Government of **Western Australia**
Department of **Agriculture and Food**

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Your Ref: Review of *Gene Technology Act 2000*
Our Ref:
Enquiries: Dr R McCauley (08 9 368 3787)
Date: 13 June 2011

Dear Madam/Sir

REVIEW OF THE *GENE TECHNOLOGY ACT 2000*

Members from the Western Australian Gene Technology Interdepartmental Committee (GTIDC) and the Department of Agriculture and Food Western Australia's Institutional Biosafety Committee (IBC) submit the following comments to the review of the *Gene Technology Act 2000.*

Yours sincerely

Dr Mark Sweetingham
Chair
GTIDC

R McCauley

Dr Rosalie McCauley
Chair
IBC

SUBMISSION TO THE REVIEW OF THE *GENE TECHNOLOGY ACT 2000*.

Over the last five years the *Gene Technology Act 2000* (the Act) has been effective and efficient. Since 2001 there has been a steady increase in the use of genetically modified organisms (GMOs) in research and the regulated community have become more familiar with the Act. In addition, the Office of the Gene Technology Regulator (OGTR) staff have gained experience in the implementation of the Act. Both of these factors have contributed to the effective and efficient operation of the regulatory scheme.

The 2005-06 review of the Act made several recommendations for improvements to the margins of the Act. The recommendations below also relate to proposed changes to the margin of the Act. The review panel should consider:

- Review and clarification of the role of Institutional Biosafety Committees (IBC) in the supervision of licensed dealings at multiuser facilities. It is not clear how the IBC of an organisation overseeing a multiuser site should operate. As multi-disciplinary research becomes more common there is a need for clarity in supervision of this research.
- Consideration of the management of dealings which are carried out by one organisation at their own facilities on behalf of other organisations. The review panel may consider:
    - Amendments to the Act Part 5, Division 2, Section 40 could create a class of licensee where organisation A is not the owner of the GMO or the intellectual property but are responsible to the OGTR for compliance with the licence conditions. In other words, reallocation of the licence to a third party for the purpose of conducting the trial.
    - An alternative would be to create a class of certification under Part 7, Division 2; Certification which would qualify an entity, which is a service provider, to be responsible for the conduct of the licence.
    - Such a facility might also be accommodated as a condition of Section 89A, Transfer of certification.
    - Under Part 5, Division 2, Section 40, (5) (a), could be an interpreted or clarified to include an entity, which is an accredited organisation with certified facilities for multiple GMO dealings.
    - It could also be possible under Part 7, Division 3 to create a definition of an accredited organisation which empowers the organisation to conduct multiple dealings involving release (DIRs) on a single site.
    - Certification of multi-user trial facilities for DIRs. Certification should cover Standard Operating Procedures, behavioural requirements, containment and streamlined reporting on all dealings at the site.
- Consideration of a mechanism to expedite review of selected DIR applications. As there is now a considerable level of knowledge of the biology of crop varieties and more experience with GM crop varieties the review panel could consider whether it would be worthwhile to develop a mechanism to expedite the license assessment of varieties with a safe history of use e.g., GM bananas.
- Review of the need for a full application process for GM crops with stacked traits where the individual traits are already approved. As an example, Food Standards Australia New Zealand approved canola with InVigor® and Roundup Ready® traits for human consumption without re-review while the Gene Technology Regulator is required to carry out a full risk assessment. Is this necessary or is there a need to reduce regulatory burden?
- Consideration of the issue of ongoing regulatory burden imposed by the lack of harmonisation between AQIS and OGTR certification guidelines. Recommendation 6.3 from the 2005-06 review of the Gene Technology Act 2000 recommended that the OGTR and AQIS harmonise their guidelines and establish a system of single audits to meet the needs of both organisations as

soon as possible. To our knowledge this goal has not yet been achieved and there is still considerable regulatory burden for those managing AQIS and OGTR certified facilities.

- Some members of the community continue to view dealings with GMOs with distrust and in some cases fear. The review panel could consider whether there should be more communication from the GTECCC to the public on the GTECCC's role and advice provided to the OGTR on license applications.