1. INTRODUCTION

1.1 The Inquiry

The Hon Mark Vaile MP, Minister for Agriculture, Fisheries and Forestry, referred to the House of Representatives Standing Committee on Primary Industries and Regional Services an inquiry into primary producer access to gene technology.

The Inquiry will report on the following areas with particular emphasis on the capacity of small and medium sized enterprises to access the benefits of gene technology:

- the future value and importance of genetically modified varieties;
- the ability of producers to compete using traditionally available varieties;
- the commercialisation and marketing of agricultural and livestock production varieties;
- other impediments to the utilisation of new varieties by small producers;
- assistance to small producers to develop new varieties and the protection of the rights of independent breeders, in relation to genetically modified organisms;
- the appropriateness of current variety protection rights, administrative arrangements and legislation, in relation to genetically modified organisms; and
- opportunities to educate the community of the benefits of gene technology.

1.2 Content of the Submission

In this submission:

- some of the benefits which gene technology can bring to agricultural production and food processing are examined;
- categories of gene technology are suggested on the basis of their risk to human health and the environment. Examples of technologies within each category are provided and the intellectual property, food safety and environmental implications of each category are considered;
- some of the regulatory issues associated with these categories are examined;
- impediments which may prevent or restrict access to gene technology by agricultural enterprises are identified; and
- some solutions to overcoming those impediments are proposed.

2. THE BENEFITS OF GENE TECHNOLOGY TO AGRICULTURE

The application of gene technology is expected to significantly increase the productivity and competitiveness of agriculture and its associated industries. Particular benefits include higher productivity through reduced production costs, increased crop yields, higher crop returns and crops which are better adapted to a range of environmental and climatic conditions.

The prospect of more efficient crops will also provide environmental benefits in the form of reduced pressure on limited soil, water and nutrient resources.

2.1 Benefits to Plant Breeding

Gene technology can assist plant breeders to identify genes responsible for desirable and undesirable characteristics in the species they are breeding. It can then provide ‘markers’ for those genes and thereby allow breeding programs to more efficiently select for or against those genes, and hence make much more rapid progress in the development of improved varieties. It can also allow breeders to ‘pyramid’ resistance genes, ie. add more than one gene, which is very difficult with conventional breeding.

Gene technology also enables plant breeders to insert valuable characteristics from other species which normally could not be crossed with the species of interest, or only with great difficulty. In the latter case there is a strong likelihood that such a cross would also bring other potentially undesirable genes with them. Plant breeders can also ‘silence’ undesirable genes in the species of interest, ie. prevent them from expressing undesirable characteristics in the plant.

The valuable characteristics which can be inserted into plant varieties include pest and disease resistance, resistance to pesticides particularly herbicides, tolerance to environmental stresses such as salinity or acid soils, improved grain quality such as improved starch characteristics in wheat, or better malting performance in barley, quite different oil characteristics in canola or sunflower which create new markets for that oil, or the creation of plants able to produce pharmaceutical products. Improved yield can be achieved through many of these or other characteristics.

These potential benefits can be provided in more detail if required by the Committee.

2.2 The World Scene[1]

The majority of field trials in OECD countries have focused on herbicide tolerance, insect resistance and product quality. Approximately 99 per cent of all field trials of genetically modified organisms (GMOs) have been plant species, the majority of which have occurred since 1993-94. The remaining 1 per cent consist of bacteria, viruses, animals and fungi. In Figures 1, 2 and 3, the number of field trials of GMOs by category, country and plant species are summarised.

Notably, nearly 80 per cent of all field trials have occurred in the United States, with less than 1 per cent conducted in Australia. The dominant crop types have been basic food and fibre staples such as corn, potatoes, oilseeds, soybeans tomatoes and cotton. With the exception of canola the main crops trialed to date have been summer crops. Cereals comprise less than 2 per cent of trials due to these crops being relatively difficult to transform.

