# STATUTORY REVIEW

of the *Gene Technology Act 2000*
and The Gene Technology Agreement

The Chair
Gene Technology Ministerial Council

Dear Minister

As members of the Independent Review of the *Gene Technology Act 2000* we are pleased to submit our report to you as Chair of the Gene Technology Ministerial Council.

In summary, we believe that the Act and the national regulatory scheme have worked well over the last five years, and no major changes are required. We have recommended a number of changes intended to improve the operation of the Act at the margin.

We would like to thank all those who took part in the Review, either by providing submissions or other information to us or by taking part in consultations.

We commend the report to you and your Ministerial colleagues.

Yours sincerely

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Chair

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## List of acronyms and abbreviations

| | |
|---|---|
| AAT | Administrative Appeals Tribunal |
| The Act | *The Gene Technology Act 2000* |
| ACVM Act | *The Agricultural Compounds and Veterinary Medicines Act 1997* |
| AD(JR) Act | *Administrative Decisions (Judicial Review) Act 1977* |
| AHEC | Australian Health Ethics Committee |
| ANAO | Australian National Audit Office |
| APVMA | Australian Pesticides and Veterinary Medicines Authority |
| AQIS | Australian Quarantine and Inspection Service |
| CCI | Confidential Commercial Information |
| COAG | Council of Australian Governments |
| CSCG | Commonwealth State Consultative Group on Gene Technology |
| DIR | Dealing involving intentional release |
| DNA | Deoxyribonucleic acid |
| DNIR | Dealing not involving intentional release |
| DPP | Director of Public Prosecutions |
| EPBC Act | *Environment Protection and Biodiversity Conservation Act 1999* |
| FSANZ | Food Standards Australia New Zealand |
| GM | Genetically modified |
| GMAC | Genetic Manipulation Advisory Committee |
| GMO(s) | Genetically Modified Organism(s) |
| GTCCC | Gene Technology Community Consultative Committee |
| GTEC | Gene Technology Ethics Committee |
| GTIMS | Gene Technology Information Management System |
| GTMC | Gene Technology Ministerial Council |
| GTRAP | Gene and Related Therapies Advisory Panel |
| GTTAC | Gene Technology Technical Advisory Committee |
| IBC | Institutional Biosafety Committee |
| ICA | Insurance Council of Australia |
| IGA | Inter-governmental Agreement on Gene Technology |

| | |
|---|---|
| IGAE | Australian Inter-governmental Agreement on the Environment |
| NHMRC | National Health and Medical Research Council |
| NGOs | Non-government organisations |
| NICNAS | National Industrial Chemicals Notification and Assessment Scheme |
| NLRD | Notifiable Low Risk Dealing |
| OCS | Office of Chemical Safety |
| Other regulatory agencies | Commonwealth agencies involved in regulating products (FSANZ, AQIS, NICNAS, APVMA, TGA) |
| OGTR | Office of the Gene Technology Regulator |
| OECD | Organisation for Economic Co-operation and Development |
| PC1–4 | Physical containment Levels 1–4 (PC4 provides the greatest degree of containment) |
| Prescribed agencies | Agencies that must be consulted by the Regulator when developing a RARMP (FSANZ, AQIS, NHMRC, NICNAS, APVMA, TGA) |
| RAF | Risk Assessment Framework |
| RARMP | Risk assessment and risk management plan |
| RNA | Ribonucleic acid |
| RNAi | Ribonucleic acid interference |
| States | Australian States and Territories |
| The Regulator | Gene Technology Regulator |
| The Review | *Gene Technology Act 2000* Review Panel |
| TGA | Therapeutic Goods Administration |
| ToR | Term of reference |
| TRIPs | Trade-Related Aspects of Intellectual Property Rights |
| WHO | World Health Organization |

# EXECUTIVE SUMMARY

## Background

The *Gene Technology Act 2000* (the Act) is the Australian Government's component of the nationally consistent regulatory scheme for gene technology in Australia. The Act was passed following extensive public consultation and inquiries by Parliamentary committees.

Section 194 of the Act require d an independent review of the operation of the Act, including the structure of the Office of the Gene Technology Regulator (the OGTR), to be undertaken and tabled in Parliament by 21 June 2006, the fifth anniversary of the Act coming into force.

The Gene Technology Ministerial Council (GTMC), which oversees the cooperative national legislative scheme, appointed the independent panel and issued terms of reference for the Review in May 2005. The terms of reference are set out in chapter 1.

## Conduct of the Review

The Review prepared five issues papers based on the key issues raised in the nearly 300 submissions received in response to the terms of reference. Extensive national public and stakeholder consultation was carried out to ensure that the Review heard, first hand, the diverse range of community views in relation to the Act.

In addition to conducting public forums and stakeholder meetings, the Review visited contained laboratories and field trial sites. In undertaking the review and deciding recommendations, the Review considered material including the submissions received, the issues raised during consultations, the experience of the first four years of operation of the Act, emerging trends and international developments in gene technology and a range of reports and related literature.

## Scope of the Act

While the Review heard a high level of support for the existing scope of the Act with its focus on health and safety of people and the environment, some stakeholders were concerned that the scope of the Act should be widened. In particular, non-government organisations (NGOs) and farmers opposed to the introduction of genetically modified (GM) crops argued that the scope of the Act should be broadened to include economic, social and marketing impacts so that the impact on farmers who choose not to grow GM crops is considered under the Act. As discussed in chapter 3, the Review concluded that the existing scope of the Act should be maintained.

## Act achieving its object

The Review also found that the object of the Act — the protection of the health and safety of people and the environment — is being achieved. It found the Act to be rigorous with a high level of transparency in relation to the regulatory system. It also found that the regulatory framework set out in the Act is appropriate and is being applied effectively. However, the operational experience of the first four years has highlighted the need for some amendments to the regulatory system.

## Operation of the Act

One of the strengths of the Act is the consultation required with States, prescribed agencies, the Environment Minister, the Gene Technology Technical Advisory Committee (GTTAC), relevant local councils and the public in respect of the Risk Assessment and Risk Management Plan (RARMP) as part of the licence approval process. This consultation is designed to ensure that all relevant issues are presented to the Regulator for consideration in her decision whether to issue a licence.

The Review concluded that the consultative structure and process generally worked well, but that it could be improved by ensuring that GTTAC's membership includes members with primary expertise in public health and environmental risk assessment, combining the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC) and no longer requiring the National Health and Medical Research Council (NHMRC) to be consulted on all dealings involving intentional release (DIR) applications. Details of these recommendations are in chapter 5.

The Review heard a range of views on the timing and duration of the assessment of applications by the Regulator. It concluded that there was a case for distinguishing between field trials and commercial releases of Genetically Modified Organisms (GMOs), reducing the time limit for assessing field trial applications but extending it for commercial releases. It also recommended that a time limit be introduced for consideration of licence variations.

A number of submissions called for more stringent application of the Regulator's enforcement powers. After considering the issue in the light of the enforcement guidelines followed by the Regulator, the Review concluded that the powers are appropriate and used proportionately. The Review recommended amendments to the Act to allow the Regulator to direct licence-holders to comply with the Act in all circumstances, and to issue temporary permits to persons inadvertently finding themselves dealing with unlicensed GMOs so that these GMOs could be dealt with in accordance with the Act.

## Regulatory burden

Many submissions from the research community suggested that the regulatory burden imposed by the Act was not commensurate with the risk posed by dealings with GMOs by researchers. In discussions with researchers the Review also heard that the different guidelines for laboratory certification used by the Regulator and Australian Quarantine and Inspection Service (AQIS) caused a number of practical problems. The Review recommended (chapter 6) lessening the burden of compliance by removing any requirement to report on dealings with GMOs exempted by regulation and reducing the requirement to report on Notifiable Low Risk Dealings (NLRDs) to an annual report. It also recommended that the Regulator and AQIS work on harmonising certification requirements and introducing a system of single audits.

## Interface with other systems

The Review was told in submissions and discussions with industry that there was a sense of overlap and duplication between the Regulator and the other regulatory agencies. Examination of the legislation and discussions with the other regulatory agencies led the Review to conclude that the agencies worked very well together to minimise duplication and ensure consistency and coherence. The Review believed that to some extent this outcome reflected the personalities of the various regulators, and recommended (chapter 7) that a forum should be established to formalise these arrangements.

A number of submissions to the Review called for a "one-stop shop" to regulate all aspects of GMOs, including their use as foodstuffs, agricultural chemicals or medicines. The Review considered that there was no evidence of failure under the current system, and concluded that the system should be maintained.

Finally, the Review examined the extent of overlap between the Act and other legislation, including State legislation. Given that State legislation was outside the scope of the Review, the Review recommended that the Regulator should take steps to align her requirements with those of Standards Australia as far as practicable.

## Changing circumstances

The Review was not told of any development in the last four years which had cast doubt on the Act's flexibility to deal with changing circumstances and emerging technologies. It recommended (chapter 8) that the Act should be reviewed again in five years to ensure that it continues to accommodate emerging trends. The Review also examined the gene technology regulatory frameworks in a number of countries including Australia's major trading partners and competitors. It did not identify any features in overseas systems that could be adopted to enhance the operation of the Australian system. Indeed, the Review concluded that the Australian system is one of the most rigorous, transparent and accessible.

## The Inter-governmental Agreement

The major issue raised with the Review in relation to the Inter-governmental Agreement on Gene Technology (IGA) was the extent to which State moratoria on the growing of GM crops had undermined the nationally consistent framework which the IGA was intended to support. As discussed in chapter 9, industry, many farming and research groups were critical of the moratoria as halting the path to market for GMO food crops approved for commercial release by the Regulator, creating regulatory uncertainty, stopping further investment in GMO food crops and limiting Australian farmers' ability to compete internationally. On the other hand, NGOs and farming groups opposed to GMOs supported the moratoria, arguing that the States should have the right to decide not to allow GM crops to be grown if growing them would threaten markets for non-GM crops.

The Review noted that there was no evidence of adverse impacts on markets, and concluded that the moratoria were having detrimental rather than beneficial impacts. It recommended that all jurisdictions should reaffirm their commitment to a nationally consistent scheme, including a nationally consistent approach to market considerations, and work together to develop a national co-existence framework.

# LIST OF RECOMMENDATIONS

## Chapter Three: Scope of the Act (Term of Reference 1)

**Review the scope of the Act to determine whether the policy objectives remain valid; and consider other issues, technologies or organisms that may be included in the scope of the Act, including:**

*a) consideration of economic, marketing and trade, cultural and social impacts, and re-examine how ethical issues are considered*

*b) the definitions in the Act, including of the environment, and the need for the definition of other terms, including health*

*c) consideration of the technologies and organisms covered by the Act*

*d) consideration of a trait based or novel organism based regulatory scope*

***Recommendation 3.1:***

The Review concluded that the policy objectives remain valid and recommends that the scope of the Act should be maintained.

***Recommendation 3.2:***

The Review recommends that the definitions in the Act remain unchanged.

## Chapter Four: Act Achieving Objects (Term of Reference 2)

**Investigate whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is still appropriate.**

***Recommendation 4.1:***

The Review concluded that the object of the Act is being achieved and recommends that the principles of the regulatory framework stipulated in section 4 be maintained. (Some legislative amendments may be required to accommodate the remainder of the recommendations in this chapter).

***Recommendation 4.2:***

The Review recommends that the Act be amended to include powers for the relevant Minister to issue a special licence in an emergency (similar to provisions in other relevant regulatory schemes).

***Recommendation 4.3:***

The Review recommends that the Regulator continue to participate actively in the development of international guidance on acceptable data packages.

***Recommendation 4.4:***

The Review recommends that technical amendments suggested by the Regulator should be made to improve the workability of the Act.

## Chapter Five: Operation of the Act (Terms of Reference 3, 4 and 5)

3. Examine the structure and effectiveness of the OGTR.
4. Review the consultation provisions of the Act including:
   a) *their effectiveness with respect to their costs and benefits, including the value of advice received, and the transparency and accountability they provide;*
   b) *the functions and roles of the statutory advisory committees;*
   c) *the statutory timeframes for applications under the Act; and*
   d) *the stakeholders included in consultations for various applications under the Act.*
5. Determine whether the powers of the Act allow enforcement of compliance which is effective and appropriate to the circumstances, including instances where GMOs may be detected that are present unintentionally.

***(Term of Reference 3)***

The Review noted that the issues raised in TOR 3 were recently the subject of an intensive and thorough review by the Australian National Audit Office (ANAO). The Review has not made recommendations additional to those of the ANAO.

***Recommendation 5.1 (ToR 4):***

The Review recommends that GTTAC should include members whose primary expertise is in public health and in environmental risk assessment.

***Recommendation 5.2 (ToR 4):***

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

***Recommendation 5.3 (ToR 4):***

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.

***Recommendation 5.4 (ToR 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.

***Recommendation 5.5 (ToR 4):***

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

- 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;
- where the Regulator gives notice of a decision that a GMO may pose a significant risk that a second round of public consultation be required on any amendments that the Regulator makes to the RARMP after the initial round of public consultation currently required under section 52. This additional consultation period should be 20 working days.

***Recommendation 5.6 (ToR 4):***

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

***Recommendation 5.7 (ToR 4):***

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.

***Recommendation 5.8 (ToR 4):***

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.

***Recommendation 5.9 (ToR 4):***

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.

***Recommendation 5.10 (ToR 5):***

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.

***Recommendation 5.11 (ToR 5):***

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.

# Chapter Six: Regulatory Burden (Terms of Reference 6 and 7)

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

### *Recommendation 6.1:*

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

### *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.

### *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.

### *Recommendation 6.5:*

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

### *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.

## Chapter Seven: Interface with Other Systems (Terms 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.**

*(Note: recommendations in relation to harmonisation between AQIS and OGTR are dealt with under chapter 6 — Regulatory burden)*

***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.

***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.

## Chapter Eight: Changing Circumstances (Term of Reference 10)

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**

***Recommendation 8.1:***

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

# Chapter Nine: IGA Achieving its Aims (Term of Reference 12)

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

***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.

***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.

***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.

***Note: Changes to the Legislation (Term of Reference 11 )***

Suggested changes to the legislation are included, where appropriate, in the above recommendations.

# 1 INTRODUCTION AND TERMS OF REFERENCE

In May 2005 the GTMC issued the following terms of reference for the Review:

The *Gene Technology Act 2000* (Commonwealth) (the Act) is the Australian Government's component of the nationally consistent regulatory scheme for gene technology in Australia. The object of the Act is to protect the health and safety of people and the environment from risks posed by, or as a result of, gene technology by identifying those risks and managing them by regulating certain dealings with genetically modified organisms (GMOs). The Act establishes a regulatory framework through which its object is to be achieved. This framework provides for a precautionary approach and an efficient and effective system for the application of gene technologies that operates in conjunction with other Australian Government and State regulatory schemes relevant to GMOs and GM products.

Section 194 of the Act stipulates that the Ministerial Council for Gene Technology must cause an independent review of the operation of the Act, including the structure of the Office of the Gene Technology Regulator (OGTR), as soon as possible after the fourth anniversary of commencement of the Act. The Act states that the review must be undertaken by people the Ministerial Council agrees possess appropriate qualifications, and include people who are not employed by the Commonwealth or a Commonwealth authority. The report of the review must be tabled in each House of the Parliament within 12 months after the fourth anniversary of the commencement of the Act.

In establishing this review to examine the operation of the Act, the Ministerial Council is aware of the Australian Government's position on biotechnology, as outlined in the National Biotechnology Strategy: Consistent with safeguarding human health and ensuring environmental protection, that Australia capture the benefits of biotechnology for the Australian community, industry and the

environment. The Ministerial Council is also aware that there are a range of concerns amongst stakeholders and the public regarding gene technology and its regulation in Australia.

Having particular regard to

a) The National Biotechnology Strategy,

b) the Senate Community Affairs Reference Committee Report on the Gene Technology Bill 2000,

c) the House of Representatives Committee on Primary Industries and Regional Services Report 2000, and

d) the experience of the first 4 years of the operation of the Act, including the recent review of the Gene Technology Regulations 2001, and noting the object and regulatory framework set out in the Act, the Ministerial Council has established the following terms of reference for the review of the operation of Act:

### *Terms of Reference*

***Scope of Act***

1. Review the scope of the Act to determine whether the policy objectives remain valid; and consider other issues, technologies or organisms that may be included in the scope of the Act, including:

    a) consideration of economic, marketing and trade, cultural and social impacts, and re-examine how ethical issues are considered

    b) the definitions in the Act, including of the environment, and the need for the definition of other terms, including health

    c) consideration of the technologies and organisms covered by the Act

    d) consideration of a trait based or novel organism based regulatory scope

***Act achieving objects***

2. Investigate whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is still appropriate.

***Operation of the Act***

3. Examine the structure and effectiveness of the OGTR.
4. Review the consultation provisions of the Act including:
    a) their effectiveness with respect to their costs and benefits, including the value of advice received, and the transparency and accountability they provide
    b) the functions and roles of the statutory advisory committees
    c) the statutory time frames for applications under the Act
    d) the stakeholders included in consultations for various applications under the Act
5. Determine whether the powers of the Act allow enforcement of compliance which is effective and appropriate to the circumstances, including instances where GMOs may be detected that are present unintentionally.

***Regulatory Burden***

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

***Interface with other systems***

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.

***Changing circumstances***

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.

***Changes to the legislation***

11. Recommend amendments to the Act (including consideration of those recommendations made by State or Territory Parliamentary Committees), or alternatives to legislation, which improve the effectiveness, efficiency, fairness, timeliness and accessibility of the regulatory system.

***IGA achieving its aims***

12. Investigate whether the Intergovernmental Agreement on Gene Technology is achieving the aims listed in its Recitals.

The persons undertaking the review are to advertise nationally, consult with key interest groups and affected parties, receive submissions, and take into account overseas experience. Those consulted should include State and Territory Governments, the Gene Technology Advisory Committees, the Australian Government authorities and agencies prescribed by the Gene Technology Regulations 2001, including the Environment Minister, as well as the public.

## Process

### Call for submissions

The GTMC released the terms of reference for the review and some background information on the gene technology regulatory system when it made a call for submissions in May 2005. At this time, the GTMC also announced the appointment of an independent panel of three people, Ms Susan Timbs, Ms Kathryn Adams and Mr Murray Rogers, to conduct the review (see Appendix 1 for details of the panel members).

Nearly 300 submissions were received (see Appendix 2 for a list of individuals and organisations that made submissions to the Review).

### Issues papers

The Review analysed the submissions and identified a number of key issues raised in relation to the gene technology regulatory system. This led to the development of a series of five issues papers, which were released in early October 2005. The issues papers provided a factual statement of how the legislation and regulatory arrangements work followed by some views that were indicative of the issues raised in the submissions. Extracts from some submissions were included in the issue papers to give an indication of the opinions held by different groups.

The five issues papers and the terms of reference they addressed were:

| Issue paper | Term of reference (ToR) |
|---|---|
| Issues paper 1: Scope and efficacy of the Act | ToR 1 — Review the scope of the Act to determine whether the policy objectives remain valid; and consider other issues, technologies or organisms that may be included in the scope of the Act;<br>ToR 2 — Investigate whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is still appropriate. |
| Issues paper 2: Operation of the Act | ToR 3 — Examine the structure and effectiveness of the OGTR (Office of the Gene Technology Regulator);<br>ToR 4 — Review the consultation provisions of the Act;<br>ToR 5 — Determine whether the powers of the Act allow enforcement of compliance which is effective and appropriate to the circumstances including instances where genetically modified organisms (GMOs) may be detected that are present unintentionally. |

| Issue paper | Term of reference (ToR) |
|---|---|
| Issues paper 3: Regulatory burden of the Act | ToR 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;<br>ToR 7 — Review the system of approvals and the application of regulatory requirements commensurate to the level of risk. |
| Issues paper 4: The Act as part of a wider regulatory framework | ToR 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;<br>ToR 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;<br>ToR 12 — Investigate whether the Intergovernmental Agreement on Gene Technology is achieving the aims listed in its Recitals. |
| Issues paper 5: An international perspective | ToR 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. |

## National consultation

The issues papers served as the basis for the national public and stakeholder consultation process, which took place around Australia in October, November and December 2005 and January 2006. Public consultations began in Canberra on 21 October, followed by the Clare Valley and Adelaide on 23–25 October, Perth on 26–27 October, Brisbane and Townsville on 31 October–2 November, Narrabri and Sydney on 6–8 November, Melbourne and Horsham on 14–16 November, Hobart on 17–18 November and Darwin on 2 December.

