

An example of how GTEC advice shapes the regulatory system is GTEC's input to the recent review of the RAF. The revised RAF reflects GTEC's input — guidance on better risk communication and encouragement to provide a more transparent approach to explaining uncertainty in the risk estimates. GTEC has also developed draft ethical guidelines in relation to GMOs as well as developing working papers and making submissions as listed below.

GTEC has produced working papers on:

- The ethical aspects of risk including multiple facets of managing risk ethically
- Release of Information and Notification under the *Gene Technology Act 2000*
- Ethical Issues Arising from the Genetic Modification of Animals (including animal welfare considerations)
- Ethical Issues Associated with Transkingdom Gene Transfer
- 'GMOs, Lay Understandings and civic ethics'
- 'A history of ideas about environmental precaution'

GTEC also made submissions in response to the:

- National Health and Medical Research Council's (NHMRC) release of Draft Guidelines and Discussion Paper on Xenotransplantation
- Draft Australian Code of Practice for the Care and Use of Animals for Scientific Purposes(7th Edition)
- Australian Health Ethics Committee (AHEC) paper Animal-to-human transplantation research: How should Australia Proceed?
- NHMRC Draft Australian Code for Conducting Research — 2004
- NHMRC National Statement on Ethical Conduct in Research Involving Humans
- Victorian Biotechnology Ethics Advisory Committee 'Statement of ethical principles for biotechnology'

The Review heard that there was considerable overlap between the roles and functions of GTEC and GTCCC and that this could be overcome and efficiency enhanced if a single committee advised on ethical and social issues as is typically the case both within Australia and internationally. For example, AHEC, the Victorian Biotechnology Ethics Advisory Committee and the New Zealand Bioethics Council all advise on ethical and social issues.

During consultations, members of GTEC expressed strong support for combining the two committees into one.

***Recommendation 5.2: The Review recommends that GTEC and GTCCC be combined into one advisory committee, with the combined functions of the two committees.***

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NGOs, consumer groups and farming groups opposed to the introduction of GMOs argued that the Regulator should consult equally with all three committees, including on licence applications, and give each committee's advice equal weighting. In contrast, industry and research groups strongly supported the current arrangement with GTTAC giving advice on applications and GTEC and GTCCC giving advice of a more general nature.

Risk communication and community consultation for commercial release licence applications were highlighted as important issues during consultations. The Review was told that commercial release licence applications have to date generated the most public interest and concern.

The Review concluded that the functions of the new single statutory committee should include providing advice within the confines of the Act, on the request of the Regulator or the GTMC, on community consultation and risk communication matters for the DIR commercial licence application process.

***Recommendation 5.3: The Review recommends that a function of the new single statutory committee include providing advice within the confines of the Act, on the request of the Regulator or the GTMC, on community consultation and risk communication matters for the DIR commercial licence application process.***

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## Stakeholders consulted on applications

Beyond the operation of the statutory committees, stakeholders expressed some concern about the appropriateness of some of the consultations, particularly related to prescribed agencies and local government.

The prescribed agencies that have statutory responsibilities relevant to the regulation of GMOs are listed below. It is important to note that along with the Regulator, these agencies are responsible for protecting public health and safety and/or the environment in relation to GMOs and GM products.

The prescribed agencies with responsibilities for regulating GMOs and GM products

- the Australian Pesticides and Veterinary Medicines Authority (APVMA) regulates pesticides and veterinary medicines, including evaluation of product efficacy issues and trade from a residue perspective;
- Food Standards Australia New Zealand (FSANZ) is responsible for setting food standards, including mandatory pre-market safety assessments of GMOs and GM products in human food;
- Therapeutic Goods Administration (TGA) regulates the quality, safety and efficacy of therapeutic products, including human medicines containing GMOs or GM products;
- National Industrial Chemicals Notification and Assessment Scheme (NICNAS) covers the evaluation of industrial chemicals, including GMOs and GM products; and
- Australian Quarantine and Inspection Service (AQIS) / Biosecurity Australia covers imported goods and quarantine including the importation of GMOs and GM products.

While the NHMRC has no responsibility for regulating GMOs and GM products, it is presently included as a prescribed agency. The Review heard that the history to the inclusion of the NHMRC as a prescribed agency related to the cross representation between the previous voluntary system (GMAC) and the NHMRC Gene and Related Therapies Advisory Panel (GTRAP).

In its submission to the Review, the NHMRC pointed out that it was not a regulatory agency like the other prescribed agencies, and noted that this situation has led it to debate what role it should take in relation to the matters referred to it by the Regulator. NHMRC expressed the view that it was best suited to providing specialist advice at the request of the Regulator, for example, where a new GMO first comes before the Regulator rather than being consulted on individual licence applications.

The Review considered whether changing the role of the NHMRC would adversely impact on the regulatory system. In consulting with the Regulator, the Review heard that, from a public health perspective, this would not be the case, as other prescribed agencies cover this area.

The Review concluded that the NHMRC could be removed from the list of prescribed agencies as this would not result in a gap in the assessment of public health. Removing the NHMRC from the list would not preclude the Regulator seeking advice from the NHMRC when it is considered necessary and appropriate.

*Recommendation 5.4: The Review recommends that, in light of the NHMRC's practical experience as a prescribed agency, its role be changed from a prescribed agency to one where the Regulator can seek its advice as appropriate.*

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### **Consultation with local government**

With reference to local government, the Review heard concerns about its ability and capacity to participate meaningfully in consultation processes. While local governments differ in size and resources, and significantly in their level of engagement with GM issues, the Review noted that they are the elected representatives of communities and concluded that it is highly appropriate that they be consulted as part of the Regulator's decision-making process.

### **Consultation on applications that present a significant risk**

The Regulator's submission recommended amending section 49 of the Act, which requires the Regulator to assess whether a proposed dealing may pose significant risks to the health and safety of people and the environment prior to preparing the RARMP. If the Regulator decides that the dealing may pose a significant risk, then the Act requires the Regulator to consult with the public on the application as well as the RARMP which she prepares.

The Review concluded that the requirement to make a judgment on the risk of a GMO prior to the development of the comprehensive RARMP is problematic. It would be more appropriate to include identification of any significant risks to health and safety of people and the environment in the relevant RARMP, after the Regulator has had the opportunity to undertake a detailed assessment of the potential risks. The second round of public consultation should then take place after the Regulator has reviewed the RARMP following the initial round of consultation under section 52. The Review concluded that section 49 should be deleted and that sections 51–52 should be amended as outlined in Recommendation 5.5 below.

*Recommendation 5.5: The Review recommends that section 49 should be deleted and that sections 51–52 should be amended to:*

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- *require the Regulator to identify whether or not the GMO poses a significant risk to the health and safety of people or the environment as part of the preparation of the RARMP;*
  - *provide that where the Regulator gives notice of a decision that a GMO may pose a significant risk that a second round of public consultation should then take place after the Regulator has reviewed the RARMP following the initial round of consultation under section 52.*
- This additional consultation period should be 20 working days.*
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## Timeframes

The statutory time frames for applications under the Act were another key theme in the consultations. These time frames are intended to provide certainty for those applying for licences and other instruments. The time frames within which the Regulator must issue, or refuse to issue, a licence or other instrument are as follows:

*Table 2: Statutory time frames for applications under the Act*

Category	Time frame
DNIR (Dealings Not involving Intentional Release)	90 working days (Regulation 8)
DIR (Dealings involving Intentional Release)	170 working days (Regulation 8)
Accreditation	90 working days (Regulation 16)
Certification	90 working days (Regulation 14)

Presently, there are no statutory time frames for some types of applications, such as variations.

Industry and research groups were concerned that the application time frames are too long, with particular concerns over DIR processes, where the Act does not distinguish between limited and controlled field trials that enable data to be collected and commercial releases. The Review heard that this lack of distinction creates inefficiencies associated with having to prepare separate, detailed applications for the field trial and then the commercial release, as well as having to wait for up to 170 working days for each licence. Notably, the Regulator also recommended that consideration be given to differentiating between field trial and commercial release licences.

The Review considers the DIR category to be a key area necessitating change based on four years' practical experience in the working of the Act. It concluded that the DIR category should be split to distinguish between field trial and commercial release licences, and that the associated information requirements and application documents be streamlined to eliminate as much duplication as possible. These changes would reduce administrative complexity for industry and research groups in the first instance, and also for the OGTR.

***Recommendation 5.6: The Review recommends that the DIR category be split to distinguish between field trial and commercial release licences.***

The splitting of field trials and commercial releases will allow appropriate time frames to be set for field trials and commercial releases. The Regulator noted that assessment of field trials is much less involved than that required for commercial releases.

The Review heard that for field trials, one round of consultation with prescribed

agencies and others specified under section 50 would be sufficient and could be done concurrently with the public consultation.

The Review therefore concluded that DIR field trial licences could be given a time frame of 150 working days (that is 170 working days minus the 20 working day consultation period). As stated earlier, if the Regulator determines that the GMO may pose a significant risk, thereby triggering two rounds of public consultation on the RARMP, the statutory time frame should be extended to 170 working days. The Review considers that this will result in important efficiency gains for industry as the bulk of the DIR applications are for field trials.

***Recommendation 5.7: The Review recommends that DIR field trial licences be subject to a statutory time frame of 150 working days or 170 working days for a GMO that the Regulator assesses may pose a significant risk.***

The Review noted that the OGTR's 170 working day statutory time frame was shorter than those of comparable regulatory agencies (see below).

#### Statutory time frames for decision-making

- OGTR DNIR licences: 90 working days
- OGTR DIR licence: 170 working days
- TGA registration: 255 working days
- APVMA registration: approx. 12 months (approx. 255 working days)
- FSANZ safety assessment: approx. 12 months (approx. 255 working days)

The Regulator recommended that the time frame for commercial release licences be extended. For a commercial release licence, as the scale would not usually be limited there are a broader range of environments and ecosystems that must be considered in the risk assessment. In her experience the Regulator pointed out that this requires more rigorous and resource intensive assessment.

The Review also considered it appropriate that the time frame allows the flexibility for the Regulator to tailor the length of public consultation to the type and extent of commercial release. The Review noted that a timeframe of 255 days would be appropriate as it would also enable the Regulator to align her decision to the greatest extent possible with the other regulatory agencies. The Review concluded that the appropriate time frame for the assessment of a commercial release is 255 working days. The Review further concluded that if the Regulator identifies that a commercial release application poses a significant risk, the additional round of consultation on the RARMP must be conducted within the 255 day timeframe.

