Resources, relevant local councils, and the Australian public.

Efficient regulation

The GT scheme is designed to ensure appropriate regulatory coverage but prevent duplication, particularly overlap with product regulators such as Food Standards Australia New Zealand (FSANZ) and the Australian Pesticides and Veterinary Medicines Authority (APVMA). 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 and FSANZ, the APVMA, the Therapeutic Goods Administration, 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. I also consult with the Department of Agriculture and Water Resources in relation to the biosecurity aspects of international movement of GMOs.

It should also be noted that GM foods tend to be processed food products such as canola oil or various soy products. When a GMO is processed so that it is no longer a viable organism, it is no longer regulated as a GMO. At that point it is only regulated as a food under the FSANZ food safety scheme. This is intended to once again avoid overregulation.

A further example of the desire to avoid overregulation is the OGTR's approach in relation to data requirements. The OGTR tries to ensure that application forms direct applicants to only provide the data that is necessary to make a regulatory decision. That is, applicants are not asked to provide excessive and unnecessarily burdensome amounts of data. The OGTR's publically available Risk Analysis Framework sets out the basis on which the Regulator makes decisions about the data that is required and how the Regulator goes about assessing that data[2].

Finally, regulatory decisions under the GT Act specify decision timeframes, which the OGTR has an excellent record of meeting.

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

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.

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 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.

Licences for field trials contain conditions that require the licence holder to keep the crop or animal in containment for the period of the trial, and in the case of crops, to monitor the trial site for a period after the trial. This is to ensure that identified risks are managed during and after the trial period.

Following requests from non-government organisations and consumer groups, the 2006 review considered whether the objects of the GT Act should be amended to include matters other than the protection of the health and safety of people and the protection of the environment. Suggested additions included social and economic impacts of the approval of GMOs for environmental release. The Review concluded that there was no compelling case for such an extension.

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

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[3] Available at http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-tech-agreement

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 and insect and virus resistance (so called 'first generation' traits), to efforts to enhance more complex environmental stress responses such as drought and salinity tolerance, as well as improvements in the nutritional quality of food (e.g. wheat and barley modified for altered grain composition or nutrient utilisation efficiency) and animal feed (e.g. perennial ryegrass modified for improved forage qualities).

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.

A number of these trials (and the laboratory work that preceded it) are undertaken by Australian researchers, including the Commonwealth Scientific and Industrial Research Organisation (CSIRO), the University of Queensland, the University of Adelaide, Sugar Research Australia Ltd, and the Victorian Department of Economic Development, Jobs, Transport and Resources, etc.

For example, the GM cotton varieties grown in Australia are developed by the CSIRO via a joint venture with an industry-owned seed distribution company. CSIRO has been developing cotton varieties since 1984 and has produced 100 varieties. This work has reduced growers' reliance on insecticides by 85 per cent and improved their water use efficiency.

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 a recent decision on the release of a commercial GM canola variety attracted 17 submissions from the public (DIR 127). The OGTR maintains a client register of over 400 individuals and organisations who receive notifications of new applications for GMOs, licences issued for release of GMOs into the environment, and significant changes to gene technology legislation.

A recent survey of community attitudes suggests that public awareness of gene technology has declined but that public concern about GM crops remains higher than some other applications of gene technology such as human therapeutics[4].

The OGTR maintains a number of fact sheets on its website that provide science-based information about a range of matters relating to GT regulation (see: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/factsheets). It also responds to some matters directly, particularly where it believes that information in the public domain is of poor quality or is obscuring more scientifically-based research. An example is the OGTR response to a report on a US pig feeding study alleging adverse health impacts of GM corn and soybeans. The

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

OGTR response (and other examples of critical analysis on regulatory and scientific matters) is available at: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/our-view.

International engagement

The Gene Technology Regulator's functions under section 27 of the GT Act, include monitoring international practice in GMO regulation, maintaining links with international organisations and GMO regulators in other countries, and promoting harmonisation of risk assessments of GMOs. Australia's gene technology regulatory scheme is widely respected internationally as an effective, yet enabling, scheme that involves rigorous and contemporary science based risk assessments.

While there are no internationally agreed standards for GMO regulation, the OGTR is actively engaged in international fora focussed on science based risk assessment, including the Organisation for Economic Co-operation and Development Working Group on Harmonisation of Regulatory Oversight in Biotechnology (OECD WGHROB) and the International Society for Biosafety Research (ISBR). The OGTR's continued engagement with the ISBR has included contributing to the organisation of and participating in, the 13th International Symposium for Biosafety of GMOs (ISBGMO), held in November 2014 in Cape Town, South Africa. ISBGMO occurs every two years and is an important forum for regulators and scientists to discuss developments in biosafety.

The OGTR provides technical advice to support Australian government delegations at meetings of the United Nations Cartagena Protocol on Biosafety to the Convention on Biological Diversity. OGTR officers have also been members of the ad hoc technical expert groups on risk assessment of Living Modified Organisms (LMOs, equivalent to GMOs). In 2012, the OGTR entered into a memorandum of understanding with the UN International Centre for Genetic Engineering and Biotechnology (ICGEB) to provide input to a training program for officials from sub-Saharan Africa about biosafety regulation.

The standing of the Australian gene technology regulatory scheme is evidenced by the continued interest of regulators from other countries to visit the OGTR to learn about the Australian scheme. This has included officials from Ghana, Uganda, India and Bangladesh. Further, we understand that Malaysia has based its GT regulatory scheme upon the Australian model (see http://www.asiabiotech.com/01/0102/0003_0009.pdf), with the potential for India to also move in this direction (see http://indianexpress.com/article/india/india-news-india/group-of-secys-recommends-promotion-of-two-gm-pulses/)

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.

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 Productivity Commission require any further information about the administration of the gene technology scheme I would be happy to provide it.

Yours sincerely

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Acting Gene Technology Regulator
23 March 2016