Experts Group on
Gene Technology

Transgenic Poppies

Report to Government on the issues raised by the application of gene technology to opium poppies in Tasmania's primary industries.

June 2001

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This paper has been prepared for the Minister for Primary Industries, Water and Environment by the Experts Group on Gene Technology in cooperation with the Gene Technology Unit, Department of Primary Industries, Water and Environment.

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CHAIR
EXPERTS GROUP ON GENE TECHNOLOGY

The picture depicted on the front cover of this document is not of transgenic poppies and is provided for illustration purposes only.

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Other Publications by the Experts Group on Gene Technology

- *Gene Technology in Tasmania's Primary Industry and Food Products: Report to Government on the Issues Associated with the Application of Gene Technology in Tasmania's Primary Industries (June 2001).*
- *Transgenic Brassica Crops: Report to Government on the Issues Raised by the Application of Gene Technology to Brassica Crops in Tasmania's Primary Industries (June 2001).*
- *Carnations with Genetically Modified Flower Colour: Report to Government on the Issues Raised by the Application of Gene Technology to Carnations with Genetically Modified Flower Colour in Tasmania's Primary Industries (March 2001).*

Disclaimer

This document has been prepared for the Tasmanian Government as background information on the issue of transgenic poppies.

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Preface

In July 2000 the Tasmanian Government imposed a 12 month moratorium on certain genetically modified plants and plant products in Tasmania whilst an intensive investigation of the issues associated with the application of gene technology in Tasmania's food and primary industries was undertaken. As part of that investigation the Minister for Primary Industries, Water and Environment, the Hon David Llewellyn MHA established a group to advise the Government on gene technology issues as they relate to Tasmanian primary industries and food products.

The Experts Group on Gene Technology are:

- Mr Robert Napier (Chair), Director of Napier Agrifutures and immediate past Associate Professor, Faculty of Rural Management, The University of Sydney.
- Dr Katrine Baghurst, Group Manager, Consumer Sciences Program, CSIRO.
- Dr Denis Saunders, Program Leader, Sustainable Landscapes Program, CSIRO.
- Professor Rob Clark, Head, School of Agricultural Science, University of Tasmania.
- Professor Jeff Malpas, Head, School of Philosophy, University of Tasmania.

In March 2001 the Hon David Llewellyn MHA requested a technical report on the issues associated with the production or presence of transgenic poppies in Tasmania.

This report does not make policy recommendations, but rather highlights the issues for consideration by Government by way of background material. The views expressed in this report are those of the members of the Experts Group on Gene Technology and do not necessarily represent those of the Tasmanian Government or the opinion of the employers or principals of the members of the Group.

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Executive Summary

Commercial opium poppies (*Papaver somniferum*) can be genetically modified by the insertion of genes that enhance alkaloid production or by sequences that "switch off" genes responsible for undesirable alkaloids. Alkaloids that are produced by commercial poppy crops include morphine, thebaine and codeine, which are essential elements in many pain relieving medicines. Poppies can also be modified for tolerance to some herbicides however indications from the alkaloid companies are that this specific modification is of little commercial interest.

Commercial poppy production in Tasmania is regulated through a licensing regime which in part is intended to reduce weedy populations of the plant and to minimise risks to human health by restricting access to crops. In the absence of a licence, possession of the plants or plant material from *Papaver somniferum* is prohibited. This regime distinguishes commercial poppy production from most other commercially produced crops. In the context of gene technology this regime imposes some extra management responsibilities on producers that are absent from other transgenic crops.

The presence of State based regulatory restrictions, in conjunction with national regulatory oversight by the Gene Technology Regulator also has implications for environmental risks posed by the presence of transgenic poppies in the State. Weediness issues are largely dealt with through State controls and anecdotal evidence suggests that commercial poppy varieties are limited in their potential for invasiveness. Extremely low rates of outcrossing to the small number of weedy relatives and unconvincing evidence of gene transfer to soil microorganisms in natural ecosystems also suggest low environmental risk. Outcrossing to a weedy subspecies of *P. somniferum (P. somniferum ssp. setigerum)* is possible however this subspecies has a limited distribution and is a prohibited plant. It is considered that the potential for varieties with specific transgenic traits to establish in native vegetation should be subject to further investigation.

Despite the low levels of known risk, further minimisation of any risk in commercial crops is possible through removal of extraneous genetic sequences such as selectable marker genes. The incorporation of genetic mechanisms to prevent pollen and seed-mediated gene flow is also possible. Should such options be available in the near future, their adoption would be likely to facilitate public and industry trust and acceptance of the technology in poppy crops.

As with all transgenic crops, management and education are paramount to ensure that environmental, consumer and market concerns can be addressed. The production of transgenic crops needs to be approached with professionalism in relation to agronomic practices, segregation and record keeping for identity preservation purposes and compliance with regulatory regimes. The fact that the poppy industry in Tasmania currently displays a general adherence to regulatory controls and is essentially a closed supply chain (and is capable of becoming more so in the future) are steps in the right direction towards effective management of transgenic varieties.

Consumer acceptance appears higher for medicinal uses of transgenic organisms as opposed to other uses for which consumer benefits are less apparent.

The main market risks appear to be associated with poppy seeds and honey as potential by-products entering the food chain. These risks are heavily linked to consumer concerns in Tasmania’s domestic and export markets. Both alkaloid companies in Tasmania have indicated that they are prepared to forego poppy seed production should transgenic cultivars be introduced. Contamination of honey by transgenic poppy pollen may be avoided by effective communication between the alkaloid companies and apiarists. The introduction of commercial crops will require further investigation of these issues in particular the effect on market perceptions of Tasmanian honey should further field trials or commercial production of transgenic poppies occur in Tasmania.

Further investigation of the effects of commercial transgenic poppy production on Tasmania’s organic farming industry is needed for more accurate assessment of the impact of potential contamination sources.

The conventional poppy industry is a significant component of the Tasmanian agricultural sector. Poppy crops are grown by an estimated 1200 farmers with a current farm gate value of about $55 million. The industry contributed approximately $220 million to the Tasmanian economy in 1999/2000. Current estimates are that world market demand will see expansion continue at the rate of at least 5% per annum for the next few years and Tasmania is assessed as having suitable land area to expand production significantly for many years to come. The value of the crop to the Tasmanian economy is therefore expected to increase. The international competitiveness of the Tasmanian crop is based on its superior productivity however the application of gene technology elsewhere has the potential to erode this advantage. Conversely the competitiveness of the Tasmanian industry would be increased by the use of the technology if production could be improved at a faster rate than that of international competitors.

Ethical considerations are similar across all transgenic applications, and stem from both fundamental concerns with the technology itself and its basic invasiveness upon other living organisms. Another basis for ethical objection may be the use to which the technology is put and whether the resultant benefits are effectively outweighed by risks posed.

Transgenic opium poppy production in Tasmania is currently at the research and development phase, with estimates putting commercial production at least 3-5 years away. Nevertheless as a closed supply chain the industry holds great promise, provided environmental (including agricultural) risks can be mitigated. It is likely that the general public would find this application of gene technology relatively acceptable due to its basis in the production of medicines, provided issues relating to by-products entering the food chain can be resolved. Further work is needed to document public and market acceptance of transgenic poppies in the context of Tasmanian agriculture and pharmaceutical production.

Introduction

This report is a technical document that is intended to capture the major scientific, environmental, management, economic, consumer and ethical issues associated with transgenic poppy species. As such, some readers may have difficulty with technical terms used. Technical terms are explained where possible.

Agricultural Significance of the Poppy

The commercial poppy species grown in Tasmania *Papaver somniferum* (also known as oilseed poppy, opium poppy or alkaloid poppy) owes its agricultural significance to the fact that it is the only plant capable of biologically synthesising the alkaloid morphine in commercial quantities (DSD, 2000a). The plant also produces other related alkaloids with commercial significance, such as thebaine and codeine, used in the production of many analgesic preparations and medicinal compounds. *Papaver somniferum* is not generally found growing in the wild, being mostly domesticated (Kapoor, 1995).

International Poppy Production

The poppy is lawfully cultivated in India, China, Egypt, France, Holland, Hungary, Greece, Spain, Portugal, Italy, Turkey, Russia, the former Yugoslavia and Australia (Kapoor, 1995). Japan and Bulgaria also grow the species on a limited scale. The market share of Tasmanian poppies has grown as a result of improved competitiveness due to increased productivity per hectare (Doyle, 2001; Fist, 2001a). Tasmania's primary competitors in alkaloid production are Turkey, France and Spain (Fist, 2001b). Of these countries Turkey is able to compete on the basis of reduced labour costs and Government subsidies, whilst France has a technically advanced industry similar to that in Tasmania and a large protected local market for codeine.

Regulation of Poppy Production in Australia

Cultivation of opium poppies is regulated by the United Nations under the Single Convention on Narcotic Drugs 1961, which is enforced nationally by the Australian Government. The Commonwealth Government has an agreement with the Australian States that commercial cultivation of the species be confined to the island State of Tasmania (Tasmanian Alkaloids, 2001).

Cultivation within Tasmania is strictly controlled and monitored by the Poppy Advisory and Control Board (PACB) which is responsible for issuing licences to growers on an annual basis. Restrictions on the importation, making, refining, preparation, sale, supply, possession, cultivation and use of *P. bracteatum* and *P. somniferum* poppy plants are provided in the *Poisons Act 1971* (Tas) which makes it illegal to possess such plants without a licence.

The Tasmanian Poppy Industry

Large-scale commercial production of poppies in Tasmania was initiated by Glaxo Wellcome (now GlaxoSmithKline) in the early 1970s, and was joined in 1975 by Tasmanian Alkaloids (now a subsidiary of Johnson & Johnson). The industry has grown rapidly in Tasmania in recent years from about 3500 ha in the late 1980s (DSD, 2000a) to almost 20 000 hectares in 2001 (Fist, 2001b). Estimates of the value of the industry to the State vary. The estimated farm gate value to growers in 1999/2000 was approximately $55 million and individual farmer returns of up to $6 000/ ha have been reported in the past (DSD, 2000a). A value of up to $220 million to Tasmania's economy has been estimated (Justice Tasmania, 2000). Current estimates are that world market demand will continue to expand at around 5% per annum over the next few years, potentially resulting in an increase in the value of the industry to Tasmania in the order of $20 million (DSD, 2000b).

Genetic Modification of Poppies: the Issues

Gene technology is the process by which living things may be altered by the insertion of ‘foreign’ genes from another organism. For a more detailed discussion of gene technology, refer to Experts Group on Gene technology (2001).

