National Gene Technology Scheme – The Third Review of the Gene Technology Scheme - Preliminary Report

The gene technology scheme is a nationally cooperative scheme between all states, territory and commonwealth governments and is underpinned in the gene technology agreement 2001. The scheme consists of the agreement, Commonwealth acts and regulation and state legislations. The scheme regulates the gene technology using a risk based approach.

The scheme is regularly reviewed as required under the agreement. So far two reviews were undertaken (2006, 2011) focussing on the operation of the scheme. The third review not only focusses on the policy objectives, but also on the rapidly developing areas of gene technology.

Third review has undergone two phases of consultation with stakeholders and third phase gives another opportunity for stakeholders to contribute to the review outcomes. NSW Health was not involved in the initial two phases of the consultation process.

Overarching Findings

Provide your feedback below, clearly identifying any specific findings you have commented on in your response.

Findings 1 - 2

1. NSW Health supports the current precautionary and risk assessment approach to human and environmental health and it should continue to be a central tenet of the regulatory scheme.

2. NSW Health also supports development of policy principles for specific topic areas.

Findings - Theme 1 - Technical Issues

Provide your feedback below, clearly identifying any specific findings you have commented on in your response.

Findings 3 - 7:

4. Biosecurity risks arising from synthetic biology and other emerging technologies should be considered and monitored by the scheme as they could have significant impact on the human health.

5. The National Health and Medical Research Council (NHMRC), in collaboration with state and territory health departments, may be an appropriate agency to consider reviewing the

application of human gene therapies. NHMRC is the national body that promotes the development and maintenance of both individual and public health standards. It is responsible for developing guidelines on matters pertaining to the environmental impacts on health (for example, blood lead levels and drinking water quality); thus, the NHMRC's input could be beneficial for state regulatory authorities such as NSW Health.

6. Post release monitoring for biological control agents should include monitoring for potential human health effects. For example, the development of a genetically modified grass may release pollen that may result in excess morbidity and mortality related to conditions such as allergies, dermal rashes, respiratory illness, or other unusual symptoms related to the release.

Findings - Theme 2 - Regulatory Issues

Provide your feedback below, clearly identifying any specific findings you have commented on in your response.

Findings 8 - 15:

8. NSW Health supports process based trigger rather than product based trigger for entry point for the scheme that gives a broad coverage of technologies.

9. Risk tiering may create an impression within the community about certain technologies being less regulated than other. Careful consideration should be given to public perception when adopting any risk tiering mechanisms within the scheme.

12. Do It Yourself (DIY) biology has the potential to create complex genetically modified organisms and educating these groups that their activities fall under the scheme would be beneficial.

Findings - Theme 3 - Governance Issues

Provide your feedback below, clearly identifying any specific findings you have commented on in your response.

Findings 16 - 28:

Response

17. While national consistency of the scheme is important, a lot of the moratoria are driven by the public perception of the GMO technologies. To address community concerns certain level of independence should be afforded to the states on the regulation.

20. NSW supports risk based assessment nature of the scheme rather than benefit consideration of the product.

22. Support development of policy principles, guidelines and codes of practise on a range of topics.

Findings - Theme 4 - Social and Ethical Issues

Provide your feedback below, clearly identifying any specific findings you have commented on in your response.

Findings 29 - 33:

29. The Office of Gene Technology Regulator (OGTR) should maintain a high level of transparency when they assess risks. Stakeholder comments should be detailed and the OGTR responses to the concerns raised should be provided with a detailed response. These should be available on the OGTR website for public to access and include a response directly to the stakeholder.

32. Ongoing engagement and public education of risks and benefits of the GMO technology would be beneficial using recognised risk communication models.

32. Surveillance of post release information and data collected should be made available on OGTR website.