Agriculture, Fisheries and Forestry Australia:

Submission to the House of Representatives Standing Committee on Primary Industries and Regional Services Inquiry into Primary Producer Access to Gene Technology.

Executive Summary

The following submission concentrates largely on providing information and analysis rather than specific recommendations. However, it does note that there is a clear need to address the reluctance of investors to support early work to commercialise gene technology innovation. While recognising constraints imposed by the nature of Australia's taxation system, it suggests that it would be worthwhile to have government agencies meet with agribusiness and finance industry leaders to discuss the commercial benefits of gene technology, and the timeframes in which these can be expected. An effective public awareness process to address consumer concern about gene technology, and the rapid establishment of a nationally uniform regulatory system for gene technology products, should also help. A transparent, scrupulously independent regulatory process is vital in gaining and keeping the confidence of the community.

Work is also under way on the question of end point royalties (EPR) as a method of encouraging further investment and commercialisation of field crop varieties. While EPR is seen as entirely commercial, the underpinning contracts may be predicated on the rights granted under Plant Breeders Rights. A Plant Breeders Rights experience survey has been commissioned by the Standing Committee on Agriculture and Natural Resource Management (SCARM), to, *inter alia*, investigate support for EPR and to identify any desirable changes or clarifications to Plant Breeders Rights, particularly those that may facilitate commercial arrangements between breeders and producers. The survey report will be submitted to SCARM later this year.

There is clearly a need to ensure that: all Australian agri-food gene technology researchers, their employers, and funders receive world class training in the intellectual property (IP) protection of their innovations; opportunities are explored for developing mechanisms, both formal and informal, to train researchers, employers and funders in the strategic management of agricultural gene technology IP and the related infrastructure; and support is initiated for the generation of a strategic portfolio of IP of enabling gene technology and isolated/improved genes, particularly those that will better position Australia to trade or otherwise gain access to foreign enabling technology or genes for use in minor crops.

Australia's national interest will be served by actively participating in the development and monitoring of the implementation of relevant international agreements. Australian agricultural interests need to be considered in developing Australia's position on international agreements, and national regulatory arrangements. Monitoring of overseas developments and progress in international agreements that affect trade in genetically modified organisms and plants is being carried out by AQIS Agricultural and Veterinary counsellors posted in our major trading destinations.

To ensure that Australia can access both the main stream (non-differentiated and genetically modified products) and specialty markets, there is a need for a certification process for products, and for infrastructure to ensure product segregation for specific markets. Quality assurance processes are increasingly forming the basis for international trade and are an accepted responsibility of industry.

In some cases, however, government oversight or audit is necessary and will need to be provided on a cost basis. At this stage in the application of gene technology, there is a need to actively explore the appropriate role for government as product segregation and certification processes are established (eg. economic research on the costs and benefits, the procedures necessary to ensure product integrity, the form of certification necessary, and the price to be charged); and the extent to which government needs to work with industry on this issue. The development of the AgriFood Biotechnology Strategy provides the most appropriate avenue for this activity.

Introduction

Gene technology has been used for over a decade to produce pharmaceuticals and the number of products being developed is increasing rapidly. Applying gene technology to agriculture has been a slower process, but genetically modified plants are now on the market, with a rapid increase possible over the next few years. The application of gene technology is less advanced for livestock industries, although recent advances in cloning have the potential to speed up this process.

Gene technology has great potential to improve Australian farming practices: providing more flexible farming systems; crops with in-built protection against pests and diseases; and, most importantly, a more sustainable environment. It also provides the potential for new product opportunities in the food industry, and for primary production to supply new markets, particularly in the chemical and pharmaceutical industries. Realising this potential would make a major contribution to improving agricultural and food industry competitiveness. However, the following are possible limiting factors:

- That Australia may not be able to develop gene technology that serves its interests.

- That Australia may not be able to access new gene technology from overseas.

- That Australia may lose overseas markets or market share because of a loss of competitive advantage due to lack of the new technology, or its inappropriate application.

Addressing these issues requires:

1. Government facilitation of research, development and commercialisation of gene technology.

2. A regulatory pathway to market.

3. Developing a positive climate of public opinion, that recognises that health and safety risks are addressed before products are placed on the market.

4. Ensuring that primary producers are aware of and have access to the new technologies.

5. Effective utilisation of a system of intellectual property rights that encourages Australian researchers to develop new technology and applications.

6. Ensuring access to overseas technology.

7. Appropriate overseas marketing of Australian products derived using gene technology; and the identity preservation and marketing of traditional, unmodified products.

1. Government facilitation of research, development and commercialisation of gene technology

- **How much gene technology R&D is conducted?**

Australia's current expenditure on agricultural gene technology is estimated to be around $100 million per year, or about 10% of total agricultural R&D expenditure. There has never been a consolidated review of scientific and technical resources available to Australia's rural industries, although several attempts have been made to develop a national database. As a result, the exact level of R&D expenditure on gene technology with agricultural applications is unclear. This matter is expected to be addressed by Biotechnology Australia, which has as one of its tasks the collection of data on Commonwealth expenditure on biotechnology R&D.

Most agricultural gene technology is being developed by public sector researchers, with CSIRO spending about $40 million per year on gene technology research in 1998. There is little private sector investment in gene technology development, probably $8-$15 million per year, by about 20, mostly small, companies.

In mid 1997, nine research and development corporations (RDCs) were funding 88 gene technology projects to a total of $28 million (about $12 million pa). These included recently completed projects, work in progress and new projects. Research topics include: improvements to pastures; animal feeds; animal breeding, health and nutrition; food processing; and enhanced product characteristics.

There are 86 sites currently registered with the Genetic Manipulation Advisory Committee (GMAC) to conduct contained genetic manipulation research in Australia. These include 28 universities, 26 medical facilities, 16 companies (and two companies that have applied for the release of genetically modified organisms - GMOs - but do not conduct research in Australia), 11 CSIRO Divisions and 4 State Departments of Agriculture.

The Agriculture, Fisheries and Forestry portfolio supports R&D via the funding provided to the rural R&D Corporations. As the Committee is aware, the Corporations are jointly funded by the Commonwealth and by industry levies. The RDCs are structured to respond to priorities identified by industry groups, and there has been a growing awareness of the significance of investing in gene technology over the past few years. The recent establishment of Grain Gene, a cooperative arrangement involving the Grains RDC, AWB Ltd and CSIRO, indicates the innovative approach that the RDCs are taking to this issue.

- **How does the scientific skills base relate to the research needs in this area?**

The biotechnology skills base that can be drawn on by rural industries is being influenced by factors facing rural science and technology generally, as well as by factors specific to biotechnology.