***Recommendation 5.8: The Review recommends that the statutory time frame for commercial DIR licences be extended to 255 working days (this is consistent with other relevant regulatory systems) to ensure that the Regulator has adequate time for assessment and public consultation. If the Regulator identifies that a commercial release application poses a significant risk, the additional round of consultation on the RARMP must be conducted within the 255 day timeframe.***

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## Licence variations

The Review also considered whether it was appropriate for statutory time frames to apply to variations to licences. Given that the time frames exist to provide a level of certainty to applicants, the Review agreed that a time frame should apply for variations. The Review heard that variations are routinely made within 90 days. The Review concluded that a 90 day time frame should apply for variations. This issue is also referred to in chapter 6.

In coming to this conclusion, the Review found that there should be constraints included in the Act to prevent a variation being used to unreasonably extend the coverage of a licence. Noting that the Act already provides in subsection 71(2) that a DNIR licence should not be converted to a DIR by variation, the Review considered that the Act should also provide that:

- a field trial should not be converted to a commercial release by variation;
- a variation should be able to be assessed by the original RARMP (that is, the variation should not present risks that have not been assessed);
- the location of the field trial can only be varied where the Regulator is satisfied that appropriate local councils have been consulted; and
- regulations may prescribe other limitations.

The Review also noted that while it was clear that the Act anticipates licence-holders seeking variations in subsection 72 (5), there is no section that explicitly states that a licence-holder can seek a variation.

***Recommendation 5.9: The Review recommends that a 90 working day statutory time frame be applied to variations for licences and there be an explicit power to allow a licence-holder to apply for a variation.***

***The restrictions on a variation should be that:***

- ***a variation cannot turn a DNIR into a DIR;***
- ***a variation cannot turn a field trial into a commercial release;***

- *the variation must be able to be assessed under the original RARMP;*
- *for a variation involving a new location of the field trial it can only be approved where the Regulator is satisfied that appropriate local councils have been consulted; and*
- *the Act should permit the regulations to prescribe other limitations.*

## ToR 5 — Effective and appropriate enforcement of compliance

During consultations the Regulator set out her approach to enforcement. In deciding what action to take in response to a licence breach the Regulator considers a range of factors, including the compliance history of the licensee, the need for deterrence and whether the breach involves an immediate risk to health and safety of people and the environment. The action that can be taken ranges from prosecution, suspension or cancellation of the licence, to directions, variation of licence conditions and cooperative compliance.

The Act has a range of criminal offences ranging from a \$5500 fine (where no fault or intention needs to be demonstrated) for an individual that breaches the conditions relating to a low risk dealing, up to a fine of \$1.1 million per day for a corporation that breaches a licence condition in a way that is likely to cause significant damage and whose action is reckless or malicious.

The penalties assigned for various offences were generally supported or received little attention in submissions, although the Review noted that the offence provisions had yet to be tested. However, one submission recommended that the offence provisions be assessed as part of this review, and that they be monitored on an ongoing basis to ensure that they are adequate and effective in ensuring compliance. Additionally, one submission suggested that the penalties were too low. The Review noted that the original penalties were developed in accordance with Commonwealth criminal law policy which stipulates that the value of a Commonwealth penalty unit be periodically reviewed. Consequently, the penalties are subject to indexation.

To date the Regulator has decided not to refer any breaches of licences to the Director of Public Prosecutions. Based on the factors set out above, the most stringent action the Regulator has taken has been to vary conditions of licences to require a licenceholder to take actions necessary to bring a licence back into compliance, to ensure ongoing compliance, or to ensure ongoing management of risks.

In submissions, groups concerned about gene technology have suggested that cooperative compliance fails to create an effective deterrent. These views were reiterated during stakeholder meetings where some groups suggested that offence

provisions need to be used to provide a deterrent against non-compliance. For example, one participant was concerned that even though there were a number of breaches of licences there had been no prosecutions.

On the other hand, industry generally supported the Regulator's approach to compliance. At stakeholder meetings many industry groups highlighted the good relationship with the Regulator allowing them to work together to develop better practices, risk management plans and crop management plans. However, some industry stakeholders wanted more clarity on instances and type of remedial actions that may be required by the Regulator.

The Review considers that the Regulator's model of compliance which includes cooperative compliance has been very helpful in educating a previously unregulated industry.

The Review concluded that the enforcement approach of the Regulator is appropriate and noted the Regulator is currently revising her enforcement protocol document which should assist the Regulator in explaining the basis of enforcement decisions. While the Review supports the model of compliance used by the Regulator, it investigated additional tools for ensuring compliance.

In stakeholder consultations one organisation suggested there were not enough tools for the Regulator to use to ensure compliance.

Currently the Regulator has powers under section 146 of the Act to give directions to a licence-holder or person covered by a licence if she believes on reasonable grounds, that:

- (a) a licence holder is not complying with this Act or the regulations in respect of a thing; and
- (b) it is necessary to exercise powers under this section in order to protect the environment

However, in her submission the Regulator noted that if she assesses a breach of a licence not to be an immediate risk to the health and safety of people or the environment then arguably she cannot direct licence-holders to comply with the licence. The Review heard that situations have occurred when a licence-holder has planted a crop in a post-harvest GMO location before permission from the Regulator has been sought. In these cases the licence-holder has always acted cooperatively to protect the health and safety of people and the environment, in accordance with the Regulator's requirements.

The Review considers that even if there is not an immediate risk to health and safety of people or the environment it is important to maintain the integrity of licences. The Review believes that the Regulator should be able to direct a licence-holder if it is not complying with the licence, the Act and/or the Regulations, irrespective of if there

is an immediate risk to health and safety of people or the environment. This would ensure that all breaches of the licence could be dealt with, increase the Regulator's compliance tools and ensure the integrity of the Regulator's licences.

***Recommendation 5.10: The Review recommends that the Act be amended so that the Regulator has the power to direct a licence-holder, or a person covered by a licence, if she believes they are not complying with the Act or the Regulations to take reasonable steps to comply with the Act or Regulations.***

### Unintended presence

During consultations, concern was expressed that a person who unintentionally has an unapproved GMO on their property is unable to dispose of the GMO without breaching the Act. The Regulator can use offence provisions or injunctions to deal with unapproved dealing with a GMO. However, these tools are not suited to this case if the person wishes to act cooperatively and to dispose of the GMO in accordance with the Regulator's requirements to protect health and safety of people and the environment.

This could be addressed by way of directions by the Regulator or the granting of a special permit for the limited purpose of disposal. Currently the Regulator only has the ability to direct licence-holders.

The Review considers in cases where unlicensed GMOs are being grown inadvertently there should be a mechanism to aid cooperative compliance. It concludes that growers (or others who find themselves inadvertently dealing with an unlicensed GMO) should be able to apply to the Regulator for a special temporary permit to allow disposal of the GMO. The Regulator could issue the permit with terms and conditions requiring the permittee to deal with the GMO in such a way as she considers will protect health and safety of people and the environment.

***Recommendation 5.11: The Review recommends amending the Act to allow the Regulator to grant a temporary permit to persons who find themselves inadvertently dealing with an unlicensed GMO for the purpose of disposing of the GMO in a manner which protects health and safety of people and the environment.***

## Term of reference 6:

Examine whether compliance and administrative costs, including information requirements, for organisations working in gene technology are reasonable and justified compared to benefits achieved and possible alternatives to legislation.

## Term of reference 7:

Review the system of approvals and the application of regulatory requirements commensurate to the level of risk.

## Current system of approvals

The scheme of the Act prohibits dealings with GMOs unless the required approval has been obtained from the Regulator. An organisation must be accredited by the Regulator to deal with GMOs which come under one of the following four categories of dealings. In descending order of risk these categories are:

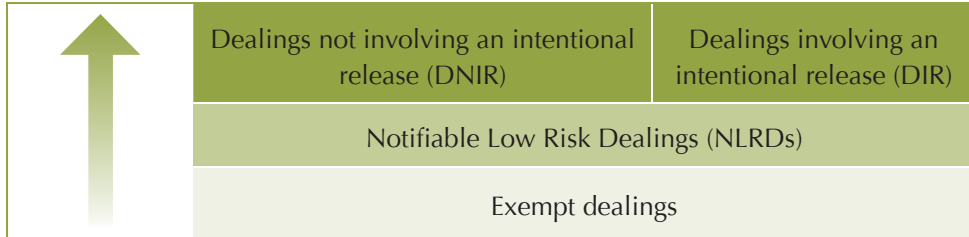
- Licensed dealings that will be released into the environment
- Licensed dealings that are kept contained in certified facilities
- NLRD that are kept contained in certified facilities
- Exempt Dealings that are kept contained in physical containment 1 (PC1) facilities.

In addition, there is a GMO register for GMOs that have been licensed and for which there is sufficient information to determine that the dealing can be undertaken without the requirement for a licence to be held by a named person or organisation.

In describing the different categories of risk, the intention of the regulatory system is to direct most effort towards the higher risk categories. Applicants must provide more detailed information for the licensed dealings than for the NLRDs and the

only information required for exempt dealings is to report on them in the accredited organisation's annual report to the Regulator. The approval processes for the various categories of dealings are described in more detail in Appendix 4.

Figure 1: Increasing risk and regulatory scrutiny



## Background on regulatory burden and administrative burden

The OECD<sup>1</sup> notes that Governments require businesses and private individuals to carry out or avoid certain actions or conduct (content obligations). Governments also require the provision of information on actions and conduct (information obligations). Both types of obligations can involve costs.

**Administrative burdens** are the costs imposed when complying with **information obligations** stemming from government regulation.

Regulatory burden is harder to define but for the purposes of this paper, **regulatory burdens** are the costs imposed when complying with both **content obligations and information obligations** stemming from government regulation.

The costs of regulatory burden

The costs of regulatory burden can include:

- a) the direct costs of **content obligations** such as the need for additional staffing, the purchase of new equipment, structural changes to buildings, legal and other external advice, travel and the introduction of staff training programs;
- b) the indirect costs of **content obligations** such as opportunity costs when organisations opt to do their business in other countries or using other technologies that are not subject to regulation;

1 *The Standard Cost Model: A framework for defining and quantifying administrative burdens for businesses*, OECD, August 2004.

**Case study:**

**Content obligations in the gene technology regulatory system**

The Regulator requires contained work involving GMOs to be done in physical containment facilities that are certified for the purpose and therefore must meet certain containment requirements.

The Regulator requires licence-holders who conduct field trials of GM crops to notify the proposed sites as GPS coordinates — this requires the use of a global positioning system unit.

The Regulator requires appropriate training for staff who work in certified facilities.

- c) the direct costs of **information obligations**, which can be increased staffing costs, the development of new reporting tools and IT support;
- d) the indirect costs of **information obligations**, which can include the opportunity costs when key staff are occupied on administrative tasks instead of the research tasks that are their core business and research funds that are directed away from research and into administration.

