

*Office of the Gene Technology Regulator*

*Discussion Paper: Technical Review of the Gene Technology  
Regulations 2001*

*Centre for Law and Genetics Submission*

*November 2016*

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The Centre for Law thanks the Office of the Gene Technology Regulator for the opportunity to comment on the discussion paper and options for technical revision set out therein. We commend the information that was put together, clear layout and the options available.

The Centre for Law and Genetics at the Faculty of Law, University of Tasmania, was established in 1994 and is primarily concerned with human genetics and health. Our comments are based on legal, ethical and social research that we have conducted and our experience on boards and committees regarding gene technology.

In particular, we note that Professor Chalmers was a member of the Member of the NHMRC Human Genetics Advisory Committee 2006-2009, and chair of the Gene Technology Ethics and Community Consultative Committee, *Gene Technology Act 2000* (Cth) 2002-12. Professor Dianne Nicol was a Member, NHMRC Human Genetics Advisory Committee Working Group on Industry and Commercialisation (2006 - 2007) and a Member of the Advisory Committee to Australian Law Reform Commission reference on Gene Patenting and Human Health (2003 - 2004). Her particular research interests concern commercialisation of genetic technologies and she was invited to be a member of the three-member panel on Pharmaceutical Patents in Australia A Harris, N Gruen and D Nicol (Review Panel), *Pharmaceutical Patents Review Final Report* (2013). Our comments are provided in line with our experience and the particular applicability of the proposed revision and impact on human genetic/health, research, treatment and commercialisation.

### **Response to introduction**

We appreciate that this review has no intention to alter the policy settings of the regulatory scheme. However, we believe that the current setting of the regulatory scheme will inform our view of which option we prefer for addressing these new techniques.

It is our understanding that the OGTR is considering the basic problem posed by new techniques, subject to the four proposed options.

We note that the current terms of the *Gene Technology Act 2000* (Cth) prescribe, as the object of that Act, "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..." [emphasis added.] In adopting this object the act includes (s.4aa<sup>1</sup>) a precautionary approach.

Our preferred option is that any amendment to the *Gene Technology Regulations 2001* (Cth) should be informed by the overall intention of the Act to pursue this approach to regulation of gene technology. In this submission, we believe our preferred option is consistent with this precautionary approach.

We also note that currently GMOs are defined as 'dealings with organisms' regulated under the Act and that the Act may allow specific processes to be excluded. Further we note, that the definition of GMO was, as stated at page 6 of the Discussion Paper, "intentionally casted very broadly to ensure that the definition did not become outdated and ineffectual in response to rapidly changing technology". This again informs our view on the preferred option, that the Act and accompanying regulations should capture a wide range of technology. This broader intention within the Act is also reflected in the commendable comments in the Discussion Paper at page 6 that the original scope of the scheme is that "moving and rearranging genes between species in gene technology and results in GMOs, whereas techniques which mimic natural processes and work through natural mechanisms do not result in GMOs."

At page 7, we also note that the intention of the Act was to take a precautionary approach in risk management. This should be considered commensurate with the general risk posed by the gene technology.

### **Consultation Questions**

#### **1. Which option/s do you support, and why?**

##### Preferred option

In consideration of the interpretation of the Act outlined above, we recommend and prefer option 2 to regulate certain new technologies.

##### Option 1

We do not recommend option 1 - no amendments.

We note that no particular pro-argument is provided and we agree with the general statements against option 1. In terms of commercialisation, we note that in argument one, we indeed see this as a con-argument: an uncertain environment is likely to deter commercial interest through commercial uncertainty in an already highly competitive field and area where research and development costs are often very high.

##### Option 2

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<sup>1</sup> 4 Regulatory framework to achieve object

The object of this Act is to be achieved through a regulatory framework which:

(aa) provides 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; and

We recommend option 2 because the amendment for these processes is consistent with the general precautionary approach set out under the Act. Additionally, we recommend it because it enables a watching brief to be kept on the development of the technology. The Regulations can always be changed as the scientific evidence becomes clearer. We note that there is to be a review of the *Gene Technology Act 2000* (Cth) later this year/next year.

We agree with the Discussion Paper that this option would give legal “clarity as to which technologies are subject to regulation.” We also agree with dot point 2 that there is not enough scientific understanding about the adverse effects at this stage and this should require oversight until the regulatory assurances under the regulation can be demonstrated.