About 90% of agricultural R&D is carried out in public research agencies. The number of agricultural researchers has declined in recent years as a result of restructuring of public administration (including down sizing; imposition of annual "efficiency dividends" on agencies; changing research priorities away from agriculture; contracting out; and privatisation) or decisions directly affecting departments of agriculture and natural resources (regionalisation; administrative rearrangements; and restructuring).

Agriculture - Research workforce (person years)

	1992-93	**1994-95**
Higher Education	2,143	1,698
Commonwealth	1,826.7	1,653.9
States	4,298.1	3,763.5

Source: Australian Bureau of Statistics.

There are also pressures on the skill base for agricultural gene technology that stem from the nature of the technology. Unlike the skills of many specialised agricultural scientists, those of gene technologists can be used in other industries and in other countries. The growth of the economic influence of biotechnology in the major economies means that there is increasing demand for these skills, particularly in medical and pharmaceutical applications.

In some countries, particularly Canada and the United States of America, biotechnology has been viewed favourably by the public and governments. In others, notably European countries, there appears to be much less acceptance of biotechnology by the community and governments. Shortages of gene technologists are apparent in a buoyant North American market, and consequently significant recruitment from Europe is taking place. This has clear implications for the availability of gene technology skills for Australian agricultural industries.

AFFA shares the concern of State and Territory Agriculture and Resource Management Departments that Australia's rural industries may not be able to capitalise on global developments in biotechnology because of potential deficiencies in the skills base of our researchers. A preliminary survey by a SCARM High Level Working Group suggests that Australia's gene technology skills base is largely in the medical sector, and that shortages of senior experienced staff for the agricultural sector are becoming apparent.

- **What can be done to help Australian companies perform R&D and achieve commercialisation in this area?**

A characteristic of Australia's industrial structure is that there are few locally owned agricultural input suppliers. Local branches of overseas-based multinational corporations, which derive their technology from overseas-owned parent companies, supply a large proportion of these inputs. When Australian researchers make a commercially valuable discovery, there may not be a local firm able and willing to complete the development and bring the product to market, or with the international

infrastructure to sell it effectively worldwide and thereby maximise the return.

Within the past decade, a number of large multinational corporations, particularly agricultural chemical companies (and some large seed companies), recognised the potential of gene technology. These businesses are moving away from a focus on traditional chemicals, which they perceive as being less profitable in the future. Their strategy is to take advantage of technological changes and to maximise their market power through linking the products of gene technology with other farm inputs, particularly chemicals.

These companies have invested in extensive research and development in their own laboratories and have arranged research alliances with universities and government laboratories. There have been several strategic buyouts or mergers (or in some cases alliances), that have reduced the number of players and increased the resulting companies' market share.

To profit from gene technology, these multinational companies seek to own or control access to it. In many instances, because these companies were early, large investors in plant gene technology research they have been able to gain powerful intellectual property positions in some of the key enabling technologies. In other cases they have acquired those key enabling technologies from public research institutions or small companies through licensing and acquisition. A number of small companies have been established with the sole purpose of "proving" a technology, in the expectation that they will then be acquired by one of the global companies before they have to engage in the costly and risky process of registering, producing and selling a product.

As a result of their take-over activities, a few large US and European companies have acquired biotechnology expertise and the ownership of genes and seed varieties. In this way, the companies have developed vertically integrated structures that can offer the seeds for genetically modified crops and, where necessary, the associated chemicals that help to increase crop yields and production efficiency, and potentially reduce input costs.

Australia has traditionally been weak in the commercialisation of research, despite many attempts to create conditions attractive to venture capital. (One of the main reasons we do not have a viable venture capital market is our capital gains tax regime.) An ASTEC report: "Gene Technology: Issues for Australia", Occasional Paper Series No.27, AGPS, Canberra: stated in 1993:

> "While there have been some successes (in diagnostic products, for example) the 1990s have confirmed that global economic structures, and the place of Australian firms within them, will continue to limit prospects for commercialisation of indigenous research."

Jensen and Thursby (1998) considered commercialisation of innovations in their paper, "Proofs and Prototypes for Sale: the Tale of University Licensing" (National Bureau of Economic Research Working paper 6698, Cambridge, Mass.) They say that most university inventions are little more than a 'proof of concept' when they are licensed, and the probability of successful commercialisation declines if the inventor

is not actively engaged in the value added process. The problem of achieving commercialisation is compounded by promotion arrangements in the research system, particularly the universities, which are based on regularly publishing novel research; researchers can adversely affect their chances of advancement by expending their effort in commercialising innovations. These factors suggest that output based payments (royalties or equity) may be more effective in leading to successful commercialisation than simply auctioning off licenses, because they provide more incentive for inventors to expend further effort in the development process.

However, Australian researchers and biotechnology companies may be able to compete through market strategies that focus on creating and adding value to intellectual property, then commercialising that property through strategic alliances. Australian gene technology companies must compete internationally for investment capital and for scientific expertise, both of which are highly mobile. Once a GMO product has been developed, companies must then sell into competitive international markets. An effective means of gaining technological, capital and market access is through strategic alliances.

Strategic alliances will only occur if each party sees a benefit to itself. The main reasons include: capturing of spill overs in benefits, or exploiting of synergies; benefiting from economies of scale, or overcoming problems of indivisibilities (that is, there is a minimum scale at which research must be carried out to be efficient); lower transaction costs (the lowering of transaction costs may be a key reason why individuals coalesce to form firms); and to enable risk sharing.

A key issue is alliances between public and private organisations involved in the research and development process. In Australia, there is increased recognition of the need for alliances to gain access to key intellectual property and to deal with poor performance in the commercialisation phase of innovations.

Ideally, strategic alliances give established pharmaceutical, chemical, or agricultural companies access to intellectual property and give dedicated biotechnology companies or researchers access to the funds necessary to commercialise that intellectual property. Alliances take four common forms: employing researchers; contracting research; licensing intellectual property; or joint ventures.

The most risk-averse method is for an established company to *employ researchers*. This gives the company ready access to any intellectual property produced, including extensive management control over the source of the intellectual property. *Research contracting* is another low risk and low return conservative approach to research and development. If and when this research results in marketable intellectual property, the company steps in and develops the property into a commercially viable product. *Licensing agreements* enable a large, established company to take existing developed intellectual property and market it. The license fee is usually a royalty on sales. This enables the established company to avoid research and development costs, while allowing the dedicated biotechnology company to leverage the market power of the established company. The most risky but rewarding strategy is the *joint venture* between a dedicated biotechnology company and an established company, with each contributing a specialty. The dedicated biotechnology company contributes technological expertise, while the established company contributes the finance,

production and marketing capabilities. Whilst this extracts complementarities from each party, it presents risk if a product is not brought to market within a reasonable time.