**Case study:**

**Information obligations in the gene technology regulatory system**

Accredited organisations are required to submit an annual report to the Regulator in a specific format.

Licence holders who conduct field trials are required to submit monthly monitoring reports to the Regulator.

**Guidance on what constitutes good regulation**

The Council of Australian Governments (COAG) has identified some practical objectives that should be taken into account in formulating regulatory measures<sup>2</sup>.

Three of these practical objectives are:

**1. Minimising regulatory burden on the public**

Legislation should entail the minimum necessary amount of regulation to achieve the objectives

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<sup>2</sup> 'Council of Australian Governments Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial councils and Standard-Setting bodies' (as amended by COAG June

**2. Minimising administrative burden**

Regulators should develop regulatory measures in ways that minimise the financial impact of administration and enforcement of regulation on governments and the sectors of the community which will be affected by them.

**3. Performance-based regulations**

Regulatory instruments should focus on outcomes rather than inputs. There should be no restrictions on the use of other standards as long as the objectives of the regulation are met.

In summary, COAG supports the need to keep the regulatory and administrative burdens to the minimum necessary to achieve the objective of the regulatory measure.

**Actions to minimise regulatory and administrative burdens**

Most Organisation for Economic Co-operation and Development (OECD) countries have programs in place to reduce administrative burdens and compliance costs. There are a range of recognised actions that can help to alleviate regulatory and administrative burden. Some of these recognised actions include:

- Streamlining process and paperwork requirements
- Quantitative targets for burden reduction
- Legislative simplification and codification
- Privatisation of certification function
- Introducing further statutory time limits and ‘silence is consent’ provisions

In examining the regulatory burden of the Act, the Review looked for opportunities where these actions could be employed without compromising the objective of the legislation to protect the health and safety of people and the environment.

**A reasonable and justified regulatory burden**

**Exempt dealings**

Research organisations stated that the current obligations to report on exempt dealings represented an administrative burden that was excessive, given that this category of dealings is exempt because they are very low risk. Research organisations argued that ‘exempt should mean exempt’. The Review heard from GTTAC that exempt dealings do not require regulatory oversight and do not need to be contained in PC1 facilities.

The Review concluded that:

- the exempt category of dealings should continue to be listed in the Regulations;

- the criteria used to assess dealings proposed for the exempt category should be explained in a document available to the public;
- the Regulator should undertake regular reviews of the list of dealings in this category;
- there should be no other regulatory requirements on exempt dealings beyond their listing in the Regulations.

*Recommendation 6.1: The Review recommends that there should be no legislative requirements on exempt dealings beyond listing of in the Regulations. The Regulator should undertake regular reviews of the listing to ensure it remains current.*

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### **Notifiable low risk dealings**

Applications for NLRDs are currently reviewed by the Institutional Biosafety Committee (IBC) and forwarded to the Regulator as a notification. The notification must take place within 14 days of the IBC assessing the work. All NLRDs are included on the GMO record which is accessible by the public.

Research organisations had two main concerns with the regulatory requirements on NLRDs: the information requirements in the application form were repetitive and excessive; and there was no capacity for variation of NLRDs so that any changes to the information (whether it was a change in contact officer or a change in GMOs) triggered the need to submit a new NLRD, resulting in additional workload for the IBC and repetitive paperwork requirements. Research organisations stressed many times throughout the consultation process that there was a thirty-year history in Australia with this type of contained research using GMOs and no reported problems. They argued that because it was low risk work with a safe history, the regulatory requirements should be simplified.

The Review heard from GTTAC that NLRD activities did not warrant the current regulatory burden since the NLRDs were by definition low risk. The Review determined that the regulatory burden for NLRDs could be reduced, while still managing NLRDs appropriately, by:

- removing the requirement to notify an NLRD within 14 days and replacing it with a requirement to report on all NLRDs in the annual report of the IBC — on the basis that during the year the IBC must keep a list of the current NLRDs being conducted by the organisation and produce it if requested by the Regulator; and
- rationalising the information requirements in the application form as intended in the review of the Regulations.

***Recommendation 6.2: The Review recommends that the requirement to notify NLRDs to the Regulator within 14 days be removed and replaced with a requirement to include a report of all NLRDs conducted in the last 12 months in the accredited organisation's annual report, and to maintain an up-to-date list for inspection and auditing purposes.***

### **Dealings not involving an intentional release**

Applications for DNIRs are reviewed by the IBC and sent to the Regulator for decision. The Regulator is allowed some discretion in consulting on DNIRs. All DNIRs are included on the GMO record. The Review noted that the Regulator is concurrently reviewing the regulations, which provide the detail for regulating DNIRs.

The main concern from research organisations regarding DNIRs was the length of time taken to process variations. Currently, there is no statutory time frame for consideration of variations and there is a perception that they may be assigned a lower priority than applications (which do have statutory time frames). Researchers argued that a lengthy delay in processing variations can result in missed opportunities for collaborations. Examples were given where a researcher may attend a conference and make contact with other researchers either within Australia or overseas working in a related field with a potential for collaboration. If the collaboration is outside the scope of a current approval, it may require either a new application or a variation. A new application has the certainty that a decision will be taken within 90 days but a variation does not.

The Review considered that it was reasonable to provide a statutory time frame for variations. This would provide greater certainty to regulated organisations and encourage the Regulator to develop decision criteria that would streamline the decision-making process. This matter was discussed in chapter 5.

### **Dealings involving an intentional release**

Applications for DIRs are reviewed by the IBC and sent to the Regulator for decision. The Regulator is required to consult on DIRs with a range of organisations and the public. All DIRs are included on the GMO record.

There were two major concerns from accredited organisations regarding DIRs. As with DNIRs, the fact that there was no time frame for considering variations led to uncertainty and missed opportunities. Commonly in the DIR category, the applicant was seeking a variation to allow a particular crop to be planted to follow on from the trial crop. Therefore a decision was needed within the window of opportunity for planting the crop. The Review agreed that a time frame for processing variations was justified. This was discussed in chapter 5.

Secondly, organisations conducting DIRs believed the information requirements for conducting early stage field trials were onerous and repetitive. They argued that there should be two categories of DIR — field trial and commercial release — and that the information requirements for field trials should be streamlined. The Review agreed that there was a good case for differentiating field trials from commercial release applications. This was discussed in chapter 5.

### **Certification guidelines**

Work involving GMOs must be conducted in facilities certified for the purpose by the Regulator. The Regulator categorises the containment levels in these facilities as physical containment levels 1–4, where PC1 is the simplest level of containment and PC4 is the most sophisticated. Most of the work approved by the Regulator is conducted in PC2 facilities. PC2 facilities include university research laboratories, animal houses, insectories and aquaria.

The Regulator can impose conditions on certification and can vary the certification.

The Review heard that the Regulator had focused considerable effort and resources into revising the certification guidelines when it was found that the original (transitional) guidelines brought over from the previous voluntary system contained many ambiguities. The process of revision had included consultation with affected parties.

Despite the efforts of the Regulator to bring clarity and certainty to the guidelines, certification of PC2 facilities remains an area causing difficulty and confusion for accredited organisations.

The Review found that concerns with certification were of two types:

- interface issues; and
- difficulty in meeting specific requirements and/or the process of obtaining a variation.

Interface issues relate to:

- conflicting requirements in the OGTR certification guidelines, the AQIS class 5 criteria requirements, the relevant Australian Standard (AS/NZS 2243.3:2002 *Safety in laboratories — Part 3: Microbiological aspects and containment facilities*) and to a lesser extent State occupational health and safety legislation; and
- facilities being audited separately by AQIS and OGTR.

The Review understood that the OGTR and AQIS requirements were addressing different risks but believed there was scope for greater harmonisation.

### **Case Study: Aquaria**

Quarantine requirements for aquaria are designed to prevent the escape of pests or diseases associated with imported fish from being introduced to Australian waterways. They restrict the flushing of water from the aquaria unless it has been suitably processed.

OGTR requirements for aquaria are designed to ensure the containment of the GMO. If the fish is a GMO they are designed to contain the fish within the aquarium but allow the aquarium water to be flushed. If the fish is hosting a GMO such as a GM bacteria or virus, then the requirement will be similar to the Quarantine requirement.

The Review also understood that both sets of requirements were based on the AS/NZS standards but with a tighter focus on managing relevant risks — for example, AS/NZS 2243 also addresses OH&S issues.

The Review heard that the OGTR and AQIS are currently seeking to harmonise their guidelines where possible. The Review supports this work and after these guidelines are harmonised recommends that the OGTR and AQIS establish a system of single audits to meet the needs of both organisations, thereby reducing the regulatory burden.

Accredited organisations also expressed some confusion about the possibility of seeking variations to the guidelines where they believed the facility could achieve a similar outcome to the stated requirement by a different means. Some organisations had successfully obtained approval for variations while others did not appear to know it was possible.

The Review concluded this confusion could be minimised by:

- providing some information and guidance on variations to accredited organisations; and
- introducing more outcome focused language to the guidelines (the Review was aware that the Regulator had moved in this direction with her revised guidelines and encourages her to go further).

***Recommendation 6.3: The Review recommends that the OGTR certification guidelines and the AQIS guidelines be harmonised as far as possible and that the OGTR and AQIS establish a system of single audits to meet the needs of both organisations as soon as practicable.***

*Recommendation 6.4: The Review recommends that the harmonisation exercise be used as an opportunity to ensure that the outcome focussed language in the certification guidelines is used to the maximum extent possible.*

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*Recommendation 6.5: The Review recommends that the Regulator develop information and guidance for accredited organisations on obtaining certification variations.*

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## Accreditation guidelines

For dealings other than those that fall in the exempt category, the work must be conducted either:

- by an organisation that is accredited for the purpose by the Regulator (it is a condition of accreditation that the organisation maintain an IBC); or
- by an organisation that has access to the IBC of an accredited organisation.

It is the IBC that reviews all applications going to the Regulator and all monitoring and compliance activities are done with the assistance of the IBC. Communication from the OGTR to the accredited organisation is usually via the IBC.

The Regulator can impose conditions on accreditation and can vary the accreditation.

The Review noted that currently it is the accreditation guidelines that require the reporting of exempt dealings in the accredited organisation's annual report. Consistent with the recommendations on exempt dealings discussed above, the Review considered that this requirement should be removed.

*Recommendation 6.6: The Review recommends the removal of the requirement in the accreditation guidelines for the reporting of exempt dealings in the annual report of an accredited organisation.*

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## Application forms

The Review considered the current application forms, noting the information required in them was directly related to the information requirements in the regulations. The Review heard that a concurrent review of the regulations was likely to result in simplified application forms. The Review supports simplifying the application forms.