We note the commendable effort to describe arguments against option two but we are not persuaded by these.

First, we do not agree that the Regulation “may not be commensurate with the risks posed.” This is not scientifically supportable at this stage. When the science is available then as we have said, the Regulation can be reversed.

Secondly we have serious reservations about comment three, the possibility of inhibiting commercialization. While researchers and technology users may be delayed in that they must obtain proper permissions for gene technology use, at present the situation is that they are unclear if they need these permissions. We are not persuaded that there is any evidence presented to support this view. It is our view that a clear decision that permissions/licences are required for genetic modification will assist with commercialisation of products. We submit that there are commercial organisations that have embraced the gene technology regime because it demonstrates compliance with the Act and an assurance to the public that the techniques used and the products developed are properly regulated. It may more accurately provide researchers, commercial developers/users and the public with assurances to support research and encourage commercialisation. At least this option is a more certain and favourable environment for commercialisation than Option 1. This rebuttal applies additionally to options 3 and 4.

Thirdly, we notice that the Australian proposal for reform was developed in conformity and with the knowledge of the New Zealand legislation, we are therefore persuaded that we should follow those amendments and not the regulatory decisions in the USA. Both Australia and New Zealand have delicate ecosystems that were influential in preferring the precautionary approach to GMOs. In addition, the extensive public consultation in NZ and this country were informed by public comments that a precautionary approach was preferred.

#### Option 3

We do not recommend this approach. It is our view that the scheme of the Act was intended not to target particular technologies which may or may not later be found to be safe or unsafe. It was, under the terms of the act, as mentioned in the Explanatory Statement (p7) to use general descriptions. Further, organisms that are not GMOs should be assessed on whether they pose risks. We notice also that the argument for option 3, that it would clarify which technologies apply, will be achieved with option 2. We see no specific advantage of only referring to the process applied. Again, we are not persuaded by the arguments raised against that this approach would impede commercialisation for the arguments set out above (under option 2).

#### Option 4

We are not in favour of option 4. It is our understanding that there is an implicit assumption in option 4, that applicants would have to produce evidence that the genetic changes are indistinguishable from the products of conventional breeding. This appears to pre-empt the science. The broader definition of GMO (under option 2) is preferred. We also note that under this option, an argument in favour is that the processes are indistinguishable from natural organisms and do not pose different risk. Again, this seems to pre-empt the science and until there is sufficient evidence we would prefer the precautionary approach to be taken.

We refer particularly to the following statement in the Discussion Paper: “Implementing option 4 would therefore need amendments to the GT regulations to exclude specific techniques or organisms, rather than provide broad exclusions...” (p 16). We do not endorse the inclusion of a negative exclusion of some techniques under the Act or accompanying Regulations. Regulation should be cast in positive terms and (under option 2) if the procedure is scientifically proven to pose no risk it can then be excluded. This approach would require an unusual amendment – that requires a list of exclusions rather than inclusion.

#### **2. Are there other risks and benefits of each option that are not identified in this document?**

We submit that implications to commercialisation would be a benefit for options 2-4, rather than a disadvantage. This is particularly applicable to option 2, where certainty is at its highest. We outline this in more detail under question 1 in our response to option 2.

#### **3. Is there any scientific evidence that any of options 2-4 would result in a level of regulation not commensurate with risks posed by gene technology?**

In our view there is insufficient evidence to assess the commensurate risk at this stage.

#### **4. How do you use item 1 of Schedule 1 and would it impact you if this item was changed?**

We make no submission on this point except in relation to listing exclusions as set out in Option 4.

#### **5. Might contained laboratory research on GM gene drive organisms pose different risks to other contained research with GMOs, and how could these risks be managed? Supporting information and science-based arguments should be provided where possible.**

We have no science-based arguments to submit.

We do, however, submit that the OGTR duties are based in normative risk assessment and taking this into account would have the ability to assess risks posed by GM gene drive organisms in the same way.

6. ***What RNA interference techniques are you using, and are there RNA interference techniques that you believe have unclear regulatory status? Please provide details of the techniques and science-based arguments for whether these techniques pose risks to human health or the environment.***

*We have no submission to make on this question.*

7. ***Do you have proposals for amendments to any other technical or scientific aspects of the GT Regulations? All proposals should be supported by a rational and a science-based argument.***

*We have no further submission to make other than to thank you for the opportunity to provide these comments.*