These consultations consisted of a forum at each location which was open to the general public. In each State capital city, meetings were held with key stakeholder groups (see Appendix 3 for a list of people who attended these consultations). The consultations allowed the Review to hear, first hand, a range of views of interested parties, including State governments, industry, researchers, farm groups, NGOs and consumers.

The Review met with the Regulator, the prescribed Australian Government agencies that also have responsibilities relevant to the regulation of GMOs and GM products, the Environment Minister and the statutory committees under the Act. In addition, the Review made a series of visits to contained laboratories and field trial sites.

## Matters considered by the Review

The Review was cognisant that the policy positions reflected in the Act were reached after extensive public and stakeholder consultation prior to the passing of the Act.

The key focus of the Review was on issues that have emerged or changed significantly since the Act was passed and on matters arising from the practical operation of the Act.

The Review took into consideration the following matters:

- the submissions in relation to the terms of reference;
- the issues raised during consultations;
- the report from the Western Australia Legislative Council's Standing Committee on Environment and Public Affairs[1];
- the experience of the first 4 years of the operation of the Act, including the recent review of the Gene Technology Regulations 2001;
- practical operational issues that have been encountered in the first 4 years;
- technological change since 2001 and emerging trends in technology;
- emerging trends and international developments in biotechnology and its regulation; and
- reports and related literature.

## Form of recommendations

Having considered the list of matters above, the Review was left in no doubt of the wide variety of strongly held opinions on whether the current regulatory system is adequate to address the risks presented by GMOs. While the Review carefully considered the merits of each proposal to change the legislation, it has only formulated specific recommendations where it concluded that changes were warranted. Where the Review concluded that no change was warranted, the report sets out the Review's reasoning for this view.

## Acknowledgments

The Review panel would particularly like to acknowledge the time, effort and assistance of those people who lodged submissions and participated in the consultation process.

The Review would also like to acknowledge the work undertaken and assistance provided by the Secretariat.

1 Tabled in the Western Australian Parliament in July 2003

# 2 BACKGROUND ON GENE TECHNOLOGY

## What is gene technology?

Gene technology involves the modification of organisms by the direct incorporation, deletion or alteration of one or more genes or genetic sequences to introduce or alter a specific characteristic or characteristics. Organisms modified using gene technology are GMOs and GM products are things, other than a GMO, derived or produced from a GMO.

There are a variety of current and potential applications of gene technology including:

- medical research, for example, basic research in biology and medicine with micro-organisms and transgenic animals (primarily mice and zebra fish at present);
- agricultural biotechnology, for example, genetic modification of crops to introduce pest resistance, virus resistance or herbicide tolerance or salt tolerance;
- therapeutics applications that involve the modification of micro-organisms to produce insulin, or the modification of crops or animals to produce proteins of therapeutic value;
- industrial applications that modify micro-organisms to produce particular enzymes.

## Development of the gene technology regulatory system

The oversight of gene technology in Australia began on a voluntary basis with the formation of the Committee on Recombinant DNA that was set up by the Australian Academy of Science in the mid-1970s. This was followed by the Recombinant DNA Monitoring Committee which was established in 1981 in the federal Department of Science. These two committees comprised a range of scientific experts that effectively

provided a peer review assessment of proposals to conduct experiments with GMOs between 1975 and 1987.

The work of these organisations was consolidated into the Genetic Manipulation Advisory Committee (GMAC) in 1987. GMAC was an administrative body founded on the initiative of the then Minister for Industry, Technology and Commerce. It was funded federally and charged with the task of assessing risks to human health and the environment in connection with gene technology and providing advice to proponents on how risks associated with work with GMOs could be managed. It also provided advice to statutory agencies responsible for product approvals that contained GMOs, or contained things that were derived from GMOs.

While GMAC had no statutory powers or functions its advice was consistently sought and complied with by Australian researchers. Although GMAC had no enforcement powers, compliance with its recommendations was a condition of research and development funding from the Australian Government.

With the advent of significant advances in the application of the technology, increased commercial involvement, and elevated community concern about GMOs, in November 1998, the Australian Government, together with the States, initiated a cooperative process to develop a uniform, national approach to the regulation of gene technology. The Commonwealth State Consultative Group on Gene Technology (CSCG) prepared a paper entitled 'Regulation of Gene Technology' and sought public and other stakeholder comment. These consultations contributed to the preparation of a discussion paper by the CSCG entitled 'Proposed national regulatory system for genetically modified organisms — How should it work?'

The discussion paper was advertised widely in 1999 in national, State, and regional newspapers; mailed directly to over 2500 individuals and organisations representing a wide range of interests and all MPs and Senators in the Australian Parliament; and posted on the interim OGTR website. More than 200 written submissions were received. This initial development of the Act was informed by Australia's first consensus conference where a range of community representatives were invited to provide comment on the management of GMOs.

In December 1999 a draft Gene Technology Bill 2000 and accompanying Explanatory Memorandum were released for public comment. Public forums were held in all capital cities and a number of regional centres. Over 750 people attended and more than 160 written submissions were received. Such extensive consultation in the development of the regulatory scheme reflects the emphasis placed on community input and participation in the decision making process in relation to gene technology. This process generated strong agreement about what should be included and excluded from the scope of the legislation. In setting up the regulatory scheme the government sought to recognise and balance both the potential of gene technology to contribute to society and community concerns over the development and deployment of the technology.

On 21 June 2001 the Act and the Gene Technology Regulations 2001 (the Regulations) came into effect, establishing the national legislative scheme for the regulation of gene technology in Australia. The Act establishes an independent statutory office holder (the Regulator), who is charged with administering the Act and making decisions about the development and use of GMOs under the Act (see Appendix 4: The Application Approval Process, and Appendix 5: Structure of the Office of the Gene Technology Regulator).

## The Gene Technology Ministerial Council and the Gene Technology Intergovernmental Agreement

The implementation of the legislation and the role of the Regulator are overseen by the GTMC. The GTMC was established by the IGA between the Australian Government and the governments of all States. The IGA also commits State governments to enacting corresponding State legislation. The entire text of the IGA can be found at Appendix 6 to this report.

Functions conferred upon the GTMC by the IGA are to:

a. issue policy principles, policy guidelines and codes of practice to govern the activities of the Regulator and the operation of the Scheme (the 'Scheme' refers to the national legislative scheme to protect the health and safety of people and to protect the environment, by identifying risks posed by, or as a result of, gene technology and by managing those risks through regulating certain dealings with GMOs);

b. approve proposed regulations for the purpose of the Scheme;

c. approve the appointment (and, if necessary, the dismissal) of the Regulator, and of the chairpersons of the GTTAC, GTCCC, and GTEC, and advise the responsible Commonwealth Minister on the appointment of the members of those bodies;

d. ensure coordination with other Ministerial Councils on matters relating to gene technology and, in particular, harmonisation of regulatory processes relating to GM products;

e. oversee generally the implementation of the Scheme;

f. consider and, if thought fit, agree on proposed changes to the Scheme;

g. initiate a review of the Scheme in accordance with the specifications of the IGA; and

h. perform any other function conferred on the GTMC by the IGA.

In summary, the role of the GTMC is to provide policy input into the implementation and operation of the regulatory scheme. In addition, the GTMC provides advice to the Australian Government Minister for Health and Ageing on the appointment of the Regulator and appointment of members of the Gene Technology Committees (see below). The GTMC is supported by the Gene Technology Standing Committee comprised of senior Commonwealth and state department officials, and the Regulator is supported by the OGTR.

The Act provides for the GTMC to issue policy principles dealing with ethical issues relating to GMOs and the recognition of areas designated under State law for the purpose of preserving the identity of either GM crops or non-GM crops for marketing purposes (section 21).

The GTMC issued its first policy principle on 31 July 2003: the *Gene Technology (Recognition of Designated Areas) Principle 2003* which came into effect on 5 September 2003. This principle allows States to preserve the identity of GM or non-GM crops (or both) for marketing purposes.

## Coordination with other regulatory agencies and NHMRC

Australia's gene technology regulatory system does not operate in isolation, but rather as part of an integrated legislative framework. While the Regulator must consider risks to health and safety of people and the environment relating to the development and use of GMOs, other agencies with complementary expertise have responsibility for regulating GMOs or GM products as part of a broader or different mandate (in this report these groups are referred to as other regulatory agencies).

During the development of the gene technology legislation, it was determined that the activities of the Regulator should not override existing legislation or result in duplication. The Act was seen as a means of addressing areas of gene technology not currently covered by existing legislation. The Act thus incorporates a requirement for the Regulator to consult with other agencies on applications for DIRs, and was accompanied by consequential amendments of the other relevant Acts, relating to mutual consultation and exchange of information regarding their assessments and approvals.

Accordingly, where other agencies approve non-viable (i.e. unable to reproduce) products derived from GMOs, advice on these decisions is supplied to the Regulator for placing on the GMO record.

There are situations where approval of particular dealings with a GMO will require approval by both the Regulator and another regulatory body. The respective roles of these agencies are listed along with the relevant legislation in Table 1. For example, while the Regulator licences the release of a GMO that is used in human medicine into the environment, the Therapeutic Goods Administration (TGA) would have to authorise its dispensation to people.

Similarly, while the Regulator must approve the environmental release of GM insecticidal or herbicide-tolerant plants into the environment, the Australian Pesticides and Veterinary Medicines Authority (APVMA), which is responsible for the regulation of all agricultural chemicals, must register the insecticidal gene or approve the application of the herbicide to which the GM plants are tolerant.

Although the focus and responsibility of other agencies which regulate products that are, or are derived from, GMOs are distinct from those of the Regulator, all the agencies have a policy of aligning the decision making processes so far as is practicable. They work closely together to ensure thorough coordinated assessments of parallel applications are undertaken and, wherever possible, that the timing of decisions by both agencies coincide. An example of where this cannot apply is when Food Standards Australia New Zealand (FSANZ) is asked to assess the safety of a GM product that will be imported for use in human food before an application to grow the GMO from which it was derived in Australia is submitted to the Regulator.

While not strictly a regulatory agency, the NHMRC is also included in the list of prescribed agencies with which the Regulator must consult. The NHMRC has a number of committees which deal with matters that relate to the work of the Regulator. For example, there is cross-membership between the Gene and Related Therapies Advisory Panel of the NHMRC and the GTTAC. There is also cross-membership between the Australian Health Ethics Committee (AHEC) of the NHMRC and the GTEC.

*Table 1: Other Commonwealth Agencies in Australia with a role in regulating gene technology*

| GM products | Agency | Portfolio | Scope | Relevant Legislation |
|---|---|---|---|---|
| GMO dealings | **OGTR** Gene Technology Regulator and Office | Health and Ageing | OGTR administers a national scheme for the regulation of GMOs in Australia, in order to protect human health and safety and the environment by identifying risks posed by or as a result of gene technology, and to manage those risks by regulating certain dealings with GMOs. | *Gene Technology Act 2000* |
| Medicines, medical devices, blood and tissues | **TGA** Therapeutic Goods Administration | Health and Ageing | TGA administers legislation that provides a national framework for the regulation of therapeutic products in Australia and ensures their quality, safety and efficacy. | *Therapeutic Goods Act 1989* |
| Health and Medical Research | **NHMRC**[1] National Health and Medical Research Council | Health and Ageing | While not strictly a regulator, NHMRC provides funding for health and medical research, advises the community and governments on a range of health and health-related ethical issues. Through its oversight of the Gene and Related Therapies Research Advisory Panel (GTRAP), the NHMRC has a specific advisory role in relation to human clinical research using gene therapy or GM cells and tissues. | |
| Food | **FSANZ** Food Standards Australia and New Zealand | Health and Ageing | FSANZ is responsible for food standards, including mandatory approvals for the safety and labelling of food produced using gene technology before it can be sold. | *Food Standards Australia New Zealand Act 1991* |

| GM products | Agency | Portfolio | Scope | Relevant Legislation |
|---|---|---|---|---|
| **Agricultural and Veterinary Chemicals** | **APVMA** Australian Pesticides and Veterinary Medicines Authority | Agriculture, Fisheries and Forestry | APVMA operates the national system that evaluates, registers and regulates all agricultural chemicals (including those that are, or are used on GM crops) and veterinary therapeutic products. Assessments consider human and environmental safety, product efficacy (including insecticide and herbicide resistance management), and trade issues relating to residues. | *Agricultural and Veterinary Chemicals (Code) Act 1994; Agricultural and Veterinary Chemicals Administration Act 1994* |
| **Industrial Chemicals** | **NICNAS/OCS** National Industrial Chemicals Notification and Assessment Scheme; Office of Chemical Safety | Health and Ageing | NICNAS administers a national notification and assessment scheme to protect the health of the public, workers and the environment from the harmful effects of industrial chemicals. | *Industrial Chemicals (Notification and Assessment) Act 1989* |
| **Quarantine** | **AQIS** Australian Quarantine and Inspection Service | Agriculture, Fisheries and Forestry | AQIS regulates the importation into Australia of all animal, plant and biological products that may pose a quarantine pest and/or disease risk. | *Quarantine Act 1908; Imported Food Control Act 1992* |

1 NHMRC administers the *Research Involving Human Embryos Act 2002*; however, research with human embryos is excluded from the scope of the Act

# 3 SCOPE OF THE ACT

## Term of reference 1:

**Review the scope of the Act to determine whether the policy objectives remain valid; and consider other issues, technologies or organisms that may be included in the scope of the Act, including:**

*a) consideration of economic, marketing and trade, cultural and social impacts, and re-examine how ethical issues are considered*

*b) the definitions in the Act, including of the environment, and the need for the definition of other terms, including health*

*c) consideration of the technologies and organisms covered by the Act*

*d) consideration of a trait based or novel organism based regulatory scope*

## Policy objectives

The policy objective of the Act is set out in section 3, which provides that:

> The object of this Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

The current policy objective was universally endorsed as remaining valid. However, there were views put to the Review to extend the scope beyond the current focus on protection of health and safety of people and the environment, which, if accepted, would create new policy objectives. These matters are discussed below.

## Consideration of economic, marketing and trade, cultural and social impacts

There were many submissions and comments during the consultations on the issues raised by paragraph (a) of the ToR: should the Act require consideration of other impacts of GMOs? It should be noted that ethical issues are considered in chapter 5 in the discussion on the committees.

Many submissions to the Review, particularly those from industry, researchers and farming organisations seeking a choice to grow GMOs, supported the scope of the existing policy objective. They argued that health and safety of people and environmental protection were appropriate objectives for a regulatory framework which they saw as rigorous, transparent and science based, and that other impacts should be assessed in other ways.

In relation to marketing and trade impacts, these groups argued that the impacts of a GMO crop were heavily dependent on market conditions in what was essentially a global market, and that these conditions changed quickly. As such, it was considered inappropriate for a point of time assessment of market conditions to inform the decision on whether or not to release a GMO for commercial cropping by producers who wished to use it.

These groups supported their view with examples of how other agricultural issues involving introduction of new varieties had been dealt with outside a legislative framework (see case study below).

**Case study:**
**Market correction — Lupini beans**

Wild forms of the broadleaf lupin *Lupinus albus* contain high levels of bitter-tasting alkaloids. Once introduced into a sweet variety, outcrossing will cause the bitter gene frequency to increase with each season. In the 1990s the Australian lupins became too bitter and consumers reacted negatively to the product. The *albus* industry put in place a management plan to reduce bitter contamination in sweet crops. The management plan included such protocols as paddocks should be free of any volunteer lupini bean plants for a minimum of 2 years before considering a following *albus* crop and a 2 km isolation from any sweet *albus* crop. After the successful implementation of this management plan, the Australian *albus* is producing sweet lupins again and consumer demand has increased.

On the other hand, a number of submissions from NGOs, consumer groups and farming groups opposed to the introduction of GMO crops argued that the scope of the Act should be extended to require examination of economic, trade and marketing, and social and cultural impacts in reaching a decision whether or not to approve release of a GMO.

These groups believed that the cultivation of GMOs in Australia would lead to 'contamination' of non-GMO crops, and could lead to erosion of Australia's 'clean, green' image in overseas markets. These effects would lead to difficulties with market access and the prices paid for Australian products, and these economic and market impacts should be taken into account in deciding whether or not to release a GMO.

These views were also expressed in meetings with stakeholders and in public consultations. During these meetings the Review asked participants who supported consideration of economic and market impacts to suggest how these could be reflected in the assessment of specific applications by the Regulator. However, no relevant operational examples were identified.

In considering this issue, the Review also examined the scope of the agencies with a role in regulating gene technology such as National Industrial Chemicals Notification and Assessment (NICNAS), TGA, APVMA, FSANZ and AQIS (referred to as other regulatory agencies in this report). These systems focus on safety, efficacy (where explicit or implicit claims are made about the worth of the product) and international trade (in the case of APVMA).

The Review considered whether there was any basis for concluding that the particular characteristics of GMOs were such that their assessment should be extended but found no compelling case for extension. On balance, the Review concluded that the policy objective of the Act should remain the protection of health and safety of people and the environment.

## Benefit assessment

A closely related issue to that of widening the scope of the Act to include economic and other impacts is whether the Regulator should have regard to the benefits as well as the risks of GMOs. While some submissions and participants in consultations argued that the Regulator should have regard to benefits as well as risks, most regarded such an extension as impractical or undesirable.

It was considered impractical on several grounds. Firstly, the existence or scale of many benefits did not become apparent for some years after the GMO was released. Bt cotton was cited as an example of where new benefits are still being identified years after commercial release. Secondly, it would be very difficult to construct a calculus for measuring risk and benefit in the same time frame and dimension. During the

consultations, an individual observed that while it might be possible to make sense of risks and benefits in the same aspect of a GMO's impact on health or the environment, trying to compare risks and benefits across different aspects would lead the Regulator up blind allies and be unworkable.

Many groups opposed to the release of GMOs argued consideration of benefits was undesirable because it might result in presumed benefits outweighing risks. At the same time some proponents of GMOs argued against consideration of benefits on the basis that it would be seen to compromise the scientific approach to risk assessment by the Regulator.

The Review concluded that the risk assessment process contemplated by the Act should not be modified to a risk-benefit assessment.

## Efficacy

One submission suggested that for the special case of GM pesticidal crops, the responsibility for assessing the pesticide should be removed from the APVMA so that the sole responsibility for approving these crops would lie with the Regulator. This submission noted that as APVMA currently includes an assessment of efficacy for pesticides, the Regulator should then be required to assess efficacy for this group of GMOs.

The Review found that inclusion of consideration of efficacy was not consistent with the finding that the policy objectives should maintain their focus on health and safety of people and the environment.

***Recommendation 3.1: The Review concluded that the policy objectives remain valid and recommends that the scope of the Act should be maintained.***

## Definitions in the Act

Paragraph (b) of the first ToR requires the Review to examine definitions used in the Act, including in particular the definition of 'the environment' and the lack of a definition of 'health'.

The environment is defined in section 10 of the Act as including:

(a) ecosystems and their constituent parts; and

(b) natural and physical resources; and

(c) the qualities and characteristics of locations, places and areas.

This differs from section 528 of the *Environment Protection and Biodiversity Conservation Act 1999* (the EPBC Act) which defines the environment as including:

(a) ecosystems and their constituent parts; and

(b) natural and physical resources; and

(c) the qualities and characteristics of locations, places and areas; and

(d) heritage values of places; and

(e) the social, economic and cultural aspects of a thing mentioned in paragraph (a), (b) or (c).