## Summary

The Review concluded that the regulatory burden on exempt dealings and NLRDs was not commensurate with these low risk activities and has made some recommendations to minimise the regulatory burden. The Review also concluded that the administrative

burden on licensed dealings (both DNIRs and DIRs) can be reduced and has made some recommendations to achieve this. Table 3 summarises the changes proposed by the Review to alleviate regulatory and administrative burden.

*Table 3: Summary of changes proposed to alleviate regulatory and administrative burden*

	Change proposed	Action to alleviate regulatory and/or administrative burden
Exempt dealings	Make exempt dealings really exempt — no requirements beyond a list of exempt dealings in regs	<ul style="list-style-type: none"> <li>• Legislative simplification</li> </ul>
NLRDs	Remove requirement to notify in 14 days of commencement of activity. Substitute reporting requirement in annual report IBC to maintain records for inspection	<ul style="list-style-type: none"> <li>• Legislative simplification</li> <li>• Streamline process and paperwork requirements</li> </ul>
DNIRs	Time frames for variations (see chapter 5 for details)	
DIRs	Time frames for variations Distinguish field trials from commercial releases and simplify information requirements for field trials (see chapter 5 for details)	<ul style="list-style-type: none"> <li>• Streamline process and paperwork requirements</li> </ul>
Certification guidelines	Greater harmonisation with AQIS certification guidelines and relevant Australian Standards and use outcome-focussed language Single audits by AQIS and OGTR	<ul style="list-style-type: none"> <li>• Streamline process and paperwork requirements</li> </ul>
Accreditation guidelines	Remove reporting requirement for exempt dealings	<ul style="list-style-type: none"> <li>• Streamline process and paperwork requirements</li> </ul>
Application format	Redesign application forms	<ul style="list-style-type: none"> <li>• Streamline process and paperwork requirements</li> </ul>
Variations	Introduce statutory time limit	<ul style="list-style-type: none"> <li>• Introduce statutory time limit</li> </ul>

## INTERFACE WITH OTHER SYSTEMS

### Term of reference 8 and 9:

8. Examine the nationally consistent scheme for gene technology regulation in Australia and identify any need for, and ways to achieve, improvements in its consistency, efficiency and coordination.
9. Examine the interface between the Act and other Acts and schemes (either Australian Government or State and Territory) that regulate gene technology and gene technology products. Identify any discrepancies including regulatory gaps and areas needing consistency and harmonisation of provisions.

### Improvements in consistency, efficiency and coordination between Commonwealth Regulators of GMOs and GM products

The Review heard from industry that there was a perceived sense of overlap and duplication between the Commonwealth regulators.

The Review interviewed the other regulatory agencies and concluded that, within their legislative constraints, they work well together with the Regulator to minimise duplication and ensure that the system works seamlessly.

However, the Review was concerned that the good relationships may be personality dependent and concluded that it would be desirable to establish a formal consultation mechanism.

*Recommendation 7.1: The Review recommends the establishment of a regulators' forum to exchange information between the prescribed agencies and the Regulator, to ensure that duplication is minimised and the systems work seamlessly between each other.*

In addition, there may be a need for more effective communication with applicants and the public to alleviate the sense of overlap and/or duplication.

The Review examined key provisions in the relevant legislation as summarised in table 4.

Table 4: Comparisons across Commonwealth regulatory agencies of various provisions

	OGTR	APVMA	TGA	NICNAS	FSANZ	AQIS <sup>1</sup>
Consideration of marketing and trade matters as part of evaluation	NO	YES Considers maximum residue limits of trading partners to test if there would be 'undue risk to trade'	NO	NO	YES However this consideration is assigned a lower priority than the health and safety assessment	NO
Consideration of benefit	NO	NO	NO	NO	YES Under its Act, FSANZ is required to have regard to the benefits and costs for Government, consumers and industry when developing or varying a standard	NO
Consideration of efficacy	NO	YES	YES	NO	NO	NO

<sup>1</sup> Based on the *Quarantine Act 1908*

	OGTR	APVMA	TGA	NICNAS	FSANZ	AQIS <sup>1</sup>
<b>Fast track approvals in an emergency</b>	NO	YES Can issue a permit for an emergency (permit does not need to be time limited)	YES Minister can automatically register a drug if it urgently needs to be stockpiled or deals with a threat to public health caused by an emergency (expires when specified in notice)	YES Minister can introduce a chemical prior to approval in an emergency if it is in the national interest and is consistent with the reasonable protection of health and safety (expires when permit is withdrawn)	YES Can issue an emergency standard (within 12 months standard must follow through normal process)	NO
<b>Post market monitoring and review of approvals</b>	YES Statutory conditions of all licences that licence holders report any additional information as to risks, contraventions of licence and unintended effects. A systematic program is also currently under development	YES And also has an adverse experience reporting program and existing chemicals review program	YES And also has an adverse reaction reporting program	NO Control from point of sale is the responsibility of the States. NICNAS post marketing surveillance is via its existing chemicals review program	YES	YES Permits may be revoked if quarantine risk alters

	OGTR	APVMA	TGA	NICNAS	FSANZ	AQIS <sup>1</sup>
<b>Public Access to data</b>	YES (see discussion in chapter 4)	YES A summary of the application is available to the public, as are summaries of major application evaluations. Full reports (without CCI) can be read in Canberra	NO	YES All assessment reports are publicly available	YES There is a public register	YES Non-confidential Import Risk Analysis Reports are publicly available
<b>Data protection</b>	YES Has the ability to declare information CCI. CCI cannot be used by the Regulator to assess an application from a different applicant	YES Has the ability to declare information CCI and also has the ability to confer data exclusivity	YES Has the ability to declare information CCI.	YES Has the ability to declare information CCI and also has the ability to confer data protection via a 5-year certificate system	YES Has the ability to declare information CCI	NO

	OGTR	APVMA	TGA	NICNAS	FSANZ	AQIS <sup>1</sup>
<b>Requirement for peer reviewed data only</b>	NO Requires raw data as well International guidance on data requirements is still under development (see text in chapter 4)	NO Requires raw data as well Data requirements are consistent with international guidelines	NO Requires raw Data requirements are consistent with international guidelines	NO Requires raw data as well Data requirements are consistent with international guidelines	NO Requires raw data as well Data requirements are consistent with international guidelines	NO
<b>Testing done by regulatory agency prior to approval</b>	NO Applicant is required to submit relevant studies	NO Applicant is required to submit relevant studies	NO Applicant is required to submit relevant studies	NO Applicant is required to submit relevant studies	NO Applicant is required to submit relevant studies	NO
<b>Testing done by regulatory agency prior to approval</b>	NO Applicant is required to submit relevant studies	NO Applicant is required to submit relevant studies	NO Applicant is required to submit relevant studies	NO Applicant is required to submit relevant studies	NO Applicant is required to submit relevant studies	NO
<b>Appeal available under AAT Act</b>	YES	YES	YES	YES	YES	NO

	OGTR	APVMA	TGA	NICNAS	FSANZ	AQIS <sup>1</sup>
<b>Review available under AD(JR) Act</b>	YES for aggrieved persons. Section 183A of the Act extends the definition of 'persons aggrieved' to include the States	YES for aggrieved persons	YES for aggrieved persons	YES for aggrieved persons		
	YES for aggrieved persons	YES, for aggrieved persons				
<b>Advisory or consultative committees</b>	YES GTTAC GTEC GTCCC	YES Industry liaison committee; Registration liaison committee; Community Consultative Committee; Manufacturers Licensing Scheme Liaison Committee	YES Technical Expert committees; Industry consultative committees	YES Technical Advisory group; Industry-Government Consultative Committee; Community Engagement Forum; State/Territory MoU Liaison Committee	YES Standards development advisory committees; Proposed community consultation committee	YES A number of industry consultative committees

The Review found that there was a high degree of consistency between systems and concluded that the following changes to the Act would further improve consistency, efficiency and coordination across Commonwealth systems:

1. Create capacity to fast track approvals in an emergency (this was discussed in chapter 4).
2. Encourage the Regulator to remain active at the international level to develop an internationally consistent data package (this was discussed in chapter 4).
3. Establish a regulators' forum with the object of maintaining and improving the transparency and seamless operation of the Commonwealth regulatory systems with responsibility for GMOs (see recommendation 7.1)

### Areas needing harmonisation between Commonwealth Regulators of GMOs and GM products

Many submissions to the Review from consumer organisations and NGOs and some individuals called for the OGTR to become a 'one stop shop' that integrates all regulatory aspects of gene technology. However, in discussing this issue during public consultations, it remained unclear to the Review whether this was a call for a single point of entry (for example, having received an application, the OGTR would refer it onto FSANZ if it was intended for human consumption) or whether this was a call for the OGTR to regulate all aspects of GMOs regardless of whether they were a food, a therapeutic good or an agricultural chemical and so on.

The Review could not find an example in the other countries examined of a gene technology regulatory agency that had such a broad mandate (refer chapter 8). Having regard to the fact that the possibility of setting up the OGTR as a one stop shop had been considered and rejected during the development phase of the regulatory system and that such a move would represent a major overhaul of all the relevant Commonwealth regulatory schemes, the Review considered that there would need to be compelling evidence that the current arrangement was failing, to justify a move to the one stop shop model. The Review did not find any evidence of a major failure.

The Review identified one area where greater harmonisation between Commonwealth regulators was desirable and had the potential to alleviate regulatory burden. This was in the differing facility certification and audit requirements of the OGTR and AQIS. This matter was discussed in chapter 6.

## Improvements in consistency, efficiency and coordination between the gene technology regulatory system and relevant State legislation

The Review heard that research and industry organisations were frustrated by the numbers of different pieces of legislation that cover similar issues and require compliance. There is a potential for compliance with one scheme to cause non-compliance with another. Research organisations stressed that practices and procedures in laboratories were designed to meet their obligations under State occupational health and safety requirements and that some OGTR requirements seemed unnecessarily duplicative.

Table 5, which was provided by the Children’s Cancer Research Institute, highlights the different regulatory schemes that must be complied with by a contained research facility, working with GMOs, in New South Wales. Applicable regulatory regimes differ between jurisdictions. Different regimes also apply in the context of GMOs to be released into the environment.

