Environmental Issues Raised by the Release and Use of Genetically Modified Plants and Animals in Australia

Submission by Environment Australia

Inquiry into Primary Producer Access to Gene Technology

House of Representatives Standing Committee on Primary Industries and Regional Services

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Summary

1. Gene technology enables the transfer of genes between species, and the modification and expression of genes within species, beyond the extent and range that would occur naturally, or that would be possible using conventional plant and animal breeding techniques.
2. The integration of genetically modified plants and animals used by primary producers will require appropriate control and careful management to ensure that the maximum benefits of the technology (including benefits to the environment) are realised, while preventing or minimising any negative impacts.
3. Environmental impacts of genetically modified plants and animals in agriculture could vary, ranging from positive to negative, depending on the case. Where genetically modified organisms (GMOs) have potential for reducing the impact of agricultural activity on the environment, and improving the sustainability of farming systems, they should be encouraged.
4. The potential for better environmental performance in agriculture through deployment of GMOs provides a strong argument for gaining experience in their release and use. Reference here is to those GMOs that have been assessed not to pose a threat of *serious or irreversible* damage to the environment. For all releases, potential hazards need to be identified, and risks assessed and managed before release into the open environment.
5. Australia needs a robust, transparent, and nationally consistent regulatory framework in which decisions on safety are made at arm's length from specific interest groups. Risks should be assessed on a case-by-case basis. Some risks will require management in both agricultural systems and the natural environment.
6. The scientific knowledge base needed to make informed risk assessments and to develop effective management plans will sometimes be inadequate. The novelty of GMOs, the fact they will continue to reproduce after release, the complexity of natural environments and ecosystem processes, and the unknown evolutionary fate of inserted genes, all contribute to the difficulties of predicting environmental impacts and developing reliable, probabilistic risk assessments.
7. Where deficient, the knowledge base should be improved on a case-by-case basis during the development period for the GMO (usually several years). This will improve risk assessment and management, and benefit both the community and primary producers by preventing or mitigating potentially negative impacts.
8. Management plans released with the GMO should contain risk reduction measures, and specify responsibilities and contingency plans. The effectiveness of management plans will need to be evaluated through monitoring to assess whether predictions of GMO safety and impacts were accurate, to adjust controls and risk management, and to inform and modulate subsequent regulation.

9. GMOs may have impacts beyond the systems into which they are released. These impacts may be at the level of genomes, species, communities, ecosystems, catchment areas and regions. There will be a need to develop and implement the best ways to effectively monitor impacts, and to specify responsibilities and contingency plans.
10. There needs to be debate about the degree to which the future regulatory scheme should rely on a single, standing expert committee as the focus for risk assessment of all applications. Environment Australia (EA) takes the view that assessments should be made by independent persons who have no active interest in promoting gene technology and who do not represent any specific interest group. This need for neutrality is a prime reason for separating provision of expert advice (which will inform risk assessment) from independent risk assessment itself, in the regulatory path. The community expects neutrality.
11. EA continues to contribute to the development of the new regulatory system for GMOs. Under new interim regulatory arrangements announced on 22 August 1999, EA will undertake full risk assessments of all proposals for general (commercial) release made to the Interim Office of the Gene Technology Regulator.

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1. Scope of Submission from Environment Australia

The Secretary of Environment Australia has been requested by the Secretary to the House of Representatives Standing Committee on Primary Industries and Regional Services (HRSCPIRS) to present a submission to the Parliamentary Committee addressing "the environmental issues raised by the release and use of genetically modified plants and animals in Australia".

The HRSCPIRS Inquiry is clearly concerned with 'access' to those varieties of plants and animals that are used for agricultural primary production. These generally comprise varieties of 'higher' plants that are used for crop production, pastures, horticulture and silviculture (eg cotton, canola, wheat, pasture grasses, eucalypts), and 'higher' animals used for livestock production or in aquaculture (eg cattle, pigs, fish, prawns). The Terms of Reference of the Inquiry do not extend to the consideration of organisms used to *protect* plant and animal varieties grown for produce, eg viruses, bacteria, and fungi used in pest or disease control.

Our submission is therefore restricted to environmental issues associated with the release and use of genetically modified (GM) 'higher' plants and animals used for primary production. Most examples will be drawn from plants, as these comprise nearly all GMOs currently under development for commercial release in Australia.

Use of gene technology and release of genetically modified organisms (GMOs) in the control of pests or diseases (eg *Pseudomonas fluorescens*, Nucleopolyhedrosis Virus), or in the environmental management, mining and energy sectors, are outside the scope of this inquiry into primary producer access to gene technology. Consequently, our submission will seldom refer to environmental issues raised by release and use of GMOs in pest or disease control or in 'environment biotechnology'.

The scope of the term 'genetic modification' used in this submission is consistent with the draft scope of Australia's future national framework for the statutory regulation of GMOs. This is the scope intended for legislation that will underpin the proposed Office of the Gene Technology Regulator (OGTR). The government's intention to establish the OGTR was announced on 11 May 1999, and the legislation is currently being drafted.

Thus, we apply the term **Genetically Modified Organism** (GMO) to describe an organism that has been modified by techniques of genetic modification, or derived or developed from such an organism, but does not include a human. An **Organism** is further defined as a biological entity capable of reproduction or of transferring genetic material (and includes a microorganism). **Genetic Modification** refers to the altering of the genetic material in an organism by a way that does not occur naturally (for example through processes such as mating or natural recombination or both).

There is already statutory regulation of some GMOs and their products under a complex matrix of Commonwealth statutory instruments (**Attachment A**) and non-statutory processes. Administering agencies of the most relevant statutory controls are the Australia New Zealand Food Authority (ANZFA), the Therapeutic Goods Administration (TGA) in the Health portfolio, and the National Registration Authority (NRA) and the Australian Quarantine Inspection Service (AQIS) in the Agriculture, Fisheries and Forestry portfolio.

In May the government announced that it would develop an enforceable regulatory system for gene technology that would fill gaps in regulation and address public concerns about safety and ensure that there is no threat to human health or the environment. The present largely voluntary system for controlling the release and use of GM plants and animals used in the open environment in agriculture ('agricultural GMOs') and other GMOs not presently regulated is administered by the Interim Office of the Gene Technology Regulator (IOGTR) in the Health portfolio. The IOGTR functions will be replaced by a consistent national statutory system administered by the Office of the Gene Technology Regulator (OGTR) under new legislation.

This new system is to operate in close collaboration with and complement existing systems for regulating food, agricultural and veterinary chemicals, industrial chemicals and therapeutic goods. New legislation is being developed to cover gaps in the coverage of existing regulatory authorities.

The EA Submission will not deal in any detail with regulation of the safety of GMOs and their products by the Interim OGTR and already existing regulatory agencies, because the Standing Committee will doubtless receive their detailed submissions. Nor will we address government policy on the regulation of gene technology to the extent already determined. However, we will comment on regulatory matters yet to be resolved or determined.

2. Background

Environment Australia follows closely developments in gene technology because of the significant potential risks and benefits it poses for the Australian environment.

Gene technology enables the transfer of genes between species, and the modification and expression of genes within species, beyond the extent and range that would occur naturally, or that would be possible using conventional plant and animal breeding techniques. It seems likely that this will revolutionise the nature of plants and animals used in primary production.

It is now possible to introduce a remarkable range of novel traits into existing plant and animal varieties. The novel traits may, for example, confer protection from pests and diseases (eg cotton expressing a pesticide), adaptation to adverse conditions such as drought and high salinity, or more efficient or more rapid use of inputs (eg fish that grow faster and larger per unit input). Of GM species currently under consideration for commercial release, a quarter are herbicide tolerant plants, a quarter increase product quality or yield, and the remainder confer resistance to pests or pathogens.

Plants can be developed for use as vaccines (eg bananas, potatoes and peas that when eaten vaccinate against lethal diseases such as cholera and measles), or as 'factories' to produce diesel substitutes or industrial chemicals. Cows can be genetically modified to produce pharmaceutical ingredients such as erythropoietin for anemia, in their milk. Gene technology also enables reliable and extensive monitoring ('diagnosis') and control over the *combination* of agriculturally desirable traits that can be brought together, and retained, in a given plant or animal variety.