A number of submissions to the Review suggested that the Act should be amended to adopt the wider definition in the EPBC Act, implicitly requiring the Regulator to have regard to social, economic and cultural impacts of GMOs.

The Review concluded that given its recommendation that the scope of the Act should not be widened to include economic and social impacts, it followed that the definition of the environment should not be widened.

While the object of the Act is to protect the health and safety of people, the term 'health' is not defined. A number of submissions suggested that the term should be defined, and suggested a definition drawn from the World Health Organization (WHO) constitution:

> *Health is the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.*

The issue attracted little comment during the consultation phase of the Review. Several individuals suggested that the term should be defined on the basis that clarity is always a good thing; but among this group there was only one supporter of the WHO definition. There were several suggestions that 'absence of disease' was preferable to 'a state of wellbeing'.

The Review noted that the term is not defined anywhere in the Australian statute book. It also noted that no case had been made out that the absence of a definition was leading to uncertainty or ambiguity in the application of the Act. It thus concluded that there is no need to include a definition in the Act.

One submission suggested that the Act should be amended to include a new definition for adventitious presence so that the unintended presence of an unlicensed GMO can be dealt with. The issue of unintended presence and how it can be more effectively managed in the Act is discussed in chapter 5.

***Recommendation 3.2: The Review recommends that the definitions in the Act remain unchanged.***

## Technologies and organisms covered by the Act

Paragraphs (c) and (d) of the first term of reference require the Review to consider the technologies and organisms covered by the Act and to consider a trait based or novel organism based regulatory scope. (Emerging technologies are discussed in chapter 8.)

The Act currently covers GMOs defined (in section 10) as organisms or descendants of organisms that have been modified by gene technology, together with anything declared by regulations made under the Act to be a GMO. It excludes human beings who have undergone somatic cell therapy and organisms declared by regulations not to be GMOs. Gene technology is defined as any technique for the modification of genes or other genetic material, apart from sexual reproduction, homologous recombination and any technique specified in regulations to be excluded from the scope of the Act. This means that the focus of the regulatory system is organisms derived by a particular process (gene technology).

In contrast, New Zealand regulates novel organisms so that the focus of the regulatory system is assessing organisms that have never been seen in New Zealand, whether they are naturally occurring or derived by a technological process. The Canadian system focus is on the traits of the organism. For example, the trait of herbicide tolerance in a crop, whether it occurs naturally or has been put into the crop by a technological process. These regulatory systems are discussed in more detail in chapter 8.

Very few submissions addressed these issues. The Review did not have any evidence presented to it that would necessitate a move to a novel organism approach.

The Review noted that a number of submissions and participants in consultations drew attention to the fact that there was no difference between the effective outcome of gene technology and other plant breeding processes including selective breeding or mutagenesis and yet only gene technology was subject to regulation. For example, tt (triazine tolerant) strains of canola had been developed through non-GM processes, while glyphosate tolerant strains had been developed through gene technology. The outcome was effectively the same: a canola variety unaffected by exposure to a herbicide which controlled weeds in the crop. Under a trait-based approach, tt strains and glyphosate tolerant strains would be subject to the same regulatory regime.

The Review noted that the focus and approach of the Act was thoroughly considered during its development and concluded that there was no evidence presented to warrant changing the current system.

# 4 ACT ACHIEVING OBJECTS

## Term of reference 2:

**Investigate whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is still appropriate.**

## Object of Act being achieved

In considering whether or not the object of the Act is being achieved, the Review examined all the terms of reference and then made an overall assessment. Having considered all the material in this report, the Review concluded that the object is being achieved.

## An appropriate regulatory framework

Section 4 of the Act provides that:

> The object of this Act is to be achieved through a regulatory framework which:
>
> (aa) provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation; and
>
> (a) provides an efficient and effective system for the application of gene technologies; and
>
> (b) operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products.
>
> *Note: Examples of the schemes mentioned in paragraph (b) are those that regulate food, agricultural and veterinary chemicals, industrial chemicals and therapeutic goods.*

This chapter focuses on paragraph 4(aa), known as the precautionary principle; looks at whether or not there is a need to introduce a strict liability regime or mandatory insurance; and assesses whether or not some changes to the regulatory system to address effectiveness and efficiency are required. Other chapters also address efficiency and effectiveness of the system. The operation of the Act in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products is addressed in chapter 7.

The Review found the Regulator's Risk Analysis Framework (RAF) provided useful context for this term of reference. The RAF was revised and re-issued in January 2005, taking into account the lessons learnt from the first four years of operation of the Act and advice from the GTEC on more effective ways to communicate risk. The Review found that the revised RAF has had a major influence on the structure and format of the Regulator's risk assessment and risk management plans (RARMPs), improving their transparency and accessibility.

## Application of the precautionary principle

The version of the precautionary principle cited in section 4 is the same as Principle 15 of the 1992 Rio Declaration on Environment and Development adopted by the United Nations sponsored conference on Environment and Development:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The version in the Act differs from the principle enunciated in the Australian Intergovernmental Agreement on the Environment (IGAE), which was concluded in 1992 between the Commonwealth, States and representatives of local government.

The precautionary principle in the IGAE is stated as:

> Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.
>
> In the application of the precautionary principle, public and private decisions should be guided by:
>
> (i) careful evaluation to avoid, wherever practicable, serious or irreversible damage to the environment;
>
> (ii) an assessment of the risk-weighted consequences of the various options.

This version of the principle is incorporated in other Commonwealth statutes dealing with environmental matters (section 391 of the EPBC Act and section 39Z of the *Great Barrier Reef Marine Park Act 1975*). Most State environmental legislation also contains this version of the precautionary principle.

Some submissions called for the wording in the Act to be amended to exclude reference to cost-effective. The Review identified many versions that are used around the world and noted that their underlying theme is a need for a cautious and careful approach to decision-making. The Review noted that negotiation of the IGAE version of the wording pre-dates the Rio version and that Parliament had chosen a form of words with wide international acceptance as the most appropriate for the Act. The Review did not identify any international developments that had occurred since 2000 to suggest a change to the wording was justified.

The Review further found that there are many possible interpretations of the wording and noted that some submissions called on the Regulator to apply the precautionary principle 'more rigorously'.

In her submission the Regulator outlined how she approached the issue:

> The Act indicates that the Regulator is required to take protective measures as a prudent and sound response in the face of a lack of full scientific certainty. The approach adopted by the Regulator in addressing s.4(aa) is outlined in the Risk Assessment Framework (RAF) document. Perceived threats should be based on credible scientific hypotheses and have a plausible causal pathway; the seriousness of the threat should be taken into account and measures to prevent damage should not be limited to bans.
>
> The RAF, while emphasising that protective measures should be both commensurate with the risk and sufficient to minimise exposure to harm, also details how a cautious approach is employed in the administration of the Act to achieve protection of people and the environment. These can be grouped into actions taken prior, during and after a proposed dealing.

The 2005 RAF essentially sets out a 'cautionary' understanding of the principle and if applied effectively and consistently, would preclude the release of any GMO that might present 'threats of serious or irreversible environmental damage' without adequate risk mitigation measures as part of the licence conditions.

The Review concluded that:

- the Regulator applies a cautionary approach to licence decisions; and
- the precautionary principle in its current form is still appropriate.

## Strict liability for contamination

Many submissions to the Review from NGOs, consumer organisations and farming groups opposed to the introduction of GM crops called for the imposition on licence-holders of strict liability under common law for any damage caused by GMOs (note the Act currently provides for strict liability for offences and this is distinct from strict liability under the law of civil liability).

On the other hand, research, industry, and other farming groups argued that such a requirement was unnecessary because the common law provided effective remedies for persons incurring damage from GMOs. They argued that imposing strict liability on licensees would stop the development and marketing of GMO crops, because licensees would not be willing to accept liability for damages caused by GMO crops regardless of the circumstances in which the GMO crops were planted or cultivated.

In considering this issue the Review noted that the law of torts is a matter for State governments. Any codification of the law to impose strict liability would thus require amendments to State law rather than the Act.

The key reasons put forward for strict liability are discussed below.

1. The common law is deficient in not allowing recovery of damages for pure economic loss that farmers might suffer as a result of unintended presence of GMOs in their crops.

The Review noted that case law was developing to recognise pure economic loss, and that the *Perre v Apand*[1] case decided in the High Court in 1999 covered many of the issues that might be expected to arise concerning losses arising from unintended presence of GMOs in non-GM crops. The *Trade Practices Act 1974* and other consumer protection legislation would also afford redress to persons affected by purchasing seed supposed to be GM-free but containing GM material.

2. It would avoid the need for persons incurring damage from GMOs to initiate legal action.

However, while making licensees of GMOs strictly liable for any damage their GMOs might cause would obviate the need for plaintiffs to prove fault, the Review noted that plaintiffs would still need to demonstrate before a court the causal link between the GMO and the damage they had incurred as well as the extent of their loss in order to receive damages.

In considering the issue, the Review noted that there is no other product in Australia which has attracted a strict liability presumption under the common law. In the

1 [1999] 198 CLR 180

past, and also in overseas jurisdictions, courts have imposed a strict liability regime in relation to 'superhazardous goods'. Given that the object of the Act is to manage risks to protect health and safety of people and the environment, it is contradictory to categorise any GMO assessed by the Regulator and licensed for intentional release as a superhazardous good.

The Review also noted that applying strict liability to a licensee of a GMO intended for cropping could create a risk that farmers using the GMO would have less incentive to take care to avoid practices that could result in unintended presence in a neighbour's field. While this could be addressed by the licensee imposing strict conditions on the end-user, this would not be as efficient as exposing the end-user to direct liability for incautious use of the GMO. In some circumstances it would be inequitable to impose strict liability on a licensee. For example, if a person deliberately distributed GM seeds across his non-GM neighbour's paddock it would be unfair to require the licensee to bear any liability for the use of their product.

The Review noted that the European Union Directive 2004/35/EC8 on environmental liability specifically excludes civil liability for property damage or economic loss from, for example, adventitious presence of unwanted GM material/traits/species from neighbouring properties in crops or wild relatives.

On balance, the Review concluded that a strict liability regime should not be introduced into the Act.

## Compensation fund

A number of groups proposing a strict liability regime drew attention to the recent Danish law establishing a compensation fund for farmers adversely affected by the unintended presence of GMOs in their crops and suggested that a similar regime may be appropriate for Australia.

The Danish scheme is funded through a levy paid by growers of GMOs for areas planted. According to the EU decision authorising the scheme[2]:

> ***Conditions for receipt of compensation***
>
> 26) Payment of compensation is limited to cases, where GM-material is found in non-GM-crops of the same type as the GM-crops or a closely related type (GM-crops, which can cross into non-GM-crops) in the same cultivation season and within a specifically determined area (distance from GM-crops). With regard to the cultivation of ecological seed corn, the only condition relates to the cultivation season.

2 http://europa.eu.int/comm/secretariat_general/sgb/state_aids/agriculture-2004/n568-04.pdf

27) Compensation is only paid out for losses if the occurrence of GM-material in injured crops, as defined above, exceeds a threshold value of 0.9 per cent. This threshold value is the limit under which genetically modified foodstuff and feed stuff do not have to be marked for contents of genetically modified organisms, refer regulation (EF) Number 1829/2003.

28) The farmer must apply for compensation no later than 14 days after the occurrence of GM-material has been ascertained. Proof of the occurrence and amount of GM-material must be undertaken by officials or authorised persons.

29) Compensation is paid out, regardless of whether the farmer, from whose fields the GM-material has spread, can be identified.

30) Only those farmers who have suffered a loss in connection with primary production are entitled to compensation.

***Amount of compensation***

31) The amount of compensation is limited to the price difference between the market price of a crop, which has to be marked for contents of GM-material, and a crop, which does not demand such marking (that is contents of GM-material of under 0.9 percent). The Danish Plant Directorate sets the market price on the basis of monthly statistics from the Food Economics Institute (Fødevareøkonomisk Institut).

32) For organic cultivation, compensation may be granted for the time, which is spent on the replanting of acreage, until production again can be sold as organic. This time depends on the type of production and is set by the Danish Law of Ecology Number 118 of 3.3.1999. Compensation only covers the differences between the market price of the products and the price which would have been attainted had they been sold as organic products.

33) If the producer has entered into a contract about delivery of GM-free products to a certain price, the compensation is based on the difference between this price and the market price. Compensation is however only paid for the part of the product, in which the contents of GM-material is over 0.9 percent, regardless which limit for contents of GM- material, producer and buyer may have agreed upon.

34) Compensation from other sources is deducted from the compensation, which is paid out under the support measures in question.

The Government then seeks reimbursement for the cost of the compensation that has been paid from the farmer from whose fields the GM material emanated (if that person can be identified). If the farmer does not agree to make reimbursement the authorities may pursue the claim in court under standard civil law provisions, where fault must be proven.

The Review noted that the compensation is limited to the difference in market price between the crop that is sold as 'GM free' and a crop that is sold as co-mingled. As no premium has yet been identified for 'GM free' commodities[3], the amount of compensation is likely to be minimal.

The Review considered whether there would be any benefits for such a scheme in the Australian context. It concluded that the need for a compensation scheme rested on the presumption that the common law and consumer protection legislation would not prove adequate in dealing with losses covered under the Danish scheme.

Having considered these issues as well as the operation of the common law and consumer protection legislation in Australia, the Review concluded that a mandatory compensation scheme such as the Danish scheme should not be introduced.

## Mandatory insurance for GMOs

A related issue to strict liability at common law was mandatory insurance. Sub section 62(3) of the Act provides that licence conditions for the release of GMOs into the environment may:

> ***include conditions requiring the licence holder to be adequately insured against any loss, damage, or injury that may be caused to human health, property or the environment by the licensed dealing.***

So far the Regulator has not imposed any conditions of this sort.

Many submissions to the Review from groups seeking the imposition of a strict liability regime under common law also called for mandatory insurance for licence holders to cover their obligations under such a regime. On the other hand, groups opposed to strict liability saw no need for mandatory insurance.

In considering this issue the Review noted that there are various mandatory schemes in Australia at present.

Some of these cover particular activities, such as driving a motor vehicle (to the extent of personal injury liability to other people) and employing staff (to the extent to which they are injured in the workplace). The policy rationale for these schemes is to afford protection to people against financial loss arising from personal injury.

3 Foster, M. 2003, *GM Canola: What are its Economics under Australian Conditions?*, Australian Grains Industry 2003, ABARE, Canberra.

Other schemes cover particular services, such as providing legal advice or building houses, to the extent to which there are deficiencies in the advice or the house. Some schemes are intended to protect consumers placing large sums of money in the hands of providers prior to completion of the service.

However, there are no products covered by statutory insurance requirements. Not even the manufacturers of products which can be seen as inherently dangerous, such as chemicals or explosives, are required to hold product liability insurance. The community instead relies on consumer protection legislation, product standards and industry codes of practice to ensure that products generally are fit for sale and to mitigate the risks of harm from potentially dangerous products. The Review sought comment from the Insurance Council of Australia (ICA) and noted that the ICA was not in favour of imposing mandatory insurance because of practical limitations.

On balance, the Review concluded that mandatory product insurance for GMOs should not be required. The Review considered that the Regulator should retain the existing power under the Act to impose such an insurance condition on a particular release if she considered it warranted by specific circumstances.

> ***Recommendation 4.1: The Review concluded that the object of the Act is being achieved and recommends that the principles of the regulatory framework stipulated in section 4 be maintained. (Some legislative amendments may be required to accommodate the remainder of the recommendations in this chapter).***

### An efficient and effective system for the application of gene technologies

The Review identified a number of changes to the Act that would improve the efficiency and effectiveness of the gene technology regulatory system. These are discussed below.

## Emergency approvals

The Regulator pointed out in her submission that she was unable to fast track an approval in an emergency. The Review noted that the Regulator had approved a genetically modified cholera vaccine for release into the environment in conjunction with the relevant approval from the TGA. It is conceivable in the future that genetically modified vaccines (either for human or veterinary use) may be required in an emergency. The current provisions in the Act would mean that such a vaccine (that may have already been approved overseas) could not be released into the environment in Australia without the standard 170 day approval process.

In contrast, the TGA and the APVMA (the relevant product regulators for these vaccines) both have emergency approval mechanisms. The Review identified that most of the other regulatory agencies have provisions for emergency approvals and that generally the power is given to the relevant Minister.

The Review concluded that the lack of emergency approval powers impacted on both the effectiveness of the regulatory system and consistency with the other regulatory groups. The inclusion of emergency approval powers would make the gene technology regulatory system more effective and bring greater consistency. It would be appropriate for this power to be given to the relevant Minister rather than the Regulator.

***Recommendation 4.2: The Review recommends that the Act be amended to include powers for the relevant Minister to issue a special licence in an emergency (similar to provisions in relevant regulatory schemes).***

## Rights of appeal and review

The Review noted some submissions sought to give third parties the right to appeal decisions of the Regulator. This issue had been considered during development of the legislation when the Senate Community Affairs References Committee recommended that the Bill be amended to provide for the right of third parties to apply for review of a decision of the Regulator. The Committee believed that the Bill unfairly discriminated against third parties wishing to appeal the grant of licences.[4]

However, the Parliament did not accept this recommendation and the Bill was passed into law without direct provision for third party appeal.

It is important to note the distinction between review by the Administrative Appeals Tribunal (AAT), which examines the merits of an administrative decision and can set aside a decision and replace it with a preferred decision, and review by the Federal Court under the *Administrative Decisions (Judicial Review) Act 1977* (AD(JR) Act), which can only go to defects in the process of decision making and remit a flawed decision to the decision maker for reconsideration.

It is a feature of many legislative schemes that only persons directly affected by a decision can access the AAT. This is intended to limit the possibility of vexatious appeals.

While Division 2 of Part 12 of the Act provides for internal review (section 181) and review by the AAT (section 183) of a wide range of decisions, it limits the right to seek a review to eligible persons. Eligible persons are defined as applicants for or holders of licences, certification or accreditation.

4 Senate Community Affairs References Committee, 2000, *A Cautionary Tale: Fish Don't Lay Tomatoes*, November, p.144.

The Review found that the current AAT appeal eligibility provisions are consistent with the legislation administered by the other regulatory agencies, except the *Quarantine Act 1908* (which does not provide for AAT appeals). The Review could not find any justification for distinguishing the Act from the legislation administered by the other regulatory agencies and concluded that the AAT appeal provisions should remain unchanged.

The AD(JR) Act allows 'aggrieved persons' access to the Federal Court. Case law has defined an aggrieved person as one who has an interest above that of an ordinary member of the public such that they will suffer a particular disadvantage from the decision beyond that of an ordinary member of the public. This definition has been widened by specific provisions in some legislation. Section 183A of the Act widens the meaning of an aggrieved person to include the States.

The Review looked at the review provisions in the legislation of the other regulatory agencies and confirmed they are similar to the current provisions in the Act (see chapter 7).

The Review also considered the appeal and review mechanisms in the EPBC Act. For environmental assessments, the EPBC Act has appeal provisions that are unusual compared with many other decision-making agencies. Under Part 3 of the EPBC Act, which relates to activities that have a significant impact on matters of national environmental significance, there is no provision for AAT appeals.

However, this part of the EPBC Act provides extended standing for AD(JR) appeals to:

- an individual (Australian citizen) if at any time in the last 2 years they have engaged in a series of activities for protection or conservation of, or research into, the environment, or
- an organisation or incorporated association whose purposes include protection or conservation of, or research into, the environment and, who engaged in a series of activities for those purposes any time in the last 2 years.

The EPBC Act and the Act differ significantly in their process and consultation provisions. Under the Act, consultation is required with the prescribed agencies, the States, the Environment Minister, relevant local councils and GTTAC in addition to the public. This is designed to ensure that all issues relevant to the Regulator's decision are presented to the Regulator for her consideration.

While the EPBC Act allows for a period of public consultation on the applicant's environmental impact statement, it does not specifically provide for consultation with the wide group described above. The Review concluded that the appeal and review provisions should remain unchanged.

