Email Submission: Eliot Palmer

Technical Review of the Gene Technology Regulations 2001

Hello

I write to make a brief submission as a private citizen, drawing in particular on:
- interest in the topic of genetic engineering
- experience in the design of risk-based regulatory frameworks
- experience in the review of regulatory proposals and impact assessments.

While I have specific employment experience in the regulatory topics at an Australian State government and regulator level, this submission is made purely in a private capacity.

I note the discussion in the paper about the risk profile of the relevant genetic engineering (GE) techniques and the comparisons of risk profile to longstanding and accepted methods including mutagensis. Given the framing of risks and the issues around trade and innovation, I would support Options 3 or 4. However I note that the technical differences from a scientific point of view are not within my experience.

Notwithstanding this, and noting the scope of the review to not address policy issues or the 'process rather than outcomes' based nature of current policy, I wish to make a brief point about the framing of the discussion around management of risk. I hope that these comments are of some value, while understanding that the legal settings (e.g. heads of power or policy considerations) may render them redundant in current context.

My observation is that GE technology is at a stage currently that is not dissimilar to many other areas that challenge regulators. That is, a broadening of the parties accessing the technology due to lower costs, with the dual challenge of not wanting to stifle innovation, while managing the risks of decentralised production and a user base that may not have the same private incentives and quality assurance processes to manage risk (compared to larger established operators).

This set of conditions sets up a different framing of the variables around risk - the scientific dimension (inherent risk of technology compared to background risks) is considered against a potentially very different risk profile in those dealing with the technology. While from a regulatory efficiency point of view, there is a need to ensure that regulation does not hamper potential innovation and allows for greater competition through low barriers to entry (which in turn may foster these risks).

This is not a unique challenge to GE, and from this point of view I would like to ask whether the assessment process has considered the scope for exemptions to be conditional on different levels of regulatory oversight. For example, if option 4 were preferred, could this be coupled with a 'lighter touch' registration system where there is opportunity for the regulator to communicate with and be aware of new entrants, allowing for adaptation to the compliance model over time. This concept of 'graduated permissioning' appears to work well in the EU Environmental regulatory space.

I do not know how such a system would operate under your current laws and the extent to which heads of power or policy constraints limit it. However, I did wish to make this brief submission nonetheless, in the hope that it might offer a perspective on regulatory philosophy that is in keeping with your technical risk assessment approach, and may be complementary to it, or point to considerations for larger future reviews.

Regards,
Eliot Palmer