In summary, gene technology provides breeders with a far-extended capacity to design, control and monitor the precise nature of the whole organism. Primary production is therefore moving into a new high-technology era which poses very significant challenges for the competitiveness, product diversification, market access, and for the structure, infra-structure, and ownership of Australia's primary industries.

Gene constructs ('transgenes') inserted into the first 'wave' of genetically modified (GM) varieties that have been or are being developed, express traits for a specific agronomic purpose, or occasionally for a pharmaceutical or industrial purpose. The environmental safety of GM varieties modified for these purposes has not therefore been the *raison d'etre* for their development, and is essentially a secondary consideration. To our knowledge, no GM agricultural variety has been modified for the specific purpose of reducing adverse environmental impacts of primary production.

While GM plants with novel pest or disease resistance traits, higher yields, or herbicide tolerance were developed for their intended improved agronomic performance, they may nevertheless coincidentally contribute to reducing the impact of agricultural activity on the environment and improving the sustainability of farming systems. This may be through, respectively, reduced use of synthetic pesticides, reduced production inputs, or the use of more environmentally benign herbicides. On the other side of the coin, there is the potential for novel weed problems to be created, inserted genes to transfer to non-target host species ('transgene escape'), and greater herbicide use.

Whether or not GMOs that are valued for agriculture will also be valued by the community in general, will depend in large measure on whether adequate controls exist to ensure that any risks to human health or environmental safety associated with the technology are identified, assessed and managed through rigorous regulatory controls. The general community needs reassurance that these measures are robust and sufficiently comprehensive, and that there is no conflict of interest in their implementation, before it will accept GMOs in agriculture and the food derived from them.

The integration of genetically modified plants and animals in agriculture will therefore require appropriate control and careful management to ensure that the maximum benefits of the technology (including benefits to the environment) are realised, while preventing or minimising any negative impacts.

Environment Australia has a key role in developing and, in part, implementing policy for environment protection and biodiversity conservation in respect of GMO release and use in agriculture. Our current roles and responsibilities here are detailed in the penultimate chapter of this submission (*EA Roles and Responsibilities in Environment Protection and Biodiversity Conservation*).

In addition to our involvement in providing for environmental safety aspects of GMOs primarily released for other sectoral purposes such as agricultural production, Environment Australia also actively encourages gene technology and biotechnology applications that have the potential to improve environmental performance and minimise impacts of human activity on the environment.

We refer here to applications relating to environmental management, mining and energy areas, such as cleaner industrial processes, waste treatment, fixation of greenhouse gases, recycling of metals and ozone depleting substances, bacterial leaching in mining, and closed-loop manufacturing and production processes. They also include applications relevant to pest and weed management in non-agricultural areas, such as genetically modified novel control agents to control foxes and other feral pests, and weeds such as mimosa.

Many of these environment management applications constitute at this stage a latent (but potentially highly lucrative) market with significant export potential. The environment biotechnology sector could well become the ‘third wave’ of biotechnology applications to be commercialised, after health and agriculture, and Australia is perhaps positioned well to ‘get in on the ground floor’ here.

There has also been relatively little investment by private enterprise or governments to apply gene technology for biodiversity conservation, such as use of GM biological agents for control of feral pests and weeds. In the marine environment, currently there are no long term proven ‘conventional’ control options for existing incursions.

Biological control applications can obviate the use of eco-toxic chemicals, with significant environmental benefits. They are effective pest control tools in some agricultural systems. The benefits of biological control could be enhanced further if gene technology could be safely used to increase the specificity of bio-control agents.

However use of gene technology and release of GMOs in the above sectors would nearly all be outside the scope of the HRSCPIRS Inquiry into primary producer access to gene technology. Our submission will not therefore address environmental issues raised by the release and use of GMOs in this ‘environment biotechnology’ sector.

3. Risks and Benefits

Precautionary approach

Release and use of GMOs has the potential for both adverse and beneficial impacts on the environment, depending on the nature of the GMO itself, the care with which it is used, and the extent to which it will remain confined to agricultural systems.

Until twenty years or so ago, the detection and management of unintended environmental damage caused by agricultural activity have been reactive. No action would be taken until there were clear signs of ongoing environmental degradation. In Australia and overseas, there is now generally an approach that aims to prevent, mitigate and manage negative environmental impacts. This is reflected broadly in the adoption of the 'precautionary principle' as domestic policy and in a number of international agreements to which Australia is a signatory, and more specifically in government policy to support ecologically sustainable development in agriculture.

The intent of the precautionary principle is that appropriate action needs to be taken to avoid the risk of serious and irreversible damage to the environment. The principle does not mean that if there is any risk at all, the action or measure should not proceed.

A formal statement of the principle is that 'lack of full scientific certainty should not be used as a reason for postponing a measure to prevent degradation of the environment where there are threats of serious or irreversible environmental damage'. The government supports the principle, as shown by its application in the *Environment Protection and Biodiversity Conservation Act* (1999).

The precautionary principle has particular application to GMOs. Not only could direct damage be serious, but ongoing and extensive because of irreversibility. Once released freely to the environment, a living organism, or a novel gene that has transferred to an unintended host, cannot be 'recalled'. A cautious and conservative approach to risk should be followed where there is insufficient scientific confidence of safety. Successful application of the principle will mean that Australia avoids expensive failures.

Genetic engineering is different

Although similar to the application of conventional breeding, in that the goal is the deliberate introduction of a desirable trait(s) into a host variety, modern genetic modification ('genetic engineering based on recombinant DNA technology) enables a scope, scale, and precision for modification of much greater dimensions.

In conventional breeding techniques, traits from only the same or closely related species are combined or introduced. Gene technology enables the transfer of genes between species widely separated in evolutionary distance, the insertion of synthetic constructs, the novel manipulation of existing genes of the species in question, and a much-extended capacity to monitor and control the variety's characteristics.

Almost certainly the majority (perhaps all) of the genetic modifications currently brought about using gene technology would never have occurred naturally. It is

therefore inaccurate to state that gene technology simply enables what was previously done, to be achieved more efficiently and with more precision.

It is true that humans have been 'genetically modifying' varieties for centuries or even millenia using conventional breeding. However, the power of gene technology to modify the genome of varieties expands greatly what was previously possible, in large part because traits can now be introduced from very unrelated organisms. This means that our experience and knowledge base for risk assessment and management is less secure. It is important that the effort made to understand health and environmental risks is commensurate with that made to develop new applications.

The many specific GMOs that have actually been developed to date without major environmental problems suggests that GMOs developed with proper care do not pose such a general threat of serious environmental damage, or that scientific knowledge is so scant, that there should be a moratorium on their deployment. Indeed, there may be net benefits for the environment. In Australia, a responsible and professional approach to the development and deployment of agricultural GMOs has always been taken, under the control of the Commonwealth Genetic Manipulation Advisory Committee (GMAC) and existing statutory regulators.

Gene pools

The genetic complement of any given organism (its 'genome') is a product of the evolutionary history of its ancestors, right back to the origin of life. Organisms that have closely similar characteristics and are able to reproduce with one another, have had a common evolutionary history. They have the same evolutionary lineage and comprise a species.

Within a species, a gene complement of an individual can recombine with that of another individual during reproduction, that is genes and blocks of genes are exchanged among complements. Individuals of the next generation therefore have mixed gene 'suites'. Different 'versions' of genes also exist and can also be swapped. Generally, individuals of a species share a common 'gene pool'.

In general, gene exchange does not occur between species. This is because various kinds of biological reproductive barriers are very effective at preventing the mixing of gene complements or exchange of any genetic material between unlike organisms. Species do not have to be very different before 'gene flow' between them can no longer occur. Indeed, it is the generation of reproductive barriers that enable speciation in evolution, and that thereafter maintains species integrity. Nevertheless, gene exchange can sometimes take place between species naturally, but then only (with probably extremely rare exception) between very closely related species through hybridisation.