## The type of data required by the Regulator

Some submissions criticised the type of data that the Regulator accepted as part of applications. This data can include unpublished research and in house studies conducted by the applicant. These submissions argued that such data lacked credibility and it followed that decisions of the Regulator based on this data also lacked credibility. The submissions called for the Regulator to restrict the data submitted to peer reviewed and published studies.

The Review heard from the Regulator that in developing her risk assessment and RARMPs she was not restricted to the information provided by the applicant and used a range of other sources such as assessments done by other regulatory agencies and the general scientific literature. She expressed concern at any restriction of accepted data to peer reviewed and published data since this would mean that she did not receive raw data on which to make her own independent analysis.

The Review heard from all the other regulatory agencies that they accept raw data and unpublished studies. These agencies rejected the suggestion of restricting data to peer reviewed and published studies as this would severely limit the value of the information they received. Further, the Review heard that the data requirements of the other regulatory agencies met relevant international standards for datasets.

The Review concluded that the type of data accepted by the Regulator was consistent with the other regulatory agencies. The Review noted that there was not yet any international consensus on datasets for GMOs. An international standard for the type of data needed to evaluate GMOs is under development and the Review heard that the Regulator is participating in this process.

The Review concluded that the data considered by the Regulator should not be limited to peer reviewed and published studies and that the Regulator should continue to participate actively in international initiatives to develop guidance on appropriate datasets.

***Recommendation 4.3: The Review recommends that the Regulator continue to participate actively in the development of international guidance on acceptable data packages.***

### Data protection

Some industry submissions called for improvements in data protection under the Act. Currently, there is provision in sections 184–187 to declare information confidential commercial information (CCI) if it meets certain criteria. In addition, some information provided to the Regulator may be patentable and subject to protection through the patents system.

One submission suggested that the Act may possibly breach Australia's obligations under the international Agreement on Trade-Related Aspects of Intellectual Property rights (TRIPS).

The relevant paragraphs of the TRIPS Agreement are:

> ***Article 39.1… Members shall protect… data submitted to governments or governmental agencies in accordance with paragraph 3.***

Article 39.3

> ***Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.***

The TRIPS Agreement therefore requires that members must protect data submitted to governments against unfair commercial use when that data is required to obtain marketing approval for pharmaceutical or agricultural chemical products which use new chemical entities.

The information that is provided to the Regulator is not required for the purpose of obtaining marketing approval for pharmaceutical or agricultural chemical products that use new chemical entities. Therefore Article 39 of the TRIPS Agreement does not apply.

The Review noted that some of the other regulatory agencies have provisions that protect data by preventing the decision-maker from using information provided by one applicant in the assessment of a similar product without the agreement and knowledge of the first applicant. However, there is no consistency across regulatory systems and the terms of the protection afforded vary greatly.

The Review heard from industry that the limited data protection available under the Act could potentially be an impediment to conducting research in Australia. The Review concluded that, if this happens, it could be counterproductive to the aims of the National Biotechnology Strategy. Therefore it should be kept under close review and consideration should be given to a process for achieving greater consistency across regulatory systems.

## Access to information

The Review heard calls to increase the information on applications that was made available to the public. The main concern was the inability to access information declared by the Regulator to be CCI and difficulties experienced in reviewing some applications other than in Canberra.

Currently under the Act, anyone can access the application and supporting documents with any CCI removed. The Review heard that in most cases copies of this information are posted out but it is the Regulator's practice that in the case of an application which runs to several volumes of information, a copy of the completed application form and the list of supporting documents are posted out. In this case the whole supporting material is made available for viewing in a reading room in Canberra or people can request relevant parts of the supporting material to be posted to them. Some people argued this impeded access unnecessarily.

The Review heard that prescribed agencies, the Environment Minister, GTTAC and the States have access to all information in the application including the CCI.

The Review noted that compared with other regulatory agencies and comparable regulatory agencies overseas, the gene technology regulatory system was amongst the most transparent, and that reading rooms in Canberra are also operated by some of the other regulatory agencies. In addition, some of the other regulatory agencies did not make any information on the application available to the public.

The Review considered the approach taken by the Regulator to public access to applications which run to several volumes was pragmatic and cost effective. The Review concluded that the current public access provisions are appropriate and should not be changed.

## Regulator's technical amendments

The Regulator also suggested minor amendments to the Act that would improve the workability of the Act but would not change the policy intention of the Act. These amendments are listed in Appendix 7. The Review supports these suggested amendments.

***Recommendation 4.4: The Review recommends that technical amendments suggested by the Regulator should be made to improve the workability of the Act.***

# 5 OPERATION OF THE ACT

## Term of reference 3, 4 and 5:

3. Examine the structure and effectiveness of the OGTR.
4. Review the consultation provisions of the Act including:
   a) *their effectiveness with respect to their costs and benefits, including the value of advice received, and the transparency and accountability they provide;*
   b) *the functions and roles of the statutory advisory committees;*
   c) *the statutory timeframes for applications under the Act; and*
   d) *the stakeholders included in consultations for various applications under the Act.*
5. Determine whether the powers of the Act allow enforcement of compliance which is effective and appropriate to the circumstances, including instances where GMOs may be detected that are present unintentionally.

## ToR 3 — Structure and effectiveness of the OGTR

The Review noted that the issues raised in ToR 3 were recently the subject of an intensive and thorough review conducted by the Auditor-General (Regulation by the Office of the Gene Technology Regulator, the Auditor-General, Audit Report No 7 2005–06, Performance Audit).

The major conclusions of the performance audit were:

29. Overall, OGTR has developed and implemented policies and procedures for the efficient and effective discharge of selected functions entrusted to it under the *Gene Technology Act 2000*. OGTR has processed applications within the required time frames and has exceeded targets for annual monitoring of DIR field trial sites.

30. OGTR has good information on its costs and resource requirements, although close monitoring of current staffing levels and the risks to attracting and retaining staff is necessary to ensure that it continues to have the staff necessary for it to effectively perform its regulatory functions.

31. Although OGTR reports a significant amount of operational information, there is room for better use of this information in measuring and improving performance.

32. The ANAO has made five recommendations and suggestions for improvement:

- The ANAO recommends that OGTR review and revise its forms and guidance documents in order to facilitate and ensure high level compliance with OGTR information requirements and to facilitate more efficient and effective regulation;
- In order to facilitate and enhance OGTR decision-making, the ANAO recommends that OGTR develop and publish clear guidance to applicants on the process and policies applied by OGTR in assessing applications for variation, cancellation, transfer and suspension;
- The ANAO recommends that OGTR adopt formal mechanisms for the review of its policy, procedure and guidance documents (and maintain records of such reviews), to ensure that they remain consistent and up-to-date;
- In order to provide better information on OGTR monitoring of licences and other instruments, the ANAO recommends that OGTR more fully explain its reported rates of monitoring, including maintaining and publishing information on the number of sites or organisations yet to be visited by OGTR. This will also enable any gaps in OGTR coverage of sites in its monitoring and inspection activities to be more readily identified;

- The ANAO recommends that OGTR seek clarification of its obligations (arising under the Act) to publicly report annual information on its operations. In order to facilitate better use of OGTR performance information and foster confidence in OGTR implementation of the Act, OGTR should assess the need for consolidated annual reporting (internal and/or external) of the performance information provided in its quarterly reports, as well as of other relevant information on its activities throughout the year.

Health has agreed to all recommendations.

The OGTR accepted all five of the ANAO recommendations and is in the process of implementing the improvements.

The Review noted that most users of the regulatory system were complimentary about the overall operation and approach of the OGTR with some minor comments in relation to the timeliness and consistency of advice. The Review considers that these issues have been picked up in the ANAO recommendations and other Review recommendations. Additionally, one submission recommended that the legislation be amended to provide for monitoring of licence-holders and DIR licences every three years. Currently there is no legislative requirement that specifies the frequency of monitoring that must be undertaken and the ANAO has recommended making more information publicly available so that any gaps in the coverage of monitoring activities can be readily identified.

The Review noted that the current arrangements provide the Regulator with the flexibility to design monitoring programs on a case by case basis and take into account the track record in compliance of the licence-holder. Based on the OGTR's adoption of the ANAO's recommendations and the OGTR's monitoring performance, the Review concluded that an amendment to the Act to specify a standard monitoring frequency was not warranted.

Due to the thoroughness of the ANAO review and its assessment of the structure and effectiveness of the OGTR, the Review has not found it necessary to make recommendations additional to those of the ANAO.

## The Regulator's interpretation of 'environment'

A number of submissions suggested that the Regulator had adopted a narrow interpretation of the definition of the environment which excluded agricultural systems, roadside verges and other non-natural ecosystems. In her submission the Regulator stated that this was not the case, and that the impact on agricultural and other non-natural ecosystems was taken into account in her risk assessments and decisions.

This issue was also raised in public consultations. However, having examined a number of RARMPs, the Review concluded that the Regulator effectively considers the impact of GMOs on the full range of relevant ecosystems.

## How the Regulator deals with public health risks

The Review noted concerns from some members of the public that the Regulator's human health assessment is limited to occupational health and safety risks and that this meant there was a serious gap in the assessment of public health risks. In consultations, the Regulator explained that to assess any given GMO, she identifies all possible human health risks but where she is satisfied that another Commonwealth regulatory agency will consider some or all of the human health risks, she does not duplicate their assessment. Thus, in the case of a GMO that will be used for human consumption, she acknowledges that FSANZ is the appropriate body to do an assessment of the food as consumed. The Regulator considers the remaining human health risks that relate to contact exposure (such as the potential to inhale the GMO or come into direct contact with it). However, for a GMO where no product regulatory agency can be identified, the Regulator would cover all human health risks.

## ToR 4 — The Regulator's role in providing information

The Review noted that some stakeholders considered that the Regulator should do more to explain gene technology and to promote the potential benefits from using this technology. The Regulator told the Review that her role was restricted to providing information on the gene technology regulatory system and explaining her decisions. The Review noted that other government agencies such as Biotechnology Australia provide more general information on gene technology and biotechnology and agreed that it was not the Regulator's responsibility to promote gene technology.

With reference to what information is made publicly available via the record of GMO and GM product dealings, one submission recommended that the existing provisions be extended substantially. The Review noted that there is already extensive information made publicly available, and that the extent of the information contained in the record is wider than that available in comparable regulatory systems. The Review thus considered it unnecessary to extend the provisions.

The Review also noted concerns from some stakeholders that there were some human health risks that were not considered by the Regulator, particularly when a GMO was still at the field trial stage. After exploring this issue in depth, the Review concluded that these concerns were a result of miscommunication, as it was clear from examining RARMPs that the Regulator, where relevant, imposed conditions on field trials of GMOs to prohibit GMOs being used as food for animals or humans. This was because at the field trial stage, the GMOs would not usually have undergone an assessment by FSANZ. To avoid these misperceptions the Review suggests that the Regulator clarify the language used in summary documents.

## Statutory advisory committees

### Roles and functions

The consultation provisions of the Act were a central element of the Review's discussions with the public and stakeholders. There were divided views on the effectiveness and appropriateness of these provisions.

There are currently three statutory advisory committees under the Act — GTTAC, GTEC and GTCCC. Communiqués providing an overview of the matters considered at each of the committees' respective meetings are published on the OGTR website.

GTTAC provides scientific and technical advice, on the request of the

Regulator or the GTMC, on:

- gene technology;
- GMOs and GM products;
- applications made under the Act;
- biosafety aspects of gene technology; and
- the need for and content of policy principles, policy guidelines, codes of practice and technical and procedural guidelines.

GTTAC's key role is to provide expert scientific advice to the Regulator on applications and on risk assessment and risk management plans.

GTCCC provides advice at the request of the Regulator or the GTMC on:

- matters of general concern in relation to GMOs; and
- the need for and content of policy principles, policy guidelines, codes of practice and technical and procedural guidelines.

GTCCC's key role is to advise on issues of concern to the community and to ensure that these are addressed in the policy underpinning the regulatory scheme. There is no analogous committee in any other jurisdiction, including internationally.

GTEC provides advice at the request of the Regulator or the GTMC on:

- ethical issues relating to gene technology;
- the need for and content of codes of practice in relation to ethical conduct when dealing with GMOs; and
- the need for and content of policy principles relating to dealings with GMOs that should not be conducted for ethical reasons.

GTEC's key role is to provide advice on the ethical dimensions of dealings involving gene technology.

Many submissions to the Review expressed concerns about the functions and roles of the three statutory advisory committees. The concerns ranged from the appropriateness of the membership to the type of advice that each provides to the Regulator, as well as the transparency in their operations and the appointment processes. In particular, the Review heard repeated concerns about the fact that the GTCCC has not been constituted since October 2004 because of delays in the re-appointment process. For this reason the Review did not have the opportunity to consult with the GTCCC. The Review noted that the appointment process for the committees was not a responsibility of the Regulator and was managed by the GTMC.

### GTTAC

Under subsection 50 (3) of the Act, which relates to dealings involving an DIR:

The Regulator must seek advice on matters relevant to the preparation of the risk assessment and the risk management plan from:

> (a) the States; and
>
> (b) the Gene Technology Technical Advisory Committee; and
>
> (c) each Commonwealth authority or agency prescribed by the regulations for the purposes of this paragraph; and
>
> (d) the Environment Minister; and
>
> (e) any local council that the Regulator considers appropriate.
>
> In practical terms, the Regulator is required to consult with GTTAC twice for DIR applications: on the application itself and in developing the RARMP.

For dealings not involving intentional release of a GMO into the environment (DNIR), subsection 47 (4) specifies that:

> The Regulator may consult:
>
> (a) the States; and
>
> (b) the Gene Technology Technical Advisory Committee; and
>
> (c) relevant Commonwealth authorities or agencies; and
>
> (d) any local council that the Regulator considers appropriate; and
>
> (e) any other person the Regulator considers appropriate
>
> on any aspect of the application.

The Regulator is effectively allowed more discretion in the choice of groups that are consulted in the case of DNIRs.

Industry, researchers and farm organisations seeking a choice to grow GMO crops were strongly supportive of GTTAC's membership and performance in evaluating licence applications. Neither of the other two committees advise on licence applications. Groups seeking a choice to grow GMOs argued that GTTAC maintains the integrity of the national, science-based, regulatory framework and were not supportive of the other committees being granted extended roles to consider licence applications.

On the other hand, submissions from NGOs, consumer groups and farming groups opposed to the introduction of GMOs argued that GTTAC's membership should include more experts in public health and environmental risk assessment to better reflect the object of the Act.

The Minister can only appoint a person as a member of GTTAC if the Minister is satisfied that the person has skills or experience in one or more areas specified under subsection 100 (5) of the Act. Public health and risk assessment are specified amongst the approximately 20 different areas of expertise. The Review heard that existing members of GTTAC have expertise in the areas of public health and environmental risk assessment, but noted that while members can claim more than one area of expertise, no members have stated that their primary expertise is in the field of public health or environmental risk assessment.

To provide transparency that public health and environmental risk assessment are considered in GTTAC's deliberations, the Review concluded that GTTAC should include members whose primary expertise is in public health and in environmental risk assessment. The issue of advice on public health grounds is also considered in Recommendation 5.4.

***Recommendation 5.1: The Review recommends that GTTAC should include members whose primary expertise is in public health and in environmental risk assessment.***

## GTEC and GTCCC

Across all stakeholder groups, there was little understanding of the function and role of GTEC and GTCCC (which both provide advice at the request of the Regulator and the GTMC) and how the input of GTEC and GTCCC shapes the regulatory system. This was a key theme in the submissions and public consultations with concerns centred on the GTCCC. It was criticised for the polarised views of its membership and its lack of concrete progress. As noted above, the Review did not have an opportunity to hear from GTCCC and was unable to assess these comments given the period since the GTCCC last met.

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.***

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.***

## 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.***

## 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:***

- ***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 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.***

## 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.***

## 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 licence-holder 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 exercises 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 permitee 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.***

# 6 REGULATORY BURDEN

## 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:

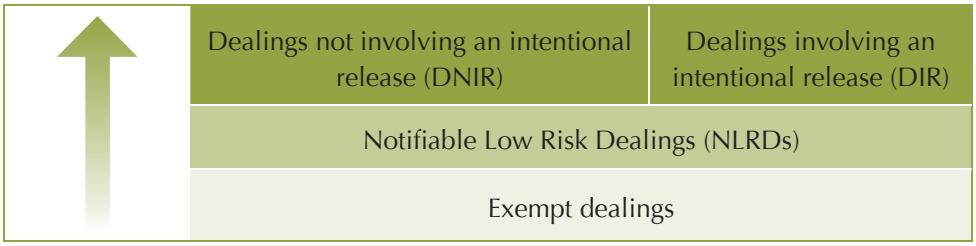
- Licensed dealings that will be released into the environment
- Licensed dealings that are kept contained in certified facilities
- NLRD that are kept contained in certified facilities
- Exempt Dealings that are kept contained in physical containment 1 (PC1) facilities.

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[1] 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[2].

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

2 '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.***

## 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.***

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

## 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.***

## 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 | • Legislative simplification |
| NLRDs | Remove requirement to notify in 14 days of commencement of activity. Substitute reporting requirement in annual report IBC to maintain records for inspection | • Legislative simplification<br>• Streamline process and paperwork requirements |
| DNIRs | Time frames for variations (see chapter 5 for details) | |
| DIRs | Time frames for variations<br>Distinguish field trials from commercial releases and simplify information requirements for field trials (see chapter 5 for details) | • Streamline process and paperwork requirements |
| Certification guidelines | Greater harmonisation with AQIS certification guidelines and relevant Australian Standards and use outcome-focussed language<br>Single audits by AQIS and OGTR | • Streamline process and paperwork requirements |
| Accreditation guidelines | Remove reporting requirement for exempt dealings | • Streamline process and paperwork requirements |
| Application format | Redesign application forms | • Streamline process and paperwork requirements |
| Variations | Introduce statutory time limit | • Introduce statutory time limit |

# 7 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[1] |
|---|---|---|---|---|---|---|
| **Consideration of marketing and trade matters as part of evaluation** | NO | YES<br>Considers maximum residue limits of trading partners to test if there would be 'undue risk to trade' | NO | NO | YES<br>However this consideration is assigned a lower priority than the health and safety assessment | NO |
| **Consideration of benefit** | NO | NO | NO | NO | YES<br>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 |

1 Based on the *Quarantine Act 1908*

| | OGTR | APVMA | TGA | NICNAS | FSANZ | AQIS[1] |
|---|---|---|---|---|---|---|
| **Fast track approvals in an emergency** | NO | YES<br>Can issue a permit for an emergency (permit does not need to be time limited) | YES<br>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<br>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<br>Can issue an emergency standard (within 12 months standard must follow through normal process) | NO |
| **Post market monitoring and review of approvals** | YES<br>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<br>And also has an adverse experience reporting program and existing chemicals review program | YES<br>And also has an adverse reaction reporting program | NO<br>Control from point of sale is the responsibility of the States. NICNAS post marketing surveillance is via its existing chemicals review program | YES | YES<br>Permits may be revoked if quarantine risk alters |

| | OGTR | APVMA | TGA | NICNAS | FSANZ | AQIS[1] |
|---|---|---|---|---|---|---|
| **Public Access to data** | YES<br>(see discussion in chapter 4) | YES<br>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<br>All assessment reports are publicly available | YES<br>There is a public register | YES<br>Non-confidential Import Risk Analysis Reports are publicly available |
| **Data protection** | YES<br>Has the ability to declare information CCI. CCI cannot be used by the Regulator to assess an application from a different applicant | YES<br>Has the ability to declare information CCI and also has the ability to confer data exclusivity | YES<br>Has the ability to declare information CCI. | YES<br>Has the ability to declare information CCI and also has the ability to confer data protection via a 5-year certificate system | YES<br>Has the ability to declare information CCI | NO |

| | OGTR | APVMA | TGA | NICNAS | FSANZ | AQIS[1] |
|---|---|---|---|---|---|---|
| **Requirement for peer reviewed data only** | 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 as well 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 |
| **Testing done by regulatory agency prior to approval** | 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 |
| **Testing done by regulatory agency prior to approval** | 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 |
| **Appeal available under AAT Act** | YES | YES | YES | YES | YES | NO |

| | OGTR | APVMA | TGA | NICNAS | FSANZ | AQIS[1] |
|---|---|---|---|---|---|---|
| **Review available under AD(JR) Act** | 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 | | | | |
| **Advisory or consultative committees** | 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 *Gene Technology Act 2000* (C'wth) and Regulations (2001) and all guidelines of the Office of the Gene Technology Regulator |
| The *Quarantine Act 1908* and The Quarantine Proclamation (1998) (C'wth) |
| The *Animal Research Act 1985* (NSW) and Regulations (1995) |
| The *Occupational Health and Safety Act 2000* (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 aboratory 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.***

# 8 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[1] |
| | | Drought tolerance | Wheat | Proof of concept[2] |
| | | Acid soil tolerance | Barley | Proof of concept |
| | | | Pasture species | Technology Discovery |
| | | Frost tolerance | 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[3] |
| | | 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[4] |
| | | Improved digestibility | Wheat, barley | Proof of concept |
| | | Improved oil quality | Cotton | Field trial[5] |
| | | 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** | Alternative sugars for food ingredient and industrial applications – isomaltose | Sugarcane | Proof of concept / Field trial |
| | | 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

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[6]. 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

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.