Agricultural applications of biotechnology currently tend to be relatively low-value and high-volume. (This scenario may change if agricultural biotechnology leads to high value, low volume products that can be used in the chemical and pharmaceutical industries). The continued pressure on farm prices and consequently farm inputs imposes a narrow margin of profitability on current and near future agricultural biotechnology inputs. Whilst they must remain as cheap and cost effective as existing non-GMO inputs, they must also generate enough income to justify commercialisation

Three basic marketing strategies are available to companies:

Specialised technology supplier - this role is vulnerable due to uncertainty over patent protection, difficulties in negotiating licensing arrangements, and the large number of competitors.

Integration into control of strategic seed markets - the integration of biotechnology into control of strategic seed markets is a market substitution, and not the development of a new market. This makes it especially vulnerable to competition from existing seed varieties. This market strategy may also lead to anti-competitive behaviour and consequent government intervention.

Capturing industrial value-added – the unique handling requirements of some varieties (such as canola) leads to vertical integration from planting to conditioning to storage to marketing. This leads to the creation of high-value low-volume vertically integrated niche markets.

- **What are the constraints to investment?**

Australia could be in a good position to take advantage of advances in this technology. We have a highly competitive export oriented agricultural sector. Export markets enable farmers to avoid the infrastructure investment limitation of a small domestic market, and allow the cost of commercialising biotechnology to be recouped through productivity increases or the creation of new markets.

Capital availability limits the commercialisation of Australian gene technology research. That availability is likely to be influenced by:

- the risk from the unknown long term impact of gene technology and difficulty in securing adequate risk insurance;

- the complex ownership of Australian gene technology IP that can arise from joint public/public and public/private funding of research;

- the use of mechanisms, skills and experience to enable gene technology innovations to move forward to the point where private venture capital becomes more readily available; and

- possible market resistance to genetically modified products.

There is a clear need to address the reluctance of investors to support early work to commercialise gene technology innovation. Something might be achieved to this end by:

- government agencies meeting with agribusiness and finance industry leaders to discuss the commercial benefits of gene technology, and the timeframes in which these can be expected;

- an effective public awareness process to address consumer concern about gene technology; and

- the rapid establishment of a nationally uniform regulatory system for gene technology products.

The process of commercialisation must be managed carefully to ensure that the forms of strategic alliance employed reflect a return on investment commensurate with the significant levels of public sector investment in basic biotechnological research.

2. A regulatory pathway to market

Gene technology can provide significant opportunities for developing sustainable production systems through advances such as reduced use of herbicides and pesticides; development of plants more suited to the climate and soil; and techniques such as bio-remediation, cleaning up contaminated sites. On the other hand, there are environmental risks, for example that the technology may facilitate production on already fragile and marginal lands.

Regulation should be designed to address the inherent environmental and health risks associated with the potential use of the new technology. This, in turn, should help provide society with a better understanding of the risks involved, how they are going to be managed, and who is responsible for that management.

Effective regulatory procedures are required for the development and use of genetically modified organisms (GMOs) in Australian agriculture and the food chain. In the short term at least, the majority of gene technology applications for release into the environment will be in agriculture. There will be implications in terms of food and fibre production, food safety, trade, crop/animal management, waste control, environmental safety and public health and worker safety.

To enhance the sustainability of agricultural systems, any adverse effects of farming on the land and environment will need to be minimised. This will include maximising the usefulness of genes and chemicals that are used in the control of pests and weeds. For example, INGARD cotton, the only commercial genetically modified crop grown

in Australia, was introduced into paddocks three years ago with strict management guidelines, and has been shown to reduce chemical use by over 50 per cent, although yields have been somewhat disappointing to date.

Several government agencies are responsible for ensuring that all genetically modified products are assessed for public and environmental safety. They cover research, field trials, agricultural and veterinary chemicals, pharmaceuticals, quarantine and food. The areas of research and field trials are currently assessed using a voluntary arrangement. The Commonwealth, State and Territory Governments are moving quickly to develop laws to ensure that all possible uses of GMOs are covered by legislation, with the Commonwealth providing $7.5 million in the last Budget to facilitate the process. AFFA is working closely with the interim Office of the Gene Technology Regulator in the Department of Health and Aged Care, and with State and Territory agriculture and resource management departments, to develop the required legislative framework.

- **Research and Field Trials**

Until new legislation is passed, all gene technology research and field trials of GMOs are assessed by the Genetic Manipulation Advisory Committee (GMAC) under a voluntary regime. This is a committee of experts established to assess the safety of gene technology. Australian researchers and companies working with genetically modified products comply with GMAC's advice, even though there is no legal obligation to do so. (GMAC biosafety guidelines are considered to be so good that they have been adopted by other countries and the World Bank, and are generally used as a model for other countries to follow).

GMAC scrutiny begins with the laboratory studies, or immediately after the quarantine service, AQIS, permits a genetically modified organism to enter the country. If the product shows no adverse signs in contained conditions, GMAC will consider a proposal for the first field trials. This may be followed in later years by proposals for larger field trials if the genetically modified product maintains its promise and continues not to show adverse traits. GMAC assesses and monitors results from all field trials. If a company is planning to commercialise a genetically modified product, it provides GMAC with a proposal. GMAC's surveillance continues up to the point it approves commercial release, and following this the product, such as a crop, is monitored by researchers, and a strict management plan is put into place.

GMAC has applications pending for the release of various GMOs into the environment. Many of these are for crops engineered to be resistant to herbicides. A major factor constraining primary producer access to gene technology is that GMAC has not felt able to recommend the release of such genetically modified crop plants into the environment in the absence of a national strategy for managing the impact of these crops on farming systems and the environment. The Standing Committee on Agriculture and Resource Management is developing some input to aid in decision-making on proposed releases, including the development of strategies to integrate herbicide tolerant crops and pastures (both transgenic and non-transgenic) into Australian farming systems; and what essential elements should be included in

management plans; and how such plans could be implemented, monitored, audited and enforced. The Task Force developing the report includes scientific and industry representatives. The report will be provided to the Interim Office of the Gene Technology Regulator, which incorporates GMAC.

- **Agricultural and Veterinary Chemicals**

The NRA's legislative responsibilities are derived from the *Agricultural and Veterinary Chemicals (Administration) Act* and the *Agricultural and Veterinary Chemicals Code Act*, and its focus is the assessment and regulation of traditional agricultural and veterinary chemicals. However, the scope of the AgVet Code also covers products of biological origin, including vaccines and microbiological pesticides. The definition of agricultural and veterinary chemical product within the AgVet Code is broad and encompasses almost all forms of pest and disease control.