Genetic engineering enables 'species barriers' to be crossed, with the potential to result in significant incursions on genome and gene pool integrity of natural species, populations and ecosystems. The introduction of genes into a species from disparate evolutionary sources (for example, from a fish or a bacterium to a plant), would virtually never occur in evolution, although there is some circumstantial evidence that it must happen from time to time (extremely rarely) over evolutionary timescales through, for example, viruses serving as intermediaries.

Selection and environmental fate of transgenes

When a transgene is introduced into individuals of an agricultural variety, the extent to which the novel gene will persist or spread within the species into which it has effectively been introduced, and/or the extent to which it will spread ('introgress') to other related species, will depend on a great many genetic, breeding system and ecological factors. During assessment of risks and environmental impacts, the questions that need answering are: will the transgene persist and spread? If it does, does it matter?

If the answer to the first question is a categorical "no", no consideration needs to be given to the second question. However, the answer to the first question would not often be a categorical "no", and so in practice, the second question almost always needs addressing.

The first question asks how prevalent the novel gene or modification will become in the gene pool of the host species, or of related species should introgression be possible. This is a question about the 'environmental fate' of the transgene or modification. This will generally depend on whether the new trait expressed by the host species through expression of the transgene, confers any advantage for the host individuals in their environment. If the trait has the potential to confer an advantage, the individuals have a 'positive selective advantage', survive and reproduce preferentially, and the transgene frequency in the species gene pool will increase and the trait be more common in populations.

'Bt' genes are bacterial genes which give the plants into which they are inserted protection against insects. Expression of Bt genes in commercial crops or plantation forest species means that the plants now produce a protein that is toxic to insect pests (for example, moth and butterfly larvae). Effectively the plants have been genetically engineered to contain a microbial pesticide that previously could be produced only by bacteria. Such plants are sometimes referred to as 'plant pesticides'.

Such a genetic modification has the potential to confer a selective advantage on individuals of the modified species growing out of cultivation, or of related species into which the gene transferred. The introduction of 'Bt' eucalypts in plantation forestry in Australia, for example, might lead to 'Bt' gene transfer to individuals of the same or related gum-tree species in natural ecosystems. Such gum-trees might survive better in the natural environment, reproduce more, and so contribute more genes (including Bt genes) to the next generation, basically because they are not eaten by caterpillars and so grow more and produce more seeds. The fate of the Bt gene would likely be its persistence and spread outside of cultivation, if other 'brakes' on reproduction within the environment were not together more influential.

The potential for such a scenario for Bt plants is very much species-specific. In the case of Bt tomatoes being developed in Australia, there are no closely-related native species into which the transgene could transfer nor do tomatoes occur outside of cultivation. In the case of Bt cotton, which has been approved for release in Australia in certain regions, related native species have been assessed to be sufficiently reproductively isolated and the risk of transgene transfer negligible in these regions.

For other genetic modifications, a potential positive selective advantage of the plant cannot be identified. Indeed, a negative selective advantage may be conferred on the organism in a non-agricultural environment. To take a hypothetical example, a plant may be modified to no longer express a natural protein such as a lectin, that would

normally defend the plant against microbial pathogens, so as to make it more palatable and less dangerous for humans. In natural environments, the plant would be more vulnerable to disease. Here the fate of the genetic modification is likely to be disappearance, or inconsequential persistence in the gene pool at a very low frequency.

In another case, any advantage may be highly conditional. An example here is herbicide tolerance. A plant expressing herbicide tolerance because it has been genetically modified to express a bacterial protein that metabolises the herbicide, will have an advantage over non-herbicide tolerant individuals of the variety only when the herbicide is sprayed.

Potential adverse impacts on the environment and biodiversity

The second question (above) asks in effect about the consequences of the introduction of the transgene or modification into complex and adaptive environments. An introduced transgene(s) or modification that is novel to an agricultural species will be environmentally significant if its expression in either the species into which it was introduced, or relatives into which it had unintentionally spread, has a direct or indirect adverse ecological effect.

Whether or not the environmental impacts will be negative, and the way in which biodiversity and the environment will be affected, will depend very much on the particular case. Indeed, the environmental impacts of a GMO may in fact be positive, and this is discussed in the next section ('Potential beneficial impacts').

Potential adverse environmental impacts could ensue through a number of risk pathways, some of which might concurrently have negative impacts on agricultural ecosystems. Some specific pathways include:

- The first wave of GMOs to be used by primary producers includes a large number of crops that are tolerant to herbicides. Overuse or misuse of herbicide-tolerant crops and pastures and the herbicides used on them, may lead to the development of other plants resistant to the herbicide. These may become novel or worse weeds in other farming or non-agricultural systems if systems are not managed.
- The deployment of GM herbicide-tolerant plants may lead to increased reliance on herbicide use by primary producers at the expense of integrated weed management, resulting in an increased herbicide burden at the ecosystem level.
- Impacts of changed herbicide use patterns may also require re-evaluation of the management of impacts on non-target vegetation (eg spray drift onto other crops and natural vegetation).
- Herbicide-tolerance genes transferring to wild populations or weedy relatives of the crop could reduce weed control options, in both other farming systems and non-agricultural or conservation areas. This could increase environmental exposure to herbicides in non-agricultural areas, especially for weed infestations where control reduces the seed banks of native plant species and destroys the habitats of native animals, resulting in reduced ecosystem representation.
- Also included in the first wave of GMOs to be used by primary producers, are crops resistant to insects. Use of these crops will place selection pressure on insects to develop resistance. In the case of Bt, it is known that this will occur

unless management measures are put in place to minimise the possibility, because resistant insects have already developed overseas in response to use of conventional, non-GM 'microbial' Bt products. Should Bt resistant insects emerge (through use of conventional Bt products or mismanaged GM Bt crops), this would compromise the use of conventional microbial Bt products and GM plants such as Bt cotton, which are relatively environmentally benign pesticides and 'plant pesticides'.

- Genes (such as Bt) that confer protection for crop plants against insect herbivory, may have the potential to transfer to wild populations of the same or closely related species. Issues that would require assessment include:
  - Does the crop species occur out of cultivation, and if so would possession of the Bt gene make it a weed or increase its weediness?
  - Can any native species related to the crop species acquire the trait through hybridisation, and if so would the trait expressed in those species reduce the abundance of native insects or make the native species more abundant in the natural environment, and perturb natural ecosystem dynamics?
- Introduction of insecticidal traits into native trees (eg Bt eucalypts) raises significant concerns about the potential for disruption of natural ecosystem dynamics, should the gene transfer to natural populations (that is, populations of the same species in non-plantation areas, or to other related eucalypt species).
- Fungicidal or virus-resistance genes introduced into crop plants to protect them against disease may transfer to weedy populations of the species or related species, where they could increase their fitness as weeds.
- In GM plants modified to be virus-resistant through, for example, coat-protein-mediated resistance, viral recombination in co-infected plants (if possible) could lead to emergence of viruses with novel plant host ranges, with unknown environmental consequences.
- Modifications for flowering time (and other phenological traits), or other adaptive traits such as drought tolerance, could extend the geographic ranges of weedy populations or related plant species.
- For GM animals, such as pigs, modifications for faster growth and larger size have the potential to increase feral animal fitness.
- In aquaculture, introduction of growth hormones (from unrelated species) into farmed species such as salmon, trout and prawns has the potential for altering population dynamics and disturbing ecosystem functions should the GMOs escape and interbreed with native species or feral populations.
- Genetically modifying the gut micro-flora of herbivores such as sheep and cattle could enable them to utilise flora which have a high fibre content, but are low in protein (a feature agriculturally very valuable during times of drought in rangelands). This could increase the grazing pressure on native and remnant vegetation unacceptably, and also increase soil erosion by wind and water.
- Non-GM insect pathogens, such as nucleopolyhedrosis virus, are used as 'microbial products' to protect crops against insect pests. The viruses can be genetically modified to express toxins (such as scorpion toxin). The GM pathogen may be more effective control agents of the agricultural insect pests, because they will now act more like a synthetic knock-down pesticide. Such a GM virus would

have the potential for adverse impacts on non-target lepidopteran host species in natural environments. If there was genetic recombination of the GM virus with closely related viruses, with different (but overlapping) host ranges, transfer of the trait to the relatives could significantly alter viral epidemics in a wider range of insect species, with unknown environmental consequences.