# 9 IGA ACHIEVING ITS AIMS

## 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 | *Gene Technology (GM Crop Moratorium) Act 2004* | 10 July 2004 | By regulation, no earlier than 17 June 2006 |
| NSW | *Gene Technology (GM Crop Moratorium) Act 2003* | 25 June 2003 | March 2008 |
| WA | *Genetically Modified Crops Free Areas Act 2003* | 21 December 2003 | 2008 |
| SA | *Genetically Modified Crops Management Act 2004* | 29 April 2004 | 2007 |
| Tasmania | *Genetically Modified Organisms Control Act 2004* | 16 November 2004 | 2008 |
| Victoria | *Control of Genetically Modified Crops Act 2004* | 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

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

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.***

***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.***

## 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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# APPENDIX 1

## 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

## 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

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, Timbrebongie 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

96. Ailleen Leddy, Jannali, NSW
97. Pete Malicki, Sydney, NSW
98. Jocelyn Kingston, Leichhardt, NSW
99. Peter Brown, Coolum Beach, QLD
100. Amanda Sutherland, Leoplod, 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, Saphire 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, Candelo, 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

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 Dommisse, 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 Rohlfs, 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

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

## 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

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 Heath and Ageing)
32. Victoria Hennig (Department of Heath 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 Hindnijer
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

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)

4. Phillip Steel (CDS/ASF)
5. Craig Dunn (Monsanto)
6. Greg Constable (CSIRO Plant Industry)
7. Greg Kauter (ACGRA)
8. Michael Murray (Gwydir Valley Cotton Growers Association)
9. Bruce Pike (CRDC)
10. Guy Roth (Cotton Catchment Communities CRC)
11. Tracey Farrell (Cotton Catchment Communities CRC and NSWDPI)
12. Bruce (Cotton R+D Corp)
13. Bethwyn Todd (Monsanto)

## Sydney (New South Wales), Monday 7 November 2005

1. Michael Matthews (Producers Forum)
2. Charles Rue (Columbian Peace, Ecology and Justice Centre)
3. Julie Gray (Biosafety Committee, University of Wollongong)
4. Maree McKay (Producers Forum)
5. Wayne McKay (Producers Forum)
6. Dougal Gordon (NSW Farmers' Association)
7. Hugh Roberts (NSW Farmers' Association)
8. Lynn Croft (Garvan Institute)
9. Lindsay Cook
10. Ariel Salleh
11. Des Boucher
12. David Anthony (Auscott)
13. Rachel Walmsley (EDO)
14. Fern Wickson (University of Wollongong)
15. Kutay Kesim (Macquarie University)
16. Selen Ayirtman
17. Jenny Dawkins (Sydney University)
18. Lisa Brycnt
19. Ashley Power (Auscott)
20. Leane Ameneiro (Auscott)
21. Greg Parle (Auscott)
22. Arthur Spellson (Auscott)
23. Gabrielle O'Sullivan (Royal Price Alfred Hospital)
24. Dan Galligan (Cotton Australia)
25. Martin White (FFP)
26. Peter Webb (Auscott)

27. Keith Osborne (Department of Environment and Conservation)
28. John Chapman (Department of Environment and Conservation)
29. G. Gallagher (AMPL)
30. Scott Rice (UNSW)
31. Helen Oakey (Greenpeace)
32. Holly Shiach (Greenpeace)
33. Dominika Rajenski (NSW Parliament)
34. Elaine Johnson (Nature Conservation Council)
35. Paul Corban (NSW Democrats)
36. Clare Hughes (Australian Consumers' Association)
37. Christopher Thomas
38. Rebecca Johnstone
39. Divya Bjargav (Spine Service Kogarah)
40. Scott Rose (UNSW)
41. Kerry Russ (Wollongong University).

## Melbourne (Victoria), Tuesday 15 November 2005

1. Solveiga Hall (Monash University)
2. Susan Houghton
3. Shena Jocelyn Cameron
4. John Bonacci (Perkins Resources)
5. Jennifer Henry (CSIRO Publishing)
6. Lorraine Ford (Southern GE-free)
7. Robyn Nolan (Southern GE-free)
8. Nancy Millis (University of Melbourne, University of La Trobe)
9. Dorothy Pottage (Gene Ethics, South GE Free)
10. Paul Taylor (University of Melbourne)
11. Brendan Crabb (WEHI)
12. Bill Heath (WEHI)
13. Helene Martin (WEHI)
14. Wendy Carter (WEHI)
15. Louise Sales (Greenpeace Local Group)
16. Tes Toop (Deakin University)
17. Naomi Stevens (Bayer CropScience)
18. Susie O'Neill (Bayer CropScience)
19. Kay Khoo (Bayer CropScience)
20. Anita Hirschorn (AusBiotech)
21. Linda Leefe (Scalzo Food Industries)

22. Sandra Neri (Scalzo Food Industries)
23. Michelle McCard (Peter MacCallum Cancer Centre)
24. Bob Phelps (Gene Ethics)
25. Mark Buckingham (Monsanto)
26. Anna Hurst (Monsanto)
27. Andrea Lines (Monash University)
28. Ellen Kittson (Victorian Dept of Human Services)
29. Fran Murrell
30. Merna Curnow
31. Robyn Male

### Horsham (Victoria), Wednesday 16 November 2005

1. David Pike (Bayer CropScience)
2. Kay Khoo (Bayer CropScience)
3. Greg Petrass (Farmer)
4. Keith White
5. Geoff Rethus (Farmer)
6. Chris Cocklin (Monash University)
7. Jacqui Bibden (Monash University)
8. Mark Johas (Farmer)
9. Geoffrey Carracher (Network of Concerned Farmers)
10. John Chambers (Farmer)
11. Mona Rule
12. Chris Kelly (Producers' Forum)
13. Scott Kinnear (BFA)
14. Bob Mackey
15. S. O'Neil (Bayer Cropscience)
16. Andrew Weidemann (VFF/BCG)
17. Eugene Duffy
18. David Fletcher
19. Angela Munn
20. Louise Stanley (Producers Forum)
21. Ellen Kittson (DHS)
22. Peter Carr (Dept Primary Industries)

### Hobart (Tasmania), Friday 18 November 2005

1. Ian MacKinnon (Farmer)
2. Ruth Trigg (University of South Australia)

3. Keith Rice (Tasmanian Poppy Growers Association)
4. Lisa Triffett (DPIWE)
5. Jim Rossiti (Organic Coalition of Tasmania)
6. Chris Hullock (DPIWE)
7. L. Shea
8. Nick Steel (TFGA)
9. J. Patil (CSIRO)
10. Greg Whitten (Organic Coalition of Tasmania)
11. John Casburn (BD Tas)
12. Ute Mueller (BD Tas)
13. Cindy Hanson (DPIWE)
14. Duncan Fanquhan (DPIWE)
15. Alex Schaap
16. Lynne Forster
17. Camille Velnaar

**Darwin (Northern Territory), Friday 2 December**

1. Strider
2. Peter Robertson (Environment Centre of Northern Territory)
3. Tom Kiely
4. Justin Tutty
5. Sue Hutton
6. Gabby Faus
7. Tony Cowen, EDO (NT)
8. Larissa Mullot (Agrifood Awareness Australia Limited)
9. Christine Long (NT Department of Primary Industries, Fisheries and Mines)
10. Sally Bothroyd (ABC Radio)
11. Murray Hird (Northern Territory Government)

# APPENDIX 4

## The application approval process outlined in the *Gene Technology Act 2000*

The Act and Gene Technology Regulations 2001 (the Regulations) and corresponding State and Territory laws provide a nationally consistent system to regulate the use of gene technology in Australia. The legislation establishes an independent statutory office holder, the Gene Technology Regulator, who is charged with administering the Act and making decisions about the development and use of GMOs under the Act.

### Types of dealings

To 'deal with' a GMO is defined in the Act (Part 2, Division 2, section 10(1)) and includes (but is not limited to): experiment with, manufacture, breed, propagate, grow, culture, import, and to possess, supply, use, transport, or dispose of a GMO.

A GMO is defined as any organism that has been modified by gene technology, or offspring derived from such an organism, or anything declared as a GMO in the Regulations.

The Act is a prohibitory scheme that makes dealing with a GMO a criminal offence unless the dealing is:

- an exempt dealing;
- a notifiable low risk dealing (NLRD);
- authorised by a licence; or
- included on the GMO register.

Exempt dealings and NLRDs are not considered to pose risks that require direct scrutiny by the Regulator in the form of case by case risk assessment. These kinds of dealings are routine laboratory techniques involving GMOs that were in use when the Act came into force and have been used safely for many years or represent minimal risk dealings when performed in contained conditions.

The Act states that the Regulator must prepare a risk assessment and RARMP for all applications involving dealings that require a licence, as part of the process of making a decision on whether to issue a licence (sections 47 and 50).

Dealings authorised by a licence are further categorised into DNIRs and DIRs.

A representation of the classes of dealings, outlining the level of risk and the predetermined management conditions (e.g. containment) is set out in table 10.

*Table 10: Classes of GMO dealings under the Gene Technology Act 2000*

| Category | Risk[1] | Licence Required | Physical containment |
|---|---|---|---|
| GMO register | ≤ minimal | No, but must be previously licensed | Possibly (containment conditions might still be required) |
| Exempt | < minimal | No, must notify IBC | Yes<br>PC1 |
| NLRD | minimal | No, dealings must be approved by IBC; OGTR notified | Yes<br>PC2 (usually) |
| DNIR | ≥ minimal | Yes, dealings must be approved by IBC; RARMP prepared, licence decision by the Regulator | Yes<br>≥ PC2 (usually) |
| DIR | ≥ minimal | Yes, dealings must be approved by IBC; RARMP prepared, extensive consultation, licence decision by the Regulator | No (although where releases are limited and controlled containment measures will be required, and licence conditions will apply) |

The licensing system is centred on a rigorous process of risk assessment based on scientific evidence. For those dealings that involve an intentional release of a GMO into the environment (DIR), the legislation requires extensive consultation with expert groups and authorities, government agencies and the public. More data must be submitted for assessment and a more rigorous assessment process is set out than is required for a dealing not involving intentional release of a GMO into the environment (DNIR).

1 The term 'minimal' has been used in the Act and Regulations in relation to these dealings and the GMO register;, however, the legislation does not provide any definition of 'minimal'. The Regulator has developed a Risk Analysis Framework in consultation with all major stakeholders including the public to explain the implementation of the legislation. Chapter 3 of this framework incorporates a vocabulary of terms and definitions to be used by the Regulator in conducting risk analysis, including attributions for relative risk estimates. The term minimal is not proposed in this context.

## Time frames

Under section 43(3) of the Act the Regulator must issue or refuse to issue a licence within a time limit prescribed by the Regulations. Similarly the Regulations prescribe a timeframe for consideration of applications to accredit organisations and to certify facilities. These statutory timeframes are shown in Table 11. They do not include weekends or public holidays in the Australian Capital Territory or periods where the Regulator has requested more information from the applicant, including information to resolve a CCI claim, and cannot proceed with the decision making process until that information has been provided.

*Table 11: Timeframes under the Act*

| Category | Time frame |
|---|---|
| DNIR | 90 working days (Regulation 8) |
| DIR | 170 working days (Regulation 8) |
| Accreditation | 90 working days (Regulation 16) |
| Certification | 90 working days (Regulation 14) |

## Dealings involving minimal risks

**The GMO register**[2] is a register provided by the Act (Part 6, Division 3) that lists dealings with a GMO that are, or have been, authorised by a licence previously but have a history of safe use. To be included on the register the Regulator must be satisfied that risks posed by the specific dealings are negligible to human health and safety or to the environment and because of the negligible risks the applicant no longer needs to hold a GMO licence for that dealing. After inclusion on the register these dealings would no longer require authorisation by a licence from the Regulator but may still have conditions attached to their registration. There are currently no GMO dealings on the GMO register. The principles of risk analysis set out in the Risk Analysis Framework are applicable to the determination of whether a GMO should be placed on the GMO register.

**Exempt dealings** are dealings with GMOs that have been assessed over time as posing negligible[3] risks to people or the environment. They comprise basic molecular biology techniques that are used extensively in laboratories worldwide. The criteria for exempt dealings are specified in the Regulations (schedule 2). A record of exempt dealings is maintained by the IBC of the organisation undertaking the dealing. Such dealings

2 It is important to note the difference between the GMO record and the GMO register. The GMO record is a comprehensive listing of all dealings with GMOs including licensed dealings, NLRDs and GM products. The GMO register lists GMOs that no longer require a licence and will only ever be a subset of dealings included on the GMO record.

3 The term negligible is defined in Chapter 3 of the Risk Analysis Framework as 'risk is insubstantial and there is no present need to invoke actions for mitigation'.

may only be undertaken in a facility which meets the PC1 standards in the Australian/New Zealand Standard 2243 (AS/NZS 2243.3 2002) or higher and are reported to the OGTR in the organisation's annual report. If dealings fall within the classification in the Regulations for exempt dealings they are not considered to require a case by case risk assessment. Examples of exempt dealings include:

- dealings with GM mice where only specific mouse genes have been deleted or inactivated; or
- the introduction of naked pieces of DNA into cells of whole animals, as long as this is incapable of giving rise to infectious agents; or
- shotgun cloning of mammalian genes, e.g. cloning of kangaroo genes into laboratory strains of the bacterium escherichia coli.

**NLRDs** are dealings with GMOs that have been assessed over time as posing negligible risks provided certain management conditions are met. The criteria for NLRDs are specified in the Regulations (Schedule 3). Such dealings may only be undertaken in a facility certified by the Regulator (usually PC2 or higher). The dealing must be considered by an IBC and the Regulator notified of the approval of the dealing within 14 days. NLRDs are included on the record of GMO and GM product dealings (see below) but do not require case by case risk assessment. Examples of NLRDs include:

- dealings with whole animals that produce a new GM animal and where the new trait can be passed on to the animal's offspring, but the animal is housed in contained conditions; or
- dealings with GM flowering plants where all pollen and seed are contained.

## Licensed dealings

Any dealing not exempt, NLRD or on the GMO register must not be conducted unless licensed.

Licence applications are considered on a case by case basis by the Regulator, who must consider whether the risks posed by the dealing can be managed to protect human health and safety and the environment. The Regulator must make a decision on whether to issue a licence to allow the conduct of that dealing and the management conditions to be imposed to manage any risks.

The legislation sets out a series of actions the Regulator must take into account in consideration of applications for licences for both for contained dealings (DNIRs) and those involving intentional release (DIRs). The Act details steps that must be taken in regard to the assessment of the application, while the Regulations detail the information that must be provided by the applicant.

For both DNIRs and DIRs the Regulations require the applicant to identify risks that the dealings may pose to human health and safety and the environment and any measures proposed to manage those risks. Both also require the IBC to have scrutinised the application to provide an evaluation report assessing the risk identification and the management proposals of the applicant.

The legislation requires the Regulator to prepare a RARMP for both DNIR and DIR applications. The risk assessment takes account of any risks to human health and safety and the environment posed by the dealing and the risk management plan determines how these risks can be managed. The Risk Analysis Framework was developed by the Regulator to inform applicants, OGTR evaluators and interested others how standards are applied to the assessment process.

The requirements of the legislation have been framed to place greater scrutiny on dealings that involve release to the environment (DIRs). The Regulator may impose conditions on all licences. In relation to field trials under limited and controlled conditions, measures are imposed to limit the persistence and spread of the GMO and its genetic material. Non-compliance with conditions placed on licences issued under the Act is a criminal offence.

For both DNIR and DIR applications the applicant must provide information specified in the Regulations as to their suitability to hold a licence. This information includes any relevant convictions, revocations or suspensions of licences under laws relating to human health and safety or the environment and an assessment of the applicant's capacity to manage any risks posed by the proposed dealings.

## Dealings not involving intentional release

DNIRs usually take place under specified physical containment conditions in certified facilities, which minimise risks to the environment. The Act requires an assessment of the risks of the dealing and preparation of a RARMP with associated licence conditions to manage the risks for DNIR applications.

The legislation does not require the Regulator to consult in relation to DNIR licence applications. Presently, advice is sought from the GTTAC and the State or Territory in which the dealings are proposed to take place during the preparation of the RARMPs for all new DNIR applications.

The Regulator considers the RARMP in deciding whether to issue a licence and in determining the licence conditions that should be imposed. Typical licence conditions require the applicant to conduct the dealing in certified facilities, to follow particular handling requirements (e.g. avoiding the use of 'sharps' and using biosafety cabinets), to train and supervise staff, to dispose of and transport the GMO appropriately, and to have, and implement contingency plans.

## Dealings involving intentional release

The Act makes no distinction between small-scale 'field trial' releases under limited and controlled conditions and releases intended to be of a general or commercial scale.

This Framework specifies the approach taken to risk analysis, which forms an integral part of each RARMP.

**Stage 1** — The applicant must prepare: comprehensive information about the proposed dealings with the GMO; possible hazards and consequent risks posed by the dealings with the GMO; and proposed ways that each of the risks can be managed. The Regulator's information requirements are set out in detail in the Regulations and the application forms for intentional release dealings with the GMOs. The applicant must ensure that all responses are supported by appropriate data and literature citations. Wherever possible quantitative data should be provided. It is expected that the applicants will collect relevant data during contained work and early trials for dealings involving intentional release of GMOs.

**Stage 2** — The IBC reviews the application and provides the Regulator with an evaluation report setting out its advice as to the completeness of the applicant's hazard identification, risk assessment and proposed risk management strategies. The IBC's role is to ensure the quality of applications submitted to the Regulator.

**Stage 3** — Section 49 of the Act requires the Regulator to make an initial consideration of whether any of the proposed dealings in a DIR application may pose a significant risk to the health and safety of people or the environment. Under Section 49(2) of the Act the Regulator must consider:

(a) the properties of the organism to which the dealings relate before it became, or will become, a GMO;

(b) the effect, or the expected effect, of the genetic modifications that have occurred, or will occur, on the properties of the organism;

(c) provisions for limiting the dissemination or persistence of the GMO or its genetic material in the environment;

(d) the potential for spread or persistence of the GMO or its genetic material in the environment;

(e) the extent or scale of the proposed dealings; and

(f) any likely impacts of the proposed dealings on the health and safety of people.

**Stage 4** — If the Regulator considers that the proposed dealings with the GMO could have a significant impact on the health and safety of people or the environment, the Regulator must call for public submissions on the application including seeking advice on the possible risks and means of managing the risks. In addition, if the Regulator

deems it necessary, public submissions can be invited on any application, for example for a novel GMO. The Regulator is required to advertise in a national newspaper, in the Australian Government Gazette and place notices on the Regulator's website. In practice the Regulator advertises more broadly, including regional newspapers and specialist interest press and will advise, by mail or email, to all persons that have registered their interest in receiving such information on the OGTR mailing lists.