*Table 5: Regulatory schemes for contained work on GMOs (New South Wales)*

The <i>Gene Technology Act 2000</i> (C’wth) and Regulations (2001) and all guidelines of the Office of the Gene Technology Regulator
The <i>Quarantine Act 1908</i> and The Quarantine Proclamation (1998) (C’wth)
The <i>Animal Research Act 1985</i> (NSW) and Regulations (1995)
The <i>Occupational Health and Safety Act 2000</i> (NSW) and Regulations (2001)
The Australian Code of Practice for the care and use of animals for scientific purposes 7th Edition (NHMRC 2004)
Australian and New Zealand Standard 2243:3 Safety in laboratories — Microbiological aspects and containment facilities (2002)

*Source: Children’s Cancer Research Institute, NSW.*

While it is outside the scope of this review to recommend changes to State legislation, the Review considered it would be desirable for the Regulator to maintain an awareness of occupational health and safety legislation and animal welfare legislation.

The Review considered that an important way to reduce the duplication in regulations for researchers is to investigate ways in which they can be made to conform with Australian Standards. The Review concluded that the Regulator should participate in opportunities for review of the Australian Standards to help her align her requirements.

***Recommendation 7.2: In the special case of Australian Standards that apply to laboratory facilities, the Review recommends that the Regulator actively participates in every opportunity for review so as to align her requirements with those of Standards Australia.***

## CHANGING CIRCUMSTANCES

### Term of reference 10:

Examine emerging trends and international developments in biotechnology and its regulation and whether the regulatory system stipulated by the Act is flexible enough to accommodate changing circumstances

### Emerging trends

Current research into GMOs that may lead to new commercial products falls into three categories:

- First generation traits: GMOs with input traits (e.g. herbicide tolerance, insect resistance, disease resistance, and salt tolerance) that provide benefits on the farm.
- Second generation traits: GMOs with output traits (e.g. nutritional properties) that provide benefits to the producer and consumer.
- Third generation traits: GMOs that can be used as factories to produce pharmaceuticals or industrial oils.

Table 6 describes first, second and third generation GM crops that are currently being developed in Australia.

Table 6: GM crops being developed in Australia

Traits		Crop	Stage in pipeline	
First generation traits	Environmental stress tolerances	Salt tolerance	Wheat	Proof of concept <sup>1</sup>
		Drought tolerance	Wheat	Proof of concept <sup>2</sup>
		Acid soil tolerance	Barley	Proof of concept
		Frost tolerance	Pasture species	Technology Discovery
		Insect pest protection – Bt/Ht	Wheat	Proof of concept
Pest control		Insect pest protection – Bt/Ht	Cotton	Field trials
		Insect pest protection – Protease inhibitors	Cotton	Field trials
		Insect pest protection – Bt	Cotton	Field trials
		Insect pest protection – VIP	Cotton	Approved for field trials
		Resistance to canegrubs	Sugarcane	Proof of concept
Disease control		Virus resistance	White clover	Field trial <sup>3</sup>
		Virus resistance	Barley	Proof of concept

1 Field trials are underway for this trait but they are proof-of-concept field trials examining performance under a natural salt gradient.

2 Field trials carried out in Mexico — no plans to commercialise in Australia.

3 No short term plans to commercialise in Australia.

Traits		Crop	Stage in pipeline
Second generation traits	Improved food, feed value and pastures	Omega-3 oil production in plants	Oilseed Technology discovery
		Starch modification	Wheat Proof of concept <sup>4</sup>
		Improved digestibility	Wheat, barley Proof of concept
		Improved oil quality	Cotton Field trial <sup>5</sup>
		Modified lignin biosynthesis	Pasture species Proof of concept
		Altered fructan metabolism	Pasture species Proof of concept
		Reduction in hayfever-causing pollen	Ryegrass Proof of concept
		Improved oil quality	Canola Proof of concept
		Improved sugar content	Sugarcane Proof of concept / Field trial
		Third generation traits	Plant molecular farming
Bioreactors producing pharmaceutical proteins	Tobacco Proof of concept		
Alkaloid production	Poppy Proof of concept		

Source: Glover, J. et al., 2005, What's in the Pipeline, Genetically modified crops under development in Australia, Bureau of Rural Sciences, Canberra.

4 Proof of concept field trial underway — large scale experiment.

5 Currently deciding whether to take to field trials.

Other first generation crops being developed overseas include: ryegrass that provides nitrogen to the soil being developed in New Zealand; drought tolerant wheat in Mexico; and drought tolerant rices in China.

Table 7 shows examples of second generation crops that are in the pipeline overseas.

*Table 7: GM feed crop traits in the pipeline worldwide*

Crop	Trait	Improvement
Lucerne	Lignin	Improved digestibility and/or low lignin
	Amino acids	Increased amino acids (methionine and cysteine)
Chickpea	Amino acid	Increased amino acids (methionine and lysine)
Clover	Amino acid	Increased amino acids (methionine and lysine)
Maize	Amino acid	High protein with balanced amino acids
	Mycotoxin	Fumosin detoxifying
	Oil	High oil content
	Oil and/or amino acids	High oil with increased digestibility
	Oil and/or P	High oil with increased P availability
Canola	Oil	Low saturates and/or high monounsaturated fatty acids and/or low polyunsaturated fatty acids
	Oil	High oil
Lupin	Amino acids	Increased amino acids
Peas	Amino acids	Increased amino acids (methionine)
Soybean	Protein levels	Increased levels of proteins
	Anti-nut factor	Low stachyose
Sorghum	Carotenoid	High carotene

*Source: Glover, J. et al., 2005, What's in the Pipeline, Genetically modified crops under development in Australia, Bureau of Rural Sciences, Canberra.*

Plant oils are currently used to produce detergents, cosmetics, lubricants, plastics, soaps and other chemicals. Examples of third generation crops that have been developed for industrial use are described in table 8. Crops and, in the future, animals may also be modified to produce pharmaceuticals, create antibodies and

vaccines. Other potentials for GM plants are for biofuels and to clean up industrial waste. However, with a few exceptions these applications are still in the technology development stage.

*Table 8: Some examples of GM oilseed crops with modified oil content)*

Crop	Modification	Stage	Use
Canola	High laurate content	Commercial	Detergent
Soybean	High oleate content	Commercial	Food, lubricants
Soybean	High linolenic	In development	Coatings
Canola	High stearate	Developed	Grease
Canola	Petroselenate	In development	Food , monomers
Soybean	Vernolate	In development	Plasticizer, coatings
Cotton	Low-saturates	In development	Food uses

*Source: Glover, J. et al., 2005, What's in the Pipeline, Genetically modified crops under development in Australia, Bureau of Rural Sciences, Canberra.*

### Definition of a GMO organism in the Act

Section 10 of the Act defines a genetically modified organism as:

- (a) an organism that has been modified by gene technology; or
- (b) an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or
- (c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;

but does not include:

- (d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or
- (e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.

In the four years since the commencement of the Act, there has been no need to use the Regulations to declare an organism to be a GMO or to declare that an organism is not a GMO. However, the Review noted that this regulation-making power provides considerable flexibility to the organisms covered by the Act.

During consultations (with the exception of ribonucleic acid interference (RNAi) technology which is discussed below) no examples were presented to the Review of any organisms or emerging technologies that were currently outside the definition of GMO. In addition, GTTAC did not identify any emerging GM technologies that need to be regulated that are currently outside the scope of the Act.

### **RNA interference**

In consultations, researchers described the emerging use of RNA interference (RNAi) technology to silence genes. RNA transfers information from the DNA sequence to make proteins. Gene silencing is a natural mechanism to degrade the RNA instructions of a gene thus stopping the gene from making its protein. As many applications of this technique change the traits of an organism but do not change its genes, they would be excluded from the current definition of a GMO.

The Review was told by researchers that there is less potential for RNAi to pose a risk to health and safety of people and to the environment since it cannot introduce new traits but rather silences existing traits. Submissions from research institutions supported the current definition of GMO and noted that if required other organisms could be brought within the scope of the definition by regulations. In this way, a particular application of RNAi technology could be brought within the scope of the Act if it represented a potential risk to health and safety of people and to the environment. The Review concluded that the regulatory system was sufficiently flexible to deal with RNAi technology.

The Review is aware that the Regulator continually monitors emerging technologies and their risks. Considering the flexible nature of the definition of a GMO, the Review saw no reason to change the definition in the Act. However, the Review considered it appropriate that the Act be reviewed periodically to ensure that it continues to address technological developments.

*Recommendation 8.1: The Review recommends the Act be reviewed in five years to ensure that it continues to accommodate emerging trends.*

### **International developments**

For the purposes of identifying international developments in the gene technology field, the gene technology regulatory frameworks of selected countries have been summarised at Appendix 8. The table includes summaries of the gene technology frameworks of the European Union, New Zealand, Japan, the United States of

## and the Gene Technology Agreement

America, Canada, Argentina and China. It is an updated version of a table contained in a Report on the Gene Technology Bill 2000 for the Senate Community Affairs Reference Committee entitled *A Cautionary Tale: Fish Don't Lay Tomatoes* (published in November 2000). The information has been updated where necessary to incorporate changes that have occurred since 2000. The information used to update the table for all countries except China was sourced, where possible, from official government websites and compiled by the Secretariat<sup>6</sup>. Sources included fact sheets, relevant legislation and interactions with overseas regulatory agencies.

Most of the countries examined do not have one overarching piece of legislation that governs gene technology regulation. Only New Zealand has attempted to centralise and consolidate its gene technology regulation, while Japan has no legislative framework, but rather a system of voluntary guidelines.

The non-centralised approach adopted by most countries means that applications to use GMOs may require approval from more than one agency/authority before being granted permission to use GMOs. For example, in Canada, approval may be needed from three agencies to approve the GMO plant for release into the environment, for use as livestock feed and for use as human food; whereas in the US, approval may be needed from both the US Department of Agriculture and the Food and Drug Administration if a plant GMO is intended for general release for the purpose of being used for human food. However, in most countries there are different application processes depending on the intended use of the GMO.

In seeking approval to use a GMO, safety assessments are required (either by the applicant or by a competent, relevant authority or both) on the potential risks to the environment and to human health. The information required for submission with the application to assess risks to the environment or human health is usually outlined in the legislation, with Canada and the European Union giving particularly detailed guidelines as to the requirements. The form of the environmental assessment varies by country, with the European Union and Canada requiring environmental risk assessments, whereas New Zealand conducts environmental impact assessments and the relevant agencies in the US may require both types of environmental assessment.

Most countries have some provision for public consultations on applications for use of GMOs (especially for releases for experimental purposes and releases for commercial purposes). For example, the European Union, the United States, New Zealand and Canada all have provision for public consultation, with the period of public consultation being no longer than 30 days in New Zealand and up to 60 days in Canada and the United States. Some countries exclude the period of public consultation from the time in which the regulator or competent, relevant authority

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6 An English language government website was not available for China and different sources were used (see Appendix 8).

is required to make a decision. This can also be the case for any time requirement involved in providing the regulator or competent relevant authority with additional information for the purposes of making a decision on the use of a GMO (as in the United States and the European Union).

