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Elton Humphery
Committee Secretary
Community Affairs Committee
Department of the Senate
PO Box 6100
Parliament House, Canberra ACT 2600

Dear Mr Humphery,

Inquiry into Gene Technology Amendment Bill 2007

I refer to the recent invitation by the Community Affairs Committee for written submissions in relation to the "Inquiry into Gene Technology Amendment Bill 2007" (herein referred to in this submission as "the Bill"). Monsanto, as a provider of gene technology to Australian farmers, has a considerable interest in this bill and we have therefore reviewed the Bill and offer a number of comments.

We note an independent panel has reviewed the Gene Technology Act 2000, involving extensive community consultation over a lengthy period. It appears that the Bill reflects the recommendations of the panel as accepted by the Gene Technology Ministerial Council. Whilst we therefore urge the committee to recommend adoption of the bill largely as presented, we do have some concerns in relation to specific sections of the Bill and these are listed below.

Items 24-35:

We strongly support the creation of a single Gene Technology Ethics and Community Consultative Committee, to replace the two current committees that perform these functions. We agree that this should improve the efficiency of operation of these committees and reduce overlap between their current operations.

However in order to maintain the impartiality of the committee, we consider that persons actively involved (either individually or as part of an organisation) in campaigning in the public arena, either **for or against** gene technology should not be permitted to be appointed to the committee. In our opinion, such persons are not necessarily representative of the community and may not present objective considerations or balanced views. Past experience indicates that these biases in persons participating in such committees can lead to polarisation of committee members, subsequently hampering the effectiveness of the committee and reducing the quality of the advice given to the Regulator. The public consultation processes already provided for in the *Gene Technology Act* give ample opportunity for gene technology advocates and opponents to contribute to regulatory decision making.

We urge the committee to recommend addition to section 108, criteria that exclude the appointment of individuals/organisational representatives actively involved in campaigning for or against gene technology.

Item 39:

Item 39 creates a new category of licence application, to be known as 'limited and controlled release' applications. This will allow a streamlined process for the assessment of such applications, that by their very nature of being limited and controlled, present lower risks.

Monsanto strongly supports the creation of this category as it should improve process efficiency, and allow the Regulators' resources to be focused on assessing less controlled releases.

We consider the definitions of limits of controls as put forward in subsections 50A(2) and 50A(3) appropriate and useful for applicants and the Regulator in deciding the categorisation of an application. We also consider the criteria given in subsections 50A(1)(b) and 50A(1)(c) appropriate.

However, we do have concerns regarding criteria listed in subsection 50A(1)(a) that requires such applications to have the principal purpose of enabling the licence holder "to conduct experiments". We consider in protecting the health and safety of people and the environment (which under section 3, is the object of the *Gene Technology Act),* the limits and controls on the proposed dealing are far more important than the purpose of the dealing.

To illustrate this, during the consideration by the Regulator of Monsanto's application for commercial use of Roundup Ready Flex cotton (DIR 059/2005), our partner seed companies were able to produce limited quantities of seed under the limited and controlled release conditions of DIR 055/2004. This enabled the produced seed to be stored and subsequently made available for use by cotton growers when DIR059/2005 was issued. However these production activities do not fit within the criteria of experiments as defined under subsection 50A(4), and thus in the future would be not allowed under a limited and controlled release. Excluding such activities from this category only delays access to technology for growers, yet provided the release fits within the meanings of 'controls' and 'limits' , there is no difference in protection of the health and safety of people or the environment.

Other examples of limited and controlled release that may not fit the definition of experiment are seed breeding activities, seed production for export, seed production for shipment to areas in Australia where commercial use of a GMO is allowed (noting that licences on commercial release could contain geographical restrictions due to differing environments in Australia), production of plant-made pharmaceuticals under limited and controlled conditions, and plantings of GMOs to demonstrate use of the technology to growers.

We urge the committee to recommend removal of subsections 50A(1)(a) and 50A(4) from the Bill.

Item 48

See above (Item 38), the same considerations apply to subsection 71(2A)(a) as to subsection 50A(1)(a).

We urge the committee to recommend removal of subsections 71(2A)(a) from the Bill.

We thank the committee for the opportunity to make a submission to their enquiry into the *Gene Technology Amendment Bill 2007.* Should the committee have any questions in relation to the comments provided above, please do not hesitate to contact myself or one of my colleagues.

Yours sincerely

David Penna
Regulatory Affairs Lead – Australia/NZ
Monsanto Australia Limited

13 April 2007