The alkaloid companies in Tasmania consider that increased productivity of alkaloids through gene technology is a realistic opportunity that has the potential to increase the competitiveness of the industry. It has the potential to create opportunities through increased production of specific alkaloids in the plant that are currently only present in very small quantities. Should the industry be excluded from such technology it is possible that the market share currently enjoyed by Tasmania may be eroded.

At least one method describing the successful genetic transformation of poppies has been published in the scientific literature (Park & Facchini, 2000), with active research known to be occurring in Canada, USA, Turkey and possibly also France. However, production of transgenic poppies in Tasmania does pose some potential problems. There is significant public and industry concern in Tasmania that production of any genetically modified organisms (GMOs) may have a deleterious effect on the State's marketing image and environment.

Generally, the bases for these concerns are that:

(a) there is likely to be a marketing advantage in the future through the avoidance of transgenic products;

(b) there may be unknown ecological consequences due to the introduction of transgenic crops such as increased weediness, sexual gene flow or unpredictable non-sexual (horizontal) gene transfer to unrelated species; and

(c) poppies cannot purely be considered a pharmaceutical crop as Tasmanian poppy seeds are sold as a food product. In reference to the latter point, both Tasmanian Alkaloids and GlaxoSmithKline have given assurances to the Tasmanian Parliamentary Joint Select Committee on Gene Technology that should transgenic poppies be introduced into the State both companies would forego seed production for food use.

Genetic Modifications

The Alkaloid Pathway

It has been stated by both alkaloid companies in Tasmania that the primary aim of genetically modifying poppies is to alter the alkaloid content or alkaloid profile of the crop (Hartnett & Rockcliff, 2001; Doyle, 2001). Production of morphine and other alkaloids in poppies occurs via a biosynthetic pathway that is regulated by both environmental and developmental influences (Facchini & Bird, 1998). The pathway includes steps that may divert alkaloid synthesis to non-commercial compounds. It is possible that at other points the pathway is restricted by rate-limiting steps, or bottlenecks.

Additionally, there are commercially important alkaloids such as thebaine and codeine that occur as intermediates in the pathway and therefore do not normally accumulate in the plant in large quantities. It is theoretically possible, given a detailed knowledge of the isoquinoline biosynthetic pathway of the poppy to increase production of particular alkaloids in the pathway by modifying rate-limiting steps or restricting alternate branches and/or steps in the pathway. Details of the genetic sequences currently being used are commercially sensitive. It is most likely that initial work will involve repeating genes already present in the poppy plant, or in other poppy species, or using antisense DNA (genes in reverse sequence) to prevent expression of alkaloid genes in the plant.

Poppy companies wish to increase the amount of particular alkaloids in the commercial product of their crop and/or decrease the amount of other alkaloids or products created by poppies that are not desirable. This is made possible using gene technology to add extra genes to speed up slow processes or to limit the effect of other genes.

Types of Genetic Sequences

Transgenic sequences may initially incorporate generic terminal sequences (usually from plant viruses or bacteria), constitutive promoters (usually from plant viruses) and selectable markers that aid in the transformation process (such as bacterial antibiotic resistance and/or herbicide resistance genes). In the future as the genomic details of diverse species become available it is possible that tissue specific or inducible promoters and sequences may be used. Such a tailored approach to transgenic crop design will allow more specific control of gene expression and further minimise any real or perceived risks posed by the transgenic crop.

Promoters are parts of the DNA sequence that "turn on" the gene. They can be turned on all the time (constitutive) or they can be activated only by certain events such as exposure to light.

Selectable marker genes allow plants or cells that have been successfully genetically engineered to be differentiated from other plants and cells, usually by conferring the ability to survive a treatment that would normally kill a plant, such as antibiotics or herbicides.

Risk Minimisation in Gene Construct Design

It is possible to remove extraneous DNA, such as selectable antibiotic markers, from transgenes using site specific recombination systems. Recombination systems involve flanking the gene with recombination sites that result in excision of the gene when a specific recombinase (enzyme catalysing recombination) is expressed. Recombination systems that have been successfully adapted to plants include Cre/*lox* (Dale & Ow, 1991), the Gin recombination system (Maeser & Kahmann, 1991), the pSR1 plasmid (Onouchi *et al*., 1995) and the FLP-frt system (Kilby *et al*., 1995). Recently, a highly reliable chemical-induced system based on the Cre/*lox* system has been developed termed CLX that may allow the routine removal of specific transgenes in cell cultures prior to production of an entire plant (Zuo *et al*., 2001). A number of other methods have also been employed to remove marker genes including homologous recombination, transposition and co-transformation (see Ow, 2000 for a summary of these methods).

Marker genes and other DNA used in genetic engineering and then no longer required can be subsequently removed using genetic techniques.

Improvement of such techniques is likely to accelerate given the European Parliament's February 2001 amendment to Directive 90/220/EEC on the deliberate release into the environment of GMOs. The Directive amendments include the provision that antibiotic resistance genes be gradually eliminated from GMOs, with a 2004 deadline for this to occur in commercial releases. Excision or replacement of antibiotic resistance genes has also been considered advisable by the UK Advisory Committee on Releases to the Environment Sub-Group on Best Practice in GM Crop Design (ACRE, 2001).

The risk of marker gene transfer through recombination of transgenic material with soil or gut microorganisms is likely to be extremely low. However, removal of such sequences achieves the following (Ow, 2001):

- lessens public concerns related to marker genes;
- removes the need for costly risk assessments;
- allows reuse of the marker genes;
- eliminates problems associated with multiple copies in sexually propagated plants (numerous homologous sequences may lead to gene silencing); and
- eliminates the chance of herbicide resistance being conferred to related weed species (where herbicide resistance genes are used as marker genes).

The removal of extraneous DNA from transgenic plants is an advisable strategy to reduce any risk to 'as low as reasonably achievable' (Ow, 2000).

Herbicide Tolerance

A small field trial has been conducted in Tasmania prior to the 2000 moratorium using transgenic poppies containing a gene for herbicide resistance to glufosinate ammonium from the bacterium *Streptomyces viridochromogenes* (GMAC, 1999). The purpose of this trial was to assess gene flow to surrounding poppy plants. According to evidence submitted to the Tasmanian Parliamentary Joint Select Committee (Hartnett & Rockcliff , 2001; Doyle, 2001) there is no commercial interest in herbicide resistance from Tasmanian alkaloid companies at this stage. Conversely downy mildew resistance would be of substantial benefit to the poppy industry and may be considered should such an opportunity become available.

Weediness of Poppies

The Poppy Advisory and Control Board

Poppy crops are grown in all recognised cropping areas in the State and are therefore subject to a wide range of climatic, geographic and ecological variables. Poppy growers must consent to general conditions of licence to grow *P. somniferum* in the State. These conditions include clauses intended to limit the occurrence of poppies as a weed. Additional measures are undertaken by the companies to ensure that *P. somniferum* weed distribution is contained. Current conditions of licence to grow a poppy crop are subject to direction by the Minister for Health and Human Services and include:

- that the Licensee takes steps within 7 days after harvesting the crop to ensure that any poppy material remaining on the land on which the crop was grown is destroyed by burning, slashing, cultivating or grazing with livestock;
- that the Licensee of a crop which the company will not harvest, takes steps to destroy the crop before a given date;
- that any regrowth of poppies from seed from any previous year shall be destroyed by spraying, cultivating or grazing with livestock; and
- that the Licensee allows a person authorised under the *Poisons Act 1971* (Tas) to inspect, at any time, the crop or the land on which the crop is to be grown or from which it has been harvested.

The PACB and field officers from both companies routinely monitor crops. The PACB, local councils and road authorities rigorously control any volunteer plants on roadsides. Planters, trucks and harvesting machinery are routinely cleaned before leaving sites to minimise dispersal of poppy seed.

Aspects of these guidelines may require modification for transgenic crops, for example, it may be recommended that stock not graze on transgenic poppy stubble if market or safety concerns arise. The guidelines may need to be strengthened or modified to ensure they remain practicable perhaps by the inclusion of mechanisms for more rigorous monitoring requirements such as routine auditing. This may particularly apply to the destruction of poppy material following a crop.

Volunteer Poppies

Following harvest, spilled seed may germinate the following autumn, although volunteer plants can be readily controlled using a range of herbicides (Tasmanian Alkaloids, 2001). It is unusual for remnant poppy seed to survive for more than three years in the field if good agronomic control measures are used, although seed stored under ideal conditions under ambient temperature may have a lifespan of 10 years. Sowing of a previous transgenic poppy trial site to pasture resulted in 70 volunteers during early winter and smaller numbers in the spring. The herbicide MCPA was used twice to control poppy regrowth and no *P. somniferum* plants have been found at the site since that time (Tasmanian Alkaloids, 2001).

Papaver somniferum occurring as a weed can easily be controlled in an agricultural environment through the application of broad spectrum and selective herbicides to which these plants are sensitive. There is no indication that conventional (non-transgenic) *P. somniferum* has ever become established as a weed in wilderness areas of Tasmania (Tasmanian Alkaloids, 2001). Factors that limit the invasiveness of *P. somniferum* include that the plant requires broken ground for establishment, good soil drainage, high soil pH and freedom from frosts during flowering. Nevertheless, if *P. somniferum* were to develop the potential to become established in remnant native vegetation adjacent to crops, there is a possibility of further expansion into wilderness areas (where active control measures are not used). Therefore, the potential for varieties with specific traits to establish in native vegetation does require investigation.

Unexpected Consequences of Genetic Modification

There is a possibility that inserted genetic material may have unexpected consequences in terms of the plant's competitive ability in a range of ecosystems.

Possible causes of increased weediness in transgenic varieties may include:

- alteration of gene expression arising from the random insertion of foreign genetic material;
- unexpected effects on insect predators or ecological tolerance that may otherwise restrict the crop's competitive ability as a weed; or

- instability of the genetic construct leading to unpredictable results.

Many of these issues are reviewed in detail by de Visser *et al*. (2000) who found that the current scientific literature cannot necessarily provide conclusive answers to these questions (see also Senior & Dale, 1999).

Unpredictable effects from seemingly unrelated genetic modifications include a report that *Arabadopsis thaliana* plants modified with a herbicide tolerance gene were able to cross more effectively to surrounding non-transgenic plants compared to the wild-type *A. thaliana* (Bergelson *et al*., 1998). Although the probability of increased competitive or invasive characteristics from random genetic events caused by transgenic recombination are low, ongoing monitoring and vigilance would be prudent to reduce risk to as low as practically achievable. Subtle effects are unlikely to be detected in the laboratory or during limited trialing. It should be noted that often invasive conventional weeds have not been considered to be a problem for many years before their aggressiveness was recognised (Marvier, 2001). The probability of increased weediness in conventionally developed cultivars is not necessarily dissimilar to that of transgenic cultivars.

