

REGULATION IMPACT STATEMENT FOR THE GENE TECHNOLOGY REGULATIONS 2001

1. Background

Scope of this Regulation Impact Statement

In early 1999, the Commonwealth Government agreed that:

- a national regulatory system for the control of genetically manipulated organisms (GMOs) and the use of gene technology be developed to replace the existing administrative system;
- the regulatory system would be managed by an independent statutory office holder (the Gene Technology Regulator); and
- the Regulator would derive power from both Commonwealth, State and Territory legislation.

Regulation Impact Statements (RISs) were prepared to guide the development of this policy and the development of the *Gene Technology Act 2000* (the Act) and related Acts. This RIS focuses on the costs and benefits of several components of the proposed regulatory scheme, as reflected in the *Gene Technology Regulations 2001*.

Background information about the current system of controls for gene technology

The Genetic Manipulation Advisory Committee (GMAC) is a non-statutory expert advisory body reporting to the Commonwealth Minister of Health and Aged Care. GMAC's membership includes a wide range of experts in fields such as molecular biology, ecology, plant genetics, agriculture and biosafety engineering.

Since 1975, GMAC (and its predecessors, the Academy of Science Committee on Recombinant DNA and the Recombinant DNA Monitoring Committee) has scrutinised the development and use of novel genetic manipulation techniques in Australia. Each proposal (whether intended as a research and development project or for the commercial release of a GMO) is considered by GMAC on a case by case basis and judged on the individual merits of the application.

To March 2001, GMAC has assessed:

- 5484 proposals for small scale contained work. Small scale genetic manipulation proposals are mostly directed at fundamental and proof of concept research in biology and medicine and are conducted within contained laboratories. Most small scale work is carried out by universities and other research organisations.
- 43 proposals for large scale contained work, such as the production of: hormones, growth factors and vaccines; enzymes for trials in patients with

enzyme deficiencies; and enzymes for use in paper pulp production. Most large scale contained work is carried out by commercial organisations (40 of the proposals were from commercial organisations and 3 of the proposals were from universities).

- 259 proposals for field trials of GMOs. Most field trials were for genetically modified plants, with the majority being for cotton or canola. The remaining field trials were for micro-organisms such as bacteria, viruses and yeast. Applications for most of the field trials came from commercial companies (44%) or the CSIRO (37%). Of the remaining field trials, 11% were conducted by universities and 8% by State government agencies.
- 9 applications for general (commercial) release of GMOs. Four of these have been approved to date: Bt cotton (which was subsequently regulated by the National Registration Authority for Agricultural and Veterinary Chemicals (NRA); a violet carnation; a carnation with improved vase life; and Roundup Ready cotton. In addition, the NRA has approved, with the advice of GMAC, the release of a genetically modified plant pesticide (in 1989) and a salmonella vaccine (in 1992).

In June 2000, the Federal Government introduced a package of three Bills into Federal Parliament for the regulation of gene technology in Australia - the Gene Technology Bill 2000, the Gene Technology (Consequential Amendments) Bill 2000 and the Gene Technology (Licence Charges) Bill 2000 – to provide more credibility to the oversight of dealings with GMOs. This package was passed by Parliament on 8 December 2001, and will form part of a national regulatory system for GMOs. The objective of the gene technology legislation is to protect the health and safety of people and to protect the environment by identifying risks posed as a result of gene technology and by managing those risks. It does this by creating laws for certain dealings (or activities) with GMOs.

The *Gene Technology Act 2000* provides that regulations can be made to prescribe matters required or permitted to be prescribed by the Act, or matters which are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

2. Problem

The Regulation Impact Statement for the Gene Technology Bill 2000 listed a range of potential benefits from the application of gene technology to agriculture, health and the environment that had been identified by supporters of this technology. These benefits included: more efficient use of agricultural and veterinary chemicals; savings in energy inputs to farm production; recovery of degraded land; research into the cause of diseases, improved biopharmaceuticals; and bio-remediation.

However, the very characteristics of gene technology which produce many of the benefits (such as the ability to introduce genes from one species into a different species) are also those that cause concerns in the community. These concerns are related to potential unintended effects on the health of people or the environment, and a number of possible risks were identified in the Regulation Impact Statement to the Gene Technology Bill 2000. These included: higher risks of allergic reactions to

genetically modified food; unknown long term consequences that may not be able to be reversed or fixed once the GMO is widely used; and crops so strong that they become weeds or pests.

There are also broader, non-scientific concerns that have been expressed about using gene technology, including ethical, social and moral concerns about the impact of 'humans playing God'.

With these potential risks and benefits in mind, the range of applications for gene technology is changing very rapidly. As also discussed in the Regulation Impact Statement to the Gene Technology Bill 2000, certain GMOs are now being developed which do not fall neatly within the mandate of existing regulators in Australia, such as the Australia New Zealand Food Authority and the Therapeutic Goods Administration. While GMAC has provided advice directly to proponents on these 'gap' GMOs, because of the administrative nature of the GMAC system, governments have had limited capacity to either monitor proponents' compliance with GMAC advice, or to enforce compliance with that advice.

In addition, more GMOs are approaching the commercialisation stage, when producers of the GMOs will be seeking to release the GMO into the environment, either for the purposes of field trials or for commercial release. The GMAC system, which was established a number of years ago, was designed to deal with research into GMOs being conducted in contained facilities, and was not established with a focus on general release.

There is therefore broad community and government concern that the current GMAC system is no longer appropriate. This is because it does not have in place sufficient mechanisms to ensure adequate openness and transparency in its risk assessment and management roles, nor sufficient enforcement capabilities, to adequately address this rapidly developing technology and ensure public health and safety and the protection of the environment.

Lack of confidence (particularly in relation to the assessment of ecological impact and the management of GMOs released into the environment) may also harm the ability of industry to market GMOs and GM products – both domestically and internationally – which have been assessed as safe for release under this system. Indeed, a growing number of Australia's overseas markets – for example, Japan, the European Union, and Sri Lanka - are now demanding that strong regulatory mechanisms be in place to regulate, monitor and record dealings with GMOs.