In 1998, approximately 28.2 million hectares (or 3 per cent of the total world crop area) were planted to genetically modified crops which consisted of 15 million hectares of soybeans, 8 million hectares of corn, 2.5 million hectares of cotton and canola, and 0.2 million hectares of vegetables. Approximately 80 per cent of these plantings were in North America, 15 per cent in South America, 4 per cent in Asia and less than 1 per cent in Europe. By 2000 plantings of genetically modified crops are forecast to increase to 60 million hectares.

In Australia there have been approximately 112 field trials of GMOs. These have consisted of 98 plant trials, 12 micro-organisms (such as bacteria, rhizobium, virus, and yeast) and two with an insect (the Bollworm). The crops most trialed have been cotton (38 field trials), canola (eight), potato (seven), clover (six) and field peas (five). Wheat and barley have each had only three field trials.

There have been three commercial releases of genetically modified crops in Australia: an insect resistant (Bt) cotton in 1996; and two varieties of carnation, in 1994 and 1996. An estimated 85,000 hectares were planted to Bt cotton in Australia in 1998 compared with an estimated 60,000 hectares in 1997 and 30,000 hectares in 1996. The 85,000 hectares planted in 1998 represented approximately 15-20 per cent of total plantings.

[1] The material in this section was primarily sourced from the following papers:

- Foster, M., Rees, C. and Toyne, C. (1999), Plant Gene Technology - Australia's Competitiveness and The Role for Government, Outlook 99, Agriculture, Vol. 2.

- Foster, M. and Rees, C. (1998), Transgenic Crops - Economic Issues and Implications, Outlook 98, Agriculture,
Vol. 2.

Figure 1. GMO Field Trials in OECD Countries, by Category

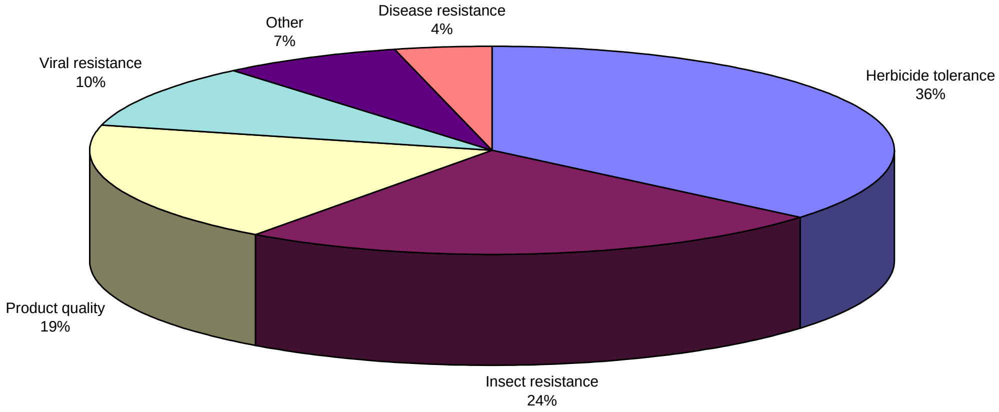
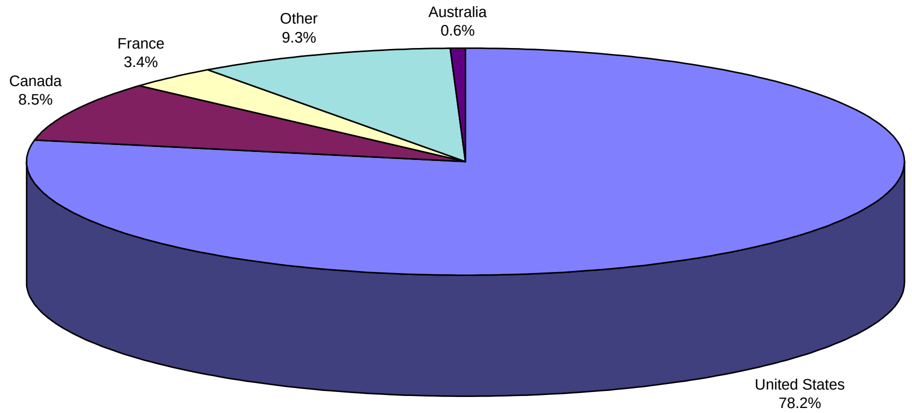
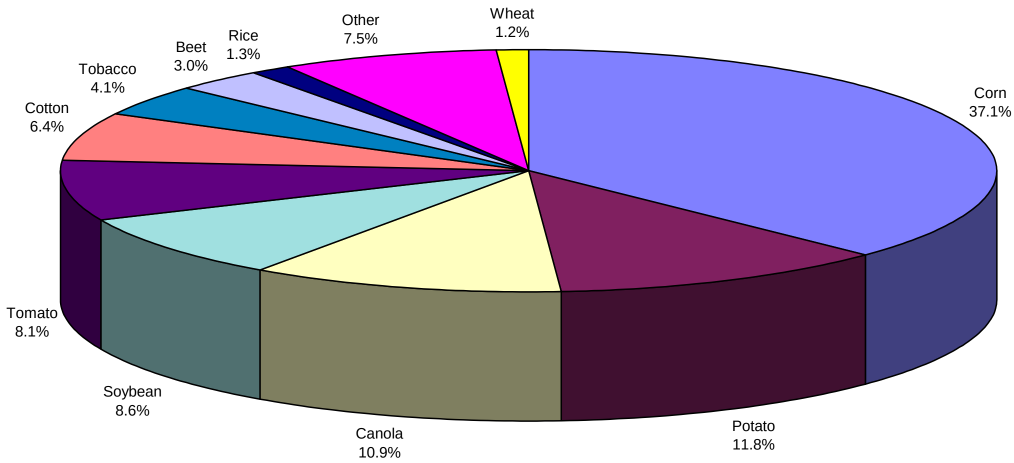


