Inquiry into Primary Producer Access to Gene Technology

Submission by Department of Foreign Affairs and Trade

Introduction

This submission summarises international developments and agreements that may be of interest to the Committee, as background to its examination of the issue of primary producer access to gene technology.

The adoption of gene technology offers considerable potential for significant improvements in agricultural competitiveness, environmental sustainability, and productivity. There are therefore important implications for Australian agricultural and agrifood producers and exporters. For this reason, trade policy issues will take on greater importance, as the use of gene technology becomes more widespread.

However there is also a considerable variation internationally in the level of public acceptance of genetically modified products. This could adversely affect the possibility both of development and of commercial exploitation, by encouraging such stringent controls that development is hindered, or more directly by making it commercially unattractive to market genetically modified products.

International developments

The issues that have emerged have included:

- the nature of the regulatory process used in different markets - timeliness, transparency, nature of safety assessment, and extent to which the process is strictly science based; and

- the best ways to ensure that consumers are fully and appropriately informed about the genetically modified products that they purchase and consume; current debate has focussed on labelling requirements.

Domestic Regulation

Many countries are still in the process of finalising their regulatory regimes, or reassessing them. The United States and Canada have the longest established regimes. Their regimes are broadly designed to encourage the production and use of genetically modified products, subject to safety assessments. In other major markets, the European Union is still developing the final form of its approach, but it tends to more restrictive requirements. There is a greater degree of consumer concern and resistance to genetically modified products in the

European Union than in the United States and Canada. Japan is also still in the process of devising its regulatory scheme, and recent indications are that they would be trying to finalise proposals by the end of August this year. Recent public consultations indicated different approaches as between consumers and industry, with consumers for example showing a strong preference for mandatory labelling of all genetically modified food, and industry more open to the potential commercial benefits of biotechnology

Differences in regulatory approach have been the cause of trade friction. This has primarily occurred between the United States and the European Union, and has centred on delays and uncertainties in the EU-approval process for United States' maize and soya into the EU market.

Labelling

The main issue currently receiving international attention is the extent to which labelling is required. There appears to be agreement that genetically modified foods that are substantially different from their conventional counterparts should be labelled as such. This would be the case when the modified product differs in respect of nutritional characteristics, appearance, taste, keeping quality or other significant property.

There has been however considerable discussion in both the WTO and the Codex Alimentarius Commission on the issue of labelling requirements for substantially equivalent products, that is, genetically modified foods that do not differ from their conventional counterparts.

In the WTO, the discussion has taken place in the Committee on Technical Barriers to Trade and has largely focussed on European Union proposals for mandatory labelling of all genetically modified foods, and their consistency with WTO obligations. The discussion has largely been critical on the grounds that there is no scientific evidence that food and food ingredients containing genetically modified organisms differ from their conventional counterparts in terms of health and safety standards. There has also been some comment of the same nature on current Australian proposals for similar labelling.

There are as yet no internationally accepted regulatory standards for foods produced using genetic modification. The Codex Alimentarius Commission, which has an international membership, and prepares and publishes standards on food, is currently preparing draft recommendations on labelling. It is dealing separately with substantially equivalent and substantially different foods. It does not expect an outcome on substantially different foods until 2001 at the earliest, with an outcome on substantially equivalent foods later than this.

Living modified organisms

There is also discussion on ensuring an adequate level of protection in the safe transfer, handling and use of living modified organisms resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity. This is being done in negotiations on a Biosafety Protocol, under the 1992 Convention on Biological Diversity. Most recent negotiations took place in Cartagena, Colombia from 14 to 23 February. Agreement on a text was not reached but it was agreed that negotiations would resume by May 2000. Australia, with other like-minded countries (known as the Miami Group, including Argentina, Canada, Chile, the United States and Uruguay) rejected the draft text that was on the table because it contained provisions that were unworkable, did not provide for adequate environmental protection, and were potentially inconsistent with WTO disciplines.

Australia has been committed to the successful conclusion of the Biosafety Protocol throughout the negotiating process. As one of the world's few biologically mega-diverse countries, with a particular reliance on our agricultural biodiversity, Australia has important interests at stake in the Protocol. Australia's objective is to achieve a workable protocol that would protect biological diversity without imposing undue restrictions on legitimate trade, imposing onerous bureaucratic procedures on exporters, or placing an unmanageable administrative burden on regulatory authorities.

WTO negotiations

We expect that trade issues related to biotechnology will be discussed in forthcoming WTO negotiations. The United States and Canada have been particularly advocating this but Japan has also proposed work be done. It is not yet clear what the focus of the work will be or how it will be organised.