Risk Assessment of New Poppy Varieties

Any specific transgenic cultivar undergoes voluntary assessment in Australia, which involves the proponent answering a range of questions relating to potential risks posed by the organism. However, given that gene expression is controlled to a large extent by environmental factors, unless the organism has been extensively trialed and monitored under strict conditions in a wide range of environments, such risk assessment is unlikely to be definitive. Nevertheless, the level of ecological risk may be determined to a large extent by the type of transgenic modification being attempted. For instance increased pest or disease resistance, seed production, ecological tolerance or plant competitiveness are traits that have a readily evident element of potential ecological risk compared to genetic modifications such as increased nutritional content in animal feed.

Changes in Weediness due to Alkaloid Pathway Modification

Possible sources of ecological advantage to *P. somniferum* from increased production of alkaloids or modification of the alkaloid profile include:

- potential increased toxicity to insect predators of poppy weeds; and
- a secondary physiological effect in the plant due to the altered levels of alkaloids.

Both sources of risk would equally apply to any conventional poppy cultivar with increased or altered alkaloid content. There is no evidence at present to suggest that conventional varieties with increased or altered alkaloid content have had an effect on weediness of *P. somniferum.* More information on precisely how soil conditions and temperature limit the weediness of *P. somniferum* in agricultural or native ecosystems would be of assistance to target monitoring. Unexpected effects arising from the genetic modification (but not necessarily due to the trait itself) could conceivably improve the plant's competitiveness in similar ways. Therefore monitoring for unexpected ecological consequences of genetic modification is prudent.

Strategies to Reduce Potential Weediness Problems

A solution to potential weediness problems in transgenic *P. somniferum* is to incorporate genetic mechanisms into the plant that would cause no, or few seed to be produced. Such technologies exist, however it is understood that they are yet to be commercialised and will require substantial future development. Genetic modifications of this sort have been referred to as terminator technology, technology protection systems or gene flow restriction technology. *Papaver somniferum* flowers do not require fertilisation or seed production in order to produce the required alkaloids. It may be possible in the future to restrict pollen production, pollen fertility or seed production through transgenic means. This would minimise the risk of increased weediness by greatly reducing the occurrence of volunteer plants.

'Terminator technology' has been widely criticised by some groups as it may result in farmers not being able to save seed for subsequent crops. Whilst this may be a legitimate concern within some scenarios, it is a condition of licence that *P. somniferum* crops grown in Tasmania must be grown from seed provided by the alkaloid company. To grow any seed from another source would be in breach of the licence, and therefore illegal under State law, and is also likely to be in breach of the Australian *Plant Breeders Rights Act 1994* (Cth). Chemical treatment of crops to reduce seed set is already being utilised by one of the State alkaloid companies and it is possible that similar methods could be further developed as an alternative to transgenic solutions.

Gene Transfer and Hybridisation

Poppy Weed Species in Tasmania

There are five *Papaver* weed species of poppy crops in the State: *Papaver dubium* (long-head poppy), *P. hybridum* (rough poppy), *P. rhoeas* (field poppy), *P. argenome* (pale poppy) and *P. somniferum ssp. setigerum* (small-flowered opium poppy) (Bishop & Pemberton, 1996). Hybridisation studies indicate that only *P. somniferum x P. somniferum ssp. setigerum* will regularly produce hybrids. However, as *P. somniferum* has a diploid genome (two sets of chromosomes) and *P. somniferum ssp. setigerum* has a tetraploid genome (four sets of chromosomes), seeds that are produced are most likely to be triploid, and may have reduced fertility (GlaxoSmithKline, 2000). *Papaver somniferum ssp. setigerum* has been identified on three properties in Tasmania, one each in Westbury, Forth and Tunbridge (Tasmanian Alkaloids, 2001). There is also anecdotal evidence of it occurring at a property near Scottsdale. *Papaver somniferum ssp. setigerum,* as a *somniferum* species is a prohibited plant under State legislation.

A possible single hybrid has been identified between *P. somniferum* and *P. dubium* after extensive attempts at hand pollination under optimised conditions. This is currently being verified (Tasmanian Alkaloids, 2001). *Papaver dubium* is a common weed in the south and parts of the north-west of Tasmania, however it is not normally a problematic weed except in crops of *P. somniferum* (Hyde-Wyatt & Morris, 1975). If hybrids are rarely formed in the field between *P. somniferum* and *P. dubium* the likelihood of introgression (stable incorporation of the gene or genes into a weed population) would be remote unless the hybrid plant was at least as ecologically 'fit' (at least as competitive in the environment) as the surrounding poppies. Any future transgenic *P. somniferum* crop expressing herbicide resistance or disease resistance would require careful examination by regulatory authorities in this regard.

Papaver somniferum and a number of related species are capable of self-fertilisation, including fertilisation prior to the opening of the flower bud (GlaxoSmithKline, 2000). Cross pollination of field-grown crops is usually in the order of 30-33% (GlaxoSmithKline, 2000), although Tasmanian trials have demonstrated a much lower rate of outcrossing at approximately 0.5% (GlaxoSmithKline, 2001).

Other Species Related to Poppies in Tasmania

Other related species that occur in Tasmania are *Papaver bracteutum*, *P. orientale*, *P. pseudo-orientale*, *P. nudicaule*, *Mecanopsis* spp. and *Escholzia californica*. These species are taxonomically distantly related and do not occur as weeds in the State.
It is extremely unlikely that hybrids would occur in nature. Controlled crosses are possible between *P. somniferum* and *P. bracteatum* however only approximately 40 *P. bracteatum* plants are currently under cultivation in the State and hybrids have extremely low fertility and very low vigour (Fist, 2001a.). *Papaver bracteatum* is also a prohibited species. There are no known Tasmanian native species that are closely related to *P.*

somniferum, and there would appear to be little risk of hybridisation between transgenic poppies and native flora.

Pollination of Poppies

Pollen of *P. somniferum* is considered to be too heavy and sticky to be wind-borne and therefore the major pollen vector is honeybees (GlaxoSmithKline, 2000; Tasmanian Alkaloids, 2001). Honeybees (*Apis mellifera*) are capable of flying considerable distances – at least 10 km in some circumstances (Eckert, 1933; Seeley, 1985). However, optimal foraging theory used in the ecological study of a wide range of animal species predicts that bees will forage on the best available food sources as near to the hive as possible. Honeybee foraging behaviour is complicated by a number of factors such as quality of the food source (pollen and nectar characteristics), attractiveness of the flower to bees and availability of other food sources (Delaplane & Mayer, 2000). Resource-rich crop plantings encourage honeybees to remain in that general vicinity, where they tend to visit a large number of plants for short intervals. Foraging distances of 2 km for commercial honeybees are believed to be common, although specific crop plants will attract bees from much further distances (Ramsey *et al*., 1999). Although typical foraging distances have been calculated for a number of crops (Moyes & Dale, 1999), no such data exist for poppy crops. Studies conducted by Tasmanian Alkaloids have shown that cross-pollination between *P. somniferum* plants within a crop was most likely to occur within 2.5 metres (Tasmanian Alkaloids, 2001).

It is possible that a range of other animal vectors such as other flying insects and birds may also pollinate poppies. The pattern of spatial dispersion of pollen among poppy crops by these vectors is unknown at this time, although there is anecdotal evidence that some beetle species have been observed foraging on cultivated poppies.

Distance of Gene Flow

There are problems in using gene flow data within crops as an indication of potential gene flow out of the crop (Gliddon, 1999; Squire *et al*., 1999). Extrapolation of gene flow data within a crop may not have relevance for gene flow out of large populations into much smaller populations such as weed communities. Studies of gene flow among small populations of Brassicaceous weed species indicate that gene flow into these populations occurs predominantly from larger distant sources rather than from adjacent small groups of plants (Ellstrand *et al*., 1989). The actual distance over which this can happen is difficult to ascertain. Pollen dispersal is often found at the maximum distance tested (Moyes & Dale, 1999).

The distribution of mating distances in seed plants predicts a non-zero probability of mating occurring at quite distant sites (Ellstrand *et al*., 1989; Cambell, 1991). The distribution is leptokurtic with a large decrease over a short distance, followed by a slow decrease at a low level for an extended distance.

Strategies for Prevention of Gene Flow

It is unlikely that isolation distances alone will completely prevent gene transfer to surrounding poppy crops. Buffer zones of non-transgenic plants provide some protection against gene flow out of the crop, but the efficacy of this method has been questioned with respect to bee-mediated pollen transfer (Delaplane & Mayer, 2000). Typical bee foraging distances, over which very low levels of cross pollination of poppy crops is possible, are likely to be in the order of 2-3 km (Ramsey *et al*., 1999), providing the crop is an attractive food source for honeybees. Such factors will have to be borne in mind by the alkaloid companies if there is a desire to replant seed from a harvested alkaloid crop or in any seed bulking activity.

Unless the genetic modification in question relates to an agronomic property such as herbicide resistance, any volunteers thus produced could be controlled in the same manner as all other *P. somniferum* volunteers. A number of solutions are either available now or will be available in the future (subject to patent restrictions and the cost of licences) to minimise gene flow risks from transgenic plants to the environment (ACRE, 2001). These include:

Plastid Transformation Technology. Small amounts of DNA exist in plant cells outside the nucleus in some cytoplasmic organelles (such as chloroplasts and mitochondria). This DNA is not usually transferred by pollen, but is inherited through the maternal parent. Insertion of transgenes into chloroplast DNA (Daniell *et al*., 1998) can also be more precise due to the smaller genome size. This would largely overcome any problems associated with honey and honeybees and would facilitate parallel production systems – ie, transgenic and non-transgenic cultivars. However, the ability of pollen to transfer plastid DNA differs between species and a specific assessment of this strategy to minimise transgene dispersal from *P. somniferum* is required. Although currently antibiotic resistance markers are used to monitor plastid transgene stability, it is understood that alternative techniques are being developed.

Male sterility. Transgenes exist to induce male sterility in plants. Methods are currently being developed to reverse or induce transgenic male sterility through the application of a specific chemical. Crops could thereby be made sterile after completion of seed bulking by applying a specific chemical to either the seed or young plants in the field.

