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15th December 2017

Gene Technology Review Department of Health MDP 1060 **GPO Box 9848 CANBERRA ACT 2601**

Re: 2017 Review of the National Gene Technology Regulatory Scheme

Grain Trade Australia (GTA) appreciates the opportunity to provide this supplementary submission to the Department of Health's Review of the National Gene Technology Regulatory Scheme. GTA has participated in the second phase consultative workshops and would like to take this opportunity to make some supplementary points. GTA's position is unchanged from its original submission and this letter supports our initial submission and seeks to reinforce or clarify some key points that have been discussed during the recent consultations.

Australia's regulatory system

GTA supports the importance of a functioning regulatory system for gene technology and believes that the Office Gene Technology Regulator (OGTR) and the supporting legislation that is in place in Australia delivers an effective and efficient system. Any changes should only enhance the scheme that is in place and working.

GTA supports the National Gene Technology Regulatory Scheme (Scheme) and believes that it has been effective in providing certainty and confidence to the industry and community in relation to GM crops. GTA also believes that Australia is seen as a model for other parts of the world in terms of its approach and regulatory outcomes. It is critical for the grains industry that there are effectively functioning regulatory systems in the countries with which it trades.

Scope of the regulatory system

GTA supports the current scope of the Scheme i.e. application to human health and environment. We do not support any extension to economic or trade issues. These are commercial issues and the Australian grains industry's market choice approach has provided an effective mechanism to meet domestic and global market requirements. GTA has recently updated the industry's market choice Framework (Market Choice Framework with GM Crops 2016).

Scheme framework

GTA supports the principle of providing more flexibility to the regulator (OGTR) to apply the regulation differently based on relative risks. The current scheme has a one size fits all approach, however, there are significant differences in the potential risks to human health and environment depending on the technology and where it is being applied.

GTA believes that focusing the Scheme around principles supported by regulations and guidelines to deal with specific technologies and risks will provide the framework for risk based flexibility in application of the regulation and enable the scheme to keep pace with changes in technologies.

As such, we support a tiered risk approach. This tiered risk approach will be a combination of process and product based risks and triggers.

A practical example of the above Framework and tiered risk approach, would be in relation to the recent OGTR review of regulations where this framework should enable OGTR to adopt Option 4 for the plant sector, while potentially maintaining Option 3 for other sectors based on the risk assessment.

The tiered risk approach would also provide the flexibility to align the assessment time for OGTR applications to the level of risk presented by each application.

It is recognised that implementation of this approach may require review and enhancement of responsibilities of the Regulator, Gene Advisory Committee and Institutional Biosafety Committees (IBCs).

Role of other regulators

It may also be appropriate to review the role of other regulators, and in particular whether there are opportunities to consolidate roles into the OGTR and reduce duplication e.g. APVMA in case of the plant sector.

There is also a need for consistency in definitions between the various regulators.

International consistency

GTA would also encourage OGTR to maintain a close involvement with international partners in the regulatory environment and to remain engaged with global initiatives.

A major challenge for the global grain trade is the lack of consistency in regulations regarding gene technology regulation globally. GTA supports the harmonisation of regulation and encourages Australia to remain involved in international forums on gene technology related issues including Cartagena biosafety protocol, low level presence, regulation of new technologies and other similar initiatives.

GTA works with the International Grain Trade Coalition (IGTC) to try and achieve global harmonisation in the approach to regulating such activities. The main aim of IGTC efforts is to achieve international alignment, i.e. adoption of a similar approach across jurisdictions leading to legal certainty as this will provide for the lowest chance of trade disruptions. Alignment and regulatory coherence will assist governments to avoid unnecessarily eroding the value of the innovation and/or driving up costs and complexity in the global food system.

Thank you for your consideration of this submission.

Regards

Pat O'Shannassy

CEO



Membership List as at 05 December 2017

Organisation Contact Website /Phone

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Level A2 (5 - 7 Million Tonnes)

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Level A3 (3 - 5 Million Tonnes)

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bunge.com/Agribusiness

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Whyalla Beef Pty Ltd

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Wimpak Pty Ltd

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