Legislation governing work with GMOs in most countries contains provisions for penalties to be applied in cases of contravention (as in the United States, Canada, New Zealand, China and the European Union). In the European Commission, member states are responsible for determining the nature and range of penalties. Most penalties involve fines or jail terms or both. Usually, common law principles apply to those harmed by the use of GMOs.

Most of the countries examined have some form of monitoring of procedures and conditions and whether they are adequate at preventing adverse effects on the environment and human health.

The Review did not find any innovative approaches to regulating GMOs that would improve the Act. The Review concluded that of the countries examined, with the exception of New Zealand, most countries had used their existing product regulatory agencies to assess GMOs and, from the community's perspective, the Australian system is one of the most rigorous, transparent and accessible. It is also flexible enough to deal with rapidly changing technology for the near future. However the Review saw a need to continue to monitor this situation on a regular basis. This is covered in recommendation 8.1.

### Term of reference 12:

**Investigate whether the Inter-governmental Agreement on Gene Technology is achieving the aims listed in its Recitals**

The IGA between the Commonwealth and the States underpins the national regulatory system for gene technology. The recitals to the IGA (see Appendix 6) state that Governments agreed that there was a need for a cooperative national legislative scheme that should:

- a) be efficient and effective;
- b) operate in a seamless manner;
- c) be nationally consistent;
- d) be based on a scientific assessment of risks undertaken by an independent regulator;
- e) ensure that the regulatory burden is consistent with the risks;
- f) be characterised by decision-making that is transparent and that incorporates extensive stakeholder and community involvement;
- g) be able to respond to the developments in gene technology; and
- h) be consistent with Australia's international treaty obligations.

Chapter 9 focusses on items (a), (c) and (f). The Review's conclusions in respect of the remaining items are set out in other parts of this Report. The Review heard that the overwhelming concerns were:

- the failure to achieve national consistency because various states had chosen to impose moratoria on the growing of GM crops;
- the lack of transparency in dealing with market considerations; and
- the resulting impact on the effectiveness of the scheme.

## Policy principles

As discussed in chapter 2, the IGA established the GTMC, which is responsible for the gene technology policy framework. The Act allows the GTMC to issue policy principles for a range of matters related to GMOs and crops. The Regulator is required to observe such principles. In short, the Regulator must not issue a licence under the legislation if it would be inconsistent with a policy principle.

To date, only one policy principle has been issued. As of 5 September 2003, States can recognise areas, designated under State law, for the purpose of preserving the identity of GM or non-GM crops (or both) for marketing purposes. This situation reflects State responsibility for economic development within jurisdictions, and accordingly, the right of States to pass laws on matters other than health and safety of people and the environment in the context of gene technology. Provision also exists for the GTMC to issue policy principles for ethical issues relating to dealings with GMOs. This has yet to happen.

Under this legislative power, all States except Queensland and the Northern Territory have imposed moratoria (see table 9) on various dealings with GMOs.

Table 9: *Gene technology moratoria legislation*

Jurisdiction	Legislation title	Commencement	Sunset
ACT	<i>Gene Technology (GM Crop Moratorium) Act 2004</i>	10 July 2004	By regulation, no earlier than 17 June 2006
NSW	<i>Gene Technology (GM Crop Moratorium) Act 2003</i>	25 June 2003	March 2008
WA	<i>Genetically Modified Crops Free Areas Act 2003</i>	21 December 2003	2008
SA	<i>Genetically Modified Crops Management Act 2004</i>	29 April 2004	2007
Tasmania	<i>Genetically Modified Organisms Control Act 2004</i>	16 November 2004	2008
Victoria	<i>Control of Genetically Modified Crops Act 2004</i>	12 May 2004	2008

The moratoria differ significantly between jurisdictions. Some prohibit the commercial production of all GM crops, not just GM food crops, and one jurisdiction

## and the Gene Technology Agreement

prohibits any dealings with GMOs except under a permit. However, some moratoria include provisions for limited and controlled trials of declared GM food crops for research purposes. Non-food GM crops, such as GM cotton, are largely unaffected by the moratoria. GM cotton is grown in Queensland and New South Wales.

Industry, farmers that support the choice to grow GM crops and research organisations were critical of the moratoria, which they viewed as:

- halting the path to market for GM food crops, which have been approved through the OGTR process, by imposing a prohibition on commercial release;
- creating regulatory uncertainty, as under the moratoria legislation there is lack of transparency in the process (including the criteria that would allow the approval of commercial releases);
- stopping further investment in food crop GMOs;
- undermining the Regulator's science-based decision in relation to health and safety and the environment;
- denying Australian farmers the ability to grow GM food crops, leaving them at a disadvantage in a competitive global marketplace;
- resulting in an inability to respond to rapid changes in the market; and
- diminishing confidence in the nation's ability to capture the benefits of biotechnology, as outlined in the National Biotechnology Strategy.

### **The path to commercialisation for GM crops**

The Review heard that even though the Regulator had approved two types of GM canola for commercial release in 2003, it would have been around 2006–2007 before they were grown on a commercial scale and not until 2008–2009 before GM canola represented more than 10–15% of total canola area planted.

The lead-in time was necessary to conduct a breeding program to include the GM traits in 'elite' varieties of canola and to implement demonstration trials for farmers. The purpose of the trials would be to demonstrate:

- weed control and farming system benefits of the GM herbicide tolerant canolas compared to conventional canola production systems, including conventional herbicide tolerant canola;
- GM canola variety performance versus conventional canola varieties;
- mandatory herbicide resistance management strategies for adoption with GM herbicide tolerant canola;

- recommended management strategies for the co-existence of GM and conventional canola production systems.

Thus, if the moratoria are lifted in 2008, it will be 2009–2010 before farmers have initial access to the GM canola herbicide tolerant technology.

The Review heard from the industry that they would not invest in variety trials even if they obtained relevant approval under the moratoria legislation, as long as there is no certainty of a regulatory pathway to commercial approval under the moratoria.

The Review heard that North and South American competitors will have the advantage of accessing and adopting the technology for over a decade and a half, with no indication that their GM canola and soya bean crops have been rejected or discriminated against in the marketplace. The North and South American experience has demonstrated that there is no apparent production, nor market access advantage for conventional canola versus GM canola.

Some farm groups that were opposed to GM canola told the Review that performance and variety trials would help address their concerns. These trials would ordinarily be part of the process of introducing a new variety but are unlikely to be conducted under the constraints of the moratoria.

In contrast, submissions from non-government organisations and from some individuals and consumer NGOs were generally supportive of the moratoria. They maintained that States have a clear right to decide whether or not to allow GM crops to be grown if there is a threat to agricultural markets.

The Review noted that it was most unusual for States to intervene in the agricultural market in this manner and this type of intervention would usually only be taken when there is strong and compelling evidence of a market failure. However, after examining a number of reports identified during consultations, the Review could not find documentary support for a market failure. The Review noted that choice of variety was usually left to the farmer who would consider market signals, customer preferences, production costs and yield among other influences.

The Review concluded that the moratoria were causing detrimental rather than beneficial impacts and were counterproductive as they were preventing the collection of information that would otherwise assist farmers in making a choice on whether to grow GM crops. The Review also concluded that the moratoria were having negative effects on the agricultural and research sectors.

The Review recognised that the actions taken by State governments had happened at a time of uncertainty in the market and that the situation had been significantly clarified since 2003. For example, the Primary Industries Ministerial Council has

## and the Gene Technology Agreement

adopted thresholds for certain GM canolas that might be present inadvertently in conventional canola. The Review noted that this action was in response to a finding that a non-GM variety of canola known as 'Grace' had a low level presence of a GM canola approved by the Regulator and that the development of a threshold had allowed trade of the 'Grace' canola to continue.

In addition, Queensland has developed a model framework for co-existence and was willing to sponsor its adoption at the national level (see Appendix 9). The Review also noted that the European Union was encouraging member states to develop co-existence frameworks for conventional, GM crops and organic crops. The European Union market was raised in consultations as a major market for Australian crops and therefore a major influence on deciding whether to grow GM crops.

The Review concluded that a national framework for co-existence would address the concerns that led to the moratoria being imposed.

The Review concluded that a nationally consistent transparent approach to market considerations should be adopted.

*Recommendation 9.1: The Review recommends that the Commonwealth and States through the GTMC reconfirm their commitment to a nationally consistent scheme for gene technology including a nationally consistent transparent approach to market considerations as soon as practicable.*

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*Recommendation 9.2: The Review recommends that the Commonwealth and States work together to develop a national framework for co-existence for non-GM and GM crops to address market considerations.*

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## Emergency regulation making

Part 3 of the IGA describes the functions of the GTMC. The Review noted that under paragraph 16(b) of the IGA the Council is required to 'approve proposed regulations for the purpose of the Scheme'.

As discussed in chapter 8, the definition of a GMO provides the flexibility to declare by regulation that an organism is, or is not, a GMO. The Review has found that this flexibility will enable the regulatory scheme to keep pace with emerging trends.

The Review was concerned that the requirement for regulations to be approved by the GTMC could inhibit the expeditious making of regulations to bring under the scope of the Act technologies appearing rapidly under unusual circumstances. It therefore proposed that the IGA be amended to allow the Commonwealth to make regulations

for a limited period in emergency situations on the proviso that it notifies GTMC. It is proposed that before the end of the limited period GTMC must agree to the regulations before they are submitted to the Executive Council for renewal. This will enhance the flexibility of the Act to deal with rapidly emerging GMO technology in the future.

*Recommendation 9.3: The Review recommends that the IGA be amended to provide capacity for the Commonwealth to declare a thing to be a GMO by regulation for a limited period in an emergency. This would be notified to GTMC in the first instance. It is recommended that GTMC must agree to the regulations before they are submitted to the Executive Council for renewal.*

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## Membership of the Panel

**Ms Susan Timbs** BCom LLB (Hons) (Panel Chair) is a solicitor specialising in environment and planning law. Ms Timbs, a former Partner of Corrs Chambers Westgarth, is a Senior Consultant in the National Environment and Planning Group of Mallesons Stephen Jaques and headed the Brisbane Environment and Planning Group until 2002 while responsible for clients operating across Australia.

More recently, Ms Timbs has been on leave from Mallesons Stephen Jaques working in a health related public policy area as National Policy Manager of Breast Cancer Network Australia.