Figure 2. GMO Field Trials by Country



Source: OECD's BioTrack Data Base.

Figure 3. GMO Field Trials by Plant Type



Source: OECD's BioTrack Data Base.

In 1997, AusBiotech Alliance (an Austrade initiative) expected the biotechnology market in total to be worth about US$58 billion by 2000. The gene technology market is not known but will be less than for biotechnology as a whole. The global biotechnology market is expected to grow at 12 to 20 per cent per year. A 1997 forecast by the US Biotechnology Industry Organisation provided the following breakdown.

World Wide Biotechnology Market - 2000

Market Sector	US $million
Agriculture and Food	19,960
-agriculture	8,048
- food	11,912
Energy	15,392
Chemicals	9,936
Health care (pharmaceutical's)	8,544
Metal recovery	4,304
Pollution Control	96

Source: SCARM High Level Working Group

Markets in food and agriculture based on biotechnology are expected to amount to $US20 billion in two years. Australia's current gene technology market share (based on Bt cotton and some cut flowers) amounts to about A$200m and could be A$300m by 2000, ie US$180m or 0.9 per cent of the global agrifood market.

3. RISK ASSESSMENT AND CATEGORISING GMOs AND GMO PRODUCTS

In developing a regulatory framework substantial emphasis has been placed on the need to establish appropriate risk assessment procedures. Essentially, such arrangements are intended to address the potential social costs associated with negative 'spill-overs' from GMOs and GMO products to human health and the environment. Risk assessment is, however, an area where poorly designed procedures can impose excessive compliance costs on applicants, which may in turn act as a disincentive to product development, thereby limiting access by producers to gene technology.

Best practice regulation in relation to risk assessment is therefore a significant issue and it is proposed in this submission that the categorisation on the basis of risk to human health and the environment of GMOs and GMO products is essential. Such an approach would provide scope to substantially reduce compliance costs associated with risk assessment. Some categories of gene technology are suggested under the following headings and briefly discussed in terms of risk assessment and regulation.

Category 1 - Gene Technologies Which Increase the Efficiency of Plant Improvement Programs

1.1 Genetic markers for the presence of genes

Genetic markers provide a means of readily and rapidly identifying the presence of a particular gene (such as a gene for resistance to stem rust) in animal and plant breeding lines. Marker-assisted selection allows increases in the efficiency of identification and selection of lines with desirable characteristics, which otherwise can take several generations of evaluation. These technologies ultimately lead to the same output from a breeding program as in the past, but in a more efficient manner, and are therefore considered to pose no greater risk to human health and the environment than traditional technologies already embodied in breeding programs. Some markers are currently available (and being used), and many more are being developed. The key issue is intellectual property and access to the genetic markers.