The above impacts are hypothetical. Potential risks become the subject of evaluation on a case-by-case basis during the risk assessment processes that underpin decision-making in regulatory systems. It is during the risk assessment process that the likelihood of possible impacts is evaluated, and any actual risks characterised.

Australia's agricultural plants and animals are virtually all species exotic to Australia. The exotic species base for Australian agriculture is in one respect fortuitous in regard to any potential for novel adverse effects of these species on the environment, consequent upon genetic modification. There is often little likelihood that transgenes will transfer to native plants and animals, because they are not usually closely related.

On the other hand, exotic weed and feral pest species are prime agents of environmental degradation and habitat destruction and loss, and some of them are agricultural species. The introduction of novel traits into such species using gene technology, and through them into naturalised wild populations and perhaps related species, has the potential to exacerbate weed or pest threats. The same gene technology, however, has the potential to be used to better control weeds and pests (next section).

For some agricultural GMOs, environmental impacts will arise from changes in scale and geographical extent of farming made possible by the new technology. For example, an agricultural system may expand because a previously economically non-viable crop is made viable through better pest or disease control. Or GM crops tailored for survival in harsh conditions may extend farming into territories where agriculture is currently impossible, with significant costs to the natural environment in terms of land degradation, and habitat and biodiversity loss.

Potential beneficial impacts on the environment and biodiversity

The same agricultural GMOs that may have potential adverse impacts on the environment, may in fact yield environmental benefits. Potential beneficial impacts include:

- *Reduction in use of insecticides.* Deployment of insect-resistant crops such as Bt cotton could lead to long-term reduction in use of insecticides in the cropping system, with benefits of reduced impacts on non-target insects and animals, reduced eco-toxic effects off-site (eg waterways), and reduced water and fuel consumption.
- *Reduction in the use of herbicides.* The use of GM crops tolerant to non-selective herbicides may result in more-effective weed control in a farming system leading to an overall reduction in herbicide use and/or reduced demand for more narrowly targeted and persistent herbicides.
- *Gains in soil conservation.* Use of some GM herbicide-tolerant crops may result in a reduction in the need for cultivation for weed control, thereby reducing degradation of fragile soils.

- *Reduction in damage caused by invasive species.* The use of highly-specific GM bio-control agents may lead to the more effective control and perhaps eradication of some exotic weeds and feral animal pests in terrestrial and aquatic environments.
- *Increased efficiency of agricultural land use.* If gene technology increases the efficiency of sustainable primary production there will be a consequent reduced pressure on environmental resources.

The potential for better environmental performance in agriculture through deployment of GMOs provides a strong argument for gaining experience in their release and use, where no threat of *serious or irreversible* damage to the environment has been identified. Where genetically modified organisms (GMOs) have potential for reducing the impact of agricultural activity on the environment, and improving the sustainability of farming systems, they should be encouraged.

Control of use and monitoring of environmental impacts will be essential to measure whether impacts are as predicted, and whether there are net adverse or beneficial impacts.

4. Risk Assessment and Risk Management

4.1 INTRODUCTION

The 'Regulatory Path' is essentially a series of functions from notification of an action, provision of information and scientific advice, risk assessment, decision-making (an 'approval'), risk management (including monitoring), and other end-use control such as compliance and enforcement.

Risk assessment is the key plank in any regulatory system. Assessment involves identifying hazards, analysing exposures and probabilities, evaluating impacts, characterising risks, and recommending management measures. Risk management is not only the implementation of management recommendations arising from the risk assessment process, but also the monitoring of implementation and impacts. This monitoring is essential for 'closing the regulatory loop', that is informing subsequent risk assessment and development of management measures. This makes regulation effective and avoids unnecessary regulation.

4.2 RISK ASSESSMENT

4.2.1 Principles

Certain fundamental generic principles underpin best practice risk assessment, whatever the regulatory system. In the context of GMOs, these principles can be stated as follows:

- No GMO or novel organism should be released into the open environment, until a science-based safety risk assessment has been conducted.

- Precautions that are applied should be based on this science-based environmental safety risk assessment.
- Assessments should be objective and science-based, and conducted at arm's length from specific interest groups and political considerations.
- Environmental assessments should be conducted on a case-by-case basis, at least until further experience and knowledge has been gained. Assessments of environmental safety of a given GMO in another country (environment) will not be applicable to safety assessment for the GMO in the Australian environment, except in certain generic respects.
- Assessments should be based on an appropriate paradigm, for example that of the United States EPA, involving three principal steps: problem formulation, exposure and effects analysis, and risk characterisation (or, in more detail, hazard identification, exposure and probability analysis, impacts evaluation, risk characterisation, and risk management recommendations).
- Assessments should involve application of clearly defined and documented processes, development and use of accepted standards and codes, specification of clearly defined data requirements, and preparation of documented assessment reports.
- Assessments should be subject to peer review and public comment.
- Responsibility for furnishing scientific information and data for risk assessment should be clearly defined.
- Environmental safety assessment should be used to provide the basis for identifying risk management measures, as appropriate and where required.

4.2.2 Assessing Risks

For all GMOs proposed for release into the open environment, potential hazards need to be identified, and risks assessed and management plans developed before release in order to minimise environmental impacts and conserve biological diversity. Where environmental hazards have been identified, the GMO will require appropriate containment. Containment provisions would be relaxed when and if adequate information was provided to justify it. Where GMOs are evaluated to pose a threat of *serious or irreversible* damage to the environment, and risks cannot be managed, release should not be allowed.

There are few GMOs currently being developed for release and use in Australia where no hazards at all can be identified and zero risk seems to be posed. Examples of extremely low risk GMOs for Australia are the Florigene carnations genetically engineered for improved vase life and for novel flower colour (violet), which GMAC approved for general release in 1995.

At the other end of the risk scale, there are few GMOs that would warrant an outright 'no' decision by a regulator by the time field trials are being proposed. Proposals where serious human health and environmental hazards had been recognised to be unacceptable, would have been abandoned during development or never left the 'drawing board' or the conception stage. An application for field release of rumen bacteria genetically modified for detoxification of the plant poison fluoroacetate

provides such an example in Australia. GMAC recommended against field release (in 1994) because of the potential for transfer of this selectively advantageous trait to feral animals.

Less serious potential adverse impacts will have been identified for GMOs allowed to be released in field trials, however, and it will be critical to manage these risks to minimise or prevent potential adverse impacts. Experience and monitoring of such GMOs in the field trial phase and after general release, will enable environmental impacts to be measured and put into perspective, and management measures to be evaluated for effectiveness.

The novelty of GMOs, the fact they will continue to reproduce after release, the complexity of natural environments and ecosystem processes, and the unknown evolutionary fate of inserted genes, all contribute to the difficulties of predicting environmental impacts and developing reliable, probabilistic risk assessments.

4.2.3 The Knowledge Base

There will often be a lack of precision in the level of risk predicted, because of scientific uncertainty. This is partly a consequence of the poor knowledge base in areas such as the general biology of native relatives to the GMO being introduced, or the dynamics of the ecosystems into which the GMO is to be released. Furthermore, assessments are almost always qualitative, because there are no data with which probability statistics for environmental responses can be calculated. This is not unusual, however, when assessing the risks posed by new organisms in ecosystems.

Where deficient, the knowledge base should be improved on a case-by-case basis during the development period for the GMO (usually several years). This will improve risk assessment and management, and benefit both the community and primary producers by preventing or mitigating potentially negative impacts. Research required to assess the environmental safety of specific proposals could be funded by the primary beneficiary (usually the proponent where costs can be passed on through commodity prices and if the proponent has sufficient venture capital).

However, some of the knowledge base needed for adequate risk assessment is not GMO-specific and the information required is more strategic and fundamental (for example basic knowledge about recombination among viruses in co-infected hosts). In other cases, there is market failure for generating the necessary knowledge, for example where the proponent is a government agency developing a GMO for a public good. These are probably valid community service obligations, requiring government support.