Fate of Transgenic Poppy Pollen in Beehives

Pollen from *P. somniferum* will inevitably accumulate in beehives where it is digested by honeybee larvae (Delaplane & Mayer, 2000). A four year study by Professor Hans-Hinrich Kaatz has reportedly found that a herbicide resistance gene originating from transgenic *Brassica napus* (oilseed rape or canola) became incorporated into bacteria and yeasts in the gut of young honeybees. This work has not yet been published, nor have the full details been released. It is therefore difficult to assess the relevance of the study to *P. somniferum* and the type of genetic constructs that may be used in poppies. If such gene transfer were to occur it could potentially compromise some antibiotic treatments for apiary diseases.

There are a number of factors that may impact upon this type of non-sexual gene transfer between diverse organisms (see following section *Horizontal Gene Transfer*). The practical implications of transgenic *P. somniferum* for honey production are discussed in the section *Management, Production and Education.*

Horizontal Gene Transfer

Horizontal (non-sexual) gene transfer (HGT) from transgenic plant material to soil microorganisms has been noted under laboratory conditions (Gebhard & Smalla, 1998; de Vries & Wackernagel, 1998; Nielsen *et al*., 1997; Buhariwalla & Mithen, 1995; Hoffman *et al*., 1994).

HGT is well studied *between bacteria* and occurs as a result of:

- transduction (infection of bacteria with a bacteriophage);
- conjugation (incorporation of genetic material from another bacterial genome); or
- transformation (uptake of foreign DNA).

There are few studies of HGT between plants and soil microorganisms. It must be emphasised that there are no known reported instances of HGT from plants to bacteria in the soil in natural ecosystems (Nielsen *et al*., 1998; Syvanen, 1999).

The frequencies of HGT from non-transformed plants are considered to be minute based on analyses of bacterial genomes, the primary constraint to HGT between plants and bacteria probably being the lack of similarities in genetic sequences (Nielsen *et al*., 1998). Where homology exists between genetically modified DNA and the genetic material of surrounding bacteria, and the organisms are cultured in an ideal environment, HGT occurs but at a very low frequency (Gebhard & Smalla, 1998; Bertolla & Simonet, 1999). The minimisation of any risk of HGT by the avoidance of bacterial sequences in transgene constructs has been proposed (Nielsen *et al*., 1998).

Transformation of Fungi

Where transformation of microscopic fungi by genetically engineered DNA has been demonstrated, the transferred genetic trait (antibiotic resistance) was rapidly lost in virtually all transformed fungi (Hoffman *et al*., 1994). The mechanism by which a fungus can take up and internalise foreign DNA remains to be identified (Hoffman *et al*., 1994; Bertolla & Simonet, 1999).

Uptake of Transgenic DNA by Soil Microorganisms

HGT of engineered DNA to soil microorganisms is unlikely as transgenic DNA is highly diluted and is generally degraded in the soil. Transgenic sequences are capable of being incorporated into a very limited number of species which must develop to a stage of competence for transfer to occur and the DNA must be stably incorporated into the bacterial genome (Nielsen *et al*., 1998; Bertolla & Simonet, 1999).

If such an event was to occur, stable introgression of the gene into the bacterial population is probably dependent on application of a selection pressure (Bertolla & Simonet, 1999; ACRE, 2000). In the case of marker genes, unless the trait confers resistance to a herbicide or antibiotic that is physiologically active against the microorganism and that selection pressure is then applied, transfer of the gene among the population is likely to be minimal over a relatively long period of time. Furthermore, the gene will disappear entirely if it adversely affects the ecological fitness of the microorganism. It should also be considered that many of the genes used for antibiotic and herbicide resistance originate from such microorganisms and that antibiotic resistant genes are already widespread in the environment (Pittard, 1997).

There are currently no published reports of stable incorporation of transgenic DNA into bacteria where no sequence homology exists. Should it be possible to eliminate bacterial sequences from transgenic constructs there would be no reason to hypothesise that plant transgene transfer to bacteria would be any more likely than any other plant DNA.

The CaMV 35S Promoter

The CaMV 35S is a viral gene promoter ('switch') derived from cauliflower mosaic virus (CaMV). As a widely-available constitutive promoter CaMV is likely to be used in initial transgenic *P. somniferum* varieties. CaMV is a plant virus that commonly infects cruciferous species. It has a double stranded DNA genome that has allowed its use in other double stranded DNA systems such as plants. The CaMV 35S promoter is commonly used in inserted gene sequences as it is particularly efficient at promoting high copy numbers of transcripts and is active in a wide variety of cell and tissue types (Hull *et al*., 2000).

Safety Concerns with the use of CaMV 35S

There has been some debate on the safety of CaMV35S promoters (Ho, *et al*., 1999), as CaMV is related to the retroviruses. Certain animal/human infecting DNA viruses such as HIV are termed retroviruses, as they are transcribed in the opposite direction to normal DNA. Retroviruses have the capacity to integrate into and out of the host genome. However, despite a great deal of work there is no evidence that pararetroviruses such as CaMV have the capacity to integrate into a plant genome, or that CaMV is able to infect, or mutate to infect, an extended range of non-plant hosts. Also it is a promoter sequence, not the intact virus or an entire viral gene (Hull *et al*., 2000).

The recombination properties of sequences within the promoter have been noted in bacterial plasmids that contain numerous copies (including reverse copies) of the promoter (Kohli *et al*., 1999). However, the possibility that enough of these recombination hotspots occur in a single copy of the promoter, or at the correct sites, to enable recombination of the promoter with another virus is highly unlikely (Hull *et al.*, 2000). The 35S promoter sequence has no inherent viral activity (ie ability to assist in self-replication and/or transfer from one host to another). Where substantial homology exists between the transgene and CaMV some recombination may be possible (Schoelz & Wintermantel, 1996), although this relates to an entire genetic sequence and not to a promoter sequence only. In the case of *P. somniferum* this is not possible because poppies are not a host for CaMV.

Prevalence of Cauliflower Mosaic Virus Infection

The safety of the 35S promoter in health terms can be best exemplified by considering that surveys in the UK have demonstrated the widespread abundance of CaMV in cruciferous crops (Hardwick *et al*., 1994; Raybould *et al*., 1999; Hodgson, 2000). CaMV infection results in more than 100 000 individual virus particles (and hence 35S promoter sequences) per cell, whereas transgenic plants usually contain one to three copies of the promoter per cell (Hodgson, 2000; Hull *et al.*, 2000). There is no evidence that consumption of naturally infected plant material in raw or processed form for many hundreds (perhaps thousands) of years has ever resulted in the transfer of viral or plant genes into the human genome.

Gene Silencing of the CaMV 35S Promoter

One interesting recent finding is that 35S promoter-driven genes expressed in a transgenic cruciferous host were "silenced" (switched off) following infection with cauliflower mosaic virus itself (Al-Kaff *et al*., 2000). Gene silencing is a common and natural phenomenon where plants (and perhaps animals) regulate over expression of genes through directed switching off of genes. In the Al-Kaff *et al*. (2000) study, if the 35S promoter were driving a herbicide resistance gene then the plant would lose its resistance ability. Again this could not occur in *P. somniferum*, as it is not a host of CaMV.

Environmental Monitoring

Reasons for Ecological Monitoring

Environmental, or ecological, monitoring should be encouraged by regulatory authorities in order to:

(a) monitor any possible risks of increased weediness or hybridisation that have been identified;
(b) identify any unexpected consequences of the transgenic crop; and
(c) provide a transparent mechanism for the public to critically assess the safeguards in place with respect to (a) and (b).

Such monitoring activities will also allow assessment of any environmental effects becoming evident at different locations, allow a rapid response to potential problems and an assessment of crop management strategies. It is possible that many of the ecological risks posed by transgenic crops may also apply to other new, conventionally bred crops. However the level of public concern about potential ecological damage caused by transgenic plants should be incentive in itself to warrant rigorous monitoring regimes.

Environmental Monitoring of Transgenic Crops

The potential ecological consequences of planting any transgenic crop have been classified into the following four categories (Pool & Esnayra, 2001):

- the development of pesticide resistance in crop pests;
- crops becoming invasive weeds;
- harm to non-target organisms; and
- gene flow from crops into related plants, viruses or other organisms.

These monitoring programs will need to be determined on a case-by-case basis taking into account:

- the genetic modification involved;
- the number and distribution of wild relatives;
- the potential of the crop as a weed;
- the area over which genetic material is likely to be dispersed;
- potential "down-stream" ecological consequences; and
- the level of public concern.

The potential ecological impact of transgenic crops can be predicted to some degree by field tests conducted prior to commercial release. However, the short time scale, a limited geographic extent of trialing and the small number of plants involved limits the chance to observe small probability occurrences that may become evident during more widespread cropping (Pool & Esnayra, 2001). Effects may also accumulate over time and only become evident after a prolonged period. Besides issues of scale, laboratory experiments or field tests will never fully replicate complicated scenarios that exist in a wide variety of ecosystems. As it cannot be predicted what the ecological impact may be with certainty, monitoring must be employed as a safeguard against detrimental effects (Pool & Esnayra, 2001).

Monitoring Gene Flow

The risks of gene flow are usually much higher between crops of closely related agricultural weed species rather than between crops and native species due to the significant reproductive barriers that usually exist between crops and native species (Daniels & Sheail, 1999). Furthermore, there are no known Tasmanian native species that could be considered at risk of hybridisation with *P. somniferum*. Related agricultural weeds are more likely to be closely related to crops in terms of their taxonomy, ecology and reproductive biology. These species also often have a long history of gene exchange with related crops.

Gene flow among non-transgenic populations is an appropriate model for predicting and monitoring gene flow of transgenic constructs (Raybould & Clarke, 1999) because transgenes are likely to be inherited in a Mendelian manner (see box below). Direct methods to monitor gene flow are the observation of pollen and seed dispersal and the movement of genetic markers (identifiable either visually or using diagnostic techniques).

Mendelian segregation is based on homologous genes occurring on matched chromosomes at the time of mating. Typically these genes are either described as being recessive or dominant. Dominant genes only require one copy of the gene to be present for expression of a trait. Recessive traits require two genes, one on each matching chromosome, in order for there to be expression of a trait. An artificially inserted transgene will typically express characteristics of a dominant gene, as there is no alternative gene on the matching chromosome if mating with a non-transgenic plant were to occur (it is said to be hemizygous). In this case the gene will be passed on to 50% of the next generation if crossing with a non-transgenic plant occurs.

Gene flow can be indirectly determined over longer periods of time based on estimated average gene flow as demonstrated by observations of dispersal and establishment over preceding years (Raybould & Clarke, 1999). This method will be more effective in determining the impact of rare or unpredictable long-distance dispersal events compared to direct methods. Indirect methods also do not overestimate gene flow over time, as this method will primarily detect gene flow where introgression of the genes into a weed population has occurred.