1.2 Doubled Haploidy

'Doubled Haploidy' is a means of generating fixed lines in a breeding program for self-pollinated species without having to go through many generations (that is, several years) of growing, evaluating and harvesting breeding lines in the glasshouse or in the field. The output from a Doubled Haploidy program is no different than that from a conventional breeding program, and hence the use of Doubled Haploidy is not considered to pose any environmental or food safety risks. There are no intellectual property issues with tissue culture, since it is a publicly available technique rather than a genetic product.

Category 2 - Genetic Transformations

2.1 Gene transfers from near relative species

Traditional plant breeding programs have long sought to introduce useful genes from related species, but it has proved a slow and difficult process by conventional means. The new gene technologies offer the opportunity to insert such genes readily into the desired varieties. As such, they provide an opportunity for improved disease resistance, stress tolerance, etc, and the potential for some substantial sustainable yield improvements where these factors are substantially limiting yield. Because these new varieties generally involve marginal changes from those developed traditionally, the risks in this area are few, at least in most cultivated crops.

Intellectual property issues are important in relation to genetic transformations, but the risk of environmental or food safety problems arising is considered to be low.

2.2 Gene transfers from unrelated species

The new technologies also allow more exotic gene transfers from unrelated species into a variety. While in many cases this is likely to be benign, the level of risk is considerably higher where such genes are brought into a cropping system. The risk that the new gene could ‘escape’ to weeds, or other plants, while very low, does exist in some situations and any nutritional changes to the grain need to be assessed for their effect on human health. There is a need to assess carefully the potential risks from this type of transformation, and to make careful assessment before the genetically modified crop is released for commercial cultivation.

A further example of genetic transformation technology is where genes of viral and bacterial antigens are introduced into insect cells so that the insect cells (in tissue culture) produce non-infectious viral and bacterial proteins for animal or plant vaccine production.

Again, intellectual property issues are important.

Category 3 - Other Gene Technologies

3.1 Terminator genes

Terminator genes, which are not yet developed commercially, are genes which prevent harvested grain being re-used as seed. Varieties with terminator genes are therefore very similar to hybrids, in that fresh seed must be purchased each year. It is considered that terminator technology poses some environmental and food safety risk. Terminator gene technology is directed at obtaining a marketing advantage for seed, and therefore intellectual property issues are important. As a result, equivalent varieties without terminator genes would have potential value for farmers.

Other Issues

A further issue which requires consideration in the context of risk assessment is the status of livestock which are fed genetically modified feeds.

4. IMPEDIMENTS TO PRIMARY PRODUCERS ACCESSING GENE TECHNOLOGY

The main ‘access’ impediments to gene technology are:

(i) the lack of an appropriate regulatory ‘pathway’ for GMO’s;
(ii) the appropriateness of the legal framework establishing intellectual property rights for the protection and hence encouragement of innovation in gene technology and the development of GM agricultural products and food;
(iii) commercial issues in relation to Australia accessing key technologies held under overseas patents; and
(iv) cost issues.

4.1 Establishing an Appropriate Regulatory Pathway

The lack of clear regulatory pathway for developers of GMOs to obtain approval for commercial release in Australia is the most important impediment for any access to gene technology. It is urgent that such a pathway be developed which enables innovative new products to be introduced to the market, after appropriate and rigorous risk assessment.

A key element of risk assessment is to avoid any adverse effects on human health and the environment, and to provide consumers with an adequate level of assurance. A further important element of risk assessment is that gene technologies are categorised on the basis of their human health and environmental risk. Consideration should be given to exempting from risk assessment, those technologies which simply facilitate research or plant breeding, and hence are of extremely low or nil risk to either human health or the environment. This would avoid unnecessary compliance costs and ensure that Australian producers are not disadvantaged relative to their overseas competitors in accessing gene technology benefits.

