MONSANTO

MONSANTO AUSTRALIA LIMITED
A.B.N. 86 006 725 560
12TH FLOOR, 600 ST KILDA ROAD
MELBOURNE VIC 3004
POSTAL ADDRESS: PO BOX 6051
ST KILDA ROAD CENTRAL
VICTORIA 8008, AUSTRALIA
PHONE 61 3 9522 7122
GENERAL FAX 61 3 9522 6122
www.monsanto.com

GTMC Secretariat
Department of Health and Ageing
MDP 138
GPO Box 9848
CANBERRA ACT 2609

14 June 2011

Dear GTMC Secretariat

RE: REVIEW OF THE GENE TECHNOLOGY ACT 2000

Monsanto Australia welcomes the opportunity to contribute to the Review of the *Gene Technology Act 2000* that was announced on Thursday 26 May.

Monsanto is an agricultural company that applies innovation and technology to help farmers around the world produce more while conserving more. We help farmers grow yield sustainably so they can be successful, produce healthier foods, better animal feeds and more fiber, while also reducing agriculture's impact on our environment. In the period that the *Gene Technology Act 2000* has been in force, we have been one of the very few companies to bring gene technology products in market in Australia, and have conducted numerous regulated field trials under the legislation. We therefore feel that we are in a strong position to provide comment for this review.

In the first instance, we would like to stress our support for the current Gene Technology Act, as administered by the Office of the Gene Technology Regulator (OGTR). The Act provides certainty for innovators by establishing a process that is both transparent and has clear timeframes, while at the same time introducing a comprehensive risk assessment framework. In addition, it is clearly accessible to interested members of the public and accountable to Federal Parliament. The staff at the OGTR does an excellent job in administering this legislation and in carrying out the Objective of the Act. As a result, Monsanto does not believe that there is a need

to make large scale changes to the processes established by this regulatory scheme. Rather, this Review should be used to reinforce all jurisdictions' commitment to a national regulatory scheme for gene technology, and to address aspects that were not foreseen at the time of drafting of this legislation.

In this regard, Monsanto supports the submission from CropLife Australia. We believe that data protection, regulatory duplication and over-regulation, and product discontinuation are important issues that have not been adequately addressed under the Gene Technology Act to date, and which require further consideration.

The introduction of a data protection scheme, as is the case for similar innovations in Australia (such as agricultural chemicals) would be welcome, and has been a request of industry for many years. We would propose a fifteen year protection time-span, especially with patents about to expire.

Discontinued products are authorized commercial plant biotechnology seed products that have reached the end of their commercial life cycle. While sales have terminated, grain and plant-derived products may still be present in the food, feed and grain supply (please note that this is a distinctly different situation from a product recall.). Product discontinuance is the process by which sales of an authorized commercial seed product are terminated, including a) cessation of commercial sales; b) use of quality management practices to minimize the presence of the discontinued product in other seed; c) notification of key stakeholders that the product has been discontinued; d) coverage of regulatory needs and e) where applicable, varietal deregistration or de-listing. Discontinued products need to be addressed with case-by-case solutions, in discussions with the registrant, since low level presence may dissipate at different rates for different products based on commodity use patterns outside the registrant's control. These products should also be exempt from new or ongoing regulatory requirements (such as annual reporting or costly monitoring where no incremental value is provided).

Monsanto also sees this Review as an opportunity to address duplication and overlap between the Gene Technology Act and other existing legislation. This leads to increased costs, as well as to uncertainty, difficulty and delay in planning for the commercial introduction of new technology. One only needs to look at the number of commercially-approved GM crops to see that this is having an effect. We therefore support CropLife Australia's call for the Ministerial Council to direct the Intergovernmental Regulators Forum to review this duplication and any other areas of regulatory overlap.

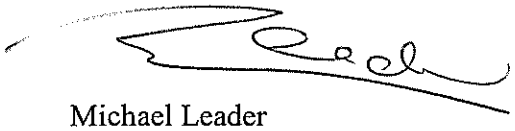
For biotechnology derived crops, Monsanto also believes that the data requirements on novel breeding techniques should be as low as is reasonable to assure for the protection of food, feed and environmental safety based on the nature and characteristics of the product. Safety assessments should be driven by characteristics of the product, rather than evaluating risk based on the process used to produce the product. Given the characteristics of biotechnology derived products and the demonstrated history of safe utilization of these products, regulations and data requirements on transgenic biotechnology products should be evaluated and excessive requirements lowered.

Not only is there duplication and uncertainty during the application process, but the history of the introduction of GM canola into Australia clearly demonstrates that difficulties also currently exist once commercial approval is actually received from all regulators (OGTR, APVMA and FSANZ). The introduction of State legislation and moratoria has significantly impacted the ability of innovators in Australia to bring gene technology products to market. Monsanto itself has been directly impacted by these decisions, having received commercial approval for Roundup Ready canola in 2003, and still not having the ability to offer this new technology to all growers in Australia who want it, or even for this approved gene technology trait to be able to be transported through some States. Not only that, but there continues to be attempts by local councils and others to prevent the trials of our second generation GM canola, which will increase the glyphosate application window for farmers (as Roundup Ready Flex has done). We continue to invest in Australia, but fewer and fewer companies are doing so. The 2006 Review of the Gene Technology Act recommended that the Commonwealth and States, through the Gene Technology Ministerial Council, reconfirm their commitment to a nationally consistent scheme for gene technology, and it is now time for this recommendation to be fully and completely implemented.

Monsanto would also like to use the opportunity of this Review to highlight the increased use of administrative conditions on field trial licences. Licences nowadays, for example, require a significant number of notifications (eg: planned planting date, actual planting date, estimated flowering date, actual flowering date, expected harvest date, actual harvest date) during the trial period which we believe are not related to risk, but more to ease of auditing. Some of these also have different notification deadlines to others. This may actually prove to be counteractive to ensuring compliance, and adds to the costs of conducting field trials. Licence conditions (including those associated with authorised persons, transport, monitoring and reporting) should reflect the realities that they are being introduced to address, rather than being too specific – otherwise they run the risk of being too prescriptive and unmanageable from a regulatory perspective (please see CropLife Australia's submission to the review of the Gene Technology Regulations as an example).

Thank you again for the opportunity to make a submission to this Review. We would also welcome an opportunity to discuss any of these aspects in more detail with the Ministerial Council, given Monsanto's extensive and successful experience with the Gene Technology Act, as well as with other such regulatory frameworks around the world.

Yours sincerely



Michael Leader
Regulatory Affairs Lead
Email: michael.leader@monsanto.com