**Ms Kathryn Adams** LLM, M Env Stud, M Bus, BSc Agr (Hons), FAICD (Panel Member) is a microbiologist and a lawyer with extensive experience in plant breeding, research and development in agriculture. She is currently a Senior Research Fellow at the Centre for Intellectual Property in Agriculture, Faculty of Law, Griffith University and a Mediator, Arbitrator and Dispute Resolution Facilitator. Previously she was the Executive Director of both Policy and Planning Divisions in the Queensland Environmental Protection Agency.

**Mr W. Murray Rogers** AM (Panel Member) is the Chair of the Quarantine and Exports Advisory Council and a member of the Agriculture and Food Policy Reference Group which is developing broad recommendations to improve the profitability, competitiveness, and sustainability of the Australian agricultural and food sector.

He has had a distinguished career with Kellogg's, both in Australia and overseas, and was Managing Director/Chief Executive Officer of the Australian Wheat Board/AWB Limited between 1997 and 2000. Mr Rogers is a Fellow of the Australian Institute of Company Directors and a Fellow of the Australian Institute of Management.

## APPENDIX 2

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### Organisations and individuals who presented written public submissions

1. Nick Pastalatzis, West Sunshine, VIC
2. Associate Professor Renato Schibeci, Murdoch University, WA
3. Margaret L. Seedsman, Clematis, VIC
4. Cotton Seed Distributors Ltd, Wee Waa, NSW
5. Mudgee District Environment Group, Mudgee NSW
6. Householders' Options to Protect the Environment, Toowoomba West, QLD
7. Professor Lawrence Cram, The Australian National University, ACT
8. Cheryl & Stephen Dooley, Glenreagh, NSW
9. Greg Seedsman, VIC
10. Vanessa Errol, Como, WA
11. Cate Kyne, State unknown
12. NSW Farmers' Association, Sydney, NSW
13. Sally Mathrick, Sound Medicine, NSW
14. Dr Susan Maastricht, Children's Cancer Institute Australia, Randwick, NSW
15. Institutional Biosafety Committee, University of Queensland, QLD
16. Samantha Dunn, Selby, VIC
17. The Western Australian Farmers Federation, Perth WA
18. Margaret Hartley, Office of Chemical Safety, Therapeutic Goods Administration, ACT
19. Cate Faehrmann, Nature Conservation Council of NSW, Sydney, NSW
20. Philip Higson, Stafford, QLD
21. Janet Grogan, Joondanna, WA
22. Auscott Limited, Sydney, NSW

## and the Gene Technology Agreement

23. Helen Chambers, Marong, VIC
24. Australian Academy of Science, ACT
25. University of Sydney Institutional Biosafety Committee, Sydney NSW
26. University of New South Wales, NSW
27. Philip Steel, Wee Waa, NSW
28. John Hamblin, Export Grains Centre Ltd, WA
29. Bill Williamson, Timbreebongie Citrus, Narromine, NSW
30. Mrs H. M. McKay, Canowindra, NSW
31. Fern Wickson, Coalcliff, NSW
32. Professor Peter Schofield, Prince of Wales Medical Research Institute, NSW
33. Dr Jeff Freeman, The Garvan Institute Institutional Biosafety Committee, NSW
34. Gary Bilton, Talbingo, NSW
35. P.E. & C.L. Williamson, Coolamon, NSW
36. Total Environment Centre Inc, Sydney, NSW
37. The Australian Society for Microbiology, Melbourne, VIC
38. Grains Council of Australia, Barton, ACT
39. Susan Hutton, Menzies School of Health Research, NT
40. Victorian Farmers Federation, Melbourne, VIC
41. Giz Watson MLC, Member for North Metropolitan Region, WA
42. Morva Rule, Marong, VIC
43. Darling Downs Cotton Growers Inc, Dalby, QLD
44. Joy Chambers, Marong, VIC
45. Paula Lambert, NZ
46. Lynne Forster, Sandy Bay, TAS
47. Tarryn Harmer, Perth, WA
48. Judy Cameron, South Geelong, VIC
49. Gene Technology Ethics Committee, ACT
50. Tania Kanavas, State unknown
51. GE Free New Zealand, NZ
52. Syngenta Seeds Pty Ltd, NSW
53. Cotton Australia Ltd, NSW
54. Victorian and Tasmanian IBC Network, VIC
55. Bio-Dynamics Tasmania, TAS
56. Dr Lindsay Cook, Lindfield, NSW
57. Prince Henry's Institute of Medical Research, VIC
58. Tracie Matthews, Young, NSW
59. CRC Sugar Industry Innovation through Biotechnology, The University of Queensland, QLD

60. Michael Matthews, Young, NSW
61. AusBiotech Ltd, Richmond, VIC
62. Avcare Ltd, Canberra, ACT
63. Florigene Ltd, Collingwood, VIC
64. Burnet Institute, VIC
65. Institutional Biosafety Committee, Prince Royal Alfred Hospital, NSW
66. Crabtree Agricultural Consulting, Northam, WA
67. Dorothy Pottage, Mount Eliza, VIC
68. South Australian Farmers Federation, Adelaide, SA
69. Fort Dodge Animal Health, Baulkham Hills, NSW
70. University of Melbourne, Melbourne, VIC
71. Monsanto, VIC
72. Conservation Council of Western Australia Inc, West Perth, WA
73. The Australian Food and Grocery Council, ACT
74. Bioproperties Pty Ltd, Glenorie, NSW
75. CSR Sugar, Milton, QLD
76. Australian Dairy Farmers Ltd, Melbourne, VIC
77. Consumers' Association of South Australia, Adelaide, SA
78. Dr A. Wendy Russell, School of Biological Sciences,  
University of Wollongong, NSW
79. Agrifood Awareness Ltd, Kingston, ACT
80. Southern GE-FREE, Moorabbin, VIC
81. Dr C. Preston, University of Adelaide, SA
82. Professor Emeritus John Lovett, Lovett Associates Pty Ltd, Hall, ACT
83. CSIRO, Black Mountain, ACT
84. Grains Research & Development Corporation, Barton, ACT
85. Institute of Public Affairs Ltd, Melbourne, VIC
86. Christiaan W. Huygens Tholen, West End, QLD
87. Velnaar Camille, Glaziers Bay, TAS
88. Cooper Travis, Maroochydore, QLD
89. Deuceney Declan, Galway, Ireland
90. J. Sykes, Adelaide, SA
91. Gil Robertson, Port Lincoln, SA
92. Holly Shiach, Sydney, NSW
93. Douglas Pye, Newcastle, NSW
94. Ute Goeft, Heathridge, WA
95. Lucy Teusner, Edenhope, VIC

## and the Gene Technology Agreement

96. Aileen Leddy, Jannali, NSW
97. Pete Malicki, Sydney, NSW
98. Jocelyn Kingston, Leichhardt, NSW
99. Peter Brown, Coolum Beach, QLD
100. Amanda Sutherland, Leopold, VIC
101. Kevin Ayres, Millswood, SA
102. Craige McWhirter, Surry Hills, NSW
103. Lisa Formosa, Ringwood, VIC
104. Maureen McNab, Glenroy, VIC
105. Mark, Sydney, NSW
106. Desiree Kozlowski, Sapphire Beach, NSW
107. Francesca Vuillemin, Sydney, NSW
108. Aillin O'Brien, Pine Grove, VIC
109. Isobel Lindley, Sydney, NSW
110. Kellie Otes, Bangor, NSW
111. Benjamin Tancred, Willoughby, NSW
112. Deb Bower, Carlton, VIC
113. Ann-Marie Denham, Carlton, VIC
114. Ruth Gilovitz, Perth, WA
115. Stacey Nelson, Sydney, NSW
116. Shane Paxton, Melbourne, VIC
117. Damon Roberts, Maroochydore, QLD
118. Donna Taanman, Hunter's Hill, NSW
119. Mal Haskins, Melbourne, VIC
120. Jasper Taanman, Hunter's Hill, NSW
121. Bridget Leggett, Toodyay, WA
122. Brett Drayton, Enmore, NSW
123. Nicola Worth, Sydney, NSW
124. Matthew Syres, Newton, NSW
125. Glenda Lindsay, Melbourne, VIC
126. Martina Meckel, Crows Nest, NSW
127. Hayley Thompson, Joondanna, WA
128. Andrea Borbas, Tawoomba, QLD
129. Mrs Z Vallings, Whangerei, NZ
130. Louise Sales, Harbord, NSW
131. Annemarie Manners, Tawoomba, QLD
132. Kerry Forrest, Launceston, TAS

133. Alyssa Tait, Salisbury, QLD
134. Kara Vandeleur, Wellington, NZ
135. Craig Walker, Sydney, NSW
136. Wendy Gooding, Brisbane, QLD
137. Tania, Brisbane, QLD
138. Virginia, Main Ridge, VIC
139. Rachel Honey, QLD
140. Paula Lambert, Mooloolah, NZ
141. Tony Cosentino, Dandenong, VIC
142. Valerie Thompson, Lismore, NSW
143. Peter Gringinger, Sassafras, VIC
144. Lynne Forster, Sandy Bay, TAS
145. Tim Gentle, Page, ACT
146. Sue Hathaway, Jurien Bay, WA
147. Sarah Neal, Sydney, NSW
148. Leahna Hardie, Upper Hutt, NZ
149. Jon Muller, Lower Hutt, NZ
150. Anastasia Turnbull, Wellington, NZ
151. Dr Robert Anderson, Tauranga, NZ
152. Samantha Mikus, Vermont South, VIC
153. Lizzie Rose, Sydney, NSW
154. Mr J Carapit, Sydney, NSW
155. Julia Sideris, Lewisham, NSW
156. Martin Sharp, Rotorua, NZ
157. Kim Brooks, Patterson Lakes, VIC
158. Tania Kanavas, United Kingdom
159. Monique Bekkevold, Galston, NSW
160. Judy Wiese, Bordertown, SA
161. Karyn Harris, Wellington, NZ
162. Dianne Green, Yeppon, QLD
163. Charles Drace, Christchurch, NZ
164. Leanne Ruditsch, Candelero, NSW
165. Guy Ousey, Dimbulah, QLD
166. Julie Robinson, VIC
167. Amber Colhoun, Sydney, NSW
168. Patrick Lias, Melbourne, VIC
169. Nico Hirzel, Melbourne, VIC
170. Sarah, Balmoral, NSW

