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
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Dear Commissioners

Submission to the Productivity Commission Inquiry into the Regulation of Agriculture

Thank you for the opportunity to provide a submission on the Productivity Commission's draft report on the Regulation of Australian Agriculture.

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.

Information Request 6.1 – Regulatory Framework for Technologies and Agvet Chemicals

Information Request 6.1 of the Commission's draft report asks how well the regulatory framework for gene technology performs; whether the institutional and regulatory objectives underpinning the OGTR are appropriate and up to date; and what improvements could be made.

How well does the regulatory framework perform?

2005-06 Review

In 2005-06 an independent statutory review of the *Gene Technology Act 2000* (the GT Act) and the intergovernmental Gene Technology Agreement 2001 found that the GT Act and the national regulatory scheme had worked well in the five years following introduction, and that no major changes were required. It suggested a number of minor changes aimed at improving the operation of the GT Act at the margin.

The *Gene Technology Amendment Act 2007* and the Gene Technology Amendment Regulations 2007 implemented the changes as agreed in the State, Territory and Australian Governments' Response to the recommendations of the review.

2011 Review

A second independent review of the GT Act was conducted for the Gene Technology Ministerial Council (now known as the Legislative and Governance Forum on Gene Technology, LGFGT) in 2011. The review concluded that the GT Act is working well and that, "The Office of the Gene Technology Regulator (OGTR) is operating in an effective and efficient manner" and that "The OGTR is providing a rigorous, highly transparent regulatory system."

The *Gene Technology Amendment Act 2015* implemented the minor and technical recommendations of the 2011 review as agreed in the State, Territory and Australian Governments' Response to the recommendations of the review in 2013.

Are current institutional and regulatory objectives appropriate and up to date (what improvements can be made)?

A third review of the GT Act is scheduled to commence in 2016/17 and, like the previous reviews, is expected to consider the effectiveness of the scheme as a whole. The scope of the review has not yet been determined. However, it is likely that the scope of regulatory coverage will be addressed in the review, both with respect to the capture of new technologies and the potential for regulatory overlap. To ensure independence, this review will be conducted by the Department of Health and overseen by the LGFGT.

Additionally, I am conducting a technical review of the Gene Technology Regulations 2001 (the GT Regulations) which is intended to ensure the GT Regulations reflect current technology and scientific knowledge.

Both reviews will allow for public and stakeholder submissions to be taken into account.

Duplication

With specific regard to concerns about duplication within OGTR's processes (as raised in Box 6.4 of the Commissions draft report) the OGTR is aware of industry concerns over the potential for regulatory overlap with the Australian Pesticides and Veterinary Medicines Authority (APVMA). OGTR has had discussions with both the APVMA as well as the relevant policy sections within the Departments of Health and Agriculture and Water Resources to investigate whether any significant overlap exists and identify alternate options for managing risks.

An important factor in considering whether there is unnecessary duplication across agency responsibilities is recognising that there are different stages in the development of a genetically modified organism (GMO) that require regulation in Australia. I am responsible for regulating the entire lifecycle of all GMOs. This includes the initial creation, laboratory testing and characterisations, pre-release testing, field trials and finally commercialisation. In comparison, the APVMA regulates the commercialisation and availability of products. Examples of agvet products which are also GMOs include genetically modified (GM) plants encoding insecticides and veterinary GM vaccines.

Consequently, there is no overlap in the regulation of the organism prior to the potential release of the GMO into the environment, as this is not regulated by the APVMA. However, both the APVMA and I regulate field trials and commercial release.

The OGTR and the APVMA operate in an integrated framework for gene technology, and work closely on the assessment of applications that fall within the responsibilities of both agencies to prevent duplication. This is addressed in the legislation for both schemes which require that the APVMA must consult with me on any application that involves a GMO, prior to granting an approval for research or registering a product, and I must consult the APVMA before making a decision to issue a licence involving the environmental release of an agvet

GMO. Wherever possible, and within the constraints of the respective pieces of legislation, the OGTR and the APVMA coordinate decision making.

For veterinary vaccines the legislation requires that:

- the APVMA manages the risks to the operator and the environment that result from use of the vaccine, as well as risks posed by the presence of residual vaccine in animal products; and
- the Regulator manages risks to human health and safety and to the environment that may arise from the import, transport and disposal of the GMOs within Australia.

As both regulators are considering human and environmental risks, we require similar information, but the risk pathways being assessed and managed are different. While each agency must address the requirements of their respective legislation, from our operational experience with approvals given to date, duplication is minimal and risk management strategies applied by one regulator may also accommodate the risks identified by the other.

Precautionary Principle/Approach

Some of the submissions to the Commission's inquiry raise the concern that the Regulator does not use the precautionary principle when making decisions regarding the regulation of GMOs.