3. Objective

The objective, as stated in the *Gene Technology Act 2000* (the Act), is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms (GMO).

This objective is to be achieved through a regulatory framework which:

- (a) provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation;
- (b) provides an efficient and effective system for the application of gene technologies; and
- (c) operates in conjunction with other Commonwealth and State regulatory schemes (eg. those that regulate food, agricultural and veterinary chemicals, industrial chemicals and therapeutic goods) relevant to GMOs and genetically modified products (GM products).

In essence, the Regulations established under the *Gene Technology Act 2000* must pursue the object of the Act and must reflect the type of regulatory framework envisaged in the Act. By way of further detail, the government objective with respect to the Regulations (as with the Gene Technology Act) is to:

- (a) pursue an efficient and cost effective approach;
- (b) continue a science based approach to the assessment of risks but including capacity for formal consideration of broader issues such as ethics;
- (c) avoid unnecessary duplication with existing regulators and provide for better coordination of the activities of all regulators involved in the approval of GMOs and GM products;
- (d) assist industry by providing a streamlined pathway for seeking and, where appropriate, gaining approval to deal with GMOs and GM products for which safety risks can be managed appropriately;
- (e) increase enforceability of the arrangements for managing risk;
- (f) achieve greater transparency and accountability; and
- (g) be more responsive to stakeholders and community views consistent with the legislation.

4. Options and Impact analysis

This section sets out the various options for each of the key components of the Gene Technology Regulations 2001. As numerous components of the Regulations are examined, for ease of reference, an assessment of the impacts (including the costs and benefits of each option) has also been included in this section.

In terms of the impacts of the Regulations and the scheme they will support, the groups most likely to be significantly affected by this initiative are:

- government – including Commonwealth, State/Territory and local governments;
- business and researchers - including large, medium and small commercial enterprises, universities and other public research organisations and users of gene technology (including primary producers);
- consumers – those actually using the end product; and
- community members – other members of the general public.

Options and Impact Analysis of key components of the Gene Technology Regulations 2001

(a) Organisms that are not genetically modified organisms

The definition of a GMO (in clause 10 of the *Gene Technology Act 2000*) includes capacity for the regulations to declare that certain organisms are not GMOs for the purposes of the legislation. This provision recognises that the definitions of GMO and gene technology in the Act are cast very broadly, and that the definition of GMO may therefore be interpreted to capture things which were not intended to be regulated under this legislation. Thus this provision provides, as far as reasonably possible, for the scope of a GMO both under the current administrative arrangements and under the legislative arrangements to be analogous.

Option 1: Prescribe a limited class of organisms in the regulations as not being GMOs

To address the problem detailed above, the regulations would set out those organisms that are excluded from the scope of the regulatory system because they have been modified by techniques that do not require regulatory oversight or that fall outside the scope of this regulatory system. These techniques would be excluded from regulatory oversight because they:

- give rise to organisms that can occur in nature, and as such do not pose a particular biosafety risk to the environment or human health and safety; and/or
- are commonly used in biological research; and/or
- have a very long history of usage in Australia and overseas.

For example, some species contain naturally occurring pieces of DNA that can spontaneously move around within the DNA of that organism. When these pieces of DNA move around they may cause changes in the characteristics of that organism, but the modified organism that results is not considered a GMO because the process is one that occurs in nature.

Option 2: Do not prescribe any organisms (as not being GMOs) in the Regulations.

This would mean that organisms such as those detailed at Option 1 would not be set out in the Regulations as being excluded from the regulatory scheme. The effect of this would be that all dealings with such organisms would require licensing, or some level of regulatory oversight, by the GTR.

Impact of option 1:

The Government would not incur any increased costs. Also, business and researchers would not be likely to incur a significant impact as a result of this option. This is because this option maintains the status quo and ensures that organisms that have not previously been considered by GMAC to be GMOs are not treated as GMOs under the new system of regulation. Consumers are not likely to be impacted by this option. In respect of the community, this option was discussed at length during public consultations on the Regulations. Most stakeholders recognised that

there would be no, or minimal, negative impact on the health and safety of people or the environment.

Impact of option 2:

The government would be expected to incur significantly increased costs. This is because all of the organisms that have previously been outside the control of the GMAC system would require regulatory oversight. It would also impact on Australia's trade with other countries because organisms (such as plants formed by in vitro fertilisation) which are currently traded freely between countries, would not be able to be imported into Australia without prior approval from the GTR. Furthermore, it would be impossible for government to effectively regulate some of the organisms, as these changes to their genetic make-up can occur in nature (ie. without human intervention).

Similarly, business and researchers would incur significantly increased costs. This option would adversely effect a number of businesses that are not otherwise caught under the regulatory scheme. Because these organisms have not been regulated by GMAC (or other regulators) in the past, it is not possible to provide an accurate estimate of the number of activities or organisations that would be effected. However, it is expected that it would be in excess of 3000 projects in various fields, including plant breeding, university laboratory research and medical research.

This option could effect consumers as the need to meet new regulatory requirements may cause some key researchers undertaking fundamental or proof of concept research (particularly medical researchers) to withdraw from gene technology work. Furthermore, higher costs of regulation could affect product prices.

Also, this option poses a cost to the community by suggesting that such organisms (including those that exchange genetic material in nature) are inherently unsafe and require regulatory oversight. This could prove damaging to the community's confidence in the new regulatory system, which follows good regulatory practice by focusing on GMOs and dealings that may pose a risk to the health and safety of people and the environment.

Conclusion and recommended option:

The Regulations incorporate Option 1. This Option is the only tenable option and ensures that activities that are not strictly gene technology are not subject to unnecessary and costly regulation that cannot be justified on the basis of risks to public health and safety and the environment.

(b) Exempt dealings with GMOs

Section 32(3) of the Act provides that certain dealings with a GMO may be prescribed as exempt dealings. There are two options for dealing with exempt dealings with GMOs in the Regulations.

Option 1: Retain the current GMAC exemptions in the Regulations with certain modifications.

The GMAC Guidelines for Small Scale Genetic Manipulation Work set out the work that is exempt under the voluntary GMAC system. The GMAC exemptions have been developed over the past 25 years, based on the experience of the Committee (including predecessors) in assessing GMO dealing applications.