Monitoring programs will be required to be systematic for maximum benefit from such programs to be realised. While monitoring will be proactive to some extent, the optimal scenario is to ‘piggyback’ the schedule onto crop inspections that may already be carried out on a routine basis. The monitoring of baseline populations with relatively stable numbers offers an effective avenue of monitoring given a wide range of such baseline populations in a range of habitats. However, the efficacy of such a system will be determined by the relevance of control crops that are used for a comparison.

Sites used would have to cover a wide range of ecological variables and be conducted over several years to obtain the most useful data.

The monitoring of trial sites for any possible HGT to soil biota remains problematic for two reasons. Firstly, it is estimated that greater than 99% of microorganisms observable in nature typically are not capable of being cultured in the laboratory using standard techniques (Amann *et al*., 1995). Secondly, suitable methods for detection of such events (which requires the differentiation of DNA incorporated into transformed microorganisms from residual plant-derived DNA fragments in the soil) have not been available (Nielsen *et al*., 1998).

Management, Production and Education

Transgenic poppies, like most crops with novel traits, require closer attention to management than conventional varieties. Global trends in developed countries are tending away from bulk commodity production into higher value diversified quality traits requiring crop segregation through the supply chain. Environmental concerns coupled with consumer unease about the effects of transgenic varieties also require that increased professionalism and management capabilities will be needed. In particular segregation, identity preservation, record keeping (for certification purposes) and reputable quality assurance systems need development.

Agronomy

Control of volunteers can be improved through more stringent application of sound agronomic practices to minimise the occurrence of poppy volunteers. Ploughing of sites immediately following transgenic crops should be avoided in order not to bury seeds, which ideally should remain close to the surface in order to facilitate the rapid germination of seeds and subsequent chemical control.

Segregation and Identity Preservation

Segregation and identity preservation (IP) requirements for *P. somniferum* crops will depend upon the need for separation of crops with different alkaloid profiles and products and any future market demands with respect to the transgenic status of the crop.

The characteristics and cost of any IP system to be used depends on:

- the specific crop;

- the environment in which it is grown;
- the purpose of the IP system;
- storage and transport systems required;
- tolerance levels for contamination; and
- rules and legislation regarding possible consequences of growing or dealing with the crop.

The most effective type of IP system is one that utilises a closed system whereby the crop is grown, harvested, stored, transported and sold in a dedicated system that does not include potential contaminants. Such systems still require methods for recording compliance to the system and possibly also monitoring of the product at one or more points in the supply chain. The importance of stringent management systems should also not be underestimated as a method to address the significant public concern that exists in the Tasmanian community with respect to transgenic crops.

Existing Closed Supply Chains in the Tasmanian Poppy Industry

The alkaloid industry in Tasmania is a specific case where closed supply chains are already established. The relevant company controls all stages of crop production including the sowing, crop husbandry, harvesting, processing and marketing of the crop. Segregation of *P. somniferum* crops is already undertaken by Tasmanian Alkaloids that uses a particular cultivar high in the alkaloid thebaine as well as the conventional morphine crop. The company has constructed two separate processing facilities to enable the complete segregation of the harvested product once it arrives at the processing plant. Such a situation presents an ideal scenario to maintain the integrity of separate products. Before the establishment of such facilities the company would harvest one crop type at a time (campaigns), periodically alternating between the crops. Substantial effort is required in planning such harvesting operations and there are additional costs involved with preparing equipment and facilities between receipt of the different crop types.

General issues that will require consideration are:

- physical separation of transgenic material prior to planting;
- recording of safe and separate seed storage and its protection from vermin;
- preventing seed spills during transport on farm, cleaning out seed drills and recording of cleanup operations, recording and monitoring of seed spills;
- physical separation of the crop during cultivation and recognition of isolation distances. This may be due to concerns regarding pollen contamination or soil

contamination by the transgenic crop. Such a concern would not necessarily have a scientific basis and may be because there is a market for a differentiated product;

- adoption of agronomic practices to minimise risk of gene flow and volunteers in subsequent crops;
- physical separation of the crop during transport and/or storage. This may be necessary to ensure against mixing of products and possibly to ensure against affecting market qualities of other products (for reasons described above);
- meticulous and accurate field records with a robust and efficient audit trail of records to show all requirements have been adhered to; and
- education of all personnel involved in the supply chain. Such education of industry personnel, farmers and the public should include the possible consequences of failing to meet management guidelines. This factor is essential in a sensitive public environment such as that which currently exists in Tasmania. For transgenic products to be used responsibly producers and all members of the supply chain will need to be able to demonstrate awareness of, and ability to manage, potential risks associated with the production and marketing of each product.

Management Practices

It is likely that some management practices currently being carried out, such as cleaning of machinery between sites and advising against livestock grazing on the stubble of certain cultivars, will require adoption on a more formal basis. Livestock grazing on transgenic poppy crops may pose livestock marketing problems in addition to any potential harm to livestock from specific future alkaloid crops.

Methods are available that will limit the distribution of poppies and weedy poppy species. These methods should be employed as much as possible to limit scientific and public concerns relating to gene transfer. Bishop (1994) suggests that these farm hygiene principles include:

- prevention of wild poppies going to seed wherever possible. Potential sources include failed crops, pasture, hay crops, and fence lines;
- preventing the introduction of hay contaminated with capsules into clean areas;
- mapping of weed infestations on farm properties and avoiding planting poppies in these areas;
- cleaning machinery, vehicles and footwear of soil before leaving weed effected paddocks;
- control of soil erosion to reduce soil movement between paddocks;

- use of a crop rotation that will enable application of standard herbicide strategies to control poppy species following alkaloid crops; and
- control of water run-off to avoid seed dispersal.

In addition to these measures it is suggested that farmers' records need to be thorough and up to date – which may be of particular use when the farm is transferred, and that livestock movement will need to be closely monitored and controlled. Graziers will have to be aware of the transgenic status of crops and that grazing the remnants of these crops may have implications for the marketing of livestock products and the transfer of transgenic seeds.

Technologies are currently being developed that will assist in reducing the potential impact of transgenic poppies on other agricultural industries and assist in post-harvest crop management. These techniques are discussed in the preceding sections *Weediness of Poppies* and *Gene Transfer and Hybridisation*.

Issues for Organic Producers

The National Standard for Organic and BioDynamic Produce (April 1998) prohibits from certification products and by-products that have been derived from gene technology. Further it should be noted that transgenic organisms are currently considered to be unacceptable contaminants by the organic certification bodies operating within the State.

Soil used for the production of any modified crops is likely to be treated as unacceptable under the current standard and by certifying bodies, therefore organic and biodynamic producers risk losing their certification for an unspecified period of time in the event that products or by-products are found to have such genetic contamination. Soil removed from sites used for production of transgenic plants may be required to be identified as such to ensure that it is not inadvertently used in an organic production system.

Issues for the Apiary Industry

At least three distinct honey types are produced in Tasmania, some of which are exported in bulk to the UK and Germany. Pre-packaged honey in containers of 4 kg or less is sent to the USA, Hong Kong, Korea and the Middle East (DPIWE, 1999). The three primary types of honey produced in the State are leatherwood, clover and blue gum. Leatherwood is the basis of the commercial industry in Tasmania (DPIWE, 1999). In 1996-1997 the apiary industry in Tasmania produced 1012 tonnes of honey and 13.9 tonnes of beeswax. The combined value of these industries was estimated at $2.1 million.

The potential impact of transgenic *P. somniferum* varies according to the honey type being produced. Generally bees collect pollen and nectar in the spring and early summer to feed the young bee larvae in the hive. During this period commercial bees are often used as crop pollinators, although some apiarists concentrate on the pollination market solely and do not produce commercial honeys.

Honey accumulation generally will begin in the middle of summer as the bees begin to store resources for the winter period when food is scarce. There may be problems for some honey producers with some transgenic crops should the honey producers wish to avoid the presence of transgenic pollen in the honey for the purposes of international marketing. According to local beekeepers, bees will usually forage within 2-3 km (which correlates well with the published literature) and therefore guaranteed segregation of commercial honey in the vicinity of transgenic crops may not be possible.

Leatherwood Honey

This honey is generally produced from early January to April in rainforests in the southern and western half of the State, usually well removed from agricultural areas. Unless hives are used in agricultural areas containing transgenic poppies, and pollen is still in the hive when transported to leatherwood areas, there is little chance for contamination of the honey to occur. The largest potential problem will be the use of hives to pollinate crops before the honey flow commences. Pollen in the hives accumulated during pollination has the potential to contaminate the leatherwood honey even if pollen is not viable and only present in trace amounts. Contamination may particularly be of concern if the transgenic material has not been approved for human consumption.

Blue Gum Honey

Small amounts of blue gum honey are produced in the State on the east coast (Triabunna/ Little Swanport region and Bruny Island). There would be some opportunity for contamination to occur should transgenic poppy crops be used in these areas, or if some honey has been collected prior to moving the bees into these areas.

Clover Honey

Clover honey is produced in agricultural areas and pollination is required for white clover pasture regeneration. However, it is understood that the best clover honey in Tasmania is produced after mid-January, when some of the poppy crops will have been harvested.

There may be opportunities for honey producers to locate apiaries away from crops that are still flowering during this period in order to obtain clover honey free of transgenic pollen.

Extensive communication will be required between the poppy industry and honey producers should transgenic poppies be grown in Tasmania. It is unlikely that transgenic poppies could be produced on a commercial scale for a number of years. Should poppy trial crops be allowed in any form during the interim it will be extremely important that honey producers are made aware of the locations of these crops in order to avoid any potential honey contamination problems. A hypothetical longer term solution to honey contamination would be to either cause any widespread plantings of poppy plants to be unattractive to honeybees (eg, flower, pollen and/or nectar characteristics) or reduce pollen production.

The primary issue for honey producers is that of continued accessibility to export and domestic markets and the implications that has for profitability and expansion. In recent years, Canada has experienced significant disruption to its honey exports into Europe due to the prevalence in its honey of pollen from GM canola. Germany in particular has been very sensitive to this issue. The effect has been to drive down the price of Canadian honey, as export markets dry up and domestic surpluses build. Although the export honey industry in Tasmania is small, it is readily identifiable overseas and there may be broader implications for Tasmania's market image should GM-free honey no longer be available.

