NSW GOVERNMENT | Department of Primary Industries

OUT18/3093

The Gene Technology Regulator
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Dear Dr Bhula,

TECHNICAL REVIEW OF THE GENE TECHNOLOGY REGULATIONS 2001: INVITATION TO COMMENT ON DRAFT AMENDMENT PROPOSALS

NSW Department of Primary Industries (DPI) welcomes the opportunity to participate in the public consultation on draft amendment proposals for the Technical Review of the Gene Technology Regulations 2001.

1. **What is your preferred option? Please explain why**

   DPI supports the amendment of the Gene Technology Regulations as proposed by the OGTR (Option 2) as it provides an appropriate balance between enabling advances and ensuring regulatory control, is consistent with past approaches to regulation and provides clarity to ensure that significant modifications are appropriately regulated.

2. **Do the draft amendments clearly implement the measures described in Section 3 of the Consultation RIS? If not, which areas of the draft amendments do you think require additional clarification and what clarification is needed?**

   The draft amendments succinctly provide clarity on the techniques that will be judged to create genetically modified organisms (ODM, SDN-2), those that do not create genetically modify organisms (SDN-1), the conditions that determine whether or not RNAi techniques create genetically modified organisms, and specific organisms that are not regarded as genetically modified organisms. These amendments would repeal Item 1 of Schedule 1.

3. **If your preferred option is Option 3, please indicate which amendments (or parts thereof) you support being progressed and why.**

   N/A; DPI supports Option 2.

4. **What are the costs and benefits to you or your organisation from the proposed amendments? Please describe these compared to current arrangements for each area of amendment:**

4.1 Clarifying the GT Regulations to take technological developments into account (i.e. in relation to SDN-1, SDN-2, ODM and RNAi)

- Provides clarity on exactly what is regulated and certainty for researchers and industry by ensuring legal clarity
- Provides public assurance of the regulation of 'high risk' technologies
- Increased transparency on gene technology techniques and the scope for compliance
- May result in some increase in regulatory burden for a subset of researchers

4.2 Repeal of Schedule 1 item 1, specifically whether you currently work with organisms that are not GMO's solely because of this item

The allowance of 12 months to apply for GMO dealing authorisations should alleviate any regulatory issues.

4.3 Updating the categorisation of contained dealings with GMO's

Nil impact is anticipated

4.4 Minor Administrative changes

Minor administrative changes are essential to ensure the language, format and nomenclature are current and non-ambiguous. Clear definitions are a key component and regarded as a strong benefit.

5. **Are the proposals to change the classification of certain NLRDs and exempt dealings (identified in Appendix B of the consultation RIS) commensurate with any risks to the health and safety of people and the environment posed by the dealings?**

   It is the view of DPI that this is appropriate.

6. **Are there any features in the options presented that you have concerns with? Or, are there any particular features that you believe should be included? Please explain why and give substantiating evidence where possible.**

   DPI has no additional issues.

Thank you for the opportunity to comment on the review.

Yours sincerely

KATE LORIMER-WARD
A/DEPUTY DIRECTOR GENERAL
DPI AGRICULTURE