REVIEW OF THE GENE TECHNOLOGY REGULATORY SCHEME – PHASE 2

INDIVIDUAL SUBMISSION

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THEME ONE: TECHNICAL ISSUES

No comments

THEME TWO: REGULATORY ISSUES

Regulatory triggers – In taking into account the above, the Review is considering the issue of regulatory triggers, and how best to undertake future policy design processes with both process and product trigger considerations in mind. Some questions to consider:

1. **What do you think is the most appropriate regulatory trigger for Australia in light of extensions and advancements in gene technologies?**

   The process based-trigger (under the Act) is most appropriate because it is an effective mechanism for initiating risk management processes through subsequent application of the Regulations. The Regulations then triage risk based on product qualities. For example they exclude technologies and organisms that are expected to pose negligible risk. The Regulations can be designed to future-proof the system, minimize the need for adjustment and integrate with other regulatory systems in Australia & internationally.

Streamlining Regulation - Phase 1 consultations identified a number of functional efficiencies that could be applied to the Scheme. The Review is exploring these issues from perspective of the existing process-based regulatory scheme. Some questions to consider:

2. **Are there any 'fixes' the scheme needs right now to remain effective?**
   The scheme must minimize delays and barriers to medical research and human clinical trials generally. Delays to clinical trials can occur when a licence is required and barriers occur when physical attributes of nucleic acids (such as 'nakedness' or persistence) automatically classify a trial as licensable. These issues need to be addressed. For example, delays can be reduced by triaging trials & having standard practices for like applications with known low risk precedents; product qualities and outcomes (related to harm) can be used to temper requirements based on necessary physical attributes. It is expected that the current Review of the Regulations will address some of these issues.

3. **How would you streamline the existing scheme?**
   Triage clinical trials by risk. Assess the trials within a time-frame that fits with ethics review processes for those trials. Low risk trials should require less time to assess than high risk trials. A gene therapy trial of a conventional replication defective viral vector that expresses a therapeutic protein missing in a patient may be an example of a low risk trial.

4. **What efficiencies could be gained through adjusting the interface between the Scheme and other regulators?**
   Some types of clinical trials (which have low risk in terms of gene technology) could go to HREC & TGA and be referred to the Gene Technology Regulator for advice if the TGA or HREC consider there are risks to the environment or the health of persons not in the trial, such as those handling the GMO. If a trial were to be referred to the OGTR by the HREC/TGA, the OGTR could assess the same documents that the HREC/TGA assessed and devise an appropriate licence based on these. In drafting a licence the OGTR could ask the applicant for further information if needed. The process could be designed to minimize unwarranted delays so that it fits reasonably with HREC/TGA expectations given the risk. Triaging could be used to determine which types of clinical trials are suitable for this approach. A gene therapy trial of a conventional replication defective viral vector that expresses a therapeutic protein may be suitable for this approach. A trial of a GM-vaccine in a large population may not be suitable and may warrant, from the outset, applications to the HREC/TGA and the OGTR. For this approach to work there may need to be a small amount of extra information provided in the HREC / TGA application (such as the name & brief details of the vector so that it is clear that the vector is a conventional low risk vector). IBC's could contribute to the triage process also if considered useful.

Risk tiering and appropriate regulation of environmental releases - the Review is exploring whether greater alignment of regulation with risk should be further developed for environmental releases. Some questions to consider:

5. **What support exists for a regulatory framework providing for tiered risk?**
   The examples given above support the idea that a system of using tiered risk would be useful.

6. **What examples exist of licence applications to the Regulator that could be 'fast-tracked', under a risk tiering system, with evidence of scientific and technical integrity that the aims of the Scheme (protection of human health and the environment) will be delivered?**
   (a) Human clinical trials that use replication defective vectors with a history of safe use and negligible risks to the environment and persons handing the GMO
   (b) Some types of contained dealings where currently licences require standard PC2 containment and adherence to AZ/NZS 2243.3 Safety in laboratories – microbiological safety.

7. **Under a regulatory framework to tier risk for environmental release, what efficiencies might be delivered to regulated stakeholders?**
   More time to devote to managing higher & complex risks

8. **How could efficiency gains to the Regulator be quantified?**
   Reduced numbers of low risk applications.

The Review is exploring whether a distinction can be made between classes of organisms so the necessary controls can be applied to the highest risks, rather than applying a one size fits all approach. Some questions to consider:

9. **In what way might different applications be treated differently (e.g. medical, agricultural, industrial, environmental, etc.)?**

   Covered under 3-9 above with respect to medical applications

Market access and international trade - The Review is exploring the practical implications to the Scheme of harmonising Australian regulation with the regulatory needs of trade partners. Another question to consider:

10. **What are the potential impacts on market access for exporters of animal or plant derived food products?**

    This question is addressed in relation to the global human therapeutics industry. (see below)

    Rephrased question:
    What are the potential impacts on market access in relation to the global human therapeutics industry?

    In relation to the global human therapeutics industry, there may be substantial impacts of a formal classification of a clinical trial or use of a therapeutic GMO under the Australian Gene Technology Regulatory Scheme on activities that global pharmaceutical companies need to undertake in Australia in relation to conducting the trial compared to other jurisdictions. This may cause Australia to miss out unnecessarily on global clinical trials. If it takes a long time to get a licence there may be a serious risk to Australia's ability to participate in, and benefit from clinical research.

THEME THREE: GOVERNANCE ISSUES

Credibility, integrity and legitimacy of the Scheme – In taking into account the above the Review is exploring opportunities to maintain and enhance the transparency of, and trust in, the governance arrangements of the Scheme. Some questions to consider:

11. **What will reassure the Australian public and regulated communities of the integrity of the Scheme?**
    The independence of the Regulator and the integrity of the science-based risk assessment process.

Agility and national consistency of the Scheme - The Review is exploring how to ensure the rate of adaptation of the Scheme keeps pace with changes in technology and community values. Some questions to consider:

12. **Does reviewing the Scheme every five years best address the needs of the Scheme? Is there a preferable option?**
    Every five years should be sufficient if the Scheme is future proofed and there is a mechanism for addressing new and emerging issues of importance.

    One mechanism for enabling new needs to be addressed as they arise is that the Regulator be allowed to make a formal determination about whether something is under the Act or not (at the moment the Regulator can only provide advice).

Harnessing the economic and health benefits of gene technology - The Review is exploring how the Scheme can harness any emerging benefits of gene technology that were not anticipated at the establishment of the Scheme. Some questions to consider:

13. **Are existing mechanisms, when used effectively, sufficient to ensure the emerging health, environmental and manufacturing benefits of gene technology that were not anticipated at the establishment of the Scheme, can be harnessed for Australians?**

    Yes provided system is future-proofed. This is covered under 3-9 & 12 above

REVIEW THEME FOUR: SOCIAL AND ETHICAL ISSUES

Access, equity and choice for Australian consumers and patients - The Review is seeking to better understand how to balance consumer choice within the scope of the Scheme. Some questions to consider:

14. **What does the public need in order to accept the increasing availability and range of use of gene technologies?**
    Assured safety and sound regulatory approaches
15. **What does the public need in order to determine whether to provide social licence for the adoption and embedding of gene technology into the culture, lifestyle, economy and health sector?**
    Consultation, assured safety, sound regulatory approaches & trust in the regulatory system
16. **What are the ethical considerations for enabling access to medical treatments?**
    Safety and equitable access, funding & payment mechanisms