Some of the issues that are liable to be raised include:

- organisation and location of the discussion (for example should it be confined to agricultural products or should it cover the full range, for example pharmaceuticals; should a special group be established, or should it be taken as one item in the broader negotiating agenda);

- extent to which trade in genetically modifed products is already covered by existing rules (particularly the Agreement on the Application of Sanitary and Phytosanitary Measures, the

Agreement on the Technical Barriers to Trade, Agreement on Trade Related Aspects of Intellectual Property);

- how the outcome of any discussions should be formulated: separate agreement; amendments to existing rules; statement or understanding confirming that they are covered; and

For Australia, a key issue is the need to ensure continued adherence to a risk-based approach which requires a scientific basis to decisions in this area, in line with the approach we have taken in other issues such as sanitary and phytosanitary measures, and food safety. We have consistently taken this line because it is in our interests as a major agricultural and food exporter that other countries are not able to impose regulations or requirements arbitrarily in ways that would damage our market access

Intellectual Property - International Aspects

Intellectual property (IP) law is part of the general regulatory and legal framework that helps determine the scope of access to gene technology. Effective, well-informed use of the IP system can contribute significantly to the access by small and medium enterprises to the benefits of gene technology. Australia's IP system conforms with the standards set out in the key international agreements relating to intellectual property rights.

The international agreements most relevant to gene technology are:

- the Paris Convention,[1] originally concluded in 1883 and most recently updated in 1967. This convention clarifies that 'industrial property' - a branch of intellectual property - extends to 'agricultural ... industries and to all manufacture or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.' Its rules cover, among other things, patents (including compulsory licensing of patents) and the suppression of unfair competition, which have direct bearing on access to gene technology
- the Budapest Convention,[2] which provides for the deposit of microorganisms in the context of patent applications for certain biotechnology inventions
- the UPOV Convention,[3] which harmonises national standards for the protection of plant variety rights
- the TRIPS Agreement,[4] which updates and extends international standards on a range of intellectual property issues, including:

[1] The Paris Convention for the Protection of Industrial Property (1967)
[2] Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977)
[3] International Convention for the Protection of New Varieties Of Plants (1991)

- the scope of patentable subject matter (including specific provisions on plant and animal patents, and plant variety protection)
- exceptions to patent rights, including compulsory licensing
- protection of undisclosed information, including regulatory test data
- measures to control anti-competitive licensing practices and conditions

Australia is also an active participant in the APEC[5] Intellectual Property Rights Experts Group (IPEG), which has been developing practical means of facilitating the use and administration of intellectual property rights, so as to cut the burden of red tape for those seeking to use the system.

These standards, and associated international and regional cooperation, help ensure that producers and users of technology are on an equal footing internationally. The international system provides for widespread dissemination of state of the art information about commercially significant developments in gene technology, through the patent documentation system. For those Australian companies and research institutions involved in developing new technologies, the international IP system is a vital mechanism for commercialising this research to reach global markets, and thereby funding further research. At the same time, general confidence in the relative effectiveness of Australia's IP system is an important factor in creating incentives for making new technologies available in Australia.

While the general framework of international agreements establishes a set of minimal standards, they also give national governments considerable scope for optimising policy settings with a view to promoting specific economic and social development goals. There is considerable international debate about the role of intellectual property rights in promoting and limiting access to the benefits of gene technology. Some factors that are often overlooked in this debate are: the function of the disclosure requirement for patent documentation in ensuring publication of new technologies and allowing scrutiny of claimed patent rights;[6] the scope for governments to address anti-competitive practices in relation to intellectual property rights, including practices which have adverse effects on trade and impede the transfer and dissemination of technology;[7] and the possibility of providing for unauthorised use ('compulsory licensing') of some patents in specific circumstances.[8]

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[4] The World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (1994)
[5] Asia Pacific Economic Cooperation
[6] TRIPS Agreement, Article 29
[7] TRIPS Agreement, Article 40
[8] TRIPS Agreement, Article 31

One area of flexibility under the TRIPS Agreement concerns the granting of patent protection for plant and animal inventions. Currently, it is optional for countries to extend patent protection to plant and animal inventions, other than micro-organisms, and inventions which are essentially biological processes for the production of plants and animals (other than non-biological and microbiological processes).[9] The extent to which this option is exercised varies widely among Australia's trading partners, and this variation is not determined just by north-south factors. At least from the point of view of the international commercialisation and marketing of agricultural and livestock production varieties, a trend towards greater harmonisation in this area would be beneficial for the Australian commercial interests concerned.

Conclusion

Trade related issues are relevant to access to gene technology, particularly regarding the commercialisation and marketing of agricultural varieties:

- the extent to which negative consumer sentiment in international markets leads to the establishment of regulatory frameworks that restrict trade in genetically modified products
- the low demand for genetically modified products in some markets;
- the nature of international agreements such as the Biosafety Protocol
- intellectual property rights and international trade rules on these; and
- outcomes of discussions in the WTO on issues such as labelling.

[9] TRIPS Agreement, Article 27.3(b)