Lack of full scientific certainty means that a cautious approach needs to be taken to assessing risks. The more scientific uncertainty there is, the more cautious the approach should be. In our view, where scientific uncertainty is high, and there is the potential for serious or irreversible environmental damage, the release of the GMO should not be allowed. Where less serious or irreversible damage is predicted, release of GMOs will require commitments to monitor impacts on the environment as a tool of risk management. For these GMOs, monitoring and risk management plans need to be in place before release.

4.3 RISK MANAGEMENT

4.3.1 Monitoring and Managing

Natural phenomena can be divided into the known, the unknown (for example species yet to be described), and the unknowable (for example the future course of speciation). Knowledge is necessary not only to assess risks; the same knowledge or additional knowledge may be required to manage those risks. No adverse impacts from GMO deployment have been reported in Australia, but few GM crops have been released with only a handful of genetic modifications made. Any long-term adverse environmental effects of GMOs may not be known or detected for many years, decades, centuries, or much longer (for example, on evolutionary timescales).

The Australian experience of introduced invasive (non GM) species since European settlement has been that adverse impacts are often not detected until they become obvious as ecosystem effects and or a threat to species (even extinctions). For the many exotic species introduced into Australia that are not weeds or serious pests, there has been an interest in understanding ecosystem management so that they do not become problematic, and in early detection of problems.

The lack of refined methodologies and of knowledge of ecosystem function and dynamics, even now make it difficult to predict and rank the invasiveness of exotic species. By the time an invasive species is recognised as a problem, it may have already become uncontrollable. The lesson is to manage risks through early detection and improved methods of monitoring. There will be a need to develop and implement the best ways to effectively monitor impacts, and to specify responsibilities and contingency plans.

Risk management for GMOs will probably require some new specific methods for detection of impacts, and methodologies for measuring impact. For example, field diagnostic kits or bio-monitoring systems may need to be developed to detect and track transgene flow. Specific adverse effects reporting systems, and perhaps some new infrastructure, will need to be established to monitor for invasiveness, detect novel herbicide tolerance, or detect insects resistant to pesticides.

Some genetically modified plants and animals will persist outside the areas of release, and transgenes may transfer to other varieties and related species. In other words, they may have impacts beyond the systems into which they are released. These impacts may be at the level of genomes, species, communities, ecosystems, catchment areas and regions. Depending on the case, monitoring of impacts will perhaps need to be conducted not only in the farming systems in which the GMO was deployed, but also in adjacent farming systems and other ecological communities such as non-agricultural land. Monitoring may need to be conducted locally and regionally.

Monitoring in the USA has shown that results from small field trials during the development phase may not reliably predict the safety (or value) of new varieties of plants. The United States Department of Agriculture has shown environmental impacts of commercially grown genetically modified crops to vary, depending not only on the crop but also regionally

4.3.2 Issues of Risk Management

For most proposals, low-level and medium-level risks will have been identified that require at least some risk management. Management plans released with the GMO should contain a treatment of risk reduction measures, and specify responsibilities and contingency plans. The effectiveness of management plans will need to be evaluated through monitoring to assess whether predictions of GMO safety and impacts were accurate, to adjust controls and risk management, and to inform and modulate subsequent regulation.

The following principles for environmental risk management should apply:

- Risk management measures should be proportionate to the level of risk.
- Management measures for specific risks should not be implemented in isolation from broader management strategies but as part of integrated management plans (eg integrated weed management plans), developed in consultation with all relevant stakeholders.
- Measures should be reviewed periodically, and impacts monitoring should be undertaken (where necessary and as appropriate) to inform subsequent development of measures and decision-making.

Issues of risk management for GMOs can probably now be characterised by category of GMO. For example, all herbicide-tolerant crops will tend to pose similar issues for risk management. **Attachment B** lists (draft) generic management issues for herbicide-tolerant crops developed by a recently convened task force of the Standing Committee on Agricultural Resources Management (SCARM) Plant Industries Committee. The Environment Protection Group of EA contributed to the work of this group in developing these management issues, because the deployment of some of these plants is likely to affect the natural environment as well as agricultural ecosystems.

Where environmental risks need to be managed outside of the farming system into which the GMO was introduced, significant questions are who should manage, and who should pay. If proponents, the farmers who use the GMO, and/or governments do not pay, risks may not be managed.

Public agencies managing public land, other farmers (such as organic growers), or other affected parties (such as apiarists, in the case where the market demands ‘non-GM’ honey) may either not have the resources to pay or, understandably, they may not view it as their responsibility to pay because they did not introduce the GMO. Where risks are not managed, environmental degradation could accrue, and costs for remediation or other environmental management may eventually be borne by the public purse.

5. Australia's Approach

5.1 OFFICE OF THE GENE TECHNOLOGY REGULATOR

5.1.1 Interim Arrangements

Robust interim arrangements for regulating gene technology while the legislation for the OTGR is being drafted, were announced on 11 August by the Minister for Health and Aged Care, Dr Michael Wooldridge. They strengthen existing arrangements by providing a more rigorous, transparent and accountable decision-making system for the commercial release of GMOs. Decisions on the general release and use of 'agricultural' GMOs will be made by Dr Wooldridge.

It will still be the case that no Commonwealth agency administers statutory powers in regard to decisions, where the GMO is not also an 'agricultural or veterinary chemical', a 'therapeutic good', or a 'food' or 'food ingredient' for the purposes of the respective legislation controlling such entities. All decisions by Dr Wooldridge are nevertheless Commonwealth decisions for the purposes of the *Environment Protection (Impact of Proposals) Act 1974* (Impact Act). In this respect, decisions that may result in, or facilitate, a significant impact on the environment must be referred to the Minister for the Environment and Heritage for examination under the Act prior to the decision being made. The Impact Act will be superseded by the *Environment Protection and Biodiversity Conservation Act 1999* in July 2000 (see below).

Under interim regulatory arrangements for GMOs for general (commercial) release (but not field trials at this stage), the government has announced that an approved management plan will be developed and will require implementation under a contract between the Commonwealth and the proponent. The contract will specify the conditions for compliance, identify a strategy for monitoring compliance, and articulate the cost of the Commonwealth's compliance monitoring strategy and mechanisms for meeting the costs. Contracts will bind proponents to taking any remedial steps deemed necessary by the Commonwealth.

It is not yet clear to what extent such contracts will provide for risk management that may be required in non-agricultural land, conservation areas, and farming systems adjacent to the one in which the GMO was released and used.

5.1.2 Towards the New System

For the control of agricultural GMOs, the control path is currently incomplete and non-statutory. Gaps in statutory control include gaps in all regulatory functions, where there is no control by an existing regulatory agency. GMOs controlled by the National Registration Authority that are or would be 'agricultural chemicals' for the purposes of the legislation would not be gaps; these would include GMOs used for pest control (though perhaps not all).

The government recognises these gaps and in October 1998 announced its intention to update Australia's current regulatory framework, including by existing regulatory agencies where appropriate. On 11 May 1999, the Minister for Health and Aged Care, Dr Michael Wooldridge, announced that new legislation would be developed to cover

gaps in the coverage by existing authorities of the regulation of GMOs. The legislation would be administered by an Office of the Gene Technology Regulator (OGTR) established in his portfolio. Environment Australia continues to be actively involved in developing and implementing the government's policy on gene technology regulation, and in the detailed negotiations with States and Territories to develop the new provisions.

5.1.3 The Risk Assessment Challenge for the OGTR

In addressing regulatory gaps and developing legislation, the government is faced with a range of major challenges, among which is the provision of best practice, neutral, and accountable risk assessment. This is of particular interest to the Minister for the Environment and Heritage and Environment Australia, because many of the potential risks arising from GMO deployment are environmental.

Options for how assessment is undertaken, and by whom, are fundamental to the design of a regulatory system. Risk assessment is the core of any regulatory framework. Risk assessment should provide for documented identification of hazards, analysis of relevant exposures and probabilities, impacts evaluation, and risk characterisation. Risk assessment reports need to provide comprehensive, documented and referenced argument and analysis to support conclusions and recommendations to the decision-maker. Reports should be defensible and open to peer review and comment.