The exemptions apply to a limited number of dealings with GMOs undertaken within contained facilities that:

- have been assessed over time as presenting no significant biosafety risks to public health and safety (including occupational health and safety) or the environment; and
- do not involve intentional release of a GMO into the environment.

This Option would involve reflecting the tenor of the current exemptions in the Regulations, but amending the wording of the exemptions to ensure that:

- they are consistent with the legislation;
- they are sufficiently certain to enable organisations to rely on them and to enable them to be enforced by the GTR; and
- the wording of the GMAC exemptions is narrowed in some instances to ensure that the exemptions do not unintentionally exempt a broader range of activities than is intended (and only cover those dealings that can be shown to present negligible risk).

Option 2: No exempt dealings or notifiable low risk dealings prescribed in the Regulations (ie. all GMO dealings to be licensed).

During consultation on the Regulations, a number of community stakeholders suggested that there should be no exempt dealings with GMOs set out in the Regulations and that all dealings with GMOs should be licensed by the GTR following a detailed case by case risk assessment.

Impact of option 1:

The impact of option 1 on the Government would be minimal. This is because this option implements the risk management approach which is at the heart of the new system, whereby government resources expended in regulating known low risk activities are minimised.

Furthermore, the majority of businesses and researchers would not experience increased costs. However, as a result of redrafting and clarifying the scope of the exemptions, in some cases the exemptions have been narrowed slightly and, as such, costs may be increased for some organisations whose work will now be treated as a Notifiable Low Risk Dealing (NLRD). It is estimated that a small, indeterminate number of projects (of 5000) (ie. nominally estimated at less than 50 projects) would be affected by the changes. For example, the exemption would not apply to those dealings with gene-knockout mice (that is, mice whose genetic modification involves deletion or inactivation of a specific gene) where an advantage is conferred on the adult animal (this would be a rare occurrence). In these cases,

the administrative burden would be small because the organisation concerned would have the necessary information readily available. In addition, the OGTR would make available resources to minimise the additional burden on those organisations.

Consumers would not experience any significant impacts.

The Community would not experience any significant impacts under this option.

Overall, this option aligns with the status quo as developed by GMAC, based on many years of experience.

Impact of option 2:

The impact of this option on the Government would be significant. This is because approximately 5000 projects that are currently exempt or notifiable (category B under the voluntary GMAC system) would require licensing by the Regulator. This would consume significant resources, and would undoubtedly detract from the important work of the Regulator in respect of higher risk dealings with GMOs which are to be licensed. It is estimated that the increased cost to government would be in the order of tens of millions of dollars.

Business and researchers would experience a significant impact under this option. This is because organisations currently conducting dealings that are exempt or notifiable under the GMAC system would need to submit comprehensive applications to the Regulator seeking a licence, as distinct from an exemption or NLRD. The details required to obtain a licence are of a higher order than the details associated with obtaining an exemption or approval as a NLRD. In particular, a licence provides for the intentional release into the environment of the GMO (eg: conducting of field trials), or for the undertaking of high risk contained research, whereas an exemption or NLRD approval does not authorise an intentional release of a GMO into the environment. As such, the evaluation and consultation requirements prescribed in the *Gene Technology Act 2000* are more significant in relation to these dealings, including potentially longer time delays and greater information-gathering requirements.

Work on many of those projects would need to be suspended while the GTR examined this information and conducted assessments. This would be likely to affect the approximately 5000 projects and would be likely to impose significant additional costs on business and researchers to compile the proposals. It is not feasible to determine the approximate cost of preparing proposals across such a wide range of projects. However, it is foreshadowed that it would be a very considerable cost to business and researchers and not financially feasible in respect of contained fundamental and proof of concept research.

Consumers would not experience any adverse impact as exempt dealings and NLRDs, undertaken in contained facilities, have been assessed over time as posing negligible risks to the health and safety of people or the environment. There would, however, be the factor of increased cost to consumers as a result of the licensing cost being applied to marketed GMO products.

The Community could perceive that action under this option would indicate that the government now considered all GMOs to require some level of regulation at a licensing standard. This would fuel existing fears amongst some sections of the community that GMOs are inherently or intrinsically unsafe. In particular, the potential risks derived from exempt dealings or NLRDs are low because neither involve release of a GMO into the environment or commercialisation of the GMO for human or animal use. Thus, the potential impact of this option would be a negative one if the cost implications of requiring licensing for exempt dealings and NLRDs meant any inhibition on work in the areas, for example, of fundamental and proof of concept medical research.

Conclusion and recommended option:

The Regulations incorporate Option 1.

[Note: It is proposed that the Gene Technology Regulations require that exempt dealings under the *Gene Technology Act 2000* can only be undertaken in contained facilities that comply with the *Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology)*. A lesser containment standard would not secure the minimal level of biosafety risk required for these dealings. This should not have a significant impact on businesses and researchers, as the majority of laboratories dealing with GMOs, including teaching and University research laboratories, are already certified to a higher containment level (PC2) than that specified by AS/NZS 2243.3:1995, as they are often dealing with higher risk category dealings at the same time, and also as an added safety precaution for staff. Indeed, the CSIRO stated in its submission that it is more convenient to have their laboratories certified to a higher standard.

Those organisations operating facilities that are not of a higher containment level would, in the main, be schools that are teaching gene technology. However, most of these organisations still ensure compliance with AS/NZS 2243.3:1995 for legal reasons, as the Standard has legitimacy being of the AS/NZS series. The Standard is specifically designed so that school laboratories can comply with its requirements.]

(c) Notifiable Low Risk Dealings with GMOs

Under the current administrative arrangements overseen by GMAC, GMAC has issued guidelines setting out “Category B” activities that require Institutional Biosafety Committee (IBC) assessment, and notification to GMAC, before the work commences.