The Commonwealth Government recently announced the creation of the Office of Gene Technology Regulator in the Department of Health and Aged Care. There are some obvious agencies which need to be and are already involved in the development of a regulatory pathway. These include agencies such as:

- the Australia and New Zealand Food Authority which has statutory responsibility for food safety;
- the National Registration Authority which has statutory responsibility for any change in registration concerning the use of a pesticide on a pesticide resistant plant, and also where a plant expresses resistance to a pest through the internal production of a pesticide; and
- Environment Australia which has statutory responsibility for protecting the environment.

Given that the primary gap in the regulatory pathway currently relates to the commercialisation of GMOs and the need to provide legislative backing to the assessment procedures of GMAC, there is an obvious need for significant technical input to risk assessment procedures. It is therefore strongly recommended that the Department of Health and Aged Care formally and regularly consult with State and Territory Governments, State and Territory agriculture, environment and health agencies, and with CSIRO.

There is much evidence that the majority of consumers do not necessarily fear the appearance of GM food on the market. However, consumers wish to know much more about the process and the products resulting from gene technology, as reflected in consumer pressure for the mandatory labelling of all GM food. It is recommended that the Commonwealth Government develop and deliver an objective communication program to lift the level of informed awareness of consumers about the benefits and risks to them and to the environment of GM agricultural products, and food.

4.2 Intellectual Property Rights

Intellectual property rights are designed to encourage innovation by providing the innovator with the exclusive right to commercialise that innovation for a set period of time, subject to the innovator making a full disclosure of the innovation. The challenge for governments is to establish arrangements which on the one hand provide sufficient incentive for innovators to develop new products, but on the other hand avoid the establishment of monopolies which restrict supply of the innovation and extract 'above normal' returns.

The appropriate form of government intervention to achieve socially desirable levels of investment in innovation is an issue subject to ongoing debate. The issue was the subject of extensive discussion in the United States during the mid to late 1980's in conjunction with the emergence of biotechnologies, and in Australia with the introduction of plant variety rights.

Patents are designed to provide commercial incentives for innovation. Costs associated with protecting intellectual property and the provision of research and development incentives are of direct relevance to producers accessing gene technology. A key issue is whether the level of incentive produced under Australian patent law compares to that provided in other countries, and whether the time limit applying to patent protection should be standardised in terms of years, or should relate to the period of time required for innovators to derive a 'normal' return on their investment.

The Standing Committee on Agriculture and Resource Management's High Level Working Group on Gene Technology has reported that patents are the preferred instrument to protect the commercialisation of gene technology innovation and that Australian patent law provides the necessary legal and commercial protection for innovation in the area of gene technology.

The High Level Working Group also reported that Plant Breeders' Rights does not provide satisfactory protection for gene technology, principally because it allows protected varieties to be used in breeding programs and for research without any reference to the owner of the variety. The PBR Act has also not provided sufficient incentive to stimulate private investment in breeding in some agricultural plants because of 'farmer privilege' which allows farmers to save the seed of a protected variety for sowing the following season. In crops such as winter cereals and pulses, farm saved seed is the norm, and therefore seed royalties provide an insufficient return on the investment in a breeding program.

This has led to the development of the 'end point royalty', where a royalty is imposed on the sale of the harvested grain. This system would provide for a greater return to the breeder (depending on the size of the royalty and the demand for the variety) and so provide a more adequate incentive for investment in breeding programs. The imposition of end point royalties does not depend on protection by patent or by PBR, but can be imposed by civil contract at the point of sale of the seed. A patent on the variety or on a gene in the variety would make the identification of such a variety easier and the civil contract more enforceable.

It is very likely that any variety developed by the insertion of a gene or genes would be subject to an end point royalty, or some other form of civil contract capable of generating a greater return to the owner of the variety than is possible from a seed royalty (see the later section on 'costs' as a possible impediment to accessing gene technology).