The Regulator must provide a copy of the application (excluding any information that the Regulator has declared to be confidential commercial information) to anyone that requests a copy.

**Stage 5** — Irrespective of whether the Regulator initially considers that the dealing may pose significant risks or not, the Regulator must seek advice on matters relevant to the preparation of the RARMP under section 50 of the Act from the Australian Government Environment Minister, GTTAC, the States and Territories, prescribed Australian Government agencies and appropriate Local Government Authorities. The Regulator usually consults with LGAs where the release is proposed to occur.

In addition, the Regulator also routinely seeks advice from other relevant Australian Government agencies such as the Department of Agriculture, Fisheries and Forestry; the Department of Industry, Tourism and Resources; and the Department of Foreign Affairs and Trade.

While the Office of the Gene Technology Regulator is located within the Department and Health and Ageing portfolio, the Australian Government Environment Minister receives special mention in the legislation in recognition of the relevance of that portfolio's responsibilities and role in administering the EPBC Act. The Regulator is required to consult with the Australian Government Environment Minister on each DIR application and the RARMPs prepared in relation to each DIR application. The Department of the Environment and Heritage is included in the consultation process via the support it provides to the Environment Minister.

**Stage 6** — The actual risk assessment process is shaped to some extent by the data requirements set out in the Regulations; however, the Regulator can require submission of any data required to comprehensively identify hazards and evaluate risks posed by the dealing. The Regulator is specifically permitted by the legislation to seek and take into account any other relevant information such as independent research, independent literature searches, the advice of any person or group, request more information from the applicant or to hold a public hearing. (What constitutes acceptable evidence is discussed in some detail in the Risk Analysis Framework).

**Stage 7** — The Regulator must prepare a RARMP in relation to the proposed dealings with the GMOs.

The preparation of the risk assessment involves identifying any hazards that may be posed by the dealings with the GMOs, and estimates the level of risk posed by such hazards based on the likelihood of the event occurring and the likely consequences of that occurrence.

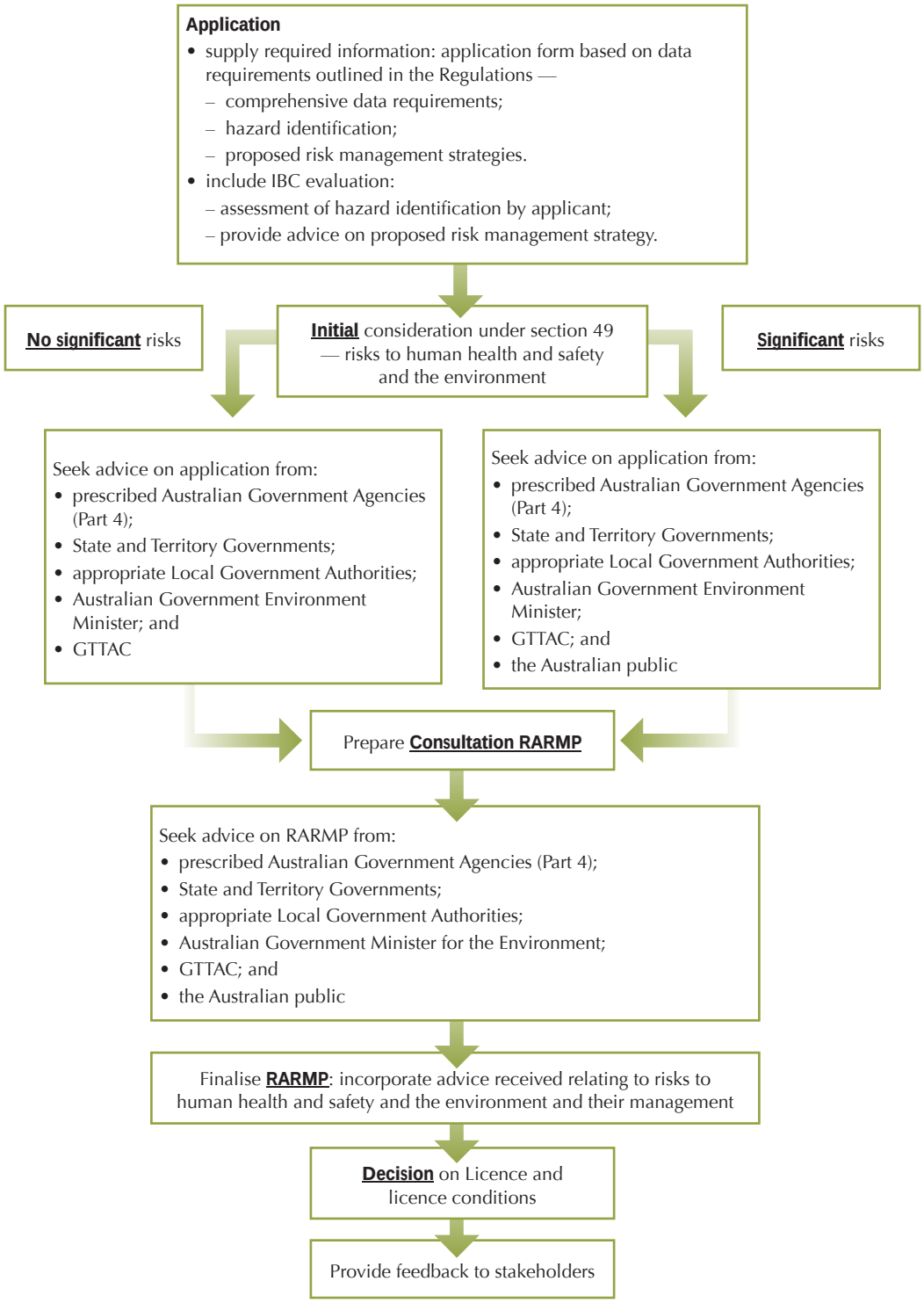
The risk management plan evaluates which of the risks to human health and safety and the environment posed by the dealing with the GMO require management, and considers how they may be able to be managed. This provides the basis for conditions that may be applied to the licence and draft conditions are included in the consultation version of the risk management plan.

**Stage 8** — Once the Regulator has prepared the RARMP under section 52 of the Act the Regulator must notify the public and invite written submissions on the document through advertisements in a national newspaper, the Australian Government Gazette and the Regulator's web site. The legislation requires that the Regulator provide at least 30 days to receive public submissions; however, the Regulator's policy is to allow 6 weeks for limited and controlled field trial applications and 8 weeks for commercial release applications or for controversial GMOs.

Under section 52(3) of the Act the Regulator must also seek advice on the RARMP from all the expert groups and authorities that were consulted on the application, and the Australian Government Environment Minister.

**Stage 9** — The Regulator finalises the RARMP, taking into account the advice provided in relation to the consultation version of the RARMP in accordance with section 56(2) of the Act. The Regulator then makes the decision on issuing the licence and any conditions to be imposed, based upon the finalised plan, having regard to any policy principles issued by the Gene Technology Ministerial Council. The Regulator must notify the applicant in writing that a licence decision has been made. The Regulator also publishes the finalised RARMP on the Regulator's website, advises all expert groups and authorities and people or organisations that have made submissions and notifies registered recipients on the OGTR mailing list.

*Figure 2: The application approval process*



## The GMO record

The Act requires the Regulator to maintain a 'Record of GMO and GM Product Dealings' (the GMO record, section 138). Details of licences issued (both DNIR and DIR), information about NLRDs and information about GM Products approved or registered by other regulatory authorities, are included on the GMO record.

The GMO record is currently divided into separate sections for the recording of:

- GM products — those used in food processing, therapeutics, and pesticides and veterinary medicines;
- Notifiable low risk dealings — NLRDs;
- Contained dealings — DNIR licences; and
- Intentional releases — DIR licences.
- The record can be accessed through the Regulator's website.

***Gene Technology Committees***

The legislation creates three committees to provide advice to the Regulator and the GTMC: the GTTAC, GTCCC and GTEC. Membership of the committees consists of persons with either expertise in one or more scientific fields (GTTAC) or with skills and experience in areas relevant to gene technology as specified in the Act.

**GTTAC** — provides scientific and technical advice, on the request of the Regulator or the GTMC, on:

- gene technology;
- GMOs and GM products;
- applications made under the Act;
- biosafety aspects of gene technology; and
- the need for and content of policy principles, policy guidelines, codes of practice and technical and procedural guidelines.

**GTCCC** — provides advice at the request of the Regulator or the GTMC, on:

- matters of general concern in relation to GMOs; and
- the need for and content of policy principles, policy guidelines, codes of practice and technical and procedural guidelines.

**GTEC** — provides advice at the request of the Regulator or the GTMC, on:

- ethical issues relating to gene technology;
- the need for and content of codes of practice in relation to ethical conduct when dealing with GMOs; and
- the need for and content of policy principles relating to dealings with GMOs that should not be conducted for ethical reasons.

***Accreditation and Certification***

Accreditation of organisations and certification of individual physical containment facilities assists in the management of risk that may be associated with dealings with GMOs by providing an administrative system in which to monitor and oversee their development and use.

An organisation undertaking certain dealings with GMOs will be required to be accredited by the Regulator (sections 91–98). The process of accreditation enables the Regulator to assess if the organisation has the resources and the internal processes in place to enable it to effectively oversee work with GMOs. Before an organisation can be accredited, it must have established, or have access to, an appropriately constituted IBC.

IBCs provide on-site scrutiny of negligible risk dealings that do not require case by case consideration by the Regulator. IBCs are required to comprise a range of suitable experts and an independent person and they provide a quality assurance mechanism that reviews the information submitted by applicants to the Regulator. The Guidelines for the Accreditation of Organisations and Guidelines for the Certification of Facilities/Physical Containment Requirements are available from the OGTR website (www.ogtr.gov.au).

The legislation allows the Regulator to certify laboratory or production facilities (sections 83–90) to ensure that they meet appropriate standards for containment of GMOs and that procedures and practices are carried out by trained and competent staff. Guidelines for certification of each type of facility (laboratory, plant house, aquaria etc) at the various levels of physical containment (PC) levels 1 to 4, are developed by the Regulator and must be complied with before a facility can be certified. All certified facilities must be inspected before certification and annually by the IBC. The OGTR inspects all high level facilities (large scale PC2, PC3 and PC4) before certification and re-certification.

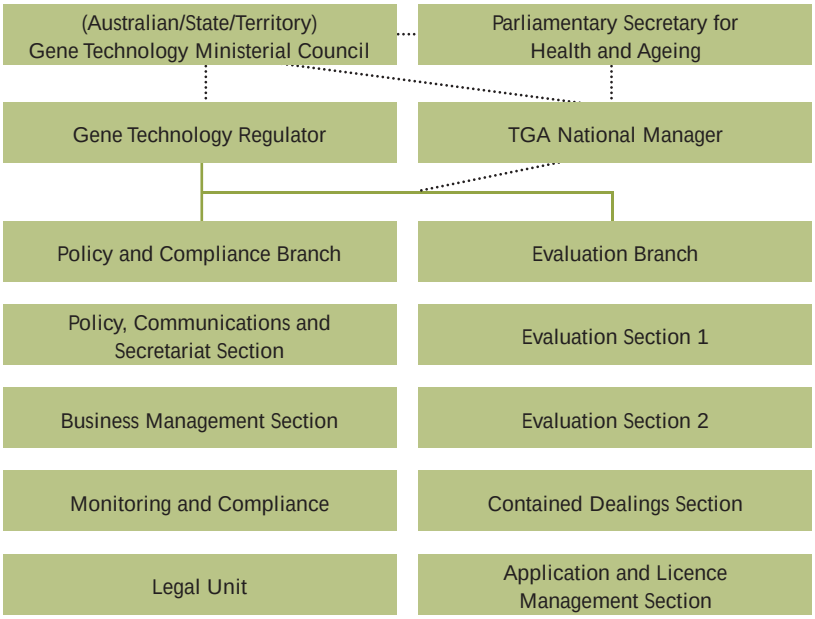
Since the *Gene Technology Act 2000* came into effect in June 2001 up until 29 March 2005, the Regulator has:

- Certified 1985 contained facilities
- Accredited 147 organisations
- Issued licences for 37 dealings involving intentional release of GMOs into the environment (DIRs)
- Issued licences for 290 dealings not involving intentional release of GMOs into the environment (DNIRs)
- Received notice of 1673 notifiable low risk dealings

# APPENDIX 5

## Structure of the Office of the Gene Technology Regulator

*Figure 3: Structure of the Office of the Gene Technology Regulator*




### Evaluation Branch

***Evaluation Section 1***

Evaluates applications for dealings involving intentional release (DIRs) of GMOs (including, to date, GM cotton, rice, white clover, papaya, grapevine) into the environment. Responsible for oversight of cotton research projects, OGTR library and reference manager database.

***Evaluation Section 2***

Evaluates DIRs licence applications (including, to date, GM canola, indian mustard, wheat, sugarcane. poppy, carnations, pineapple). Also responsible (with Evaluation Section 1) for transfers, variations and surrender of DIR licences, plus DIR standard operating procedures and templates.

***Contained Dealings Evaluation Section***

Evaluates applications for dealings not involving intentional release into the environment (DNIRs) also known as 'contained dealings'. The Section also handles notifications of low risk dealings (NLRDs) viral DIR applications (e.g. cholera and bovine adenovirus vaccines) plus training for organisations and/or institutional biosafety committees (IBCs).

***Application and Licence Management Section***

Responsible for receiving/acknowledging all applications, processing accreditation applications, managing Gene Technology Information Management System (GTIMS) data, coordinating reviews (e.g. guidelines for contained facility certification) and certification applications.

***Science Cohort***

Senior OGTR staff members have been given responsibility for developing and managing major science policy projects which impact across the office (e.g. review of the risk analysis framework, organisation of national IBC forum, APVMA/TGA science forum, authoring scientific papers and oversighting research).

## Policy and Compliance Branch

***Business Management Section***

The Business Management Section (BMS) delivers business management services in partnership with the Therapeutic Goods Administration and the Department of Health and Ageing. The Section provides Divisional Liaison Officer services including administrative and financial reporting.

BMS roles include: account payments; budgets; financial planning; stores acquisition; staffing/human resource management; staff training; accommodation; property and asset management; and ongoing development of GTIMS.

***Monitoring and Compliance Section***

The Monitoring and Compliance Section focuses on the management of dealings for field trial sites and within contained facilities to ensure:

- minimisation of the risk of dissemination of a GMO and its genetic material;
- minimisation of the risk of persistence of a GMO in the environment; and
- full control of a GMO is maintained.

The Section is committed to carry out inspections each year of at least 20% of current field trial sites, post harvest field trial sites and certified PC3, PC4 and PC2 Large Scale contained facilities. PC2 and PC1 (lower risk) facilities are inspected randomly. The work includes monitoring, auditing, practice reviews, risk assessment and management, investigations and reporting.

***Policy, Communication and Secretariat Section***

Provides policy, information and coordination support for the Office and acts as the coordination point with other agencies and organisations involved with the regulation of genetically modified organisms.. Specifically, the Section manages the OGTR website www.ogtr.gov.au, the 1800 181 030 toll-free telephone number and ogtr@health.gov.au email inquiries.

Other activities include: production of quarterly/annual reports, coordination of relationships with other Australian Government agencies, speeches, cross-OGTR projects (e.g. review of Gene Technology Regulations 2001, international regulatory policy and (with TGA) coordination of ministerial correspondence, briefings and parliamentary liaison).

Responsible for committees established to assist the Gene Technology Regulator and Ministerial Council perform functions specified in the *Gene Technology Act 2000*:

- Gene Technology Community Consultative Committee (GTCCC): provides advice to the Regulator and Ministerial Council on matters of general concern to the community in relation to GMOs.
- Gene Technology Ethics Committee (GTEC): provides advice on ethical issues relating to gene technology and the need for, and content of, any codes of practice or policy principles proposed by the Regulator or the Ministerial Council.
- Gene Technology Technical Advisory Committee (GTAC): provides scientific and technical advice on all issues related to GMOs to the Regulator and the Ministerial Council.

***Legal Unit***

Provides legal advice to the Regulator and OGTR on the operation of Commonwealth and State laws affecting the functions of the Regulator and the Office, including the setting of licence conditions and handling confidential commercial information (CCI).

# APPENDIX 6

## The Inter-governmental Agreement on Gene Technology

AN AGREEMENT made the eleventh day of September Two Thousand and One, between —

The COMMONWEALTH OF AUSTRALIA ('the Commonwealth') and

The STATE OF NEW SOUTH WALES;

The STATE OF VICTORIA;

The STATE OF WESTERN AUSTRALIA;

The STATE OF QUEENSLAND;

The STATE OF SOUTH AUSTRALIA;

The STATE OF TASMANIA;

The NORTHERN TERRITORY OF AUSTRALIA and

The AUSTRALIAN CAPITAL TERRITORY

(collectively called 'the States and Territories').

### Recitals

The Commonwealth and the States and Territories, recognising that there are existinglegislative schemes that regulate some products of gene technology, have agreed that:

A. there is a need for a co-operative national legislative scheme to protect the health and safety of people and to protect the environment, by identifying risks posed by, or as a result of, gene technology and by managing those risks through regulating certain dealings with genetically modified organisms; and

B. the Scheme should:

(a) provide an efficient and effective regulatory system for the application of gene technologies;

(b) operate in a seamless manner in conjunction with existing Commonwealth and State regulatory schemes relevant to genetically modified organisms and products derived from such organisms (for example, the schemes that regulate food, therapeutic goods, agricultural and veterinary chemicals and industrial chemicals);

(c) be nationally consistent, drawing on power conferred by the Commonwealth, State and Territory Parliaments;

(d) be based on a scientific assessment of risks undertaken by an independent regulator, whose decisions must be consistent with policy principles issued by a Council of Ministers concerning social, cultural, ethical and other non-scientific matters (which principles must not derogate from the health and safety of people or the environment);

(e) ensure that the regulatory burden is commensurate with the risks and consistent with achieving the objectives referred to in Recital A;

(f) be characterised by decision-making that is transparent, and that incorporates extensive stakeholder and community involvement;

(g) be able to be amended to respond to the development of gene technologies and their uses; and

(h) be consistent with Australia's relevant international treaty obligations.

**THE PARTIES AGREE AS FOLLOWS —**

**PART 1 — PRELIMINARY**

1. This Agreement may be cited as the Gene Technology Agreement.

2. This Agreement commences upon execution by the Commonwealth and four other Parties (which shall include at least three States).

3. The purpose of this Agreement is to facilitate a national gene technology regulation scheme.

4. This Agreement is not intended to create any legal or justiciable obligation whatsoever upon any of the Parties, either as between them or as between a Party and any other person. All disputes arising between the Parties which relate to this Agreement or associated matters will be resolved in accordance with clause 41.

5. In this Agreement, unless the context otherwise requires —' Commonwealth Act' means the *Gene Technology Act 2000* of the Commonwealth; 'Council' means the Ministerial Council established by Clause 13 and defined by section 10 of the Commonwealth Act;
'Legislation' includes regulations;
'Party' means a signatory to this Agreement;
'special majority' means at least two-thirds of the Parties;
'Scheme' means the totality of the legislation enacted and to be enacted by the Parties under this Agreement;
'State' does not include the Australian Capital Territory and the Northern Territory of Australia;
'State or Territory Bill' means a State or Territory Bill referred to in Clause 9 and 'State or Territory Act' has a corresponding meaning;
'wind-back provision' means section 14 of the Commonwealth Act; and
terms defined in the Commonwealth Act have the same meaning when used in this Agreement.