It is intended that the category of notifiable low risk dealings (NLRD) prescribed under the legislation allows for “Category B” dealings. In particular, NLRDs are dealings that the Regulator considers to be of particularly low risk, but which do not warrant exemption from the provisions of the Act. The low risk will usually be because the GMO is biologically contained (ie. it has a reduced ability to survive or reproduce in the open environment), is not pathogenic and does not produce new proteins that are of high risk because they are toxic. The limited differences are that under the statutory scheme, the organisation must be accredited, and if working with human pathogens, the work must be undertaken in accordance with the relevant Australian standard.

The Act allows regulations to be made setting out categories of work with GMOs that are NLRDs and conditions that must be complied with in relation to NLRDs.

Option 1: Existing GMAC Category B activities prescribed in the regulations as NLRDs.

This option would involve basing the list of NLRDs on the GMAC Category B dealings. Such dealings with GMOs:

- have been assessed over time as presenting minimal biosafety risks where such risks can be properly managed through containment of the GMO in a laboratory certified to Physical Containment Level 2. For example, some of the factors considered in assessing a GMO to be of low risk (with the low risk able to be managed through containment measures) include the extent to which the GMO is 'biologically contained' (because it has a reduced ability to survive or reproduce without human intervention) and the properties of the GMO including the inability of the GMO to be a pathogen or pest or produce toxic proteins; and
- do not involve the intentional release of a GMO into the environment.

Furthermore, the regulations would require that dealings with such GMOs must:

- be assessed by the applicant's IBC;
- be notified to the GTR;
- be conducted within conditions of physical containment (PC2);
- if transported, be transported only in accordance with strict Guidelines for transportation issued by the GTR; and.
- not involve release of the GMO into the environment.

In essence, the status quo of GMAC Category B activities, including notification and, for example, transportation requirements, would be retained in these proposed NLRDs requirements. However, the wording of the GMAC Category B activities would be narrowed in some instances so as to ensure that the NLRDs do not unintentionally catch a broader range of activities than is intended.

Option 2: No notifiable low risk dealings prescribed in the Regulations.

During consultation on the draft Regulations, some community stakeholders suggested that there should be no NLRDs with GMOs set out in the Regulations, and that all dealings with GMOs should be licensed by the GTR following a detailed case by case risk assessment.

Impact of option 1:

The impact of option 1 on the Government would be minimal. The option ensures that such activities attract an appropriate level of regulatory oversight, which based on GMAC experience, accurately reflects the level of risk posed by such dealings.

In respect of business and researchers this option would not have a significant impact, as the key aspects of the current administrative system are maintained. In essence, the status quo is maintained for business and researchers

Consumers would experience no, or minimal, impact under this option.

The Community would experience no, or minimal, impact under this option.

Impact of option 2:

The impact of this option on the Government would be significant. The effect would be that approximately 1700 projects that are currently Category B work (under the voluntary GMAC system) and approximately 300 new projects per annum would require licensing by the Regulator. This would consume significant resources and detract from the important work of the Regulator in respect of higher risk dealings with GMOs. It is estimated that the increased cost to government would in the first year range from \$15 to 20 million, and in each subsequent year approximately \$2.5 to 3 million.

The impact on business and researchers of this option would be significant. Not only would industry bear the significant costs of the Regulator (if cost recovery is introduced) but industry would also bear significant internal costs associated with preparing applications seeking a licence for the work. The application requirements for licences are significantly more detailed than those for NLRDs.

Consumers would be impacted upon by this option where a decision was made to fully or partially cost recover the operations of the regulatory system, and thus business would need to recoup those costs from consumers.

In respect of the Community, this option would not be likely to have a significant impact, other than that taxpayers would bear the cost in the absence of a cost recovery regime.

Conclusion and recommended option:

The Regulations incorporate option 1 for the following reasons:

- existing GMAC IBC arrangements for handling small scale genetic manipulation work in a physical containment facility (ie. NLRDs) have operated efficiently and effectively for some time. It is a procedure with which gene technology research organisations are familiar and as such costs of compliance are unlikely to increase significantly;
- the costs of requiring all NLRDs to be licensed would be in the range of \$15 to 20 million with no expected benefits to the community (in terms of protecting the health and safety of people and the environment).

[Note: The referencing of *Australian Standard AS/NZS 2243.3:1995 (Safety in laboratories: microbiology)*, under either option 1 or 2, as a condition relating to NLRDs will not have a significant impact on businesses and researchers. This is because only a small section of the Standard, relating to vaccination, is actually called up in the Gene Technology Regulations, and these vaccination requirements are already recommended by GMAC. These particular requirements are unlikely to vary significantly in the future, as they already require vaccination when dealing with human pathogens, and organisations have systems in place to ensure that such vaccination is undertaken. There are no known instances of non-compliance with the vaccination requirements.]

(d) Licensed dealings with GMOs – Information requirements for applications

Section 40 of the Act provides that an application submitted by a person for a licence authorising dealings with GMOs must contain such information as is prescribed in

the Regulations (if any) and such information as is specified in writing by the Regulator.

Option 1 – Prescribe detailed information in the Regulations.

This option would involve prescribing in Schedules to the Regulations very detailed information that the Regulator requires from the applicant in order to make an assessment of an application to deal with GMOs.

This approach is based on:

- the existing GMAC Guidelines;
- submissions made on the *Gene Technology Act 2000* and on the August 2000 and January 2001 draft of the Gene Technology Regulations; and
- international precedent, including the European Council Directive 90/220/EEC.

This option would also be supplemented by a requirement that the applicant must take account of the risks the proposed GMO dealing may incur in relation to the health and safety of people and the environment. If the applicant is not able to provide all relevant data and references, the Regulations require that the applicant must state what information is incomplete or unavailable, indicate the significance of the information, and in the absence of comprehensive scientific data provide a theoretical analysis of any risks posed.

Option 2 – Prescribe in the Regulations very general classes of information required by the Regulator.

This option would mean that instead of prescribing very detailed information requirements in the Regulations, the Regulations would be a lot simpler and would simply state that the Regulator required information against 6 key headings (eg. the genetics of the GMO, risk assessment information, risk management information etc.) This is a less prescriptive approach than option 1, and leaves responsibility with the organisation for identifying the types of information required to establish the safety of the proposed dealings with the GMO.