The gene technology scheme is by nature precautionary as no dealings involving the intentional release of a GMO into the environment can be conducted without approval, and all such approvals are predicated on the results of a scientific risk assessment. This precautionary approach is further enshrined in section 4(aa) of the GT Act which includes "that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation". This text is reflective of Australian government obligations as a signatory to the UNEP Rio Declaration 1992.

In conducting a risk assessment, it is important to avoid underestimating or missing substantive risks. Therefore, my evaluators take a cautious approach, postulating and considering an extensive list of potential risk scenarios. A risk is only identified for further assessment when a risk scenario is considered to have some chance of causing harm. Pathways that do not lead to an adverse outcome, or could not reasonably occur, do not advance in the risk assessment process. Identified risks are characterised in relation to both the likelihood and seriousness of harm, taking into account information in the application, relevant previous approvals and current scientific/technical knowledge. As a result, most identified potential risks are subsequently classified as negligible risks after more detailed consequence and likelihood assessments.

The approach we use also includes consulting a number of people with relevant expertise in the risk assessment process and extensive internal review, and in the case of environmental releases, external review of the risk assessment as required by the GT Act.

However, even after assessing all available data it may be that some uncertainty as to the safety of a proposed release may still exist. Therefore precaution is applied through a gradual step-by-step approach to managing new GMOs until sufficient knowledge and experience are acquired to provide confidence in their safety. This is achieved through the issuing of limited and controlled licences which place restrictions on the release, such as physical barriers, isolation distances and modified work practices, as well as limits on the access, scale, locations, duration and types of activities. This allows relevant data to be obtained while minimising the potential risks involved.

Caution is incorporated in the decision-making processes under the GT Act through express requirements to identify significant risks to people or the environment posed by any of the dealings. Where a significant risk is identified the GT Act requires a longer consultation period to allow for more complete consideration of the adequacy of measures proposed to manage the identified risk. The GT Act also requires that I must not issue a licence for an application if risks cannot be managed in such a way as to protect the health and safety of people; and the environment. Once a licence has been issued, caution continues to be applied through the regular monitoring of field trials to ensure required reporting of any adverse events and compliance with licence conditions.

The current regulatory system for gene technology is science-based and robust and has been working well for more than 15 years. The precautionary principle applies when there are threats of serious or irreversible environmental damage. To date, the Regulator has not identified such a situation in the applications assessed.

Risk Communication

The Productivity Commission's draft report on the Regulation of Agriculture in Australia also discusses (including as part of Draft Recommendation 6.1) the provision of accurate information about the risks and benefits to the Australian community from GM technologies.

Risk Analysis Framework

While the provision of information on benefits from GM technologies is outside the scope of the role of the OGTR, the OGTR's *Risk Analysis Framework* (2013) represents a key document for informing applicants, stakeholders, the public and other domestic and international regulatory bodies about the rationale and approach adopted by the Regulator in undertaking risk analysis and arriving at risk management decisions and licence conditions.

Chapter 6 of the *Risk Analysis Framework* presents the main objectives of risk communication and the approach that the Regulator takes to fulfil these objectives. It also includes a discussion of some theoretical elements of risk communication and risk perception.

In practice, the Regulator and the OGTR aim to:

- Raise awareness of Australia's regulatory system for gene technology nationally and internationally;
- Undertake rigorous, science-based risk assessment and risk management of dealings with GMOs in an open and transparent manner;
- Communicate the reasoning behind licence decisions in an open and objective manner in clear language;
- Listen and respond, in a timely manner, to relevant concerns of stakeholders; and
- Periodically review communication strategies and practices of the OGTR to ensure effective, appropriately targeted and efficient communication with stakeholders.

Effective risk communication is central to effective risk analysis. The goals of risk communication relevant to regulation can be categorised as follows:

- *Engagement* – to involve internal and external stakeholders in the regulation of risk through dialogue.
- *Informing* – to foster understanding of the risks amongst different constituencies (e.g. licence holders and others from the regulated community, as well as researchers, farmers, health workers, industry, consumers, interest groups and the general community). The information can relate to the existence, nature, form, likelihood,

significance, evaluation, control measures and monitoring of the risks, including the quality of evidence, inherent uncertainty and compliance with licence conditions.

- *Building trust* – to promote trust and credibility in the ability of the Regulator and the OGTR to effectively regulate gene technology.

The OGTR achieves the above listed aims and goals by undertaking a range of public engagement activities through the publication of information on the OGTR website, and directly notifying people/organisations on the OGTR Client Register including:

- Notifying the public when an application has been received to release a GMO into the environment;
- Inviting the public to comment on Risk Assessment and Risk Management Plans (RARMPs) which are developed for each application to release a GMO into the environment;
- Notifying the public about the OGTR issuing a licence to release a GMO into the environment; and
- Notifying the public of significant changes made to gene technology legislation.