Those assessing risks should be able to access whatever experts and sources best meet the needs of accurately determining the nature and likelihood of impacts arising from the action being assessed. Assessors should be independent persons who have no active interest in promoting gene technology and who do not represent any specific interest group. The need for neutrality is a prime reason for separating provision of expert advice (which will inform risk assessment) from independent risk assessment itself, in the regulatory path. The community expects neutrality.

Risk assessors also need to be trained and experienced in regulatory systems, the legislation administered by the regulator, administrative law, national and international standards and codes, linkages with other regulatory systems, and international obligations and harmonisation efforts.

These are all arguments for assessments to be conducted, or at least coordinated, as a function of Commonwealth regulatory agencies (as is the case in regulation by existing regulators of GM products, ie the TGA, AQIS, ANZFA, NRA, NOHSC and EA). Assessments could be undertaken by accredited, independent, professional risk assessment consultants if they can demonstrate 'no conflict of interest' and suitable professional skills to those responsible for coordinating risk assessment. There are few, if any, developed countries that rely on a standing expert committee as the focus for risk assessment of GMOs.

Further, it would be desirable that the OGTR not duplicate the expertise already within the Commonwealth for risk assessment, for agricultural and veterinary chemicals, industrial chemicals, therapeutic goods, foods, and imports. The network of Commonwealth risk assessment units involved in these systems undertake assessments in different safety sectors, ie pest risk analysis (AQIS), human health (TGA), occupational health and safety (NOHSC), environment (EA), residues (NRA),

and foods (ANZFA). The OGTR could make use of this existing network.

Many of the risks associated with the deployment of GMOs and their products, while posed in a unique context (in a GMO), are not in themselves sufficiently novel to require different expertise (eg for assessment of weeds issues, toxicity issues, pest issues, environmental pollution, food safety, etc). 'Biosafety' assessment is not a unique category of assessment on a par with 'toxicology', 'residues', 'OH&S', or 'environmental impact', 'human health' categories. 'Biosafety' is really just 'safety', and includes all the above categories.

The disciplinary expertise uniquely required to assess GMO safety is molecular genetics. Agencies such as AQIS and TGA have built up an 'in house' capacity in this discipline as required. Assessment of the safety of GMOs or GMO products is not the exclusive preserve of specialist experts at the cutting edge of research in molecular genetics.

The current arrangements for risk assessment are primarily based on a committee of part-time assessors comprising the GMAC. EA doubts whether such a system will be able to meet all aspects of the risk assessment challenge for the OGTR described above. There needs, therefore, to be debate about whether the future regulatory scheme for GMOs in Australia should rely on a standing expert committee as the focus for risk assessment. It is not yet clear how much the proposed Genetic Technology Advisory Committee (GTAC) in the OGTR will in effect be the *de facto* risk assessor in the new system. GTAC will replace the current GMAC.

Nevertheless, the new OGTR should build on the existing GMAC 'experts committee' system for regulation of agricultural GMOs at the contained research phase. The GTAC could also provide independent expert advice on non-contained proposals, but the OGTR should build primarily on the risk assessment expertise already in the Commonwealth (for existing regulatory systems) for assessment of releases into the open environment (including field trials). This would have the advantage of providing a smooth transition for risk assessment, from the current largely voluntary framework to a statutory framework.

A further challenge to the operations of the OGTR is funding of the risk assessments. At present, full cost-recovery is planned. However, in early stages of the OGTR, full cost recovery from only a small number of proponents may not generate sufficient revenue to cover the costs of the scheme and/or the charges could prove to be prohibitive to industry and serve as a significant disincentive to applying gene technology.

Proponents should bear the principal costs of risk assessment and of generating data and information required by regulators for safety evaluation. However, there may be a need for regulators to acquire information that would apply to applications from a range of commercial proponents or to public good proponents, such as public institutions proposing an application to control feral pests. In these cases, and for some monitoring and evaluation of risk management after release of a GMO in order to inform and modulate subsequent regulation, the costs will not be attributable to commercial proponents, and the option of government funding needs exploring.

5.2 ENVIRONMENT AUSTRALIA'S ROLE – NATIONAL

5.2.1 Risk Assessment in the Environment Protection Group

Under new interim arrangements announced by Dr Wooldridge on 11 August, Environment Australia will prepare full environmental assessments of the impact of genetically modified organisms proposed for general (commercial) release for the IOGTR. Arrangements may be extended or adapted to apply to field trials, but in the meantime the Environment Protection Group of EA will continue to provide comment (as an observer) to the GMAC on the release of GMOs for field trials (non-commercial release). An example of EA comments provided to GMAC in its assessment of a GMO is provided at **Attachment C**.

Under existing bilateral arrangements, EA also undertakes environmental assessments for the NRA on the environmental safety of GMOs that are 'agricultural chemical products' for the purposes of the legislation, as well as on chemicals such as herbicides used on genetically modified organisms. Through provision of comments to GMAC and environmental assessment for the NRA, Environment Australia was involved in the approval for commercial release of the first genetically modified crop in Australia, Bt cotton, which was registered by the NRA as a 'plant pesticide'.

5.2.2 Environment Protection and Biodiversity Conservation Act

On 22 June 1999, during the Senate Second Reading on the *Environment Protection and Biodiversity Conservation Bill 1998[1999],* Senator Hill announced that "matters that affect the environment will be referred to the environment minister for assessment and advice by that independent regulator. That will ultimately be provided for through an amendment to this legislation, when it passes, in conjunction with the law that is going to be put in place to set up the new GTR." The intent is that environmentally significant decisions of the OGTR will be referred to the Minister for Environment and Heritage for environmental impact assessment before release of a GMO into the open environment. The amendment will be drafted as part of the development of the legislative framework for GMOs.

This foreshadowed amendment is consistent with the obligations under the interim arrangements for general release proposals announced on 22 August, through application of current *Environment Protection (Impact of Proposals) Act 1974*, which will be repealed when the EPBC Act takes effect.

5.2.3 Access to Biological and Genetic Resources

EA (Biodiversity Group) is the joint lead agency with AFFA in the Commonwealth, working with States and Territories to develop a nationally consistent approach to the issues of access to genetic resources and the sharing of benefits from the use of those resources.

In addition, Environment Australia will be implementing the Biotechnology Australia work program on access to genetic resources. This seeks to achieve a streamlined path for the biotechnology industry to access Australia's biological resources. Outcomes from the work program will be:

- a clear policy and regulatory framework for access to and the management of biological resources (ex situ and in situ);
- an integrated permit system providing streamlined access to biological resources for the biotechnology industry;
- clarification of the ownership of biological resources, other than where ownership is affected by Native Title claim;
- accelerated development of a national system of biological resource centres including plant genetic resource centres for food and agriculture; and
- improved industry access to documentation of biological resources;
    - the establishment of a database and website providing information on ownership, access procedures and benefit sharing guidelines;
    - an assessment of the extent to which the documentation of material held in existing ex-situ collections meets the needs of the biotechnology industry;
    - the identification and evaluation of source material for the biotechnology industry held in plant genetic resource centres, and fisheries and forests collections; and
    - accelerated development of the infrastructure and science base for documenting biological resources (in situ and ex situ).

Environment Australia will also prepare regulations under the new *Environment Protection and Biodiversity Conservation Act 1999* to control access to biological resources in Commonwealth areas. During debate on the Bill, the Minister announced his intention to 'cause an inquiry to be undertaken to give indigenous Australians and all Australians interested in the issue the opportunity to participate in a public debate so that the issue of access to biological resources can be further developed'.

5.2.4 Wildlife and Marine Conservation

The use of technologies that reduce habitat destruction or biological invasions are supported by Environment Australia. This could include application of GM control agents, if they were safe.

The Marine Group of Environment Australia would welcome gene technology research and development that aims to address the urgent need for control agents for pests in the marine environment. Development of controls for introduced marine pests is at an early stage. However existing outbreaks pose major threats to environmental values and maritime industries, especially shellfish industries (including abalone harvesting).