Economic and Market Issues

Current Status of the Poppy Industry

The estimated 1999/2000 farm gate value of the poppy crop to Tasmanian growers was $55 million, with a value of approximately $220 million to the Tasmanian economy (Justice Tasmania, 2000). The area devoted to the cultivation of poppies was about 3500 hectares in the late 1980s, but this has increased to 20 000 hectares in 1999-2000. Precise information is not readily available due to confidentiality requirements however in recent years both yields and morphine content have continued to increase as cultivars and cultivation practices improve.

There has been a substantial increase in prices paid to growers, approximately matching increased production costs. Improvements in yields, alkaloid content and management have ensured a steady increase in returns per hectare. As a result poppies are one of the most important crops in the State and are very competitive in international markets. Over the last two decades poppies have been a rapidly growing component of primary industry in Tasmania.

The operations of the two poppy processing companies in Tasmania are quite different. GlaxoSmithKline Pty Ltd at Latrobe undertakes basic processing, which involves separating seed from poppy straw. At the GlaxoSmithKline Pty Ltd Port Fairy factory in Victoria opiates are extracted and concentrates of poppy straw and codeine phosphate are produced for the local and export markets. The Westbury operation of Tasmanian Alkaloids Pty Ltd involves the processing of poppy straw and the extraction of opiates on site. Codeine phosphate, thebaine and some thebaine derivatives are also produced at Westbury. The seed is also cleaned, graded and bagged for export.

The north-west region of the State continues to produce approximately 50% of total State poppy production, with the northern and southern regions sharing the balance. Poppies offer many benefits to the Tasmanian economy. They can be grown in rotation with other intensively produced crops, providing a viable crop alternative for the farmer. Apart from the farmers and contractors who benefit from seasonal operations, over 200 people are employed full time by the two companies. The poppy industry provides support for local communities and has real growth potential both in exports and employment. The two existing companies have invested in infrastructure and have suitable marketing in place.

Future of the Tasmanian Poppy Industry

It is difficult to accurately quantify the costs and benefits involved in the introduction of transgenic poppies. There are likely to be potential benefits from improvements in productivity through the use of gene technology. One estimate is that the use of gene technology in poppies could triple the ex factory value of production to $600 million within the next 10 years (TFGA, 2000).

Potential benefits from the use of gene technology include (TFGA, 2000):

- reduction in the quantity and costs of inputs;
- increase in output and income;
- better quality products;
- reduced environmental impacts; and
- assist Tasmania to maintain its competitiveness.

In addition, if alkaloid content and yields can be improved then this provides an alternative to continually increasing the land used for poppy production. Land is a scarce resource and producing more product from the same amount of land appears to be an attainable benefit for the Tasmanian poppy industry.

Of course, with the advent of full cost recovery under the new licensing regime for gene technology, costs to companies are likely to increase with respect to indirect costs for preparation of applications for licences and direct costs for payment of licence fees. Another consideration is the potential costs of licences for some generic gene constructs, such as herbicide resistant markers, that may be required to complete a specific genetic modification of a poppy. This would be in addition to the substantial research and development costs in creating transgenic plants.

Both Tasmanian Alkaloids and GlaxoSmithKline have commenced development of transgenic varieties in order to maintain the competitive advantage they have built up over many years. There are various incentives for poppy companies to continue to invest in the development or purchase of gene technology. It appears evident in the poppy industry that there is a need to capture sufficient additional market share from competitors to justify the cost and for the business to survive in the market. Improvements in productivity to date have been reflected in increases in output and employment, as well as improvements in returns to growers. However it is not only these improvements in productivity which are an issue for the industry. The viewpoint has also been put forward that Tasmania may lose the high value poppy industry if the use of transgenic crop is prohibited.

Costs to producers intending to grow transgenic poppy varieties may include information gathering necessary to ensure proper management of the crop, more thorough record keeping and meeting training needs. Additional costs may arise from requirements to use crops in specific rotations to enable adequate volunteer control, or from the need to plant non-transgenic buffer rows or create isolation distances between crops. Increased seed costs (due to the value added nature of the traits) may also occur. There are also potential legal costs if there is damage to the environment or the livelihood of other producers. These input costs will need to be met from increased returns – an equation that it is at this stage difficult to accurately quantify.

Effect on Market Image of Tasmania as 'Clean and Green'

Aside from direct costs to producers, the use of gene technology in poppies may impact negatively on the "clean and green" image of Tasmania. According to an Industry Audit by the Department of State Development in 2000 (DSD, 2000b), the value of Tasmania's clean, green image is currently estimated to be worth approximately $600 million to the agriculture, aquaculture, fishing, food and beverage sectors. The impact of transgenic poppies on this marketing image will be difficult to determine and may depend on what the public of a target market perceives as a wholesome image.

What is actually meant by 'clean and green' will also be important in assessing whether market confidence in the 'Tasmania' image will remain if Tasmania pursues gene technology. The potential conflict between the existence of genetically modified crops and Tasmania's clean green image has been raised in many forums in Tasmania and is subject to investigation by the Parliamentary Joint Select Committee on Gene Technology. The authors are aware that the Select Committee has received evidence of an independently commissioned Newspoll survey of consumers in Melbourne and Sydney where respondents were asked to identify products that come from Tasmania. Of those that identified poppies, almost half indicated that they would be less positive towards Tasmanian foods if GMOs were present in agricultural production systems.

A report commissioned by the Tasmanian Government on GMO/non-GMO foods in Japan, which in particular addressed whether the production of GMOs in the State would affect the 'clean and green' image, indicated that GMO production would probably be seen to conflict with a 'clean' image (AusTrade, 2000).

In the context of Tasmania's market image, the potential negative externalities of this product are uncertain and will in large part depend on the future acceptance of and demonstrated ability to manage the technology. The majority of Tasmanian poppy production is sold as a commodity on the world market. Tasmanian poppies are sold as processed products with little reliance on the Tasmanian marketing image. However the potential for negative effects on Tasmanian products that do rely on the clean and green image if transgenic poppies are grown in Tasmania should not be ignored.

The image of Tasmania as a whole may be influenced by unpredictable publicity associated with the use of gene technology. Such publicity from the use of GMOs in just one Tasmanian industry could harm the image not only associated with agriculture but also with the food retail and wholesale industry and the Tasmanian tourism industry.

Whilst market perceptions of genetically modified products are difficult to ascertain it is an issue which needs to be addressed and a key cost to consider.

Consumer Considerations

Consumer understanding and acceptance of products of genetic modification serve as important indicators of the likely support for transgenic products. Numerous consumer surveys have been conducted in Australia and in other countries to try to ascertain not only what degree of acceptance of transgenic foods is evident but also to determine whether consumer attitudes towards transgenic foods will influence purchasing behaviour.

Consumers appear selective about the types of applications of gene technology that they will support (Einsiedel, 1997). Consumer surveys in Australia, Canada, Japan, the United Kingdom and Europe tend to reveal greater acceptance of medical applications, in particular for production of medicines and vaccines than for food products produced by biotechnology (Karmaldeen & Powell, 2000).

There are two main dimensions to the issue of public acceptance of transgenic poppies:

- public attitudes towards transgenic plants; and
- public attitudes towards transgenic pharmaceuticals.

Unlike genetically engineered carnations with modified flower colour, transgenic poppies (not modified for flower colour) have the primary end use of a therapeutic good, having been produced for refinement into a product for medical use. It is important to note that the authors are unaware of any consumer or public survey that has specifically sought to assess consumer acceptance of transgenic poppies. Indicators of acceptance can, however, be obtained from assessing data available on public attitudes to medicinal or pharmaceutical end uses of gene technology. Until specific questions are asked of consumers regarding their acceptance of the growth of transgenic crops for end product use in the pharmaceutical industry it will be difficult to know how readily the public will accept this use of the technology.

This section deals with the specific issue of acceptability of transgenic poppies, rather than genetic engineering as a whole, and therefore gender, age, and socio-economic biases are not addressed.

Consumer Attitudes in Australia

One early survey of public attitudes towards genetic engineering in Australia was conducted by the Commonwealth Department of Industry, Science and Technology (DIST) in 1994. General public support was found for transgenic applications, with medicines rating highest amongst the applications listed. CSIRO Health Sciences and Nutrition has conducted three postal surveys of consumers in 1998, 1999 and 2000.

The 2000 CSIRO survey confirmed the earlier work of the Department of Industry, Science and Technology in finding general support for medical and pharmaceutical applications of gene technology. Although acceptance of these applications had dropped slightly between 1998 and 1999 it rose again in 2000 to the same level as 1998. The major findings of the CSIRO surveys were an increase in perceptions of danger to the environment, health and safety from transgenic plants. However these studies have also indicated that there is greater acceptance of transgenic plants when related to specific beneficial end uses if risks to the environment and to health and safety were reduced or absent.

International Consumer Attitudes

These Australian findings have been echoed in surveys overseas. For example a 2000 survey of consumers in the United Kingdom and some European communities found the development of pharmaceuticals was seen as beneficial and therefore acceptable by consumers (Frewer, 2000). Another survey conducted in Canada by Pollara Research found that the majority of Canadians are prepared to accept unintended risk and even abandon ethical concerns about biotechnology if there are benefits in health and medical care, except for the insertion of human genes into other animals (xenotransplantation) (Pollara & Earnscliffe, 1999).

Whilst many variables may affect survey results across target groups, it can still be said with a reasonable degree of confidence that the public tends to view medical applications of gene technology more positively than other applications. The problem arises, however, when attempting to draw conclusions of consumer/public acceptance for transgenic poppies from survey data where this particular product has not been used as an example of a ‘medical’ or ‘pharmaceutical’ use of the technology. However, if the general observation holds true, that the public tends to be more accepting of risks if outweighed by benefits, it may well be that transgenic poppies are viewed more favourably than food or relatively non-beneficial non-food uses of the technology.

Ethical and Social Issues

Introduction

Discussion of the ethical issues surrounding GMOs has often tended to remain at the level of mere exchange of opinion and the issues at stake here have so far been little explored, in any sustained way, in the academic literature. This should not be taken to imply, however, that such issues are relatively unimportant or that they can safely be ignored. GMOs and the technology that gives rise to them provoke some quite basic questions about our relationship to technology as well as to the natural world around us. It also brings to light concerns about corporate responsibility, about consumer rights and control, and about the rights of farmers and producers themselves. These issues are deserving of much closer examination than they have so far received. Unfortunately, the current regulatory framework provides little opportunity for ethical considerations to be brought directly to bear on decisions relating to GMOs and the focus of much of the public discussion so far has been on the evaluation of risk and risk minimization rather than of ethical propriety as such. Yet if we accept that ethical considerations have a fundamental role to play here, then we should be prepared to give those considerations appropriate weight in the decision-making process.