**PART 2 — NATIONAL GENE TECHNOLOGY LEGISLATION**

6. Unless the Council otherwise determines in accordance with Part 5 of this agreement, the Commonwealth will use its best endeavours to ensure that the Commonwealth Act, among other things, continues:

(a) to provide for a Gene Technology Regulator (the Regulator) to oversee and manage the assessment of risks to the health and safety of people and the environment associated with dealings with genetically modified organisms (GMOs).

The Regulator is:

(i) to be appointed and dismissed only with the approval of a majority of the jurisdictions (except where the Commonwealth Act provides that dismissal by the Governor-General is mandatory);

(ii) not to be subject to direction in performing functions and exercising powers under the Scheme, but will be bound to act in accordance with policy principles issued by the Council, and is to have regard to policy guidelines issued by the Council; and

(iii) at the request of the Council, to develop draft policy principles, policy guidelines and codes of practice, and provide information and advice to the Council;

(b) to prohibit persons from dealing with a GMO unless the dealing is exempt, is a notifiable low risk dealing, is included on the GMO Register or is licensed by the Regulator;

(c) to provide for a risk assessment process that requires the Regulator to seek advice from the States and Territories on an application for a licence to authorise the intentional release into the environment of a GMO, both on matters relevant to the preparation of the risk assessment and risk management plan, and on that assessment and plan following their preparation;

(d) to provide for the Council to issue:

(i) policy principles in relation to ethical issues, recognising areas (if any) designated under State law for the purpose of preserving the identity of GM crops or non-GM crops for marketing purposes, and other matters prescribed by regulation (which may relate to matters other than human health and safety or the environment);

(ii) policy guidelines in relation to matters relevant to the functions of the Regulator; and

(iii) codes of practice in relation to gene technology which may be applied by the Regulator as conditions of a licence;

(e) to provide for a Gene Technology Technical Advisory Committee, the chairperson of which is appointed only with the approval of a majority of jurisdictions. The members of the Committee are to be appointed on the basis of their skills or experience in one or more scientific disciplines. The Committee is to provide scientific and technical advice, at the request of the Regulator or the Council, on: gene technology, GMOs and GM products; applications made under the Scheme; biosafety aspects of gene technology; and the need for and content of policy principles, policy guidelines, codes of practice, and technical and procedural guidelines;

(f) to provide for a Gene Technology Community Consultative Committee, the chairperson of which is appointed only with the approval of a majority of jurisdictions. The members of the Committee are to be appointed on the basis of skills or experience of relevance to gene technology. The Committee is to provide advice, at the request of the Regulator or the Council, on: matters of general concern in relation to GMOs; or the need for and content of policy principles, policy guidelines, codes of practice, and technical and procedural guidelines;

(g) to provide for a Gene Technology Ethics Committee, the chairperson of which is appointed only with the approval of a majority of jurisdictions. The members of the Committee are to be appointed on the basis of their skills or experience in ethical issues or certain other fields relevant to ethical issues posed by gene technology. The Committee is to provide advice, at the request of the Regulator or the Council, on: ethical issues relating to gene technology; the need for and content of codes of practice in relation to ethics in respect of the conduct

of dealings with GMOs; and the need for and content of policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons;

(h) to provide that when a State or Territory Act is declared by the responsible Commonwealth Minister to be a corresponding State law and that State or Territory gives a wind-back notice to the responsible Commonwealth Minister, the application of the Commonwealth Act in that State or Territory is limited so that it does not apply:

(i) to a dealing that would otherwise have been regulated by the Commonwealth Act only because of section 51(ix) of the Constitution (the quarantine power); or

(ii) to a dealing with a GMO undertaken by a higher education institution or a State or Territory agency (including a State or Territory instrumentality or a company controlled by a State or Territory), or by a person authorised to undertake the dealing by a licence held under a State or Territory Act by a higher education institution or a State or Territory agency;

such dealings are to be regulated by the corresponding State law;

(i) not to preclude any State or Territory law that is capable of operating concurrently with the Commonwealth Act from operating according to its terms (other than a law not forming part of the Scheme which regulates dealings with GMOs by reference to their character as such and which is prescribed under the Commonwealth Act);

(j) to allow the relevant agency of each State and Territory access to all information (including confidential commercial information) provided to the Regulator by a person who intends to deal with a GMO in connection with an application or notification under the Scheme, for the purpose of the States and Territories performing duties or functions under the Scheme; and

(k) to provide for the Regulator to maintain a publicly available record of all dealings in Australia that involve GMOs or GM products, including particulars of the dealings (other than confidential commercial information).

7. The Commonwealth will also use its best endeavours to ensure that the Gene Technology (Consequential Amendments) Act 2000 continues to require that existing regulators of GM products (including those established by the existing schemes for the regulation of food, therapeutic goods, agricultural and veterinary chemicals and industrial chemicals):

(a) seek advice from the Regulator in relation to any application for approval of a GM product;

(b) take such advice into account in making a decision under the relevant scheme; and

(c) notify the Regulator of all decisions made in relation to GM products to enable those decisions to be entered on a central, publicly available database of all GMOs and GM products, maintained by the Regulator.

8. The relevant responsible Commonwealth Minister will recommend to the Governor-General the making of regulations:

(a) under the Commonwealth Act, to provide (among other things) that the chairperson of each of the Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Committee and the Gene Technology Ethics Committee will be dismissed only with the approval of a majority of jurisdictions (except where the regulations provide that dismissal by the Minister is mandatory); and

(b) under the Trans-Tasman Mutual Recognition Act 1997 (Commonwealth), to exclude from that Act the laws forming part of the Scheme; and will maintain those regulations unless the Council otherwise determines in accordance with Part 5 of the agreement.

9. Each State and Territory will submit to its Parliament as soon as possible a Bill or Bills to form part of the Scheme, for the purpose of ensuring that the Scheme applies consistently to all persons, things and activities within Australia. Each State and Territory will use its best endeavours to secure the passage of the Bill or Bills submitted to its Parliament, as introduced, and commencement of the Act(s) by 31 December 2001.

10. The Bill or Bills referred to in clause 9 will, among other things:

(a) confer functions and powers on the Regulator, the Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Committee and the Gene Technology Ethics Committee in the same terms as those in the Commonwealth Act;

(b) prohibit persons from dealing with a GMO unless the dealing is exempt, is a notifiable low risk dealing, is included on the GMO Register, or is licensed by the Regulator;

(c) provide for a risk assessment process that requires the Regulator to seek advice from the States and Territories on an application for a licence to authorise the intentional release into the environment of a GMO, both on matters relevant to the preparation of the risk assessment and risk management plan, and on that assessment and plan following their preparation;

(d) provide for the Council to issue:

(i) policy principles;

(ii) policy guidelines; and

(iii) codes of practice; as defined in the Commonwealth Act;

(e) bind the Crown in right of the State or Territory (as the case requires);

(f) provide for information referred to in Clause 6(j) which is confidential commercial information to be kept confidential (except as authorised or required by law), and for a criminal penalty for any agent of the State or Territory who breaches that obligation; and

(g) appropriate for payment to the Commonwealth amounts equal to the amounts received or recovered by a State or Territory under a State or Territory Bill.

11. Each State and Territory will use its best endeavours to ensure that its law(s) forming part of the Scheme continues to provide for the matters described in clause 10.

12. A State or Territory which wishes the wind-back provision to operate in relation to it will give to the responsible Commonwealth Minister as soon as practicable after the enactment of the State or Territory Act(s), a written wind-back notice.

**PART 3 — THE GENE TECHNOLOGY MINISTERIAL COUNCIL**

13. There is established a Council of Ministers to be known as the Gene Technology Ministerial Council.

14 The Council consists of one member from each Party, who shall be the Minister nominated by each Party's Head of Government. That Minister will be responsible for presenting the view of his or her Government as a whole on the matters considered by the Council.

15. A Minister of a Party who is not a member of the Council may attend and participate in any meeting of the Council as an observer, but may not vote.

16. The functions of the Council are to:

(a) issue policy principles, policy guidelines and codes of practice to govern the activities of the Regulator and the operation of the Scheme;

(b) approve proposed regulations for the purpose of the Scheme;

(c) approve the appointment (and, if necessary, the dismissal) of the Regulator, and of the chairpersons of the Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Committee, and the Gene Technology Ethics Committee, and advise the responsible Commonwealth Minister on the appointment of the members of those bodies;

(d) ensure co-ordination with other Ministerial Councils on matters relating to gene technology and, in particular, harmonisation of regulatory processes relating to GM products;

(e) oversee generally the implementation of the Scheme;

(f) consider and, if thought fit, agree on proposed changes to the Scheme;

(g) initiate a review of the Scheme in accordance with Part 6; and

(h) perform any other function conferred on the Council by this Agreement.

17. A member of the Council may appoint another Minister to act in his or her stead for the purpose of any meeting or decision of the Council. An acting member has, for the purposes of this Agreement, all the powers and functions of the Minister who is the member of the Council, and is to be responsible for presenting the view of his or her Government as a whole on the matters considered by the Council.

18. The Council will meet at such times and places as a majority of the Council determines.

19. The chairperson of the Council until 30 June 2002 will be the responsible Commonwealth Minister. Thereafter, the chair of the Council will be rotated annually (or at such longer intervals as the Council may determine).

20. The quorum for a Council meeting will be at least half of the members of the Council.

21. Questions arising in the Council will be determined in accordance with the Scheme, or otherwise by a majority of all members of the Council (except in the case of a resolution referred to in clause 33, which will be determined by a special majority).

22. Subject to clause 21, a question arising in the Council may be determined without a meeting in such manner as the Council determines (including by teleconference, videoconference, mail, or electronic mode of communication). In all cases, a copy of the proposed resolution will be circulated to all members of the Council before a vote is required.

23. Where a matter under consideration by the Council affects the functions of another Ministerial Council, the chairperson will initiate discussions with the chair of the other Ministerial Council(s). In such discussions, the chair of the Council will act in a manner consistent with his or her capacity as a representative of the Council.

24. The Council may invite a representative of another Ministerial Council to attend and participate in a meeting of the Council as an observer.

25. Subject to this Agreement, the Council may regulate its own procedure, and for that purpose the Council may make, amend and revoke rules of procedure.

**PART 4 — ROLES OF THE PARTIES IN THE ADMINISTRATION AND ENFORCEMENT OF THE SCHEME**

26. The Parties intend that a State or Territory which wishes to assist in the administration and enforcement of the Scheme will negotiate with the Commonwealth with a view to concluding a bilateral agreement on a fee-for-service basis. The negotiations will consider the resources and expertise required by the State or Territory, the level of payment for the proposed services and any other relevant matter. Any agreement will be consistent with clauses 27, 28 and 29.

27. The Commonwealth will reimburse a State or Territory for reasonable costs incurred by a State or Territory in relation to:

(a) the performance of functions delegated by the Regulator under the Scheme to a State or Territory official;

(b) the exercise of powers conferred under the Scheme on a State or Territory official who is appointed by the Regulator to act as an inspector; and

(c) the provision of advice and assistance requested by the Regulator (other than under a mandatory provision of the Scheme requiring the Regulator to seek comments), including the provision of location-specific information relevant to applications.

28. The States and Territories will be responsible for other costs incurred by them in connection with their participation in the Scheme, including:

(a) costs incurred in providing advice to the Regulator on applications and on draft risk assessments and risk management plans (other than costs referred to in paragraph 27(c));

(b) costs incurred in bringing a prosecution under a corresponding State or Territory law; and

(c) costs incurred in contributing to policy development, including costs associated with meetings of the Council and meetings of officials.

29. Where the services of a State or Territory official are made available to assist the Regulator, the Commonwealth will pay the State or Territory an amount equal to the employment costs (comprising salary and on-costs) of the official for the duration of the secondment, in proportion to the percentage of the official's time spent assisting the Regulator in connection with the performance of the Regulator's functions.

30. The Commonwealth will enable access for States and Territories to both publicly available and confidential information held by the Regulator in connection with applications, notifications and licences, and monitoring, inspections and enforcement under the Scheme. Electronic access will be provided to publicly available information and, where appropriate security arrangements permit, to confidential information.

31. The Parties will informally exchange information of a kind, and at intervals, to facilitate the effective and efficient operation of the Scheme.

**PART 5 — MAINTENANCE OF A NATIONALLY CONSISTENT SCHEME OVER TIME AND AMENDMENT OF THE SCHEME**

32. The Parties agree to use their best endeavours to ensure that the legislation forming part of the Scheme (including all subordinate instruments) will remain nationally consistent.

33. Any Party that proposes to amend its legislation forming part of the Scheme will submit the proposed amendments to the Council for consideration before introduction of the amendments. The amendments will be submitted at least one month before introduction (unless a different minimum notice period is determined by the Council). Each Party agrees that it will not introduce such an amendment unless the Council has by special majority resolved to approve the proposed amendment.

34. Where the Council approves an amendment to legislation forming part of the Scheme, all Parties will (unless otherwise agreed by the Council) introduce appropriate amendments to their legislation to ensure that the Scheme remains nationally consistent.

35. Any Party that proposes to introduce legislation that would affect the Scheme (but not amend legislation forming part of the Scheme) will give written notice to the Council of the effect of its legislative proposals on the Scheme, at least one month before introduction of the legislation (unless a different minimum notice period is determined by the Council).

36. Each Party will use its best endeavours to ensure that any subordinate instrument issued by the Council is not disallowed by its Parliament.

**PART 6 — REVIEW OF IMPLEMENTATION AND EFFECTIVENESS**

37. The Parties will review this Agreement and the Scheme no later than four years after the commencement of this Agreement. Further reviews will be conducted at intervals of no more than five years.

38. Each such review will invite public submissions and be conducted in consultation with:

(a) the Regulator;

(b) the Gene Technology Technical Advisory Committee, the Gene Technology Community Consultative Committee and the Gene Technology Ethics Committee; and

(c) such scientific, consumer, health, environmental, and industry groups as the Parties consider appropriate.

**PART 7 — AMENDMENT OR VARIATION OF AGREEMENT**

39. Where a Party considers that an amendment to this Agreement would be desirable, it may request consultations with the other Parties.

40. Any amendment to this Agreement agreed upon by all Parties will be contained in a notice signed by and given to all Parties, and the notice will include the date on which the amendment will come into force.

**PART 8 — DISPUTE RESOLUTION**

41. Where a dispute arises under this Agreement:

(a) the members of the Council will negotiate to resolve the dispute; and

(b) if the negotiation fails, the Council will refer the dispute to Heads of Government or their nominated representatives to seek a resolution.

**PART 9 — WITHDRAWAL AND TERMINATION**

42. Any Party that intends to withdraw from this Agreement must give at least 12 months notice in writing to each of the other Parties. At the expiration of that period, the Party may withdraw from the Agreement by giving written notice to all other Parties stating the date that the withdrawal will be effective.

**IN WITNESS WHEREOF** the Parties have executed this Agreement as at the day and year first above written.

Signed By:

The Honourable John Winston Howard MP )
Prime Minister of the Commonwealth of Australia ) _____

The Honourable Robert John Carr MP )
Premier of the State of New South Wales ) _____

The Honourable Stephen Phillip Bracks MP )
Premier of the State of Victoria ) _____

The Honourable Geoff Gallop MLA )
Premier of the State of Western Australia ) _____

The Honourable Peter Douglas Beattie MLA )
Premier of the State of Queensland ) _____

The Honourable John Wayne Olsen MP )
Premier of the State of South Australia ) _____

Mr Jim Bacon MHA )
Premier of the State of Tasmania ) _____

The Honourable Denis Burke MLA )
Chief Minister of the Northern Territory of Australia ) _____

Mr Gary John Joseph Humphries MLA )
Chief Minister of the Australian Capital Territory ) _____

# APPENDIX 7

**Australian Government**

**Department of Health and Ageing**
**Office of the Gene Technology Regulator**

## Technical amendments recommended by the Regulator

***Section 10 — Definition of 'deal with'***

Currently, possession, supply, use, transport and disposal of a GMO are only dealings when they occur 'in the course of' the defined dealings. However these things can happen other than in the course of the defined dealings. A GMO may be possessed or transported for reasons which are not in the course of conducting experiments, growing, breeding etc. For example, a GMO intending to be displayed in a museum simply as an item of interest would not be caught as a 'dealing'. It is recommended that the definition be revisited with a view to anticipating circumstances where the possession, supply, use, transport or disposal of a GMO should be considered a dealing in its own right.

***Section 43(2)(d) — The Regulator's legislative capacity to cease consideration of an application***

For the reasons discussed in the background to Recommendation 5.1 of the Regulator's submission it is not clear whether section 43(2)(d) of the Act can be interpreted as a capacity of the Regulator to end consideration of an application after its consideration has been commenced but not completed due to a failure by an applicant to provide information.

The recommendation is that paragraph 43(2)(d) be amended to allow the Regulator to exercise a discretion to consider the application withdrawn where there has been a failure by the applicant to provide requested information within a specified time period irrespective of when that request for further information occurs.

***Section 56 — Matters to which the Regulator is required to have regard for Division 3 applications (DNIRs)***

There is no express requirement under section 56 that in considering an application for a dealing which will not involve the intentional release of a GMO into the environment (a Division 3 application), the Regulator should have regard to RARMPS and submissions prepared under section 47. Regard to these matters is probably implied as a necessary step in taking into account all relevant considerations. However section 56 expressly requires regard to be had to RARMPS and submissions with respect to Direct Intentional Releases (Division 4 applications) and the recommendation is that a similar requirement be express with respect to Division 3 applications.

***Section 57 Consideration of suitability to hold licence***

Currently this can only happen after the processes required by Part 5 of the Act. If an applicant turns out to be unsuitable the extensive assessment and consultation process will have been an inefficient use of resources. Unsuitability to hold a licence could be added to the list of circumstances under subsection 43(2) where the Regulator does not have to consider an application for a licence.

***Sections 72, 89 and 97 — Variations to conditions of licence, certifications and accreditations***

The global requirement under sections 72, 89 and 97 that the Regulator provide formal written notice to a licence holder when a variation to the licence is proposed by the Regulator is ill suited to minor variations and/or variations which do not carry natural justice implications. This obliges the arguably unnecessary application of resources. Consideration should be given to identifying more specifically in the legislation circumstances in which notice would/would not be required.

***Transfer of Certifications***

There is currently no provision allowing for the transfer of a certification from one certification holder to another. It is recommended that relevant provisions be included.

***Section 92 — Accreditation of organisations using host IBCs***

There is no express provision in the Act for the accreditation of organisations proposing to use the IBC of another accredited organisation. In practice, the Office offers accreditation to these entities by recognising an intention to use another IBC in guidelines issued under section 98. The intention to use host IBCs consequently becomes a matter to which the Regulator must have regard pursuant to paragraph 92(2)(d).

It is recommended that a better approach is to include a capacity to use a host IBC as an express matter to which the Regulator must have regard under section 92.

***Section 92 — Definition of IBC under section 10 and implications for operation of section 92***

Under section 10 an IBC 'means a committee established by an accredited organisation as an IBC'.

Paragraph 92(2)(a) requires the Regulator, in considering an application for accreditation, to have regard to whether the applicant organisation has established, or proposes to establish, an IBC. However the definition of IBC effectively means that an organisation cannot have an 'established' IBC at the time of application because it is unaccredited. Administering the provision is further confused by the requirement that the Regulator have regard to 'proposals' to establish an IBC.

The preferred option of the office is that an applicant for accreditation have established, or in place, a committee capable of being described as an IBC under the legislation once accredited, and that section 92 not contemplate accreditation being given on the basis of proposals to have a requisite committee in place in the future. In other words, the committee capable of acquiring status as an IBC under the Act should be in place before an organisation considers applying for accreditation.

***Section 78 — Register***

Subsection 78(3) prevents the Regulator from giving effect to a determination that a dealing be placed on the register if a licence is still in force. A dealing conducted in the period between cancellation or surrender of a licence and registration of the relevant dealing would be rendered unlicensed and therefore illegal. The problem can be overcome by the Regulator stipulating a date on which the determination comes into effect which coincides with a date of cancellation or surrender. But the better option would be to make some express reference to the status of the dealing (e.g. deeming the dealing authorised) in the intervening period between cancellation or surrender of a licence and the registration of the relevant dealing.

