GRDC Grains Research & Development Corporation

13 April 2007

Community Affairs Committee
Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600

Mr Elton Humphery
Committee Secretary

Dear Mr Humphery,

The Grains Research and Development Corporation (GRDC) welcomes the opportunity to provide a submission to the Senate Standing Committee on Community Affairs in relation to the Gene Technology Amendment Bill 2007 (the Bill).

The Corporation is a major supporter of plant breeding and agronomic research programs that are carried out by both public- and private-sector research organisations across Australia. Some of this research includes the application of gene technology and other innovative technologies that have been developed from the research field of biotechnology.

The GRDC wishes to comment on two parts of the Bill, namely Part 6 which relates to inadvertent dealings, and Part 3 which relates to increasing the efficiency of the regulatory system by improving the process by which licences are initially considered and streamlining the application process for licences involving a limited and controlled release of a genetically modified organism (GMO).

The GRDC supports the amendments in Part 6 to the Bill as proposed. The amendments would provide a sensible solution to allow individuals who unintentionally come into possession of a GMO to dispose of the GMO without breaching the Act.

However, the GRDC believes the Bill would be improved by a minor amendment to Item 38 that relates to Part 3. Specifically, Item 38 should be modified to retain the requirement to consult with the Gene Technology Technical Advisory Committee (GTTAC) when dealing with limited and controlled release applications, for reasons detailed in the body of the submission.

The GRDC would be pleased to discuss the issues raised in this submission in more detail should the Committee so wish.

I look forward to seeing how the amendments proposed in the Gene Technology Amendment Bill 2007 are incorporated into the next revision of the *Gene Technology Act 2000*.

Yours sincerely

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Grains Research & Development Corporation

Submission

Gene Technology Amendment Bill 2007

13 April 2007

The Grains Research and Development Corporation (GRDC) is a major supporter of plant breeding research in Australia. This research is carried out by both public- and private-sector research organisations, including State Departments, the CSIRO, universities, Cooperative Research Centres and a number of private breeding companies. Some of the plant breeding research supported by the Corporation involves the application of gene technology and other innovative technologies such as functional genomics and the use of molecular markers that have been developed from the research field of biotechnology. When used together, the application of these technologies can greatly improve the speed, efficiency and precision of plant breeding.

The GRDC is pleased to offer the following comments in relation to Part 6 and Part 3 of the Bill which are both relevant to the Corporation and a number of its research partners.

Part 6 — Inadvertent dealings

Part 6 to the Bill proposes amendments to allow the Regulator to grant a temporary permit to a person who finds himself or herself inadvertently dealing with an unlicensed genetically modified organism (GMO). The licence will be issued to the person for the purposes of disposing of the GMO in a manner which protects the health and safety of people and the environment.

The object of the proposed amendments is to allow a person who has unintentionally come into possession of a GMO to dispose of the GMO without breaching the Act. Under the current Act, the Regulator can rely on the offence provisions or injunctions to deal with unapproved dealings with a GMO. However, these tools are not suited to a case where a person wishes to act cooperatively and dispose of the GMO in accordance with the Regulator's requirements to protect the health and safety of people or the environment.

The GRDC supports the amendments in Part 6 to the Bill as proposed. The amendments would provide a sensible solution to allow individuals who unintentionally come into possession of a GMO to dispose of the GMO without breaching the Act.

Part 3 — Assessment of applications: limited and controlled release and consultation on significant risk

Part 3 relates to: 1) improving the process by which licences are initially considered; and 2) increasing the efficiency of the regulatory system by streamlining the application process for licences involving a limited and controlled release of a GMO.

Item 36 would repeal section 49 of the Act. Under this section, the Regulator is currently required to assess whether a proposed dealing may pose a significant risk **BEFORE** developing a Risk Assessment and Risk Management Plan (RARMP). This has proved problematic, as it can be difficult for the Regulator to make a judgment on the risk of a GMO prior to the development of the comprehensive RARMP. Item 36 would repeal this requirement, thereby allowing the Regulator to identify the significant risk **AFTER** he or she has developed a RARMP under section 50 of the Act.

Item 39 would insert a new section 50A into the Act. This section would create a new category of licence application, to be known as 'limited and controlled release' applications.

Item 38 would amend subsection 50(3) of the Act to make clear that **if an application is a limited and controlled release application, the Regulator does not need to seek advice** from the States (including the Australian Capital Territory and the Northern Territory), the Gene Technology Technical Advisory Committee (GTTAC), prescribed Commonwealth authorities and agencies, the Environment Minister, or local councils on the preparation of an RARMP.

These amendments recognise that an application for a release of a GMO for the purposes of obtaining experimental data will generally be limited in terms of time, spatial scale and location and have containment measures to restrict dissemination. In contrast, applicants wishing to intentionally release a GMO may wish to produce that GMO commercially and will generally seek a licence with as few restrictions as possible. Hence, licences for 'intentional release' would need to undergo a more rigorous risk assessment process than licences for a limited and controlled release.

The GRDC's understanding of the *Gene Technology Act 2000* and its proposed amendments in relation to limited and controlled releases (e.g. experimental trials) are as follows:

1. The Regulator must prepare a Risk Assessment and Risk Management Plan (RARMP).

2. The Regulator must determine if there is any SIGNIFICANT risk and must notify the public if he/she has found a SIGNIFICANT risk (Item 44). The proposal specifically allows the Regulator to identify a significant risk **AFTER** the RARMP has been established (Item 36). This amendment is counter-intuitive unless one assumes that a standard RARMP can be (or has been) developed to deal with any risk that may be inherent in any experimental trial.

3. When it comes to limited and controlled release applications (Item 39) the Regulator will no longer be required (Item 38) to consult with State, Territory and Commonwealth authorities, the Environment Minister, local governments, and the GTTAC. The GRDC interprets these amendments to mean that the consultation waiver is tied to the release category (limited and controlled) but not to

the risk. This makes no sense whatsoever—even if one accepts that the RARMP would deal with any risk that may be inherent in any experimental trial (as noted above)—and needs urgent reconsideration. The GRDC is concerned that the GTTAC may not formally see an application for a limited and controlled release. This raises the possibility of a situation where the Regulator could find it difficult to determine whether a GMO may pose significant risks (see Item 36 on p.12 of the Explanatory Memorandum), but does not consult with scientific peers who could help him/her to make that judgement. The GRDC would argue that the Regulator exposes him/herself to unnecessary criticism when taking sole responsibility for the preparation of the RARMP. Clearly, a technical peer review process would be highly desirable for limited and controlled release applications as well. By retaining a consultation process of some sort on the RARMP, Item 38 would also become consistent with Item 44, under which a significant risk must be identified prior to the consultation process on the RARMP.

On the basis of the above, the GRDC recommends that Item 38 be modified to retain the requirement to consult with the GTTAC when dealing with limited and controlled release applications.

END