## and the Gene Technology Agreement

171. Sam David, Greenvale, VIC
172. Charles Newman, Thornlie, WA
173. Alex Muir, Sydney, NSW
174. Anthony Bruzzese, Keilor East, VIC
175. Elizabeth Di Paola, Mitcham, VIC
176. Garry Jones, George Town, TAS
177. Mark Jones, Brisbane, QLD
178. Annemarie Knight, Lower Plenty, VIC
179. Murray Kirby, United Kingdom
180. Samantha Bell, Gold Coast, QLD
181. Hadi Jalgha, Lindfield, NSW
182. Dr Elvira Dommissie, Christchurch, NZ
183. Arius Tolstoshev, Melbourne, VIC
184. Rania Romanos, Melbourne, VIC
185. Andrew Forsythe, Fortitude Valley, QLD
186. Narelle Tildesley, Bicheno, TAS
187. Susan McMullen, Sunrise Beach, QLD
188. Aldo Ruggieri, Leichhardt, QLD
189. Robyn Aldrick, Melbourne, VIC
190. Enrico Malcisi, Thora, NSW
191. John Finch, Cairns, QLD
192. Anna Ritman, Melbourne, VIC
193. Suelynn Morley, Perth, WA
194. Chris Ennis, Two Rocks, WA
195. Belinda Towns, Melbourne, VIC
196. Hope Foley, Maroochydore, QLD
197. Andre de Almeida, Melbourne, VIC
198. Phillip Kemp, Sheffield, TAS
199. A Rohlf, Sydney, NSW
200. Suzanne Kowalski-Roth, Sydney, NSW
201. Fiona Deegan, Sydney, NSW
202. Goksu Dines, Harbord, NSW
203. Lynn Brett, Dubbo, NSW
204. Michael Wright, South Coogee, NSW
205. Kerry Ross, Sydney, NSW
206. Kyle Scott, Lake Manmorah, NSW
207. Jerard Grant, Brisbane, QLD
208. Sandra Scott, Melbourne, VIC

209. Lauryn Ireson, Melbourne, VIC
210. Tony Ireson, Melbourne, VIC
211. Nathan Henderson, Katoomba, NSW
212. Trina, Sydney, NSW
213. Ian Hehir, Dee Why, NSW
214. Allan W. Clancey, Moorooka, QLD
215. Bayer CropScience, VIC
216. Professor Suzanne Cory, The Walter and Eliza Hall Institute of Medical Research, Melbourne, VIC
217. Greenpeace, NSW
218. Serve-AG Pty Ltd, TAS
219. Australian Seed Federation, Manuka, ACT
220. Dow AgroSciences Australia, ACT
221. Nufarm Limited, Laverton North, VIC
222. Cooperative Research Centre for Innovative Dairy Products, Melbourne, VIC
223. Cotton Research and Development Corporation, Narrabri, NSW
224. Pastoralists and Graziers Association of Western Australia, Belmont, WA
225. Adrian Gibbs, Yarralumla, ACT
226. Amanda Gothard, Bulimba, QLD
227. Deakin University, Geelong, VIC
228. Lea J. Gow, Unknown
229. Braidwood Greens, Braidwood, NSW
230. ARC Centre of Excellence for Integrative Legume Research, The University of Queensland, Brisbane, QLD
231. SGA Solutions Pty Ltd, VIC
232. Dr Sylvia Lachberg, The University of Western Australia, WA
233. Australian Network of Environmental Defenders' Offices, NSW
234. Molecular Plant Breeding CRC, Bundoora, VIC
235. Monash University IBC, VIC
236. Doreen Mackie, Edith Cowan University, Joondalup, WA
237. Victorian Department of Human Services, Melbourne, VIC
238. Pacific Seeds Pty Ltd, Toowoomba, QLD
239. Rugby Trading Co, Goondiwindi, QLD
240. Heath Parker, Logan Village, QLD
241. Ludwig Institute for Cancer Research, Melbourne, VIC
242. Mark Waud, Kendenup, WA
243. Kris Hanna MP, Member for Mitchell, SA
244. Australian Pesticides & Veterinary Medicines Authority, Barton, ACT

## and the Gene Technology Agreement

245. Office of Research, Flinders University Adelaide, SA
246. National Council of Women of Australia Inc Ltd, Deakin, ACT
247. Department of Primary Industries, Water and Environment, TAS
248. Institute of Health and Environmental Research Inc, Kensington Park, SA
249. Tony Cush, Gwydir Valley, NSW
250. GeneEthics Network, Carlton, VIC
251. National Farmers' Federation, Barton, ACT
252. Food Standards Australian & New Zealand, Barton, ACT
253. Professor Barry Marshall, The University of Western Australia, WA
254. Rick Calitz, Glenusk, TAS
255. Jeff Bidstrup, Warra, QLD
256. Producers Forum, NSW
257. Mr Mark Smith, Westmead, NSW
258. Network of Concerned Farmers, WA
259. ABB Grain Ltd, Adelaide, SA
260. Australian Oilseeds Federation, NSW
261. Biological Farmers of Australia, Brisbane, QLD
262. Office of Gene Technology Regulator, Woden, ACT
263. Australian Consumers' Association, Marrickville, NSW
264. Victorian Department of Human Services, VIC
265. Kim Chance MLC, Western Australia Minister for Agriculture and Forestry, WA
266. The National Health and Medical Research Council, ACT
267. South Australian Government, SA
268. Queensland Government, QLD
269. Australian Government, Secretaries' Committee on Biotechnology, Civic, ACT
270. Malcolm Carpenter, Macquarie Valley, NSW
271. Michele Smith, Billy's Creek, NSW
272. Madonna Hodges, Earlwood, NSW
273. Tara Cully, Brisbane, QLD
274. Mark Bailey, Dallas Texas, USA
275. Chris Grant, Footscray West, VIC
276. Garry Jenkins, Mulgrave, VIC
277. Monette Lee Smith, Tallebudgera Valley, QLD
278. Noelle Rattray, Hobart, TAS
279. Ian MacDonald MLC. NSW Minister for Natural Resources, Primary Industries and Mineral Resources, Sydney, NSW
280. Brooke Corrigan, North Lambton, NSW

## APPENDIX 3

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### List of attendees who appeared before the panel at public consultations

#### Canberra (ACT), Friday, 21 October 2005

1. Gordon Abraham
2. Pat Osborne
3. Kim Sweeney
4. Adrian Gibbs
5. Juliet McFarlane (Network of Concerned Farmers)
6. Ross Downes
7. Andreas Betzner
8. TJ Higgins (CSIRO)
9. Mikael Hirsch (CSIRO)
10. Peter Stoutjesdijk (CSIRO)
11. Donald McFarlane (Canola Grower)
12. Maarten Stapper (IHER member)
13. Geoff Davies (ANU)
14. Tracy-Anne Jolly (OGTR)
15. Toni Cuthbertson (OGTR)
16. Al Turello (OGTR)
17. Declan O'Connor-Cox (OGTR)
18. Mick Letts
19. Peter Arkle (NFF)
20. Jutta Tuerck
21. Ryan Wilson
22. Zoltan Lukacs

## and the Gene Technology Agreement

23. Maree McKay
24. Pennie Scott
25. Deborah Stanley (AusBiotech)
26. John Lovett (Agrifood Awareness Australian Limited)
27. Barry Rolfe (ANU/RSBS)
28. Karen Elsom (Business ACT)
29. Steven Bailie (Australian Democrats)
30. Greg Ash (NHMRC)
31. Peter McInnes (Department of Health and Ageing)
32. Victoria Hennig (Department of Health and Ageing)
33. Peter Gullett (Farmer)
34. Jing Chung (IP Australia)

### **Clare Valley (South Australia), Sunday, 23 October 2005**

1. John Cornish (Department of Primary Industries)
2. John Lush
3. Robert Martin
4. Felicity Martin
5. Bill Adams

### **Adelaide (South Australia), Monday, 24 October 2005**

1. John Harvey (GWRDC)
2. Elaine Attwood (former GTCC)
3. Helen Halley
4. Diana Palmer (Genetic Ethics)
5. Anne Collins
6. Rosemary Ryall (Flinders IBC)
7. Hilary Little (Greenpeace)
8. Jan Nield (University of Adelaide)
9. Stephanie Agius
10. Tony Moore (ACA)
11. Paula Nixon (SA Genetic Food Information Network)
12. Lesley Wyndram

### **Perth (Western Australia), Wednesday, 26 October 2005**

1. Anne Healey (Consumers Association of WA)
2. Jeffrey Harwood (Murdoch University)
3. David Groth (Curtin University)
4. Selwyn Snell (Single Vision Grain Australia)

5. Julie Newman (Network of Concerned Farmers)
6. Brenda Moore
7. Stuart Moore
8. Elizabeth Rowell
9. Yuki Ghantous (Ghantous Group)
10. Andy McMillan (WA Farmers)
11. Ian Edwards (AusBiotech)
12. Rhys Ainsworth (CBH Group)
13. Sylvia Lachberg (UWA)
14. Scott Lundlum (WA Greens)
15. Chris Florides (Saturn Biotech)
16. Mike Jones (Murdoch University)
17. Vanessa Error
18. Janet Grogan
19. Lea Walsh
20. Eddie Noonan
21. Annemarie Hindniger
22. Steven Cross
23. Sue Sutherland

**Brisbane (Queensland), Tuesday, 1 November 2005**

1. Ann Trezise
2. Regis M Dunne
3. Philip Hudson
4. Scott Hamilton
5. Hayley Brotherton
6. Susan Goddard
7. G. Smith
8. L. Smythe
9. Peter Leeton
10. Suzanne Morris
11. Donald MacFarlane
12. Jean Fleming
13. Georgia Hamilton
14. Higia Romanch
15. John Bates
16. Ben Huang
17. Charles Lawson

## and the Gene Technology Agreement

18. Stephen Hubicki (ACIPA)
19. Andrew Perkins
20. Robyn Wallace
21. Stevens Brunbley
22. Ross Gilmour
23. Christine Morris
24. Nigel Kimball
25. Janet Grice
26. Dale Leary
27. Doug Anderson
28. Ian Harris
29. Mathew Kunkel
30. Daniela Tickel
31. John O'Hair
32. Sonya Brown
33. Margaret Brown
34. Shin-Nig Then
35. Charles Nelson
36. Peter Twine (CRC Sugar)
37. Astrid Gesche (QUT)
38. Katie Steele (UQ)
39. Barbara Hocking (QUT)
40. Jeff Smith (Environmental Defender's Office)

### **Townsville (Queensland), Wednesday, 2 November 2005**

1. Leigh Winsor (James Cook University)
2. Terry Morton
3. Peter Collins
4. Beth Ballment
5. Jean Dartnall
6. Kelly Buchanan
7. Graham Burgess
8. Darren Schliebs (CSR)

### **Narrabri (New South Wales), Sunday 6 November 2005**

1. Andrew Watson (Producers Forum)
2. Terry Haynes (Producers Forum)
3. Steven Ainsworth (Monsanto)