The NRA, while having overall legislative responsibility, engages the assistance of various other agencies in this task. The NRA also utilises the scientific input of experts around Australia and overseas.

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) assessed and approved the Bt gene in INGARD cotton (Bt cotton) and has been involved in the consideration of other products in consultation with other agencies.

- **Quarantine**

The Australian Quarantine and Inspection Service has developed new procedures that require the notification of the intention to import genetically manipulated plants. This is based on the principle of minimising the risk of introduction of pests. AQIS is regulating the importation of genetically manipulated plants that have been produced by means of modern biotechnology and assessing these for any additional risks associated with the genetic modification.

Under the *Quarantine Act 1908* and the associated *Quarantine Proclamation 1998*, all GM plant imports entering into Australia are subject to controls to manage the risk of introduction, establishment and spread of pests and diseases that may endanger the health or life of humans, animals or plants. Modifications to the genome of a plant may confer pest and disease traits to an organism that are not present in its unmodified or native form. As with non-genetically modified imports, controls may be imposed on genetically modified material as a result of the quarantine risk assessment. AQIS has assessed more than thirty applications for the importation of genetically modified organisms.

AQIS conducts risk assessments to identify potential quarantine pests, to analyse their risk of introduction, establishment and spread in Australia and, importantly, to evaluate management options to minimise these risks where necessary. The assessment methodology involves examination on a case-by-case basis of genetic, biotic and environmental attributes pertaining to the GM plant. Factors considered during the risk assessment include the origin and function of the donor genetic

material, the nature (phenotype) of the traits when expressed in the GM plant, the nature of the parent organism and the end use of the genetically modified plant. Other features examined include weed potential and any pest and disease risks. Risk assessments are based on scientific principles and must be supported by scientific data.

Risk assessments are conducted in a manner that is consistent with World Trade Organisation (WTO) agreements and the standards developed under the auspices of the International Plant Protection Convention (IPPC). In addition, assessments may also be expected to meet the requirements for the Convention of Biological Diversity's Biosafety Protocol which is currently under international negotiation for the regulation of international trade in living modified organisms (LMO's).

AQIS is also a key agency involved in the newly established national regulatory framework created to ensure the environmental plus human health and safety issues are addressed in the development and use of gene technology in Australia. To achieve this, the Government made a decision in early May of this year to create the Office of the Gene Technology Regulator (OGTR) to coordinate and oversee all the agencies and regulatory authorities having responsibility for gene technology in Australia. The OGTR will also have regulatory responsibilities in its own right relating to the health and safe use of gene technology.

AQIS is also refining its import system for live animals and reproductive material to facilitate the identification and assessment of material that is genetically manipulated. The regulation of GMOs by AQIS arose from the 1996 Nairn review of Australian quarantine which recommended that AQIS consider all quarantine risks associated with GMO's produced by means of modern biotechnology. The recommendation has particular importance with regard to agriculture, as the vast majority of GMO's entering Australia at present are plants.

AQIS regulations have several aims: consistency with the proposed national framework for gene technology regulation; consistency with the requirements of AQIS's Import Risk Analysis process; consistency, as far as possible, with current AQIS operational requirements; recognition of the benefits that genetic manipulation can offer, by minimising disruptions to trade; ensuring consistency with international agreements and obligations; and ensuring that the system has sufficient flexibility to meet changing circumstances, consonant with AQIS's quarantine responsibilities

3. Developing a positive climate of public opinion, that recognises that health and safety risks are addressed before products are placed on the market

Public attitudes to genetic modification vary around the world. Broadly, it is more accepted in Canada and the United States of America and less accepted in Europe. Public opinion is not fixed and peoples' opinions change. Over recent years, Canadians have tended to become more favourable to gene technology, whilst Europeans have become more opposed.

Public opinion surveys indicate a broad trend towards acceptance of biotechnology in North America. An extensive study carried out in Canada in 1993 highlighted three distinct attitudes: 25% of respondents expected more benefit than danger from biotechnology; 24% expected the reverse; while 39% believed it may be equally beneficial and dangerous. A more recent survey of Canadian attitudes found a high level of respondents (87%) were positive about biotechnology and, specifically, that they agreed '(Canada) must pursue opportunities presented by new technologies to maintain current quality of life'. Surveys of public attitudes towards biotechnology in the US throughout the 1990s found consistently positive attitudes toward agricultural biotechnology. More than half of US respondents in 1994 and 1997 believed that biotechnology already provided benefits for them, while almost three quarters of respondents in 1992 and 1997 believed that they would benefit from biotechnology in the future.

Nevertheless, the United States has recently announced a series of steps aimed at addressing consumer fears about the safety of genetically modified foods. This includes an independent scientific review of its approval process for new genetically modified crops.

Conversely, comparisons of the 1996 'Eurobarometer' survey with those of 1991 and 1993 indicates that optimism in Europe about the contribution of biotechnology to improving the quality of life has declined. A 1993 survey indicated that almost two-thirds of the German public were opposed to genetic engineering. In the same German study, just less than three-quarters of the same respondents were in favour if genetic engineering was to treat disease. In general, support for biotechnology is higher for medical than agricultural applications. In Canada, the public expressed a strong preference for biotechnology over conventional technologies when it replaces the use of chemicals in the environment. In the UK, transgenic animals are more acceptable if the benefits afforded by them are viewed as offsetting the perceived risks.

In Australia, a 1994 study detected generally positive to neutral attitudes to biotechnology, with just a small number opposed. However, a 1998 study found that 'most ordinary Australians' were concerned and fearful of genetic engineering and cloning. Similarly, low levels of optimism about biotechnology have been found in New Zealand. A 1994 study of public attitudes towards genetic engineering in Australia revealed that support is high for medical uses but much lower for genetically modified foods.

- **Factors influencing public opinion**

Extensive research, using surveys and interviews, has highlighted the main factors influencing public opinion on biotechnology. Cultural, gender and age differences influence priorities, and the relative importance attached to each factor varies. However, the issue of risk ranks consistently as the major determinant of opinion on biotechnology.

C.R. Deane covered many of the relevant issues in her paper, "Public Perceptions and Risk Communication in Biotechnology", Proceedings of the Accounting for Risk in International Agreements conference, February 1999, Melbourne. Scientists and the

general public have different concepts of risk. Risk assessment is the scientific evaluation of risk, comprising the identification and characterisation of hazards, the probability of their occurrence and the consequences of their occurrence; risk management is concerned with identifying, documenting and implementing measures taken to reduce risk. The public, on the other hand, is less concerned with probabilities and tends to focus on the consequences for them personally should the risk materialise. Risks are viewed according to the magnitude of their potential unwanted consequences and the potential benefits.

