**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.