The particular ethical and social issues that relate to GMOs are varied and complex. However, there are at least two broad, and partially overlapping, categories of concern. The first relates to the nature of the technology as such and the ethical propriety of the sort of direct intervention in basic life structures that gene technology involves. The second relates to the use of the technology and the circumstances surrounding that use.

Not only do these two sets of issues sometimes overlap, but they will also interact with one another. For instance, in some cases, concerns about the invasiveness of the basic technology may be counterbalanced by the benefits the technology may bring in relation either to human welfare (in terms of human health or more general cultural and social well-being) or to the welfare of the non-human environment. On the other hand, where the benefits are minimal or the use to which the technology is put somewhat frivolous, then greater weight is likely to be given even to relatively minor concerns concerning the ethics of the technology as such.

For the most part, these considerations apply in much the same way to gene technology irrespective of whether it is employed in food production or elsewhere. Food technology does raise some special concerns relating to possible risks to human health (and consumer sensitivities also seem much higher in relation to the use of GMOs in food), but the ethical considerations are much the same.

Objections to the Technology of Genetic Manipulation

One of the longstanding objections to genetic modification of living organisms, and a frequent point of concern expressed in many surveys, opinion polls and in the Tasmanian Government public consultations, has been the supposed "unnaturalness" of gene technology and the idea that to use such technology is to 'play God'. Such views are expressed in a variety of ways from the religious and aesthetic to the environmentalist. Often they reflect a basic disquiet felt by many people with what they view as excessive technological intervention in the "natural" world. Although apparently quite widespread, such views are not always well-*articulated*. This does not mean, however, that they are not well-*founded* or that they cannot be elaborated upon in a coherent fashion.

It is relatively easy to see how one might arrive at such views on the basis of religious commitments. For many indigenous peoples, for instance (and this is clearly so in respect of the New Zealand Maori community) suspicion and hostility towards GMOs is likely to be expressed in terms of the violation, through the use of gene technology, of a certain 'sacredness' that pertains to the natural world. Such 'sacredness' implies a need for appropriate respect and a sensitivity to the proper boundaries of human action.

Such a view is not restricted to indigenous communities alone. In New Zealand, for instance, the Quaker Spiritual Ecology Group of The Religious Society of Friends commented that:

> *"We base our concerns about genetic modification (GM) on the spiritual and ecological understanding that all life is sacred, and that all life forms are interdependent and interconnected. The coherence of the biosphere is complex, and precious. Maintaining bio-diversity and the integrity of ecosystems is vital to keep the whole in balance. GM threatens both." (Quaker Spiritual Ecology Group, 2000).*

In similar fashion, the latest statement from the Holy See, issued in November 2000, states that GMOs are a contravention of God's will.

It is interesting to note, however, that this latter statement seems flatly to contradict the tentative expression of support for gene technology advanced by the New Zealand Catholic Bishop's Conference who declared that:

> *"We do not see the technology of genetic modification in itself to be in conflict with ethical values. However, most human inventions can be used for benefit or to harm, and there may be uses of GM which are unethical or unwise." (New Zealand Catholic Bishops Conference, 2000).*

Thus, while there are clearly certain overlapping concerns about the ethical propriety of GMOs that seem common to a range of different religious positions, there is also some divergence of view here. At the same time, it is also worth noting that, where religious opinion is neutral on the ethical acceptability of gene technology as such, the main concern then seems to rest on the question of the uses to which the technology is put and the consequences of that use.

The notion that there is something ethically problematic about gene technology itself, however, need not rely only on the idea that there is a certain 'sacredness' to nature or to life. Another way of formulating the ethical issues at stake may be in terms of the inherent value of nature as such (a value that may be expressed in terms of the idea that there is a *prima facie* obligation not to interfere in nature without 'good reason' or to minimize such interference) or in terms of the inherently 'violent' nature of the technology.

The indirect forms of genetic modification that are part of traditional breeding methods may thus be viewed as operating in accord with already existing processes, attending to those processes and working with them (and so working with the organism as a whole) in such a way that they are seen as continuous with those processes. The breeder, one might say, makes use of the already existing evolutionary processes, merely adjusting the direction of those processes. New forms of genetic modification, on the other hand, operate in a much more interventionist manner, and at a much more fundamental level, such that the normal process of species modification is interrupted or even circumvented as the underlying processes and mechanisms come under the direct control of the gene technologist. From this perspective, the very power of gene technology is a mark of its radical and 'violent' character. A concern with the violence of the technology, variously expressed, would seem to underlie a broad band of opposition to GMOs from both religious and secular quarters.

Another way in which one might elaborate on the ideas at issue here, again without resorting to obviously religious language, is by reference to notions of rights and obligations. It might be argued that human beings have certain obligations or duties, precisely by virtue of the technological power at their disposal, to the organisms and environments around them. The idea that power brings obligations with it is fairly commonplace and is sometimes expressed in terms of some sort of guardianship role or a 'duty of care'. Such notions apply where there is seen to be a need to acknowledge some set of rights or obligations with respect to an object and yet where the object is vulnerable in some way and unable to take proper care of its own interests (and so is typically unable to give or withhold consent). The natural world, and the living organisms within it, may be seen as just such objects. In that case, one might even hold that the natural world and the species within it have certain interests that deserve respect and that human beings therefore have obligations to protect those interests or at least to act in ways that take proper account of them (there are obvious versions of this sort of view in contemporary discussions of environmentalism within both the popular and academic literature).

The question of obligations and rights can also extend to the rights of individuals to choose whether or not to consume GM food. Part of the answer to this may lie in labelling of GM food, however it seems likely that the spread of GE material will make it impossible for any food to be considered completely GE-free. Again, the nature of the technology is such that it may change the very character of the natural world so that it is no longer possible to exercise certain choices – such as the choice to avoid genetically modified products. In this respect, the spread of GE material within the production cycle (which already seems to be occurring and may be an inevitable result of the application of the technology in even a limited manner) may also affect producers, making it impossible for a producer to opt out of GE production as a degree of GE contamination may become an inevitable part of production processes.

What this last consideration (discussed further below) indicates is a concern with the way in which the technology may itself fall outside of our control so that certain choices are made unavailable to us. More generally, one may argue that the very power and breadth of gene technology is a deep source of ethical concern because of the way in which it will alter, in ways we cannot predict, the choices available to us and the framework within which our choices are made. One way to put this point is in terms of the difficulty of making reliable judgements concerning the risks associated with the technology. This is not to say that we cannot make judgements of risk where the parameters of such judgement are already well-established, but that we cannot always be sure how to set the parameters within which such judgement should be carried out. This is especially so if we broaden the concept of risk beyond risk merely to the immediate environment or to physical human health, but include the possible social, economic, cultural and broader environmental uncertainties that may be associated with the technology.

Certainly one might take much of the disquiet concerning GMOs as actually stemming from the thought that gene technology encourages (and indeed carries within it) a way of viewing the world and the things in it merely as resources or material available to be manipulated and transformed according to human plans and projects. The natural world, the world of living things, thereby becomes something that is viewed as malleable and transformable in accord with human wants. The question is whether this kind of attitude towards the things around us, especially living things, is ethically appropriate and what changes might it imply for our conceptions of the natural world and for our own self-conception? For indigenous cultures, for whom the relation to the natural world is extremely important, gene technology may be seen, in this way, to threaten the basic conceptions of the relation between humans and their world that underpins those cultures. It would not be surprising, therefore, to find that indigenous peoples view gene technology with suspicion and even hostility (as the Maori seem to view it in their submissions to the New Zealand Royal Commission on Genetic Modification).

This is not just a matter of how we *see* ourselves and the world around us, since the changes in conception and self-conception at issue here are likely to be closely tied to basic changes in organisms and environments themselves. Thus it may be that the application of gene technology will, in the long-term, actually give rise, for instance, to a loss of diversity of species – through the development of 'improved' strains that dominate over others – or a loss of differentiation between species. One small example of the latter may be the loss of differences in flower colour from species to species through the use of genetic modification such as that involved in the production of the 'blue carnation'. Carnations, like roses and lilies, do not in 'nature' produce blue flowers. This is a major distinguishing factor between these flowers and, say, delphiniums. The use of gene technology to extend the naturally occurring colour palate of flowering species thus reduces the differentiation between species – the increase in possibility for variation within the species can thereby be seen as reducing the variation across species and so, in one sense, reducing the richness of the natural environment. If such richness is valued (and it would seem that for many people it is valued), then this reduction must be viewed as ethically problematic.

The considerations summarized here are capable of a variety of formulations and they are also, in many cases, indicative of quite fundamental tensions within contemporary society. From a public policy perspective, they are difficult considerations of which fully to take account, precisely because they offer little room for compromise. If the very technology of genetic manipulation is ethically suspect, then the only proper course would be to avoid it altogether. But this is clearly not an available option. Yet while the use of the technology is inevitable, it will be extremely important to demonstrate some awareness of the breadth of ethical views in relation to the technology, and, wherever possible, to indicate that such considerations have not simply been ignored or disregarded in the process of policy formulation or in individual decisions. The ethical concerns associated with the technology thus suggest the need for governments and other public bodies to be seen to exercise great care in its introduction.

Considerations Relating to the Uses of Gene Technology

While the objections to gene technology as such are quite general in character, the ethical considerations that relate to the *uses* of gene technology, for the most part, require us to focus more directly on particular cases. Consumer surveys seem to indicate that much of the public acceptability of gene technology does vary from case to case, and that it is also directly tied to the benefits that the technology brings.

In some cases, concerns about the interventionist character of the technology (where those concerns are not such as to rule the technology completely out of consideration as ethically unacceptable) may be counterbalanced by the benefits the technology may bring in relation either to human welfare – in terms of human health or more general cultural and social well-being – or to the welfare of the non-human environment. Benefits such as advances in medicines and vaccines may well fall within this category. This viewpoint is very much reflected in the New Zealand Bishops Conference submission to the New Zealand Royal Commission. Alleviating poverty in underdeveloped and developing countries is often touted by proponents of the technology, who state their belief that it is ethically and morally wrong to not pursue gene technology for this very reason. This position is frequently met with cynicism on behalf of consumers. This is more likely to be a symptom of suspicion regarding the motives of corporations that have developed the technology rather than a blanket rejection of the view.

Of course, where the benefits are minimal or the use to which the technology is put somewhat frivolous, then greater weight is likely to be given even to relatively minor concerns concerning the ethical propriety of the technology as such. An example of this may be the ‘blue’ carnations. It is difficult to identify any actual harm that arises from this particular use of gene technology, yet the benefits are also correspondingly slight.