The public's view of risk associated with biotechnology depends on many factors in addition to probability and harm. Primary among those is the question of benefit. The public's view of risk is moderated by the benefits. Different societies perceive the risks associated with biotechnology differently because the benefits have different implications for them. As the perception of risk varies when weighed against the benefits, consideration of the benefits is a critical factor when judging the level of risk acceptable to the public.

For example, the benefit of increased food resources may outweigh environmental risks when considering the introduction of genetically modified crops into a country in which food is in short supply. In Western societies, food supply is generally not restricted, so the benefit of increased food carries less importance. If, on the other hand, the introduction of genetically modified organisms is perceived as a threat to the food supply, the reaction is quite different. This may partly explain the opposition in developing countries to the proposed use of the Technology Protection System (TPS) or 'terminator' technology in genetically modified crops.

The perceived benefit is a main reason that genetic modification for medicinal purposes has greater acceptance than in agriculture; the benefits are more obvious to consumers and may be dramatic, even life-saving. Where consumer benefits are not obvious and direct, such as for herbicide, disease or pest resistant crops, public acceptance is lower.

Whether the risk is voluntary or imposed is also a significant factor in shaping people's perceptions of risk. People are more concerned about risks that are imposed than those accepted voluntarily. Concern about labelling products containing genetically modified organisms is driven by the public's desire for choice. The issue of labelling has become of great public concern in Europe, and more recently in Japan and Australia. Public opposition to genetically modified soybeans imported into Europe from the US was greatly exacerbated by the absence of labelling. The public had been primed by the media and special interest groups to distrust official assurances about the safety of the produce. They believed that there could be significant risks involved. The absence of segregation and labelling caused the perceived risks to be imposed rather than voluntary; the risk to the public was imposed by others, who were seen to benefit from imposing the risk.

The recent decision to label products containing genetically modified organisms in Australia may reduce public concerns by offering them the choice of whether or not to purchase such products and making the perceived risks voluntary rather than imposed. However, labelling products that are derived from genetically modified crops, but are biochemically identical to those that are non-genetically modified, for example sugar, could lead to a challenge under the WTO Agreement on Technical Barriers to Trade.

A lack of public accountability, and secrecy surrounding developments in gene technology, adds to the perception that the risks are imposed on the public by 'others', who can be construed as a small number of large multinational companies. People also judge risk according to their perception of those controlling it. If those in control have a history of secrecy, or if they are perceived to influence regulatory and public policy decisions, the perceived risks are amplified. Public concerns have been expressed through consumer associations and other non-government organisations.

A transparent, scrupulously independent regulatory process is vital in gaining and keeping the confidence of the community. In addition to their desire to be involved in the process, the public favours a high degree of government regulation. One of the main points of public concern identified in several studies is that certain aspects of biotechnology are perceived as being vulnerable to abuse, leading to a strong desire for government regulation. This is true even in countries where the public are very positive about biotechnology.

Public information campaigns on gene technology tend to focus on making the public familiar with the intricacies of the technology and reducing the opposition to the technology by reducing the 'unknown'. Several experiences have shown this tactic not to work; it often strengthens peoples' opinions, both in support of and opposition to the technology (e.g. the UK consensus conference).

The consensus conference in Australia this year on genetic modification of food showed that, while information on the technology was wanted, more important was an understanding of how the technology could be used and the consequences of its use. The public was not interested in following a detailed debate on technical issues but was very interested in the social and economic consequences of adopting, or not adopting, the technology. For technical information, such as safety issues, the clear consensus was that a scientific assessment was required from an independent government authority with an interest in protecting public health. Another clear message was that science was not the only basis for decisions on genetic modification in the food chain: ethical, social, economic and environmental issues also need to be considered.

Trust in information sources is also important in informing public opinion. Those with a vested interest in selling are not trusted, and the information they provide becomes 'tainted'. "Vested interest" can include the commercial interests, the researchers and, for agriculture, the primary producers who may be seen to gain from the technology. The provision of balanced information from trusted sources, stating realistically the potential benefits and risks from using the technology, is needed to inform the public.

One important aspect of communication and education that is often neglected is listening. Rather than providing large amounts of information, which becomes impossible to digest, efforts need to be made to answer the questions the public want answered in a way that is easy to comprehend. How the technology could affect individuals, their families and communities must be considered. Over the next year, the Bureau of Rural Sciences will be producing a series of publications explaining biotechnology, its applications and the issues that arise.

4. Ensuring that primary producers are aware of and have access to the new technologies

- **How can farmers best be encouraged to use gene technology?**

There may be a role for government in providing information on the uses to which gene technology may be put, as well as the need for risk management: for example, ways of reducing the risk of pest and weed resistance developing from the use of crops modified to protect themselves against pests and herbicides. The private sector, however, should be responsible for promoting the application of the technology, as this will be based on commercial decisions.

Genetically modified crops may add to the varieties available to be used by primary producers, rather than totally replacing traditional varieties. One factor that may be important in farmers' decisions on whether to use the new varieties will be the expectations of improvement compared with what happens in practice. Any given genetic modification is likely to be available in a restricted number of varieties, none of which may be fully appropriate for the local conditions. For example, Bt cotton in Australia did not provide the yield advantage it did in the US, and the price charged in the first year was relatively high, although in subsequent years Monsanto decreased the price.

- **The use of Plant Breeders Rights in facilitating access to gene technology**

In terms of access to the new technology, the *Plant Breeders Rights Act* was introduced to support the competitiveness and sustainability of Australian primary industries by encouraging investment in plant breeding; facilitating access to elite varieties from overseas; and speeding technology transfer:

- More than 2400 applications for registration of new varieties have been received including 6 genetically modified varieties (5 cotton and 1 subterranean clover). Approximately 850 agricultural varieties have been registered

- Commonly, patented genes are licensed for incorporation into existing adapted varieties

- 75% of registrations are from private sector breeders in Australia and overseas.

Increasingly, private breeders located overseas are requiring plant breeders rights (PBR) protection for their varieties before releasing them in Australia.

The scope of protection granted by PBR focuses on the commercial use of a variety's propagative material and extends to the exclusive right to: produce or reproduce; condition for propagation; offer for sale; import or export; or stock the material for any of the previous purposes. In certain circumstances these rights can be extended:

- To include the harvested material or products obtained from harvested material if the grantee has not had reasonable opportunity to exercise their rights on the propagative material

- To another variety that has been essentially derived from the PBR variety (including other varieties that cannot be reproduced without the repeated use of the PBR variety).