4.3 Commercial Issues

Australia currently undertakes approximately two per cent of worldwide research in gene technology. A consequence of the much greater investment in gene technology in the United States, Europe and to a lesser extent Japan, is that key enabling gene technologies are protected by patent owned by overseas biotechnology companies. Whether these companies make these key technologies available to Australian researchers and plant breeders, and under what conditions, is of critical importance to our agriculture and food processing industries.

The kind of enabling technologies affected are the two main methods of inserting new genes into plant tissue (the 'Agrobacterium', and the 'particle gun' methods), the best promoter sequences which 'turn on' the gene so that it is actually expressed within the plant, and some of the best 'marker' sequences which allow breeders to select out those parts of the tissue which have actually accepted the new gene, and integrated it into its DNA.

To date, Australian experience in accessing these technologies is mixed. It is relatively easy to obtain research licences to use these enabling technologies in Australia. However, it is a different story when it comes to commercialising the results of this research. In one instance, permission to proceed to commercialisation of a lupin variety dependent on a patented technology was refused. In another instance, a major biotechnology company signed a contract to make available its herbicide resistance gene to an Australian canola breeding program. The gene for another herbicide resistance has been made relatively freely available.

The overseas owners of these technologies have the legitimate right to protect their interests by either providing, or denying, access to their technology to Australian researchers and breeders. It might be thought that they would almost automatically agree to licence their technology to researchers and breeders with reputations for integrity, in order to increase their commercial return. However, that has not necessarily been the case. There may be issues of product security, whereby owners of the technology may be concerned about the risk of losing control of their product under some circumstances in Australia, or they may have concerns relating to litigation over product safety under Australian conditions and law. Alternatively, they may simply consider that the crops on which Australian breeders are working are not of sufficient worldwide commercial significance.

In this latter respect, some Australian crops such as lupins and chickpeas, are minor crops on the world scene, while some major crops in the USA and Europe are minor crops here, for example soybeans and maize.

If the owner of the key technology does not have an interest in licensing that technology in Australia on normal commercial terms, then we will either have to accept that decision and wait for the patent to expire before we can have access to it, develop some alternative method of doing what that technology can do, or develop some intellectual property which is of interest to that owner, and use it as a bargaining 'chip' for access. Each of these alternatives has its cost, and Australia will have to develop a national approach on an industry by industry basis to minimise that cost, and maximise the benefit to that industry.

A potential attraction which Australia does have is the germplasm of breeding programs. This is the outcome of many years of crossing and selection, and is very well adapted to the almost unique Australian environment of climate, soil and disease types. If an overseas company wanted to begin plant breeding using gene technology in Australia, it would save a great deal of time and effort if it could gain access to the advanced breeding lines of our breeding programs. Our breeding programs may then be able to develop strategic alliances with overseas owners of key gene technology, if those companies decide that the Australian market is worth their investment. This has happened in several instances eg. Bt cotton and 'Round up Ready' canola. However, the opportunities here appear to be limited currently.

A further option is to develop some uniquely Australian intellectual property in gene technology which is attractive to overseas companies, and hence sufficiently valuable to bargain with to enable access to other gene technologies.

4.4 Cost Issues

In the case of Bt cotton, varieties claimed to be resistant to the *Helicoverpa* moth were made available to the Australian industry, but at a cost which was close to the estimated savings in insecticide. The mechanism to impose this cost was innovative, in that the company only made the seed of the varieties available after the grower signed a contract for access to the technology. The fee was based on the area intended to be sown, and after it was paid, the grower was then authorised to buy the seed.

It is likely that companies owning potentially valuable genetically modified varieties will find other innovative ways of ensuring they don’t have to rely only on seed royalties to generate a return on their investment.

The cost of the regulatory pathway will be reflected in the cost of products to the agricultural and/or food processing industry. One of the outcomes of any regulatory pathway may well be a requirement for farmers to enter into some form of agreement to use a genetically modified product or variety only in a particular way, and subject to certain monitoring. This is already being developed by some companies proposing to release genetically modified plant varieties to ensure that the advantage those varieties confer is not lost, and/or any risk of using those varieties is minimised, eg. special conditions covering the use of herbicides on herbicide resistant varieties to reduce the risk of resistance developing in weeds through over use of that particular herbicide.