Fact sheets on a number of topics, plain language *Question and Answer* documents comprising a series of questions and corresponding answers on licence applications and the Regulator's decision, as well as *Summaries of RARMPs*, are also published to facilitate public understanding of the risk assessment process.

Sources of Evidence

I note that some members of the public have expressed concerns that the OGTR relies solely on scientific information provided by the applicant when conducting a risk analysis.

I would like to clarify that in order to satisfy myself that any risks can be managed appropriately, in addition to a critical assessment of the data provided by the applicant, expert evaluators at the OGTR analyse published literature (both domestic and international) and consult with members of the Gene Technology Technical Advisory Committee and other prescribed agencies. In addition, I have the power to commission independent research should there be a gap in in the scientific literature.

Quality of evidence

I also note that claims have been made to the Productivity Commission and other forums that there is no scientific proof of GM food safety. I would like to take this opportunity to highlight that section 56 of the GT Act requires that I not grant a licence unless I am satisfied that any risks posed by the dealings proposed to be authorised by the licence are able to be managed in such as was as to protect the health and safety of people; and the environment.

My evaluators give consideration to a range of factors in determining the quality of any evidence including reliability (the accuracy and integrity of experimental design, methodology and statistical analysis used to report data and conclusions), expertise (the standing of the author(s) or expert(s) presenting the data) and robustness (whether data from disparate sources, experiments or researchers support similar conclusions).

Scientific papers published in peer-reviewed journals generally provide some assurance of quality; however, even such papers can vary in quality. Wherever possible, my evaluators check that the conclusions of the authors or experts presenting particular evidence are supported by other data reported by different authors. A judgement must also be made about the expertise of the authors or experts presenting the data.

Peer-reviewed papers are often regarded as high-value evidence, but they are not automatically accepted and used in the risk assessment without further evaluation. Their appropriateness, transparency and robustness are all factors in determining how much reliance can be placed on each piece of evidence for the purposes of making a regulatory decision. An example of the OGTR's critical analysis of the quality of evidence is available on the OGTR website for a study which claimed adverse health effects in pigs that were fed genetically modified feed. The OGTR examined this publication in consultation with Food Standards Australia New Zealand and relevant regulatory agencies from other countries. All agencies reached the conclusion that this study was of poor quality and does not provide grounds for reconsideration of existing GM crop or GM food approvals or assessment processes.

Additional information on the quality of evidence used in risk identification and risk characterisation is included in Chapter 4 of the Risk Analysis Framework.

Communication and engagement concern highlighted in the Commission's draft report

With regard to the concern highlighted in the Productivity Commission case study interviews (appendix C) from a cotton farmer who felt that lack of communication and engagement led to a heavy-handed decision, I would like to note that when field trials are undertaken, the OGTR communicates regularly with the holder of the relevant licence for that activity. After a licence has been issued the licence holder is required to explain how they intend to comply with the licence conditions. The licence holder has the right to appeal any licence conditions that are imposed. The licence holder can also request the conditions be changed if the risks can be managed by a different method, are unnecessary or cannot be adequately met.
Where farmers are sub-contracted by licence holders to undertake work associated with the licence, the licence-holder is required to ensure that the contractor has read, understands and is willing to comply with all of the licence conditions that apply to them prior to undertaking any work with GMOs.

Biohacking

I am aware that some concerns around biohacking (also known as DIY-Bio, citizen science or community science) were raised during recent public hearings. The biohacking movement is concerned with making science accessible to the general public and provides shared laboratory facilities and equipment to interested members of the public.

My office has been engaged with Sydney and Melbourne Biohackers for 5 years now. The people involved are fully aware of the OGTR and the need to comply with gene technology legislation. These groups have certified laboratories in both Sydney and Melbourne and are currently carrying out work with GMOs that would meet the 'exempt' category. They have also cultivated links to university Institutional Biosafety Committees which can assess proposed experiments and provide advice on how to comply with the legislation.

With respect to regulatory coverage, work with GMOs in Australia requires authorisation under the GT Act. This includes work undertaken by individuals outside of certified facilities.

Recently my staff attended two biohackers conferences in Sydney at the Australian Technology Park (ATP) and the University of Technology Sydney (UTS). The conference presentations included reference to my office and the need to comply with the legislation. There was general acknowledgement that compliance with the legislation was required for the work to be allowed to continue, and that legal penalties would apply for unauthorised work with GMOs.

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

Dr Raj Bhula

Gene Technology Regulator

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