Balanced against the rights granted to the owner of the new variety, certain rights are also allowed for public and private interests. These include:

- Farm saved seed (the ability of farmers to save seed of a PBR variety to establish subsequent crops of that variety). It is important to note that patents do not include a similar provision

- The right to use the variety as a food, food ingredient or fuel; or for any other purpose that does not involve reproduction (including the production of sprouts)

- Any act that is done privately for non-commercial purposes, experimentation or for the purpose of breeding other plant varieties.

PBR promotes producer access to new varieties by imposing important conditions. Grantees are required, within two years of the grant of PBR rights, to provide reasonable public access to the variety. Reasonable access is defined in terms of price, quality and quantity to meet market demands. Should reasonable public access not be provided, compulsory licenses can be issued for the production and sale of the variety. A compulsory license entitles the grantee to 'reasonable remuneration' consistent with the normal course of business.

Another condition of continuing PBR protection is access by breeders of other new varieties to the propagative material of a PBR variety for the purposes of testing and comparison.

It is also important to note that the granting of rights is independent of the exercise of those rights. For example, while the right to sell a variety may be granted, the exercise of that right may be restricted by other regulations, including, in the case of genetically modified varieties, approval for use and release by the Office of the Gene Technology Regulator.

Currently the grains industry is considering the question of End Point Royalties (EPR) as a method of encouraging further investment and commercialisation of field crop varieties:

- While EPR is seen as entirely commercial, the underpinning contracts may be predicated on the rights granted under PBR

- A PBR user experience survey has been commissioned by the Standing Committee on Agriculture and Natural Resource Management (SCARM), to, *inter alia*, investigate support for EPR and to identify any desirable changes or clarifications to PBR, particularly those that may facilitate commercial

arrangements between breeders and producers. The survey report will be submitted to SCARM later this year.

PBR legislation attempts to provide a balance between the rights of breeders and those of producers and users:

- Minor changes may facilitate commercial arrangements between breeders and producers; however any significant moves to decrease the already limited monopoly granted under PBR are likely to reduce the incentive to develop or release elite material in Australia

- If, on the other hand, the PBR monopoly is significantly strengthened, the cost of producer access to new varieties may increase, especially if the production of substitute varieties is curtailed through restrictions on the use of enabling technologies

- Significant changes to PBR legislation have implications for Australia's conformity to the International Union for the Protection of New Varieties of Plants (UPOV) convention. Lack of conformity could result in owners of genetically modified varieties choosing not to release their material in Australia.

5. Effective utilisation of a system of intellectual property rights that encourages Australian researchers to develop new technology and applications

- **How can Australia use intellectual property to its best advantage?**

A key feature of the biotechnology revolution is that it is being driven by protection of biological innovations by utility patents, rather than the more traditional form of plant variety rights. The increased use of these patents may mean that changes are necessary to Australian innovation policies with regard to biotechnology.

The ability to patent biotechnology innovations represents a marked strengthening of IP regimes. Some of the observable effects of this strengthening are: greater private sector involvement in biotechnology, because it has better enabled investors to capture the benefits of innovations generated by their investments; problems of access to knowledge for some players, as owners of technologies act to restrict use of their technologies so as to maximise returns to themselves; and a flurry of mergers and takeovers, because of the improved ability to capitalise on innovations generated through research.

There are indications that the public sector use of the intellectual property (IP) system in Australia is less than optimal. Part of the difficulty is due to a lack of understanding of the IP system, and its under-use, particularly because of financial restraints in the tertiary education sector.

It can cost $500,000 to gain full patent protection for a discovery, and double that per year to protect the patent from illegal use or challenge. The returns to Australia from

patents may only amount to modest revenue streams from licensing, unless the relevant companies exist in Australia to exploit the value of the patents. Australia's industrial structure only supports a handful of enterprises that are large enough to utilise the patents world-wide, and not many large, new enterprises are likely to appear in the short to medium term. There are signs, however, that a number of small spin-off companies from university research are being established.

Issues associated with the management of intellectual property, especially for small breeders, include factors relating to the ability of Australians to:

- gain appropriate IP protection for their gene technology research; and
- leverage better access to foreign enabling gene technology which is protected by international patents through:
  - strategic ownership of IP for locally developed enabling gene technology and isolated/improved genes that foreign companies are likely to want, and hence be willing to trade or enter into a favourable commercial arrangement to acquire
  - developing superior germplasm as the base of new cultivars or organisms.

The *Plant Breeder's Rights Act 1994* (PBR) provides breeders with a reasonably easy and inexpensive method to protect new varieties, including genetically modified varieties.

This is achieved by balancing the two conflicting needs of breeders ("the breeder's dilemma") *viz.* breeders need to be able to use and incrementally improve existing varieties, while simultaneously needing to protect the new varieties so produced:

- PBR allows the use of a PBR variety to breed other varieties (freedom to operate), and
- In situations where the incremental improvement is relatively minor, PBR recognises the major contribution of the first variety by allowing joint control of the derived variety (this encourages the continuing investment in traditionally bred varieties, into which genetically modifying material is introduced). Alternatively, where the improvement on the first variety is large, the breeder of the derived variety can market the new variety without reference to the breeder of the first variety (freedom to commercialise).

PBR protection is potentially available to the breeders of all new varieties regardless of the size of the breeding enterprise.

In Australia, plant variety protection is available under the *Plant Breeder's Rights Act 1994* (PBR) and/or the *Patents Act 1990* (Patents). Both schemes grant intellectual property rights and confer a commercial advantage to the holder of those rights. In the case of PBR, the rights are of a limited and prescribed nature and do not extend to genes or processes for manipulating them. Both schemes allow for the granting of

rights to genetically modified varieties and dual protection is available. The schemes can operate in parallel.

The PBR scheme has been specifically designed for plant varieties and is in accordance with the only internationally accepted convention on the matter, the International Union for the Protection of New Plant Varieties (UPOV), and falls within the bounds of the World Trade Organisation TRIPs agreement (Trade Related Aspects of Intellectual Property). Currently there are 44 members of UPOV including the EU, USA, Canada, Japan, New Zealand, China and the Russian Federation. Administration of all PBR schemes is similar, allowing a high degree of reciprocity. For example, protection can be applied for in other UPOV member states based on information collected in local trials.

In Australia, PBR protection is available to varieties in all plant species, provided they satisfy the eligibility criteria, including fungi and algae (but excluding bacteria, bacteriodes, mycoplasmas, viruses, viroids and bacteriophages).