Impact of Option 1:

This option provides advantages for government in that the GTR will be provided with certain baseline information by all applicants. This arrangement may make it easier to assess applications, meaning that assessment processes can commence shortly after the receipt of the relevant application without the need for the Regulator to pursue further information from the applicant. This will help to make the process more transparent, as all proponents, irrespective of levels of sophistication, will be required to submit certain information.

Business and researchers would be expected to experience essentially existing costs. This is notwithstanding that the new arrangements are a composite of the existing GMAC Guidelines, ideas presented in submissions on the draft regulations, and international precedent. However, the major influence on the development of option 1 would be the GMAC Guidelines. The advantage for businesses and researchers under this option is that it provides applicants with a substantial amount

of guidance about the information required by the Regulator. During consultations on the Regulations this type of guidance information was identified as a high priority by many businesses and researchers. However, the disadvantage is that by being prescriptive, it may be necessary to change the requirements over time to reflect the Regulator's evolving requirements and industry practice.

Consumers would not experience any, or only minimal, impact as a result of this option.

The Community would not experience any, or only minimal, impact as a result of this option. An exception would be that this option provides a benefit through stressing the 'arms length' nature of the relationship between the GTR and industry and researchers.

Impact of Option 2:

The impact of this option on the Government is that the GTR would be required to undertake a far more strenuous examination of exactly what information has been provided before the risk assessment process could commence.

In respect of businesses and researchers, it is anticipated that there could be some advantages for larger business, on the proviso that they have a clear idea of exactly what information is relevant to assessing and managing any risks. Conversely, smaller organisations, particularly research organisations, may be significantly disadvantaged and this option may affect their competitiveness within a global science system. This, ultimately, would affect the small to medium-sized Australian enterprises that stand to benefit from Australian science.

The experience of other regulatory bodies, for example, the National Registration Authority for Agricultural and Veterinary Chemicals, is that industry wants to know what information is required for evaluation so as to provide a full data package for evaluation. In the case of an application submitted to the Regulator for licensing a GMO dealing, the information requirements will need to meet the statutory requirements for a licence to be granted. The information could be provided under either option 1 or 2. However, it is be foreshadowed that under option 2 there would be more 'clock-stop' situations and disputes over what information is required. This is because the Regulator has certain statutory duties which must be fulfilled. Thus it appears on balance to be appropriate to set out for industry and researchers the information required to readily facilitate determination of an application for licensing a GMO dealing.

Consumers are not likely to experience any significant impact beyond a potential impact on the pricing structure of GMO products arising from changes in the uptake of research outcomes between small Australian and large multinational organisations.

Also, this option would be expected to have a negative effect on building community confidence in the regulatory system. Furthermore, the mixed format of the information provided by applicants could make it more difficult for community

members to build some expertise in this area so as to allow them to comment on proposals.

Conclusion and recommended options:

The Regulations incorporate option 1.

(e) Evaluation of applications for licence, accreditation of organisations and certification of facilities – Time limits

Option 1: No time limits prescribed in the legislation

The effect of this would be that the Regulator would not be limited as to the time period during which he/she must decide an application for a licence, accreditation or certification.

Options 2: Time limits prescribed in the legislation. Time limits being: 90 days for applications for accreditation and certification, 90 days for applications not involving intentional release of a GMO into the environment, and 170 days for applications involving intentional release of a GMO into the environment.

The timeframes proposed (as detailed above) have been:

- based predominantly on the experiences of GMAC in evaluating applications over a considerable number of years. For intentional releases the proposed timeframes are slightly longer than the former GMAC timeframes (single round of public consultation) because of the new requirements in the legislation for two rounds of public consultation on applications. The timeframes are, however, equivalent to the GMAC timetable implemented during late 2000 where two rounds of public consultation are undertaken;
- developed using comparisons to existing regulators. For example, the NRA takes 6 months for evaluation of applications for the registration of agricultural and veterinary chemicals. In addition, there are other allied evaluations, which provide an evaluation period of 8 months, eg. application to vary a condition of approval of a label to permit a change of a technical nature.

Option 3: Time limits prescribed in the legislation with capacity for “clock-stops”

This Option would mirror option 2 (in terms of days set for evaluations) but would also include “clock stops”. The clock would stop for periods when the Regulator is awaiting information requested from the applicant, during public hearings (which have the capacity to introduce a number of unknown variables), during consideration of an application to declare certain information confidential commercial information, and while the GTR is awaiting advice from the Gene Technology Ethics Committee (time frame for reply to be stipulated by the Regulator).

Option 4: Requirement that applications be submitted by one of 6 dates (for intentional release of a GMO into the environment).

In the first consultation draft of the Regulations (August 2000) it was proposed that applications for intentional release be deemed to have been submitted on the first of six dates after the application is submitted. This was consistent with the approach currently adopted by GMAC.

Impact of option 1:

For government, this option would have some advantages, since it would allow unlimited time for consideration of applications. This would be consistent with current GMAC arrangements whereby there are no written administrative guidelines for timing. There are, however, informal evaluation times, refer option 2.

For business and researchers, this option would have enormous costs implications. This is because there would be no certainty about when the GTR would make a decision, for example on a proposed licensed dealing, thus it would make business planning extremely difficult. This would be likely to provide a disincentive to research and commercialisation activities in Australia, and make it more likely that larger corporations would conduct their activities overseas.

For consumers, this option would be likely to create additional costs to consumers, where the GTR took a long time to consider applications. As larger organisations would be likely to undertake substantial research and commercialisation activities overseas if option 1 was adopted, this could also reduce consumer choice because fewer GM products may be marketed in Australia.

During consultations, certain sections of the community stated a preference for option 1.

Impact of option 2:

This option would have potential cost implications for Government, as a decision would always be required within the statutory timeframe, even where the GTR required additional information to make that decision. As such, option 2 could compromise the integrity of the regulatory system. For example, where an applicant took 30 days to provide additional information on a proposed licensed dealing, the GTR would still be forced to make a decision within 170 days.

For business and researchers, this option would offer a very high level of certainty.

Consumers, under this option, might have some concerns about the GTR's need to rely on industry-provided information.