Concerns regarding the ethically problematic character of the technology (which will probably always be present in the use of this technology) thus need to be balanced, together with an assessment of risk, against the possible benefits. The difficulties attached to the assessment of risk have already been noted – the far-reaching character of the technology changes the very framework of decisions and judgement. However, if one assumes that one can minimise the uncertainty at issue here, such that reliable assessments of risk can be made, then decisions about the ethical acceptability of GMOs, will indeed tend to devolve onto the question of the possible costs (the risks) balanced against likely benefits.

Whilst individuals may engage in this sort of cost-benefit calculation regarding their personal use of the products of gene technology, a common expectation is that governments will be involved in assessing risks in the first instance. Australia has recently adopted a framework for environmental and human health and safety risk, housed within the *Gene Technology Act 2000*. The Commonwealth legislature has indicated its belief that assessing these risks falls within the purview of the central government. Under the *Gene Technology Act 2000* the Federal regulator has an obligation to conduct a thorough assessment of the risks to the environment and to human health and safety posed by certain dealings with GMOs.

Ethical, socio-political and economic risks are not directly provided for under the legislation, however two committees have been established in order to advise the Gene Technology Regulator and the Governments of Australia on ethical and community concerns and issues arising from the use of gene technology. It would not appear that these committees have any direct risk assessment role, however, in regard to particular applications of the technology, and as such may be ‘toothless tigers' in a regulatory scheme devoid of any ethical principles upon which to govern the applications of gene technology in Australia.

It will be imperative that any assessment of the risks and benefits of gene technology undertaken at the governmental and regulatory level be seen to be authoritative, independent and reliable by the wider community. For this reason, it will be extremely important that governmental and regulatory bodies not be seen to be too closely allied with the interests of the GMO industry. Given the value of caution in this arena, it would be better for such bodies to be seen to be slightly suspicious of the technology, than already having decided in favour of its application.

Corporate Control of Agriculture and Commercialisation of Gene Technology

Of particular prominence in the debate thus far has been the role of the multinational corporations in commercialising and thus controlling use of gene technology. Corporate control of agriculture and the food system raises two main concerns: control of multinationals over the food people eat, and the potential for market concentration to adversely impact upon farmers and their control over their businesses.

One of the factors influencing the acceptance of GM crops is that the main drivers of the technology tend to be multinational corporations whose primary interest lies in producing returns to shareholders and is not focused on wider public good. Making profits, after all, is the primary reason for the existence of corporations.

This concern was summed up in a recent submission to the Tasmanian Government:

> *'People feel that power of decision-making over the food they eat, and also over related issues that may affect their safety, is being taken out of their hands. They feel increasingly that these decisions are being made by corporations (and their technologists) for commercial reasons without regard to public well-being'. (Newman, 2000).*

Costs of compliance with regulatory regimes may well impact more on smaller research firms than on large multinational corporations. The cost of preparing documentation for application for approval of field trials and management of those trials is significant. These costs are likely to be significantly increased in the future. The result of substantial regulatory costs may well be that control of gene technology and innovations are restricted to those that can afford to be involved in developing gene technology, perpetuating the dominance of multinational corporations.

Whilst biotechnology and gene technology may have potential to greatly assist farmers in agronomic benefits and, in the future, producing value-added produce this may come at a cost to farmers in respect of the degree of control they have over outputs. Whether this control is actually any less than that already experienced by farmers remains to be determined, however it still forms one element of the concerns to be addressed.

Given the high level of control sought by the companies in order to protect market share and intellectual property it could be questioned if it is a Commonwealth or State responsibility to pay for expensive monitoring activities resulting from failure to control plants at trial sites or paying for testing of produce where contamination occurs. In these instances costs are essentially externalised by the companies, leaving taxpayers to pay for environmental remediation or support hazard control where contamination has occurred.

Intellectual Property and Patents

To a large extent the degree of control over the development and products of gene technology by multinational corporations is dependent upon the extent of intellectual property rights they hold over protein expressions in GM crops and genetic modification processes. The basis of intellectual property law is the notion that proprietary interests in creativity should be able to be protected. The availability of legal measures to protect genetic modification technology appears to be a cause of consternation to the public, as some find property rights over living things to be morally reprehensible.

The legal frameworks for protection of proprietary interests relevant to gene technology include patent law and plant breeder's rights.

Exclusive rights to exploit an invention are provided for in the *Patents Act 1990* (Cth). This Act allows an invention to be patented for up to 20 years if it relates to a manner of new manufacture, is novel, inventive, is useful and has not already been commercialised. Whilst the *Patents Act 1990* expressly excludes patenting of humans, inventions related to modified living organisms, including transgenic organisms such as bacteria, plants and non-human animals can be patented.

Intellectual property in transgenic plant cultivars can also be protected for up to 25 years pursuant to the *Plant Breeder's Rights Act 1994*, which gives exclusive rights to marketing of new varieties, provided the cultivar is distinct from other varieties and the differences are stable. This is different from patents as the end use of the 'invention' is protected rather than the processes used to produce it.

Options for Public Policy

How does one handle these kinds of ethical and social concerns? First, they have to be acknowledged. Second, they indicate the inappropriateness of any blanket judgement in relation to the ethical propriety of gene technology as such. As a result it may be important to recognise the technology as problematic and as therefore requiring just the sort of regulation as has so far been established (although it is noted that ethical issues do not appear to have been given much priority under the existing administrative framework or the new scheme shortly to be in operation).

Further clarity of ethical principles is necessary and should guide gene technology and its uses. It is thought that the Gene Technology Ethics Committee created under the *Gene Technology Act 2000* would be a good place to start, however until more detail on the workings of that group are available the probability of such occurring is difficult to determine.

These ethical, socio-political risks may, in the end, be the main reason for the public being concerned about gene technology, especially in the scenario where other risks are absent or minimised. This makes the ethical and related concerns all the more important to be addressed by regulators and those involved in research and commercialisation of products of gene technology.

Ethical Considerations and Transgenic Poppies

In the light of the foregoing discussion some points of note specifically in relation to transgenic poppies can be made. Whereas flowers such as blue carnations display more prominently their modified status, transgenic poppies are not purchased directly from retailers, and the modification is virtually invisible. The poppies have a lower profile in the consumer arena, as does their use as a therapeutic good.

Small by comparison to alkaloid output is the food by-product of transgenic poppies, that of poppy seed. Unlike alkaloid production, poppy seeds are a potential food use of this transgenic organism and as such the same ethical concerns may arise as for other food uses of transgenic crops. Whether or not this has a significant impact on the balancing of ethical concerns would depend on the individual or public's view as to whether the benefits of transgenic poppy seed production outweigh the risks. It may well be that transgenic poppy seeds are ethically unacceptable as they have negligible consumer benefits and may be seen as benefiting only the commercial interests that produced them.

As stated elsewhere in this report, the primary aim of this particular genetic modification is to increase alkaloid output in poppies that are produced primarily for therapeutic or medicinal purposes – the production of morphine and codeine. The possibility that the sale of poppy seeds from transgenic poppies may be foregone by Tasmanian poppy companies has also been raised.

It is well documented in consumer surveys reported above that there is a greater level of consumer acceptance of transgenic therapeutic goods than food uses of transgenic crops which have been engineered with production oriented traits. This disparity may arise due to perceived greater benefits of cost-effective medicines as opposed to purely production oriented traits, perhaps a perception that medicines undergo more rigorous testing than food crops, or even that perhaps the consequences of treating an already ill or injured person with transgenic products are more morally acceptable than other applications of the technology and thereby constitute an ethically justifiable risk.

It is suggested that in this case the balance is likely to be in favour of this crop, due to the low level of risk of environmental and human health and safety issues and consumer acceptance of gene technology used for medical purposes.

Research and Development

Commercial production of transgenic poppy varieties is some years away and to date only a limited number of field trials have been conducted using herbicide tolerance (used to study gene flow) and increased alkaloid pathway modifications.

Economic data regarding the costs and benefits to the industry need to be examined in the light of more precise knowledge of the cost of the generation of transgenic poppy plants and likely costs to farmers and others in the supply chain. These costs need to be balanced against any increased yields or other benefits gained. Research is required to address the identified issues of concern through appropriate design of transgenic constructs, development of methods to minimise gene flow and reduction or elimination of the use of antibiotic resistance marker genes.

The development of methods to reduce pollen or seed-mediated gene flow or to remove extraneous transgenic sequences will be prohibitively expensive for Tasmanian alkaloid companies to undertake. However, the feasibility of adopting or licensing these technologies may be investigated. Although representing a substantial additional development cost, it is likely that such technologies will facilitate public and industry acceptance of transgenic poppies. Genetic technologies of particular interest are cytoplasmic genetic modifications (genes are not usually transmitted in pollen) and methods to cause production of sterile seed ("terminator genes" or "technology protection systems").

More information on precisely how soil conditions and temperature limit the weediness of *P. somniferum* in agricultural or native ecosystems would be of assistance in the targeting of monitoring for any potentially problematic characteristics. More detailed information on the probability of hybridisation between species where populations coexist would also be of benefit to any ecological monitoring program.

Research on the foraging behaviour of honeybees and other pollinators of poppy crops such as birds and other insects is required. In addition studies of honeybee behaviour in the vicinity of poppy crops and the fate of poppy pollen in the hive would be of particular value to the apiary industry.

The potential risks and benefits of grazing livestock on poppy stubble require clarification. If livestock producers are willing to allow livestock to be grazed on poppy crop residues and it is safe to do so then methods to prevent the dispersal of seeds to other paddocks may be required.

A major challenge facing any Government, industry or agricultural community desiring the introduction of transgenic crops in the current market environment is going to be the development of effective management capabilities. These will need to be developed throughout any supply chain that includes transgenic crops to enable the minimisation of risks. The development of extension or learning programs for all those in the supply chain will be necessary to achieve such outcomes.

Agricultural issues to be addressed include an assessment of the applicability of current agricultural practices for obtaining maximum volunteer control and the possibility of reducing or eliminating seed production by transgenic poppies. Mechanisms for information exchange between poppy companies and other agricultural industries that are potentially effected by transgenic poppies, such as organic producers, apiarists and graziers should also be investigated. Of particular importance is the sharing of information relating to the location of proposed transgenic poppy crop trials.

Consumer and industry surveys are needed that specifically address the issue of transgenic alkaloid crops in Tasmania and the consequences of their introduction for attitudes and behaviour, both within the State and overseas.

There is large scope for future research and development to clarify these issues and create greater public and industry certainty of the effects on Tasmania of the introduction of transgenic poppies.

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