Other than allowing the protection of plants that include genetic material that is not from plants, PBR does not treat genetically modified varieties any differently from those produced by conventional breeding.

More information on the PBR system is presented above in Section 4. Patents and plant variety rights are not the only forms of protection of intellectual property for plants. For example, various levels of protection are provided by the hybridisation process; the 'Terminator' technology that ensures sterile seeds; and the 'Verminator' technology, which can ensure growers have to use particular proprietary chemicals.

- **How can expertise in intellectual property management be fostered in Australia?**

Biotechnology is increasingly being presented as the new technological wave set to revolutionise global production and trade in nearly all sectors, none more so than agriculture. Potentially enormous commercial gains are available to the holders of intellectual property in major biotechnological innovations. For example, the patent owner of a gene may not only control which species the gene is inserted into, but also the countries to which the end product is exported. Importing for sale is an exclusive right, so a licensor cannot freely import the product into a country in which another licensor has the right of sale. In this way, patent owners can divide up world markets. Thus, the development and implementation of an intellectual property system is a key issue for governments.

Intellectual Property (IP) control is fundamental to the commercial development of gene technology, and in recouping the research, development, distribution and marketing costs of new products. Managing IP is not just learning how to obtain good IP protection of innovations, but equally about strategic positioning. That is, judging which patents are worth getting, being fully aware of the need for "freedom to operate" in any particular area, and including IP issues and the development of a business plan as part of the decision to undertake research (rather than as a follow-up activity). There is clearly a need to ensure that:

- all Australian agri-food gene technology researchers, their employers, and funders receive world class training in the intellectual property (IP) protection of their innovations;

- opportunities are explored for developing mechanisms, both formal and informal, to train researchers, employers and funders in the strategic management of agricultural gene technology IP and the related infrastructure; and

- support is initiated for the generation of a strategic portfolio of IP for enabling gene technology and isolated/improved genes, particularly those which will better position Australia to trade or otherwise gain access to foreign enabling technology or genes for use in minor crops.

- **The international situation in patent protection**

In a general sense, implementing an IP system in any country involves three key groups of decision-makers:

- legislators, and the legislation relating to intellectual property;

- administrators, and the administrative procedures relating to the legislation;

- judges, and the judicial processes concerning the legislation and its administration.

All these decision-makers will, to varying degrees, reflect the culture of the country in which they operate, and may thus have a liberal, conservative or market-based perceptions of the interaction between intellectual property and genetic engineering.

Intellectual property outcomes in any jurisdiction are the result of the interaction of legislative, administrative and judicial decisions. In any country, such decisions were for many years strongly influenced by community views about the relative benefits and risks of IP protection.

It is generally believed that the role of an intellectual property regime is to strike an appropriate balance between several conflicting interests. The desired outcomes of an IP regime are to:

- allow sufficient market incentives for creation, while minimising the costs of innovative activity;

- provide for timely disclosure of new information and permit reasonable fair use with economic and social goals in mind;

- limit the scope of the protection in order to strike a balance between competing needs for development and dissemination; and

- provide coherent interaction with other regulatory systems i.e. competition policy, trade regimes and technology development programs.

A well-designed intellectual property system finds a careful balance between encouraging innovation and the equitable sharing of the benefits of innovation for the public good. Where this balance lies will depend very heavily on factors such as trade, the level of research being conducted, the state of economic development, consumer attitudes, and the regulatory system.

The past twenty years has witnessed an acceleration in the rate of the globalisation of trade in goods and services, information and, most recently, finance. With this has come increasing pressures to harmonise arrangements between nations to facilitate such trade through a variety of international agreements. In the case of intellectual property, this has resulted in pressures to strengthen and harmonise national IP systems. International agreements, most notably the *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*, emanating from the 1994 Uruguay GATT Round, are now a major factor impinging on the nature of the IP system within individual countries. Nevertheless, they still retain a certain degree of flexibility. Evidence for the diversity of approach to legislation concerning IP and biotechnology is found in a 1985 study by the Committee for Scientific and Technological Policy of the Organisation for Economic Cooperation and Development which reported on a survey sent to members and concluded that

> *In no other field of technology, old or new, do national laws vary on so many points and diverge so widely as they do in biotechnology.*

Since 1985 all OECD countries have joined the WTO and are therefore under the TRIPS obligations. Consequently, a later survey conducted in 1998 found greater uniformity, but still a variety of differing approaches to the IP protection of biotechnology.

A recent study by KE Maskus on “The International Regulation of Intellectual Property”, to appear in “Weltwirtschaftliches Archiv”, has shown that countries with high levels of innovation and per capita income are likely to have the strongest patent protection.

6. Ensuring access to overseas technology

The major multinational companies have naturally focussed their attention on the crops with the largest global markets, such as maize, cotton, soybean and canola. Australia is significant in the cotton market, but not in maize, for example; Australia is exposed to the vagaries of those companies that dominate the relevant research. For example, one solution to the development of herbicide-resistant grasses in wheat crops is to engineer wheat with resistance to inexpensive herbicides. However, this may not be sufficiently profitable to interest the private sector. Herbicide-resistant wheat has only been generated by the private sector (Monsanto) for expensive hybrid wheat for the western European market, not for use in low-input, dryland wheat.

An equally significant issue is represented by those cases in which the multinationals have developed, and hold the rights over, a herbicide resistance gene of significant potential use in a minor crop, but for commercial reasons refuse to license it to others.

For example transgenic herbicide-resistant sunflowers, potentially useful for controlling broomrape, were not provided to European and Israeli researchers by the U.S. developers because "the species crosses with wild sunflowers". Instead the US researchers abandoned years of work on the sunflowers. While their concerns were possibly justified in the United States, where wild sunflowers are a native weed species where sunflowers are cultivated, they were irrelevant in Europe and Israel, because the nearest weedy wild relatives were on the other side of the Atlantic Ocean, and sunflower pollen is short lived.

In pursuit of market strategies, multinationals may not permit the widespread use of their technology in a variety of crops. They are often unwilling to license the core technologies that are needed for the development of new genetically modified crops, or they set very high prices for licences to use their technologies. While anyone can use patented products and processes for research purposes, agreement needs to be obtained from the owner if the research results are to be commercialised.

In these circumstances, local researchers need to develop technologies to match Australian needs. Gene technology R&D is comparatively cheap, but the cost of bringing new varieties to the market can be significant. Agricultural producers need rapid access to innovative products at prices that maintain their competitiveness and that of all downstream production. Where they get these products - from local or from global companies - is often immaterial to them, provided the price is acceptable.

