

# CSIRO Submission

# 2017 Review of the National Gene Technology Regulatory Scheme

September 2017

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# 1 Introduction

This document contains responses to Terms of Reference set out in the Background Paper distributed by the Department of Health. CSIRO undertakes research that includes internally funded discovery and technical development, industry and stakeholder funded discovery and development research and fully customer prescribed technical delivery or analytical work. As an industry linked innovation catalyst CSIRO seeks to ensure that opportunities for innovation are maintained. However as a trusted advisor to the Australian Government and the Australian people our aim is to provide impartial advice and to maintain public confidence in the safety and benefit of scientific developments. Technological developments and decades of experience are presenting challenges to the appropriateness of the current gene technology scheme. CSIRO maintains strong international networks and is involved in all of the key international fora at which the risks and benefits, opportunities and challenges of the most recent breakthroughs in biotechnology are discussed.

This Review of the National Gene Technology Regulatory Scheme has been the subject of consideration and consultation within the Business Units of CSIRO, particularly Agriculture & Food, Health & Biosecurity, and Land & Water which interact closely with customers and stakeholders that have significant interest in gene technology and biotechnology innovations. In relation to Gene Technology CSIRO has customers, clients and stakeholders principally in primary production industries, the health industry and the environment. Some gene technology activity also relates to synthetic biology with customers in the synthetic chemicals, fibres and biologicals industries. This stakeholder profile provides the context for this submission.

## 2 Summary

1. The scheme should be based on scientific evidence and any regulation commensurate with the risks posed.
2. The current scheme is unable to respond rapidly to new technological developments. The scheme has been able to capture all gene technology techniques. However, the scheme has not been able to effectively address new technologies as they arise or to deal with them in a manner relevant to their inherent risks (cf. arguably over-regulation of minor gene editing vs. potentially under-regulation of synthetic gene drives).
3. The current scheme is limiting the ability to moderate regulation where long experience has demonstrated safety. Consequent over-regulation is imposing costs on the Commonwealth, industry, and research bodies, and providing a brake on innovation and application of gene technologies.
4. The regulator should be funded adequately by government to avoid regulatory failure and provide rapid processing of applications. Funding of the scheme should avoid hindering innovation or access to the technologies.

## 3 Technical Review

CSIRO previously made a submission to the Regulator's review of Gene Technology Regulations which dealt in part with addressing lack of clarity or regulation out of proportion to risk. The CSIRO submission is available from the OGTR website

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/reviews submissions-htm>.

## 4 Faster response to technological developments

There are several areas to review the legislation in order to better equip the regulator to respond rapidly to technological developments.

**Example 1.** Appointment of new skills to the Gene Technology Technical Advisory Committee

*Current situation:* In part 8 of the Gene Technology Act 2000 it describes the size and composition of the Gene Technology Technical Advisory Committee (GTTAC) in paragraph 100. The act stipulates the skills and expertise that committee members must have. A maximum of 20 individuals can be appointed to the committee. This can however be supplemented by “expert advisors”, who can be appointed by the Minister to give advice to GTTAC to help it advise the regulator.

*An example of developments in the science and its application:* The recent severe and repeated bleaching events on the Great Barrier Reef in response to elevated sea temperatures have resulted in discussions and preparatory science exploring more extreme interventions in reef restoration. One of the avenues being explored is the genetic modification of one of the coral symbionts to be better adapted to elevated temperatures<sup>1</sup>. If successful this could result in an application to release a genetically modified organism into the marine environment. Whilst ecology is a mandated skill set in the Act, expertise in Marine Biology and hence an understanding of the marine environment is not a mandated skill set.

*Proposed changes:* (i) review the rigid nature of the skill set listed in the act as a requirement for GTTAC and explore mechanisms to allow fast changes to the composition (ii) allow the regulator rather than the Minister to appoint experts to advise GTTAC if new skill sets are required.

The potential release of modified marine organisms would also mean that a release could not be contained within a national boundary. Is the current legislation able to deal with this scenario?

**Example 2.** Potential future synthetic biology applications are growing more sophisticated. The review of the scheme should consider whether this developing area is adequately addressed. The review should examine mechanisms to allow the Regulator to apply a scientifically informed, risk based approach to regulation of new gene technologies.

As highlighted by the recent technical review of regulations, the current legislation is unable to make quick adaptations to the development of new technologies and alter the level of regulation in line with the level of risk.

The above examples highlight that new, more responsive decision making in relation to the operation of the scheme are required to help future proof the scheme. These might be but not limited to (i) ability to obtain relevant expertise into GTTAC, (ii) a more efficient process to determine what is not gene technology (iii) ability to reduce the level of regulatory oversight to account for accumulated experience (iv) ability to increase level of oversight where additional risks are identified.

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<sup>1</sup> Levin RA et al., (2017) Engineering strategies to decode and enhance the genomes of coral symbionts. *Frontiers of Microbiology* 8 Article 1220.

## 5 Moderated regulation where long experience has demonstrated safety

### **Less regulation for well assessed species, traits and in particular species/trait combinations**

Many of the DIR applications submitted under the scheme have been for a few crops and traits. Common combinations are cotton and insecticide/herbicide traits and canola with herbicide traits. The process of regulating the fifth application involving the same crop/trait combination is currently identical to the first. Accumulated experience of field trials and commercial releases is not taken into account. A mechanism to move those, species, traits and in particular the same species/trait combinations to a simpler and quicker regulatory process would have the effect of freeing up resources of technology developers, regulators and those they have to consult under the existing framework. The proposed change would be in line with the risks posed to the environment and human health.