Community groups did not support this option as it would appear likely to create a perception that the GTR was unduly reliant on the quality of applications submitted by proponents.

Impact of option 3:

Government would experience advantages under this option, since it allows adequate time for a full consideration of an application, but also makes provision for

additional time under limited circumstances. This would ensure that the GTR is accountable for efficiently managing its own processes, but the integrity of those processes will not be unduly affected by outside factors beyond the GTR's control, such as the need for an applicant to provide further information.

Business and researchers under this option would be encouraged to carefully manage their responsibilities in respect of application processes, since time will be lost where further information is required. Thus, applications should be as comprehensive as possible.

Consumers, as a result of this option, would be likely to increase their confidence over time, and should not have major costs to consumers.

The transparency of this option would build community confidence in the national regulatory system over time.

Impact of option 4:

Government would experience some advantages under the 'batched' approach of this option as it would facilitate the bulk processing of each common stage of the applications, eg. mailing applications to evaluators for consideration. However, it could also lead to high peak workloads for the Regulator.

For business and researchers, this option could potentially present disadvantages by adding artificial deadlines for applications and introducing a lack of flexibility for applicants.

This option would have no, or only minimal, impact for consumers.

This option would be expected to stretch community resources because there would be 'peak' workload times when community members would be expected to provide input on a large number of applications over a short period of time. For example, each application is likely to require a different response, and if there are several to be responded to in the same 30 day period, responses received during public consultations suggested that this would be more likely to disadvantage the public than to advantage it. In turn, this would be likely to damage community confidence in the national regulatory scheme as the peak workload would, in effect, undermine the community's scope for involvement because of pressure of time to provide comments.

Conclusion and recommended option:

The Regulations incorporate option 3. Option 3 strikes an appropriate balance between the need for the GTR to provide a comprehensive regulatory assessment process and the interests of business and researchers, the community and consumers in regulatory certainty. There would be a nett benefit to the community as a whole.

(f) Certification of facilities and accreditation of organisations – Transitional arrangements

The *Gene Technology Act 2000* (Division 5 of Part 12) describes transitional provisions to assist in the transition of the current voluntary arrangements overseen by GMAC to the new regulatory system proposed in the Act.

In particular, section 190 provides that if the GMAC has issued an advice to proceed immediately before the commencement of the Act, the advice is deemed to be a licence under the Act for a period of two years, or when the advice to proceed expires, whichever is the sooner.

One of the issues that was not addressed in the Act was transitional arrangements for accreditation of organisations and certification of facilities.

Option 1: Prescribe transitional arrangements in the Regulations for accreditation of organisations and certification of facilities.

Under this option, Regulations would provide that:

- all existing PC2 facilities (excluding PC 2 Large Scale facilities) notified in writing by GMAC before the commencement of the Act (that is, all existing ones) will be deemed to be certified under the *Gene Technology Act 2000* for a period of two years after the commencement of the legislation. This “deemed certification” would be conditional upon the facility being maintained in accordance with the GTR’s guidelines for certification that would mirror the existing GMAC guidelines for containment facilities. These arrangements would apply to approximately 1300 existing PC2 facilities.
- all existing PC3, PC4 and PC 2 Large Scale facilities and other facilities notified in writing by GMAC before the commencement of the Act will be deemed to be certified under the *Gene Technology Act 2000* for a period of one year after the commencement of the legislation. As for PC2 facilities, this “deemed certification” would be conditional upon the facility being maintained in accordance with the GTR’s guidelines for certification that would mirror the existing GMAC guidelines for containment facilities.
- all organisations that receive a notice from the GMAC before the commencement of the legislation, are taken to be accredited organisations for two years. To maintain their “deemed accreditation”, organisations would need to comply with guidelines issued by the GTR.

Before the end of the transitional period, organisations and managers of facilities would need to apply to the GTR for recertification of the facilities and reaccreditation of the organisation against criteria set by the Regulator. It is also proposed that the Regulator will implement a rolling schedule of re-approvals to minimise peak work periods.

Option 2: No transitional arrangements for organisations that currently have an IBC or facilities that have been certified by GMAC/IBCs.

Under this option, organisations dealing with GMOs and all facilities in which work with GMOs is conducted would be required to be accredited/certified by the

Regulator from the first day of operation of the new legislation. The effect of this would be that from 21 June 2001 organisations would not be able to undertake dealings with GMOs until they had been accredited by the GTR and their facilities certified by the GTR. This would affect approximately 120 organisations (undertaking in excess of 2000 distinct projects), 1300 PC2 facilities, 22 PC3 facilities and one PC4 facility.

Impact of option 1:

Government. The cost impact under this option would be minimised because it provides for a staged implementation of the new arrangements.

The cost imposed on businesses and researchers under this option is not likely to be significant. However, during the transitional period industry and researchers will have to comply with guidelines for accreditation and certification issued by the Regulator. As these will be based on the current GMAC Guidelines, they are unlikely to impose any significant costs of compliance on industry.

The direct impact of this option on consumers and the community would be minimal.

Impact of option 2:

From the Government's perspective, this option is not administratively acceptable. The effect of this option is that the Regulator would receive approximately 1300 applications in respect of PC 2 facilities and also be required to determine applications for certification of PC 3 and PC 4 facilities. The applications would need to be processed within the 90 day statutory timeframe. Similarly, over 120 organisations would apply for accreditation and these would also need to be processed within 90 days. This would impose an unmanageable burden on the Regulator.

In respect of businesses and researchers, this option would have a significant effect. This is because it would effectively mean that all work with GMOs would halt until the organisation was accredited by the GTR and the facilities certified under the Act. Under this scenario work with GMOs could cease for in excess of 5 months. It has not been possible to determine the cost to businesses and researchers.

Concerning consumers and the community, the direct impact of this option would be minimal. However, it could have flow-on effects to consumers if it resulted in GMO work being suspended for a prolonged period. During consultations, the community recognised the benefits of grandfathering existing certifications and accreditations, but supported an approach whereby after a certain defined period of time, facilities and organisations would be reassessed by the Regulator as proposed in option 1.

Conclusion and recommended option:

The Regulations incorporate option 1.