All of these special conditions will increase the cost of using the GM varieties to which they apply. This will be in addition to the costs imposed by the owner of the plant variety through either imposing innovative mechanisms for farmers to access the technology, through high seed cost, or through high end point royalties.

It is possible that the costs charged by companies for access to gene technology may represent a barrier to small and medium enterprises. However, it is unlikely that this would be significant, as cost will usually be on a per unit of area basis, or per unit of seed. Furthermore, many new technologies similarly involve increased costs prior to the benefits being realised.

Hence, NSW Agriculture sees no justification for governments to provide direct assistance to small and medium sized enterprises, purely on the basis of the direct costs which they may elect to incur. No producer or food processor is compelled to use any particular plant variety or product, and their choice on whether to or not to use a GM variety or product will depend on whether they believe it will be of advantage to their enterprise. Their assessment of the advantage will include factors such as the cost of accessing that produce/variety, the marketing advantages or disadvantages which the product/variety confers, the environmental or sustainability benefits the product/variety confers, and their assessment of the overall economic benefit to their enterprise.

Two further factors which will increase costs associated with GMOs and GMO products, and hence impact on access to gene technology by primary producers and the international competitiveness of Australian agriculture are; (i) the extent of mandatory labelling requirements; and (ii) the extent to which Australian industries are forced to segregate product on the basis of it containing genetically modified product or ingredients.

Where products are assessed as being ‘substantially equivalent’, the case for mandatory labelling is not strong. Where consumers continue to have a preference for modified or non-modified products, then information provision (some of which may be achieved by labelling) can be achieved by allowing industry to voluntarily respond to that demand.

In relation to product segregation, primary producers and their associated industries would incur significant costs should they be required to segregate product as a result of either domestic or overseas labelling and/or market requirements. Labelling requirements for example, and subsequent segregation, may have significant unintended side effects such as primary industries being required to invest in additional storage and transport infrastructure, and buffer zones between crop types being required. Minimising the need for segregation will minimise these types of segregation costs, which would be borne by industries as a whole, with significant costs also being incurred by producers of non genetically modified produce.

5. INTERNATIONAL TREATIES

Of significance to the World Trade Organisation is that gene technology has the potential to influence the competitiveness of countries and hence may provide an impetus for further protectionism. An important outcome from the Uruguay Round of multilateral trade negotiations was the international Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which applies to patents on new plant varieties.

The Agreement requires signatory countries to make patents available for inventions which meet the criteria for patentability, without discrimination in relation to where the invention occurs. The Agreement attempts to harmonise the types of intellectual property which may be subject to patent, how long patent protection will apply, and the instances in which inventions may be exempt from patent.

The opportunity to alter patenting arrangements for biological processes on an international basis will arise this year with the review of certain aspects of the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS).

6. POSSIBLE SOLUTIONS TO ACCESS ISSUES

Some possible solutions for the identified actual or potential problems of accessing gene technology for the consideration of the Committee include the following.

1. The Department of Health and Aged Care to move as quickly as possible to develop an appropriate regulatory framework which provides a clear pathway for the commercialisation of GM processes, products and food, and which protects human health and the environment and provides an appropriate level of assurance to consumers that their concerns have been met.

That as part of the risk assessment procedures within that regulatory framework:

- gene technologies be subject to categorisation on the basis of their risk to human health and the environment, and that categorisation be made subject to monitoring and review; and

- a communication strategy is developed to objectively and appropriately inform the community about the benefits and risks of the use of gene technology in the development of agricultural plant varieties, and in food processing.

2. In the development of this regulatory framework, the Department of Health and Aged Care consult with State and Territory Governments (and through them agriculture, environment and health agencies), the Australia and New Zealand Food Authority, the National Registration Authority, Agriculture, Fisheries and Forestry - Australia and the CSIRO.

3. Australia should develop bargaining strategies to access key gene technology owned by overseas biotechnology companies.