5.3 ENVIRONMENT AUSTRALIA'S ROLE – INTERNATIONAL

5.3.1 Transboundary Movement

The major issue in relation to the import and export of GMOs is whether the genetic modification would introduce traits that would constitute a novel pest or disease risk, or increase an existing pest or disease risk. The most recent Quarantine Proclamation (for the purposes of the *Quarantine Act 1908*) now provides for the evaluation of novel pest and disease risks posed by an imported GMO for the purposes of quarantine control. An imported GMO would also be controlled under the new interim arrangements of the IOGTR, and by any other relevant existing regulator after import for their purposes (eg a living GM food by ANZFA). Any gaps in import and export control at present need to be identified and filled during development of the new national system for gene technology regulation.

Wildlife Australia regulates the export and import of prescribed organisms under the *Wildlife Protection (Regulation of Exports and Imports) Act 1982*, to meet Australia's obligations under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and to protect Australian flora and fauna. If a prescribed organism was also genetically modified, it would remain subject to the Act.

5.3.2 Biodiversity Protocol

A protocol on biosafety is being negotiated under the Convention on Biological Diversity to address international concerns about potential risks to biodiversity from the movement between countries of living genetically modified organisms. Negotiations to date have reflected the need for international cooperation to protect biodiversity and the need to harmonise and streamline administrative requirements. It is not anticipated that significant changes to Australia's domestic legislation and administrative arrangements will be required.

The Biodiversity Group of EA is involved in the ongoing international negotiations with Parties to the Convention on Biological Diversity to develop a legally binding Biosafety Protocol. The Protocol was not finalised as planned in February this year as Parties were not able to reach consensus. It is now intended that the Protocol will be finalised prior to May 2000. The Department of Foreign Affairs and Trade takes the lead within the Commonwealth on these negotiations but Environment Australia is also actively involved.

5.3.3 OECD Working Group

The Working Group on Harmonization of Regulatory Oversight of Biotechnology (WGHROB) is a subsidiary body to the Joint Meeting of the Chemicals Committee and Working Party on Chemicals of the Environment Directorate of the OECD. The Group's primary function is to implement projects which promote the international harmonisation of regulatory oversight, while ensuring safety. Projects include publishing science-based consensus documents, participating in 'outreach' projects (eg on-line information dissemination, workshops), and working on specific issues such as standardisation of consensus documents.

Environment Australia currently chairs the Joint Meeting and leads on WGHROB participation. The program is almost all funded through non-OECD budget sources, and Environment contributes financially (albeit minimally) to WGHROB projects. It is likely that the portfolio will become more active in international harmonisation efforts, now that familiarity with gene technology is increasing to the stage where standardisation of requirements and protocols is becoming possible.

The work of the Group will be of increasing value in assisting in rigorous safety evaluation of the products of gene technology with respect to environmental and health safety, while avoiding non-tariff trade barriers.

Attachment A

Current Statutory Regulatory Systems for GM Products

Currently, genetically modified (GM) products in Australia (other than those used in human gene therapy), are subject to controls under five regulatory systems.

Foods (including GM foods) are regulated under the *Australian and New Zealand Food Authority Act 1991* (Cth), administered by the Australia New Zealand Food Authority (ANZFA) and accompanying State/Territory legislation. ANZFA has undertaken extensive consultation and analysis on regulatory arrangements and labelling for foods derived from GMOs and the Australia New Zealand Food Standards Council (ANZFSC) – the Ministerial Council responsible for food matters - has agreed on a standard for foods made with gene technology. This standard requires assessment and approval on a case-by-case basis for GMO-derived foods.

In addition, ANZFSC has directed ANZFA to develop an amendment to the labelling provision of the standard to extend labelling to all foods produced using gene technology. It has also asked ANZFA to develop a definition for genetically modified foods which takes into account that some food ingredients may be derived from genetically modified organisms but are not themselves genetically modified. These amendments are due to be discussed by ANZFSC in October. If agreed to by ANZFSC, these will be more stringent requirements than those applied in the United States.

Therapeutic goods (including genetically modified therapeutic goods) are regulated under the *Therapeutic Goods Act 1989* (Cth), administered by the Therapeutic Goods Administration (TGA). The TGA is part of the Commonwealth Department of Health and Aged Care. No living GMOs are yet marketed for therapeutic use in humans. However, products in development which are living GMOs include vaccines for cholera and HIV, and treatments of cancer.

Agricultural and veterinary (AgVet) chemicals (including GM AgVet chemicals) are regulated under the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth), administered by the National Registration Authority (NRA) and accompanying State/Territory legislation. The NRA takes advice from other agencies such as TGA, Environment Australia and National Occupational Health and Safety Commission as part of its assessment processes.

The Agvet regulatory scheme is centred around the Agvet Code which was established under the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth), and provides for the evaluation, registration and review of agricultural and veterinary chemicals and their control up to the point of retail sale. Assessment of the chemicals includes a consideration of the public health, occupational health and environmental impact of their use. State and Territory Agriculture authorities retain responsibility for control of use activities, such as licensing of pest control operators and aerial spraying.

If the use of an agricultural or veterinary chemical will result in a residue in a food, it is referred to ANZFA for assessment and incorporation into food standards after that chemical has been approved and registered for use by the NRA. Therefore, responsibility for enforcement and compliance is shared between the Commonwealth, State and Territory Agricultural authorities and State and Territory Health authorities.

In 1996, after a lengthy period of assessment involving public consultation, the NRA registered the product, INGARD Gene Bt Monsanto (a gene derived from the bacterium *Bacillus thuringiensis*, that produces a highly specific insecticidal protein [*Bt* endotoxin], toxic to the major caterpillar pests of cotton). The gene is inserted into commercial cotton plant varieties. Limits were placed on the scale of planting of cotton containing the Ingard gene, and farmers were, and remain, required by contract to comply with strict conditions on how they grow the crop.

Industrial chemicals are regulated through the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cth), administered by the National Occupational Health and Safety Commission (NOHSC) and accompanying State/Territory legislation. NICNAS considers the occupational health and safety, public health and environmental issues associated with the industrial chemical.

NOHSC is a tripartite forum of government, employer and employee representatives established within the Employment portfolio. NOHSC regulates industrial chemicals under the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cth) which describes the National Industrial Chemicals Notification Scheme (NICNAS).

Imports/exports are regulated under the *Quarantine Act 1908* (Cth), the *Imported Food Control Act 1992* (Cth) and the *Export Control Act 1992* (Cth) administered by the Australian Quarantine and Inspection Service (AQIS) and also under Wildlife Protection legislation administered by Environment Australia.

AQIS, within the Agriculture portfolio is responsible under the *Quarantine Act 1908* (Cth) for ensuring that products imported into Australia do not lead to the introduction of, establishment and spread of pests and diseases which may endanger plant, animal and human life or health. Proposals to import goods are assessed using an Import Risk Analysis process in accordance with the international standard prepared under the auspices of the International Plant Protection Convention Secretariat, under the World Trade Organisation Sanitary and Phytosanitary Agreement. This process considers the pests and diseases of quarantine concern that may be associated with an imported product and establishes appropriate management procedures.

Certain prescribed specimens of wildlife and products derived from wildlife are regulated by Environment Australia under the *Wildlife Protection (Regulation of Exports and Imports) Act 1982* to meet Australia's obligations under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and to protect Australian flora and fauna. If a prescribed organism is also genetically modified, it would remain subject to this Act.

The Australian Customs Service (ACS) and AQIS also have a general border control role. For example, under the *Customs Act 1901,* ACS would not allow the importation of therapeutic goods without the relevant permit issued by TGA. AQIS also administers the *Imported Food Control Act 1992* to check compliance of imported foods with domestic food legislation.

In response to requests from overseas governments, AQIS has been required to issue certification under the *Export Control Act 1992* attesting to the freedom from GMOs in commodities such as grain and seeds. AQIS' ability to issue such certification is reliant on the absence of GMOs in commercial crops. In future, however, AQIS will require evidence from industry that GMOs are traceable and segregated from non-GMO product.

Attachment B

Generic Management Issues for Herbicide-Tolerant Crops

1 Arising from herbicide use

Deployment of HT crops will result in changes in the way in which herbicides are used, with potentially positive or negative impacts on the environment.