(g) Committees

The *Gene Technology Act 2000* establishes three statutory Committees – the Gene Technology Technical Advisory Committee (GTTAC) the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC).

The Act provides that the Regulations may prescribe matters relating to:

- the members of the Committees (including terms of appointment, disclosure of interest etc); and
- the operation of the Committees (including procedures for convening meetings, the way matters are dealt with, reporting requirements etc).

An issue is the need for some limits to be placed on Committees to ensure that the costs of running the Committees are not excessive.

It is therefore proposed that certain disciplines be imposed through the Regulations to ensure that the Committees are able to operate effectively and fulfil their functions in the most cost-effective manner.

Related options and impacts are as follows:

- rather than all meetings being held face-to-face, there is capacity for Committees to meet by videoconference or teleconference. The Regulator, through the Department of Health and Aged Care, would have available such facilities for committee work. In respect of GTTAC, videoconferencing of a 2 day meeting would attract a saving of approximately \$10,000 to 15,000, similarly GTCCC and GTEC would attract a saving of \$4,000 to 5,000. Teleconferencing would attract a higher saving because the major infrastructure cost would be the cost of the SDT call to each Committee member.
- rather than the calling of face-to-face meetings being at the discretion of the Committees, such face-to-face meetings of the Committees being determined in consultation with the Regulator at the beginning of each year, and no additional face-to-face meetings held without the agreement of the Regulator. This ensures that the Committees have adequate face-to-face meeting time (to enable them to fulfil their functions), without the potential costs being open-ended; and
- requirement that the Committees act with as little formality and as quickly as the requirements of the legislation and a proper consideration of the issues allow.

These measures are intended to keep costs to a minimum level necessary for the functioning of the Committees, with a positive impact on government or, under cost recovery, on business and researchers. As such, these measures address the issue raised during the consultation process of the need to constrain the cost of operating the Committees.

Consultation

a) The consultation process

In August 2000, an early draft of the Regulations was released for public consultation. The IOGTR received over 60 submissions suggesting changes to the regulations and each of these submissions was responded to individually. The draft regulations were also made available to the Senate Community Affairs References Committee and other Parliamentarians. A number of recommendations to improve the regulations were made by the Committee and by Senators during debate of the Gene Technology Bill 2000.

Suggestions made by stakeholders were referred to both the Commonwealth State Consultative Group on Gene Technology (a body of senior government officials overseeing the development of the legislation) and the Genetic Manipulation Advisory Committee (GMAC), for consideration and advice.

After detailed consideration of the issues, a revised draft of the regulations was prepared and circulated for comment in January 2001. The draft Regulations were accompanied by an Explanatory Guide explaining the rationale for the changes made to the first draft of the Regulations and seeking further comments. The Regulations and the Explanatory Guide were placed on the IOGTR website, direct-mailed to approximately 4000 individuals and organisations who had registered (with GMAC or the IOGTR) an interest in receiving information on the regulation of GMOs and advertised in newspapers throughout Australia.

Written submissions were invited from interested organisations and individuals. In addition, consultation on the revised Regulations were conducted in each capital city in Australia throughout February and March 2001. Invitations to the consultations were sent to approximately 3500 organisations and individuals. Over 340 people attended the face-to-face consultations and some 84 written submissions were received on the Regulations.

b) Results of the consultation on the Regulations in relation to each of the key components of the Regulations

Organisms that are not GMOs and Exempt Dealings with GMOs

A broad range of comments were received in relation to this component of the Regulations. Some submissions called for there to be no exemptions under the new regulatory scheme, while others were very specific in their desire to have certain dealings made exempt or included as a NLRD. These were not segregated into particular stakeholder groups, with, for example, some consumer groups accepting that certain organisms should be exempt from the definition of GMO, and some researchers offering suggestions for limiting the exempt classifications in relation to particular dealings (eg: with knockout mice). Others called for exempt dealings to be undertaken in high containment facilities, and for Institutional Biosafety Committees to make decisions as to whether a dealing is exempt, rather than leaving these decisions up to the researchers.

Notifiable Low Risk Dealings with GMOs

Again, a broad range of comments were received in relation to this component of the Regulations. Some submissions called for NLRDs to be carried out only in high containment level facilities, while others called for all dealings with GMOs to be licensed by the GTR. A number, as in the case of exempt dealings, were very specific in their desire to reclassify certain NLRDs as either exempt or requiring a licence. The Regulations reflect an approach that attempts to maintain the status quo in relation to current GMAC Category B activities, with some minor amendments made as a result of consultations, so as to ensure protection of the environment and of public health and safety. There was less concern and comment expressed over this category of dealings than in relation to exempt dealings, as NLRDs are subject to greater legislative scrutiny and will be notified both to the Regulator and to the public.

Licensed dealings with GMOs – Information requirements for applications

The vast majority of submissions were supportive of the information requirements placed on applicants under the Regulations, including those received from researchers and businesses. This latter group could see that these requirements mirrored to a significant extent those already required by GMAC, and accepted, by and large, that the legal controls over dealings with GMOs had to be rigorous and accountable. In fact, some researchers and businesses, along with many other submissions, offered suggestions for further information requirements which should be prescribed in the Regulations. Many of these suggestions were included in the final version of the Regulations. Others believed that the list of prescribed information requirements seemed to be thorough, as well as providing a successful hybrid of detailed lists with flexible application. There was also a call to attempt to ensure that these requirements are harmonised with those required by other regulatory agencies.

Evaluation of applications for licence, accreditation of organisations and certification of facilities – Time limits

A full range of comments was received in relation to this component of the Regulations. Some organisations believed that the time limits prescribed were too long, especially in such a competitive area. It was claimed that these time periods would allow overseas colleagues to respond to new experimental approaches and the like more rapidly, thereby hindering the development of a ‘Smart Australia’. Others believed that the time limits, as prescribed, would make it difficult for some organisations to obtain adequate input from their members, and do not provide the Regulator with enough flexibility to, for example, commission research. The stop-clock mechanisms were seen by some as a positive step for the protection of the public and of the environment. Still others felt that the time limits were reasonable, but requested that some disciplines be placed on the stop-clock mechanisms so as to ensure certainty in the application process. The ‘batching’ calendar approach to applications was also raised as lacking flexibility and would result in a ‘lumpiness’ to the seeking of public comment on the applications.