It is possible to leverage better access to gene technology that is owned by overseas interests by owning the IP of strategic or “enabling” gene technology and isolated and improved genes. Foreign companies are likely to want these, and may be willing to trade them for access for access to their own IP. Another way is through the development of superior germplasm for new cultivars and breeds.

7. Appropriate overseas marketing of Australian products derived using gene technology; and the identity preservation and marketing of traditional, unmodified products.

- **How can producers be given support in identifying overseas markets for products derived from gene technology; or, conversely, identify markets that prefer traditional products?**

The perceptions of governments and consumers in relation to genetically modified agrifood products vary considerably. There is significant resistance to gene technology derived foods in Europe and Japan, and it will be some years before there is a consistent approach to the issue across a range of countries. This resistance is of great potential importance to Australian primary producers. For example, the current level of agricultural exports to Europe (14% of Australia’s agricultural exports), where genetically modified foods are largely rejected, is twice the level of exports to the United States (7% of total), where genetically modified foods are more accepted.

Markets can be expected to develop, or to continue, for products that can to be ‘certified’ as being free of gene technology. This raises the need for a certification process for products; the need for infrastructure to ensure product segregation for

specific markets; and the question of the costs and benefits to both industry and governments.

Countries seeking to export gene technology products may be at a competitive disadvantage in gaining access to markets if national biosafety legislation, quarantine impediments, or domestic labelling requirements discriminate against those products. Australia may become one of those markets if it introduces labelling requirements where substantially equivalent genetically modified foods (which do not raise health issues) are treated differently from conventional foods. This could give rise to a WTO challenge, or costly retaliatory actions that could adversely affect our trade interests. The processed food industry in Australia has exports valued at $A11 billion per year. To maintain that position and improve it, the industry needs to be able to utilise the latest technologies, including gene technology. Regulations that impede its capacity to penetrate growing export markets will reduce its output, and therefore its need for increased agricultural production.

The adoption of gene technology that promotes more environmentally sustainable farming practices, and consequent reduction in contamination of the environment, may also provide substantial competitive advantage. Accessing that competitive advantage will require an effective international trading system that takes account of properly assessed risks and the safety of products. On the other hand, Australia can expect to encounter problems capturing benefits from gene technology if international environmental and safety requirements are set unnecessarily high. Australia's national interest will be served by actively participating in the development and monitoring of the implementation of relevant international agreements. Australian agricultural interests need to be considered in developing Australia's position on international agreements, and national regulatory arrangements.

- **How can appropriate separation of genetically modified and traditional products be effected in overseas trade?**

Importers in overseas markets such as Japan are already inquiring into the background of products, eg. whether beef and pork is derived from animals fed on genetically modified feed. The Japanese conglomerate Mitsui is already talking to Australian bodies about issues such as grower certification of produce that is not genetically modified. In addition, there are already commercial products that can be used to test for certain classes of genetically modified produce.

Short-term markets for Australian products free of gene technology may be available as long as genetically modified varieties are not commercially available. In the medium term, there is likely to be a "specialty" market for gene technology free products, which may compete with the "organic produce" market. In the longer term, the method of production may decline in importance to consumers, provided the product meets relevant safety standards.

To ensure that Australia can access both the main stream (non-differentiated and genetically modified products) and specialty markets, there is a need for a certification process for products, and for infrastructure to ensure product segregation

for specific markets. Quality assurance processes are increasingly forming the basis for international trade and are an accepted responsibility of industry.

In some cases, however, government oversight or audit is necessary and will need to be provided on a cost basis. At this stage in the application of gene technology, there is a need to actively explore the appropriate role for government as product segregation and certification processes are established (eg. economic research on the costs and benefits, the procedures necessary to ensure product integrity, the form of certification necessary, and the price to be charged); and the extent to which government needs to work with industry on this issue. The development of the AgriFood Biotechnology Strategy provides the most appropriate avenue for this activity.

Monitoring of overseas developments and progress in international agreements that affect trade in genetically modified organisms and plants is being carried out by AQIS Agricultural and Veterinary counsellors posted in our major trading destinations.

- **Current situation on co-mingling of products in the US and Australia**

American agricultural production and transport systems, for grains for example, are designed to transport in bulk, not to maintain separation of varieties. American attitudes to international controls on trade in genetically modified organisms (in the Biosafety Protocol negotiations, for example) have reflected the potential difficulties for American producers in keeping conventional and genetically modified products separate on the way to market.

The advent of additional value-enhanced crops, both genetically-modified and conventionally-bred, may bring higher costs to preserve and deliver this value to specific end-users. The most stringent handling system - identity preservation - requires that a crop be completely isolated: in the grower's field; through harvest and on-farm storage; to the elevator and subsequent shipment to the final destination. There can be no co-mingling with similar crops. Such identity preservation might be required for "organic" produce. For some traits, controls over storage and assembly from farm to processor may be less stringent if testing can verify the desired quality. For these traits, segregation, rather than the more stringent identity preservation, might be the more accurate term.

It is anticipated that the marketing arena in the US in particular will see a clash between the traditional volume-dominated system and the developing need to handle smaller quantities of specialised products at higher unit costs. Signs are emerging that the major agribusiness firms, including grain merchandising companies and large cooperatives, are also preparing for these marketing changes. For example, Cargill, a major agribusiness firm, has started a program through its seed division to provide farmers with bins for handling value-added production, to help producers gain entry into markets where they can gain premiums for their crops.

Australia does not face quite the same difficulties with co-mingling of products. Nevertheless work is proceeding on the practicalities of the issue, and AQIS has been involved in assuring the status of products for some specific markets already. It is

likely that the issue of "identity preservation", and the separation of products of different status with respect to genetic modification, will continue to grow.

- **Recent EU moratorium on genetically modified foods**

It seems increasingly likely that there will be continuing markets for products derived from traditionally bred food animals and plants, at least in the short to medium term.

The EU recently declared its intention of introducing a moratorium on the approval of new genetically modified foods, until new rules can be agreed to reassure consumers of their safety. Environment ministers signalled the temporary ban recently, which is likely to delay commercial production of genetically modified foods in Europe, probably until 2002 at the earliest. Genetically modified foods already on the market will not be affected. In the meantime, risk assessment and monitoring arrangements for genetically modified crops are also to be considerably strengthened. Labelling rules will be tightened.

This latest move will increase trade tensions between the EU and the US. However, the US has reacted calmly to the latest developments in the EU. American interests apparently feel that the EU regulatory process has been slow and cumbersome to date, and has operated as a *de facto* moratorium in any case. The US is considering launching a WTO case against the EU because of continuing obstacles to imports of US genetically modified crops. The situation is claimed, for example, to be costing US corn farmers about $200 million annually in lost sales to the EU.