

TECHNICAL REVIEW OF THE GENE TECHNOLOGY REGULATIONS 2001

SUPPLEMENTARY PAPER:

International considerations - Regulatory implications for trade and market access of GM agricultural crops

Purpose of this paper

To outline and acknowledge potential regulatory implications for trade and market access that may be associated with amendments to the Gene Technology Regulations 2001 (the GT Regulations).

The potential issue

A separate consideration to the scientific and risk-based foundation to the recommendation to exclude organisms modified using SDN-1 from regulation, is the issue that these amendments may have implications for trade and market access.

This may come about through potential non-alignment with trading partners on what constitutes a genetically modified organism (GMO) and the associated impacts on Australia's ability to meet another country's import requirements.

For example, being excluded from the regulatory system in Australia might mean that should a country specify import requirements for SDN-1 organisms, such as prior risk assessment and approval, that this cannot be met through the gene technology legislation.

Current trade context for new technologies

Behaviours of trading partners vary considerably and can change at any time. Trade interactions are complex and multi-faceted; situations can shift with commodity type, points in time, demand, supply and issues around public perception.

To-date several major agricultural exporting nations have clarified their approach to the regulation of site-directed nuclease (SDN) technologies for crop plants. The United States, Argentina, Brazil and Chile have each formulated a position that is consistent with, or has more exclusions than, amendments proposed by Australia.

New Zealand has also clarified its approach, whereby all organisms modified using SDN techniques are GMOs. On 25 July 2018, the Court of Justice of the European Union handed down a decision that the European GMO Directive is applicable to all SDN techniques. It is too early to ascertain how the European Commission will implement the decision, or how jurisdictions within the European Union will approach the issues raised by the decision. It is worth noting that the European Union, despite it being one of the most highly precautionary markets for genetically modified (GM) products, imports large volumes of GM crops for stockfeed and biofuel purposes.

Many other countries are still to form views or positions on the regulation of SDN technologies.

Factors to consider in formulating a view on trade and market access implications

- a) *Scientific risk based regulatory system* - To avoid confusion and competing priorities, Australia's regulatory scheme deals separately with scientific risk-based decisions on human health and environmental issues, and those relating to commercial marketing, trade or market access. Australia has an internationally recognised reputation for having a functional scientific risk based regulatory system for managing human health and environmental risks.

The recommended amendments to exclude SDN-1 organisms are based on science and risk, noting that the organisms produced would have a risk profile the same as organisms carrying natural mutations, or derived through conventional breeding techniques.

- b) *Clarity* – Note that the resulting clarity from the Technical Review could have a positive effect of assisting trade and market access. Some stakeholders have indicated that, depending on how a trading partner's definitions and requirements are constructed, defining SDN-1 organisms as not being GMOs may provide trade advantages (ie. the commodity is not referred to as GM).
- c) *Detectability* – This is a key limitation for compliance with any trading partner requirements. The genetic changes brought about using SDN-1 are detectable with prior knowledge. However, the provenance of these genetic changes cannot be proven, as the same changes can occur by natural mutations or using conventional breeding techniques. In practice, it would be unfeasible to ensure compliance via a testing or monitoring regime if SDN-1 organisms were to be regulated as GMOs.

Potential responses or approaches to possible market implications

It is not clear whether marketing implications will arise due to the proposed amendments to the GT Regulations, noting that several countries have clarified their positions to be consistent with, or have wider exclusions than, the Technical Review recommendation. However, many others have not formulated a position at this stage, and the implications of the recent European Union Court of Justice decision are yet to become clear.

There are varying policy responses and tools to address potential market issues, and these could be applied depending on the circumstances. These include:

- a) *Self-regulatory market mechanisms* – the private sector responds to market signals and adapts to meet the demand. This could include segregation, co-existence and identity preservation systems.

Segregation, co-existence and identity preservation systems are operating for other commodities and could apply in this situation (noting the organic industry has concerns about the effectiveness of these approaches). Due to detection limitations for identification of products derived from SDN-1 organisms, a system of segregation would likely be based on product characteristics or qualities (i.e. oil content), or documentation and declarations.

- b) *Regulatory approval, certification pathways or registration systems* – this category of response can be applied to marketing issues, for example, as occurs for export certification approvals for the organic industry, other traceability systems or the model used for biosecurity.
- c) *Moratoria/bans/specified crop free zones* – legislative prohibition on the cultivation and/or presence of certain crops within a country or region.

Noting Finding 15 of the Scheme Review Preliminary Report, Australian Government agencies, including the OGTR, will continue to monitor developments in regulatory coverage of new technologies. Australia will participate in international dialogues with Governments to work cooperatively to minimise unnecessary barriers to trade and other issues related to the regulatory oversight of products of SDN technologies, including by exploring opportunities for regulatory alignment through various international fora (i.e. OECD, APEC and the Global Low Level Presence Initiative).

This work would seek to promote constructive dialogues with trading partners and agriculture stakeholders on trade and economic issues related to SDN technologies. This information could inform further work on GT Act definitions being progressed through the work plan for the Review of the Scheme under Finding 4 of the Preliminary Report.