Where a DIR application is similar to those previously assessed, the Regulator could begin consultation in advance of RARMP preparation. In the event the RARMP identified new or higher risks, an additional consultation period could be held. The effect would be to shorten the application approval process where new risks are not identified. Such a mechanism could also pave the way for a simplified licence variations rather than having to traverse the whole process from the start for different sequences resulting in the same trait outcome.

### **Reduced regulation for NLRDs**

*Why do NLRDs exist?* NLRDs are dealings suitable for containment in PC1 or PC2 facilities. As such, and insofar as microbial dealings are concerned, they must be considered as having the same risk profile to human health and environmental safety as work with Risk Group 2 micro-organisms that require similar containment. And yet there is a major discrepancy between these two sorts of manipulation with respect to regulatory burden: governmental reporting and criminal sanctions. We make the following queries:

1. Why are there criminal sanctions associated with NLRDs, when the equivalent non-GMO risk category (work with RG2 microbes) carry no such legal or community sanction?
2. The criminal penalties for organizations or individuals could be reviewed to ensure that they are also in proportion to risk to human health and the environment.
3. Could NLRDs be treated the same way as RG2 micro-organisms – mandate Notification to the IBC, rather than to the OGTR, and remove the sunset clause provisions? Does the experience of the last 17 years under the scheme support the level of regulatory and administrative attention that they receive?

We make the following alternative suggestions for discussion and consideration:

1. Simplify the provisions for NLRDs so that they are reportable to, and assessable by, the IBC rather than Notifiable to the OGTR. Remove the criminal sanctions and sunset clause provisions that were introduced only a few years ago; or
2. Alternatively, remove the NLRD provisions in the Act, and make NLRD “Exempt dealings suitable for PC1 or PC2 containment”, with no sunset clause or criminal sanctions other than those that apply to Exempt dealings – i.e. intentional release. Something similar may be achieved by broadening the dealings included in the exempt category commensurate with risks as demonstrated over the life of the scheme.

*NLRDs in Large-Scale Facilities:* The transactional costs of NLRD applications are often burdensome in terms of delay and red-tape. This is particularly the case in experimental facilities trying to maintain a client-responsive fast-turnaround, such as our fermentation capability. Is there a more streamlined way of approaching NLRDs for short-term and one-off large-scale fermentations?

Why should dealings that are larger than 25L in volume and which are carried out in a large-scale facility be NLRD rather than Exempt? If the purpose, design and construction of the large-scale facility is to mitigate the risk of fermenting larger volumes, how can a >25 L fermentation in such a facility carry a bigger risk-profile than a 24 L fermentation in an ordinary laboratory? We argue that, provided dealings are carried out in facilities that suit the scale, they should not be out-rated in risk. Rather, the risk should be intrinsic to the nature of the dealing, not its scale.

## 6 The regulator should be funded adequately

The OGTR needs to be resourced to carry out its functions. The temptation to see users pay as a means of covering some of the costs of the OGTR could drive perverse and counterproductive behaviour. It may lead to (i) aggregation of multiple proposals into one application, (ii) drive some people to avoid the process (iii) the potential for perception or reality of over servicing if users were to be charged for site/facility visits by the OGTR (iv) stifling of innovation.

The current costs of meeting regulatory requirements means that bringing to market new technologies is restricted to large organisations, charging for regulatory services could further drive concentration of effort in undertaking DIR and commercial release activity.

Some of the proposed changes suggested within the submission here could mean that there would be a change in resource use in the OGTR. If some of the regulatory procedures were to be reduced in light of experience and understanding of risk, resources could be redirected to the more strategic requirements necessitated by rapidly developing new technologies and applications. More effort could be expended on: understanding the risks of new technologies and their mitigation or control; assessment of which of the new technologies should not be considered as gene technology (i.e. regulated); and matching regulatory process to risk. This would replace more operational and in some cases repeated activities that do not deliver additional benefit to the environment or human health.

Another benefit of altered resource allocation could be an improvement in the timeframe for certification of PC2 facilities and other administrative actions. Currently the certification of facilities takes the full 90 business days limit, except in exceptional circumstances. This acts as a disincentive to de-certifying facilities not in active use, as the delay is too long in the event a new need arises.

## 7 Other issues

### Clarification of key terms:

Key terms were not always clearly defined. This was particularly applying to defining Gene Technology and genetically modified organisms. Additional clarity would assist with providing certainty to future regulatory decisions.

### Coverage of human beings:

Section 10 Definitions of the Act, makes provision for the meaning of *genetically modified organism*. Part (d) should be revised to exclude everything after *a human being*. This would make all human beings exempt from the act. The rationale is that there are medical advances that could be used in the future that fall outside of the current exemption. This would cause particular problems if some of these techniques were legally used in some jurisdictions but were not legal in Australia.

Whilst it may not trigger regulation under the current act, “three parent babies” – humans that are a product of mitochondrial replacement technique – could be considered an example. The technique now exists and the procedure is legal in certain jurisdictions. It would be unconscionable for the Regulator to have ultimate authority over such people if they were to enter our country. What, precisely, would the Regulator do with a foreigner who is considered a GMO?

The mitochondrial replacement technique itself is currently illegal in Australia under other legislation (The Human Cloning for Reproduction Act 2002). Part (d) of the definition is a relic from before this latter Act came into existence and should be amended to take into account the global reality. There should be no adverse consequences as the intention of Part (d) for domestic purposes is covered by the 2002 human cloning and reproduction Act. In the event that this latter Act were amended some time in the future, its operation should not be affected by the Gene Technology Act.

CONTACT US

**t** 1300 363 400

+61 3 9545 2176

**e** [csiroenquiries@csiro.au](mailto:csiroenquiries@csiro.au)

**w** [www.csiro.au](http://www.csiro.au)

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