Development of a new weed flora in farming systems:

- The deployment of HT crops in Australia will provide a platform for weed control that may make it possible to achieve more effective control of some important agricultural weeds.
- However, if a given herbicide is used too frequently the risk of herbicide resistance emerging *de novo* in a species increases (this may arise in common weed species or in species which were not previously significant weeds).
- The widespread adoption of Integrated Weed Management (IWM) processes will prevent or reduce the risk of *herbicide resistant* weed populations developing.
- Should resistance arise despite the use of IWM, early detection of such herbicide resistant weeds will allow more effective management and minimise potential negative impacts.

Patterns in the frequency and type of herbicide used:

- The introduction of HT crops will cause changes which may be beneficial, resulting in reduced weed control costs and/or reduced environmental impacts (eg. a net reduction in the use of persistent herbicides).
- However, the effect may vary between different farming systems and regions. Studies on their effects in Australia will allow the benefits from the deployment of HT crops to be maximised. For instance, the use of Triazine Tolerant canola (a non-transgenic HT plant) may increase the use of atrazine, which has some known negative environmental impacts.

Extent of herbicide use in farming ecosystems:

- The widespread deployment of HT crops and pastures may result in better control or eradication of weed populations in agricultural ecosystems, leading to overall reduced use of herbicide.
- However, should herbicide resistant weed, pasture or crop escapes become more difficult to control in non-target farming systems there may be a net increase in the use of more potentially harmful herbicides at the system level.

Change in cultivation practices:

- Australia's fragile soils may be better preserved by the deployment of rotations of crops with tolerance to broad-spectrum herbicides. The rotations may also produce economic gains.
- On the other hand, reliance on herbicides may be engendered with extensive HT crop and pasture introductions.

Methods of applying herbicides may change:

- Changed application methods may either add to or reduce farm input costs.
- Changed application methods may have different environmental impacts (eg. require more or less soil cultivation).
- Potential herbicide spray drift damage on non-target, non-HT crops and pastures, or natural/native vegetation, may be more or less likely.

2 Arising from the competitive effects of herbicide tolerance in agricultural species

The deployment of HT crops in farming systems may shift the competition balance between beneficial plants and weeds in the following ways:

- When treated with the designated herbicide the herbicide tolerance trait will provide a competitive advantage for the HT plant over other susceptible plants and weeds. In the absence of the designated herbicide there is no *per se* competitive advantage.
- The herbicide tolerance trait might be accompanied by other traits which confer competitive advantages or disadvantages (eg. as in the lower yields experienced with Triazine tolerant Canola in the absence of weeds).
- Should the competitive advantage of the HT crop be increased by the use of herbicide treatments (or by other introduced traits), it may then have the effect of increasing the HT plant's potential to become a weed of the system in which it was deployed, or in other agricultural systems and/or non-agricultural land.
- Volunteer plants (those left unharvested or grown from shed seed) may become weeds in a succeeding crop or pasture if the designated herbicide is used for weed and volunteer plant control in the succeeding crop. This may also be a particular concern where the herbicide is used for weed control in the fallow periods following an HT crop.
- If the HT crop plant is itself a weedy species in non-agricultural land, the HT trait could confer competitive advantage on the plant where the herbicide is deployed.

3 Arising from lack of containment of intentionally introduced herbicide tolerance

Should a herbicide tolerance trait enter the genome of other varieties of the crop species, or that of closely related plant species, the following issues may need to be considered.

Transfer of the herbicide tolerance trait to other varieties of the same species:

- The net effect of transfer may be neutral (eg confers no selective advantage or disadvantage in the absence of the HT plant herbicide, that is, selection may only apply where the herbicide is used).
- The transfer could increase the possibility of the recipient variety becoming a weed of the system in which it was deployed, in other agricultural systems and/or non-agricultural land.
- The transferred trait might positively or adversely affect crop agronomy of the recipient variety.
- Adverse commercial impacts may result from the transfer of the HT trait to non-HT varieties or related species may have adverse commercial impacts on industries dependent on that crop (eg. organic crops, meat, dairy and apicultural industries).

Transfer of the herbicide tolerance trait to other closely related species:

- The net effect of this may be neutral.
- Transfer may increase the weediness of weedy species, or species previously not considered as weeds.
- Related species may become weeds of the farming system in which the HT plant was deployed, in other agricultural systems and/or in non-agricultural land.

Attachment C

An Example of EA Comments Provided to GMAC

EA Comments on Issues to be Addressed during the Course of Development of a Commercial Genetically Modified SNPV

PR–86. "Dispersal ecology of a genetically marked* Helicoverpa armigera *singly-enveloped nucleopolyhedrovirus (HaSNPV) in the cotton agro-ecosystem".
And ***NRA PERMIT No: 1212 . Genetically Marked HaSNPV***

From an environment perspective, most issues that need to be addressed during the course of commercial HaSNPV product development relate to the fate and impacts of the recombinant HaSNPV and the transgene. The greatest potential environmental hazards identified by EA at this stage are indirect impacts on natural ecosystem dynamics through changed virus epizootics, and transfer of the transgene (through recombination) from HaSNPV (with a relatively very specific host range) to other viruses with consequent impacts on a much wider range of host insects.

- Relevant background information to enable better risk assessment. It is generally recognised that risk assessment should be based on a good knowledge of the ecology of the wild type virus and of the recombinant virus (Cory & Entwistle 1990). Godfray (1995) states that "we urgently need to know more about baculovirus ecology in natural as well as agricultural ecosystems". There seems to be a need for more basic knowledge on:
  - the molecular basis for specificity (eg compared, for example, with the reasonable extent of data available on caliciviruses);
  - how closely related the different wild type NPVs are (eg more sequence data to test for congruence);
  - diversity of native baculoviruses and their host ranges in *natural* ecosystems;
  - importance of wild type NPVs in *natural* ecosystem dynamics;
  - importance of *Helicoverpa* species in *natural* ecosystem dynamics;
  - biotic dispersal agents of NPVs in the Australian environment; and
  - persistence of occluded NPVs in the environment (including in the soil and as latent infections).
- Insect and other species host range of the modified HaSNPV. Confirmation would be required of host range of the modified HaSNPV (including studies testing an appropriate taxonomic sample of insects and of other major groups for degree of permissiveness) and on the potential of recombinant virus to adapt to alternative hosts (eg during serial passages). Gröner (1986) notes a number of studies undertaken to adapt baculoviruses to alternate hosts by serial passage of virus through the candidate hosts.
- Recombination between modified HaSNPV and other NPVs. Data on the potential for, and impacts/consequences of, transgene transfer to other NPV species, other baculoviruses, and other virus genera. Some NPVs have wider host ranges than HaSNPV eg (eg AcMNPV). Mixed infection experiments would be needed, including perhaps with other viruses of the host species (ie Iridoviruses and Poxviruses). For example, it is known that cotransfection of AcNPV DNA with a specific fragment of another NPV (BmNPV) can generate a host range-expanded virus (Maeda *et al.* 1993).
- Ecological impacts of modified-HaSNPV epizootics on *Helicoverpa* and any other susceptible species populations, and on ecosystems, in non-agricultural areas. Changed impacts could arise from a change in epidemiology and/or host range of HaSNPV due to the genetic modification *per se*, from competitive interactions between wild type and

recombinant HaSNPV, and from transgene transfer to other viruses through recombination. There is the potential for modified HaSNPV to become naturalised in natural populations of *H. punctigera* and also *H. armigera* and the other two native *Helicoverpa* species at least (in arid Central Australia), and beyond, if recombination occurs.

- Impacts of modified HaSNPV on parasitoids of permissive *Helicoverpa* species. eg will there be long term deleterious impacts on natural parasitoids?
- Potential for dispersal of recombinant HaSNPV to other jurisdictions. For example, it is known that *H. armigera* can travel as far as New Zealand (Gregg *et al.* 1995). It is also known that HaSNPV can be latent in its host.
- Ecotoxicity of scorpion toxins to non-target species. Ecotoxicity test data would be required, especially for birds and other predators.

A general question is what other strategies are being considered in the development of an efficacious, safe recombinant baculovirus for insect control, eg development of a 'disabled' NPV or co-occluded preparations.

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