On balance, the majority of stakeholders supported the time limits prescribed in the Regulations, including the associated clock stop arrangements.

Certification of facilities and accreditation of organisations – Transitional arrangements

There was wide support for the implementation of transitional arrangements for accreditation and certification. Some submissions did not support the accreditation of organisations. However, these comments related to the concept of accreditation as a whole, as prescribed in the *Gene Technology Act 2000*, and not to the implementation of transitional arrangements to cover those organisations currently undertaking dealings with GMOs.

Committees

A number of submissions and other comments received in relation to the proposed committees related to the quorum required in order to make decisions. Also mentioned were the terms of appointment of the Chairs of the committees, the perceived effectiveness of the disclosure of interest provisions, and the processes by which the committees should be able to obtain information. In particular, some submissions expressed the view that there should be defined operational guidelines for the committees, while others wanted the committees to be free to operate as they choose. A number of commentators felt that the disclosure of interest provisions should be extremely broad, with some commentators going so far as to state that persons with such interests should not be members of the committees at all.

On balance, the majority of stakeholders supported changes made to disclosure of interest provisions from the first draft to the second draft of the Regulations.

6. Implementation and Review

Implementation

The new national system for the regulation of gene technology and GMOs will commence on 21 June 2001. The proposed Gene Technology Regulations will also come into effect at this time.

Review

Section 194 of the *Gene Technology Act 2000* provides that the Ministerial Council on Gene Technology (established under the Inter-Governmental Agreement on Gene Technology) must cause an independent review of the operation of the Act, including the structure of the Office of the Gene Technology Regulator, after 4 years operation of the Act. This review will include a consideration of any delegated legislation that is part of this legislative scheme. The Report of the review is to be tabled in Parliament.

In addition, a person can, at any time, request the Regulator to review the exempt and notifiable low risk dealings prescribed in the Regulations, with a view to either

adding or removing certain dealings with GMOs from those categories on the basis of risk to health and safety of people or to the environment.

7. Competition Principles Agreement Statement

In respect of conducting a 'Legislation Review' as set out under the Competition Principles Agreement (11 April 1995), the guiding principle is that legislation (including Acts, enactments, Ordinances or Regulations) should not restrict competition unless it can be demonstrated that:

- the benefits of the restriction to the community as a whole outweigh the costs; and
- the objectives of the legislation can only be achieved by restricting competition.

However, it is notable that the provisions of 'Interpretation' relevant to that Agreement provide at clause 1(3) that:

Without limiting the matters that may be taken into account, where this Agreement calls:

- (a) for the benefits of a particular policy or course of action to be balanced against the costs of the policy or course of action; or
- (b) for the merits or appropriateness of a particular policy or course of action to be determined; or
- (c) for an assessment of the most effective means of achieving a policy objective;

the following matters shall, where relevant, be taken into account:

- (d) government legislation and policies relating to ecologically sustainable development;
- (e)
- (f) government legislation and policies relating to matters such as occupational health and safety, ...;
- (g)
- (h) the interests of consumers generally or of a class of consumers;
- (i) ...
- (j) ...

The Regulation Impact Statement for the Gene Technology Bill 2000 explained the extent to which the new regulatory system for genetically modified organisms restricts competition. The new regulations do not add to this.

Do the benefits to the community outweigh the costs?

The benefits of introducing this new regulatory system, both for the community at large, and for industry, are set out in the Regulation Impact Statement for the Gene Technology Bill 2000. The costs to the community were also explored in that document. It was concluded that, given the substantial benefits of the new regulation both to the community, in terms of the protection of health and safety and the environment, and to industry, in terms of providing a pathway to market for GMOs judged to be safe, the benefits of the system will outweigh the costs of regulation.

The proposed regulations to be made under the new *Gene Technology Act 2000* do not add substantially to these considerations, as they are not affecting the fact that there will be assessment of GMOs by an independent Regulator, and they ensure a level of regulation that is commensurate with the risks involved. The information requirements prescribed in the Regulations are on a par with those required in other regulatory systems, for example in the European Union and New Zealand, and the timeframes equivalent with those of similar domestic regulators.

The notion of varying the level of regulations in accordance with the risks involved is already prescribed in the *Gene Technology Act*, and has been mirrored in recent international legislation, such as the new European Directive on GMOs. The prescription in the regulations should therefore not serve to lower the community's confidence in the regulatory scheme.

Can the Governments objective only be achieved through restricting competition?

As detailed in **Part 1 - Background** to this RIS, an administrative scheme (based around the Genetic Manipulation Advisory Committee) has been operating for a number of years providing oversight in relation to research with GMOs, field trials involving GMOs and the commercial release of GMOs not regulated under existing regulatory schemes. This administrative scheme was based on voluntary compliance by industry and as such did not restrict competition.

However, as also outlined in this Regulation Impact Statement, there are a number of problems associated with continuing a voluntary administrative scheme of this nature (including regulatory uncertainty, an inability to enforce conditions and compliance with GMAC requirements etc).

The Regulation Impact Statement for the *Gene Technology Bill 2000* discusses Governments' examination of a range of options for addressing these problems, and explains that the approach finally adopted, whereby high risk dealings must be licensed by the Regulator and undertaken within accredited organisations (who have an IBC) was the only option that ensured that a number of important criteria were met. These criteria included a comprehensive assessment of the risks posed to public health and safety and the environment in relation to dealings with GMOs; a high level of transparency and stakeholder involvement in decision making; and regulatory certainty for industry in terms of timeframes and assessment processes.

The regulations to be made under the *Gene Technology Act 2000* do not detract from this reasoning and, if anything, ensure that the new regulatory system can adequately meet these criteria by, for example:

- prescribing information requirements for the undertaking of risk assessments;
- prescribing timeframes for the undertaking of risk assessments;
- ensuring advisory committee procedures are transparent; and
- prescribing those dealings which must be licensed, and the conditions (including containment) under which lower risk dealings can be undertaken.