***Section182 — Out of time deemed rejection of applications***

Section 182 deems an application rejected if a decision has not been made in time.

It is unclear whether deemed rejections are appellable decisions for purposes of section 179, and if so, whether they are reviewable internally or by the AAT. We recommend that this position be clarified by amendments to the provision.

***Section 185 — Confidential Commercial Information***

Under section 10 'confidential commercial information' currently means information declared by the Regulator to be confidential commercial information under section 185. As a result,

there is currently no express protection from release under s 54 for applications for CCI as opposed to declared CCI and

only release of declared CCI would attract a criminal penalty so release of undeclared but potential CCI can occur with immunity.

It is recommended that the definition be amended, e.g. as follows:

*'confidential commercial information' means*

*(a) information declared by the Regulator to be confidential commercial information under section 185 and/or,*

*(b) information which is the subject of an application for a declaration that information is confidential commercial information under section 185 but on which the Regulator has yet to make a decision.*

# APPENDIX 8

## Comparison of gene technology regulation for selected countries

## REGULATION OF GENE TECHNOLOGY IN EUROPEAN COMMUNITY

**SUMMARY** — The EC has issued a number of directives that relate to different uses with GMOs and GM products.

- In relation to the use of GMOs, there are three relevant d irectives: contained use of GM micro-organisms; deliberate release of GMOs into the environment and placing on the market; and protection of workers from the risks of exposure to biological agents.
- In relation to GM products, there are also a number of relevant directives: additives in feeding stuffs; medicinal products; and novel food.

| **Contained work with GMOs** | |
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| Responsible agency | • The Council of the European Communities. |
| Legislation | • Council Directive 90/219/EC for contained use of genetically modified micro-organisms. |
| Assessment process for the contained use of genetically modified micro-organisms. | • A notification is submitted to the competent authority when a facility is to be first used for operations for contained use of genetically modified micro-organisms. The information required for the notification includes: information about the physical location of the installation; information about the micro-organism; information on methods for handling, waste treatment and protective and supervisory arrangements; and accident and emergency procedures.<br>• Competent authorities acknowledge the receipt of the notification.<br>• The competent authorities then examine the conformity of the notification with the Directive.<br>• The competent authority may request more information or modify the initial notification or limit the time for which the contained use should be permitted or prescribe conditions on its use.<br>• The competent authority may modify, suspend or terminate the contained use if significant consequences may arise from risks posed. |

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| Consideration of ethical issues | • See comment for 'public consultation on applications' below. |
| Public consultation on applications | • The Directive provides that if a member state considers it appropriate, it can consult with the public and other groups on any aspect of the proposed contained use. |
| Conditions that may be applied | • The Directive provides that competent authorities may grant approvals subject to conditions. |
| Monitoring, surveillance and enforcement powers | • The Directive provides that member states shall ensure that the competent authority organises inspections and other control measures as appropriate to ensure compliance with the Directive.<br>• An assessment of environmental considerations by the user is required which includes details of: techniques for detection, identification and monitoring of the micro-organism; detecting transfer of new genetic material to other organisms. A summary of the assessment is required in the notification to the competent authority.<br>• Member states are required to send to the Commission, at the end of each year, a summary report on the contained uses notified under article 10 (2) including the description, proposed uses and risks of the genetically modified micro-organisms. |
| Penalties | • The Directive does not include any penalties as it is up to individual Members States as to how they implement the Directive (through legislation) and the penalties imposed. |
| **Intentional releases of GMOs in the environment** | |
| Responsible agency | • The Council of the European Communities. |
| Legislation | • Directive 2001/18/EC of the European Parliament and of the Council regulates the deliberate release of GMOs into the environment (mainly part B of the Directive). |

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| Coverage of the legislation | • The deliberate release of GMOs into the environment for experimental purposes (e.g. for field testing). |
| Assessment process for intentional experimental releases of a GMO into the environment (field trials and general releases) | • An applicant is required to obtain written authorisation from the competent national authority of the member state within whose territory the experimental release is to take place, on the basis of an evaluation of the risks presented by the GMO — or GMOs — for the environment and human health.<br>• To obtain the authorisation, an application must be made that includes details as specified in article 6 of Directive 2001/18/EC, which stipulates that information be provided regarding: the GMO; personnel and training; conditions of release; interaction between the GMO and environment; a monitoring plan to track the effects on human health or environment; control, remediation methods, waste management and emergency response plans.<br>• The decision to reject or accept the application rests solely with the competent national authority and therefore is a national procedure.<br>• The competent national authority approves the application if it considers that it complies with the Directive 2001/18/EC.<br>• If authorisation is granted, the applicant (or notifier) may release the GMO in compliance with the conditions set out in the authorisation. |
| Consideration of ethical issues | • The Directive does not make any reference to the need for ethical matters to be considered. |
| Public consultation on applications | • The Directive provides that the competent authority shall consult the public in relation to the deliberate release of GMOs. |
| Conditions that may be applied | • The Directive provides that competent authorities may grant approvals subject to conditions. |

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| Monitoring, surveillance and enforcement powers | • The Directive provides that member states shall ensure that the competent authority organises inspections and other control measures as appropriate to ensure compliance with the Directive.<br>• A monitoring plan must be included in the application for deliberate experimental release of GMOs and should: incorporate surveillance for unanticipated, adverse effects; identify who will carry out the tasks involved in monitoring; and facilitate observation of the release of the GMO into the environment. |
| Penalties | • The Directive does not include any penalties as it is up to individual Members States as to how they implement the Directive (through legislation) and what penalties they impose. |
| **Placing GMOs (or products containing GMOs) on the market** | |
| Legislation | • Directive 2001/18/EC of the European Parliament and of the Council regulates the deliberate release of GMOs into the environment (mainly part C of the Directive). |
| Coverage of the legislation | • Placement on the market of GMOs for cultivation, import or processing into industrial products. |
| Procedure for the placing of GMOs or products containing GMOs on the market. | • To obtain the written authorisation, an application (known as the 'notification') must be made to the competent national authority of the member state that complies with article 13 of Directive 2001/18/EC, which stipulates that information be provided regarding: the diversity of sites for the use of the GMO, including research on its effects on human health and the environment; environmental risk assessment; conditions for use and handling of the GMO and GMO products; the proposed period of consent (not greater than 10 years); a monitoring plan; a proposal for labelling; and a proposal for packaging.<br>• The national authority issues an opinion in the form of an assessment report once the notification is received. |

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| Procedure for the placing of GMOs or products containing GMOs on the market (continued) | • In the event of an unfavourable report, the notifier may apply to competent authorities of other member states.<br>• In the event of issuing a favourable report, the member state informs other member states through the European Commission.<br>• Member states examine the report and issue observations or objections.<br>• If there are no objections, the member state that issued the assessment report authorises that the GMO be placed on the market.<br>• When objections are raised a conciliation phase is entered so that issues can be resolved.<br>• If objections still exist at the end of conciliation, the European Commission takes a decision by consulting the European Food Safety Authority.<br>• A draft decision is then presented to the regulatory committee (composed of representative from member states).<br>• If the committee gives a favourable opinion the Commission takes the decision.<br>• If the committee's opinion is unfavourable, the report is referred to the Council of Ministers where a decision by majority is taken.<br>• If the Council of Ministers does not act within three months, the decision is taken.<br>• The decision to reject or accept the application is not a national procedure and involves all member states. |
| Consideration of ethical issues | • There is provision for ethical matters to be considered in deliberate release of GMOs or in placing GMOs (or products containing GMOs) on the market. |
| Public consultation on applications | • There does not appear to be any express or mandatory requirement for public consultation. |

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| Conditions that may be applied | • The Directive provides that competent authorities may grant approvals subject to conditions. |
| Monitoring, surveillance and enforcement powers | • The Directive provides that member states shall ensure that the competent authority organises inspections and other control measures as appropriate to ensure compliance with the directive. |
| Penalties | • The Directive does not include any penalties as it is up to individual Members States as to how they implement the Directive (through legislation) and the penalties imposed. |
| **Placing on the market GMOs intended for food or feed** | |
| Legislation | • Regulation (EC) 1829/2003 of the European Parliament and of the Council.<br>Commission Regulation (EC) 641/2004 on detailed rules for the implementation of Regulation (EC) 1829/2003. |
| Coverage of the legislation | • The placing on the market of GMOs intended for food or feed and of food or feed products containing, consisting of or produced from GMOs.<br>• Applications to place a food product contains or consists of GMOs is subject to regulation 1829/2003. |
| Assessment procedure for placing on the market GMOs intended for food or feed | • An authorisation must be obtained before placing on the market a GMO for food/feed use (including food/feed containing ingredients produced by a GMO; food/feed produced from a GMO; an ingredient produced from a GMO or food/feed containing that ingredient).<br>• The application is sent to a competent authority in the member state.<br>• The application is acknowledged in writing in 14 days. |

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| Assessment procedure for placing on the market GMOs intended for food or feed (continued) | • The application is immediately sent to the European Food Safety Authority (EFSA).<br>• EFSA then informs other member states, the European Commission and makes the information in the application available to the public.<br>• The application includes information on: applicant particulars; the transformation events used; compliance with the Cartegena protocol on biosafety; method of production and manufacture; research and analysis that the food/feed is safe to humans/animals and the environment; any ethical and religious concerns; methods of detection; a proposal for post-market monitoring.<br>• EFSA will give its opinion on the application within six months of receiving a completed application (excluding time required to provide additional information).<br>• Before giving its opinion, EFSA may: ask for a safety assessment of the food/feed assessment body of a member state; ask a competent authority of a member state to conduct an environmental risk assessment; arrange for the detection method to be tested/validated; examine applicant submitted data that shows the food/feed is not different in characteristic to its conventional counterparts beyond accepted natural variations.<br>• EFSA consults with the competent national authority of the member state and the competent authority has three months to make its own opinion known.<br>• If the opinion is in favour of authorisation, conditions and restrictions in relation to marketing, monitoring or protection of environment/ecosystems may be made.<br>• EFSA gives its opinion to the European Commission.<br>• The Commission gives a draft of the decision to the Committee on the Food Chain and Animal Health within three months of receiving the decision from EFSA with an explanation if its opinion differs to that of EFSA.<br>• The European Commission informs the applicant of the decision made without delay.<br>• Decisions taken by EFSA may be reviewed under the European Commission's own initiative, at the request of a member state or any person directly and individually concerned. |

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| Consideration of ethical issues | • This must form part of the application.<br>• The Commission, on its own initiative or at the request of a member state, may consult the European Group on Ethics in Science and New Technologies or any other appropriate body it might establish, with a view to obtaining its opinion on ethical issues. |
| Public consultation on applications | • EFSA is required to make applications available to the public.<br>• The application, supplementary information, opinions from competent authorities and monitoring reports are required to be made public.<br>• There is provision for the establishment of a community register of genetically modified food and feed. The register is to be made available to the public. |
| Conditions that may be applied | • Conditions relating to use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of GMOs or food containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas. |
| Monitoring, surveillance and enforcement powers | • There is a provision for a monitoring plan to be included in the application, where appropriate.<br>• Authorisations are valid for 10 years, subject to renewal.<br>• The authorisation holder is required to submit reports to the European Commission as part of the monitoring process, if it is a condition of the authorisation.<br>• The European Commission has established a community register for all GM food and feed. |
| Penalties | • Granting of authorisation does not lessen civil or criminal liability of any food operator with respect to the food. |
| **Movement of GMOs between countries** | |
| Legislation | Regulation (EC) 1946/2003. |
| Coverage of the legislation | Unintentional movements between member states and exports to third countries. |

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| Procedure for transborder movement of GMOs | **GMOs intended for deliberate release into the environment**<br>• The exporter needs to notify the competent authority of a Party or non-Party (to the Cartegena protocol) in writing before the first intentional transborder movement of a GMO intended for deliberate release into the environment.<br>• The notification shall contain: details of importer and exporter; dates of transport; details of the GMO and the modification; the intended use; suggested methods for safe handling, transportation, storage, packaging and use. The Party of export shall send a written reminder to the competent authority of the Party of import if the exporter has not received a response from the importer regarding the notification within 270 days. The reminder contains a deadline for response of 60 days.<br>• A decision to grant permission for transborder movement of GMOs is based on a risk assessment.<br>• GMOs intended for deliberate release into the environment may not need to be subject to this procedure if it has been deemed not to have likely adverse effects on biological diversity and human health.<br>**GMOs intended for direct use as food/feed**<br>• Decisions about transborder movement are required to be provided to the Biosafety Clearing-House (established under the Cartegena protocol) by the European Commission or member state in which the application for movement was made.<br>• The exporter shall respect the decisions taken by a Party on the import of GMOs.<br>**Unintended movement of GMOs**<br>• When a member state becomes aware of the occurrence of the unintentional movement of GMOs under its jurisdiction, it is required to: inform the public and the European Commission; consult affected member states regarding appropriate responses and necessary action (including emergency responses). |
| Consideration of ethical issues | • There was no specific mention of consideration of ethical issues in Regulation (EC) 1946/2003. |
| Public consultation on applications | • The notification, the acknowledgment of receipt and the decision of the Party are made available to the public. |

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| Conditions that may be applied | • There are obligations placed on the exporter of GMOs in relation to the information that needs to be provided regarding the particulars of the GMO and any information about transport, safe handling, storage and monitoring of the GMO. |
| Monitoring, surveillance and enforcement powers | • There does not appear to be any specific mention of monitoring, surveillance and enforcement powers. |
| Penalties | • Regulation (EC) 1946/2003 states that member states shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measure necessary to ensure that they are implemented. |
| **Policy and Governance issues** | |
| Liability for contamination | • Directive 2004/35/EC8 on environmental liability with regard to the prevention and remedying of environmental damage was adopted in April 2004. This Directive is aimed at prevention and remediation of significant damage to water, land and protected species and habitats. Within this scope, a regime of strict liability is foreseen for environmental damage from GMOs, i.e. there is no requirement to demonstrate negligence or criminal damage. The Directive provides member states with a duty to order responsible operators to undertake preventive or remedial action, and a discretionary power to carry out the work themselves and then recover the costs from the operator. Nevertheless, in situations where an operator can demonstrate that the damage in question was the result of emissions or events explicitly authorised or where the potential for damage could not have been known when the event or emission took place, member states may allow the operator not to bear the cost of remedial actions. The Directive specifically excludes civil liability for property damage or economic loss from, for example, adventitious presence of unwanted GM material/traits/species from neighbouring properties in crops or wild relatives. |

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| Liability for contamination (continued) | • Denmark also has a no fault compensation fund. The Danish scheme is funded through a levy on areas planted to GM crops. Under the scheme: payment of compensation is limited to cases where GM-material is found in non-GM-crops of the same type as the GM-crops or a closely related type … in the same cultivation season and within a specifically determined area; compensation is only paid out for losses if the occurrence of GM-material in injured crops, as defined above, exceeds a threshold value of 0.9 per cent; the farmer must apply for compensation no later than 14 days after the occurrence of GM-material has been ascertained; compensation is paid out regardless of whether or not the farmer can be identified. The government then seeks reimbursement for the cost of the compensation that has been paid from the farmer from whose fields the GM material emanated.<br>• Germany has introduced a strict liability regime. |
| Expert committees | • The procedure for placing GMOs on the market allows the European Commission to consult with a relevant scientific committee and with a relevant ethical committee either on its own initiative, or at the request of a member state.<br>• The European Commission, on its own initiative or at the request of a member state, may consult with the European Group on Ethics in Science and New Technology in relation to genetically modified food or feed.<br>• Upon receiving applications for placing on the market GMOs for food or feed use, the European Commission seeks opinion/consultations from EFSA and the Committee on the Food Chain and Animal Health. |
| Research | • Data obtained from research and developmental releases concerning the impact of GMOs on human health and the environment are required as part of the notification necessary for submission to the competent authority in the member state before the product can be placed on the market. |

| **Other** | |
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| The precautionary principle | • Directive 2001/18/EC took into account the precautionary principle when it was drafted and mentions the precautionary principle in relation to environmental risk assessments.<br>• Directive 1946/2003/EC is in accordance with the precautionary principle. |
| Cost recovery | • Not applicable. |
| Moratorium | • Not applicable. |
| Other | |

## REGULATION OF GENE TECHNOLOGY IN NEW ZEALAND

**SUMMARY** — One primary piece of legislation covers research with GMOs and release of GMOs into the environment in New Zealand — the Hazardous Substances and New Organisms Act 1996 (HSNO Act).

- The Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM) contains additional provisions that relate to approvals for Agricultural Compounds and Veterinary Medicines that are or contain genetically modified new organisms, while the Medicines Act 1981 contains provisions relating to approvals required in relation to human medicines that are or contain genetically modified new organisms. Foods and food products that are, or contain genetically modified new organisms, or produced using gene technology, must also be assessed for safety for human consumption in accordance with the Australia New Zealand Food Standards Code.
- There is no single statutory link (or one-stop shop) between legislation to regulate GMOs and GM products (such as GM therapeutics and agricultural and veterinary chemicals). However, in 2003, the HSNO Act and Medicines Act together were amended to improve the overall effectiveness of the operation of the HSNO Act and reduce compliance costs (while not increasing risk to the public health or the environment), and provide a fast-track process for low-risk organisms, including low-risk GMOs, used in both human and animal medicines, and for use in emergencies.
- Exports of genetically modified organisms that constitute living modified organisms as defined under the Cartegena protocol on biosafety to the Convention on Biological Diversity are regulated under the Imports and Exports (Living Modified Organisms) Prohibition Regulations 2005 to the Imports and Exports (Restrictions) Act 1988.

| **Contained work with GMOs** | |
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| Responsible agency | • Environmental Risk Management Authority (ERMA). |
| Legislation | • Hazardous Substances and New Organisms Act (HSNO Act). |
| Coverage of the legislation | • The HSNO Act covers research work with GMOs. |

| Intentional releases of GMOs in the environment | |
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| Responsible agency | • Environmental Risk Management Authority (ERMA). |
| Legislation | • Hazardous Substances and New Organisms Act (HSNO Act). |
| Coverage of the legislation | • The legislation covers the importation (including for release), development, field testing and release from containment of new organisms (including GMOs).<br>• A genetically modified organism includes, unless excluded by regulations, any organism in which any of the genes or other genetic material: (a) Have been modified by in vitro techniques; or (b) are inherited, or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques. The term in vitro is not defined. |
| Assessment process for contained use of GMOs | • The Act allows ERMA to delegate assessment decisions in these cases. For example, approval decisions may be delegated to the Chief Executive of ERMA New Zealand or to approved Institutional Biological Safety Committees (IBSCs). The definition of 'low risk' in this case is set out in regulations made under section 41. |
| Assessment process for intentional releases of a GMO into the environment | • Any person importing or releasing a 'new organism' into the environment must apply to the ERMA for approval. Approval may be given if the new organism is not likely to cause:<br>– any significant displacement of any native species within its natural habitat;<br>– any significant deterioration of natural habitats;<br>– any significant adverse effects on human health and safety;<br>– any significant adverse effect to New Zealand's inherent genetic diversity; or<br>– disease, be parasitic or become a vector for human, animal or plant disease, unless that is the purpose of the application. |

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| Assessment process for intentional releases of a GMO into the environment (continued) | • In addition, the positive effects of the GMO must outweigh the adverse effects of the GMO and the need for caution in managing adverse effects where there is scientific and technical uncertainty (about those effects) shall be taken into account.<br>• For approvals for conditional release approvals, the controls that will be imposed on the approval, and whether the controls are likely to be effective in meeting the objective of the controls, may be taken into account in ERMA's assessment of the application. |
| | The HSNO Act describes a specific procedure which must be followed in relation to each application. When ERMA receives an application it must:<br>– inform the Minister for the Environment and any government department or crown entity that is likely to express an interest in the application;<br>– in relation to applications involving new organisms, inform the Department of Conservation and any local authority (within the meaning of the Local Government Act 2002) if, in the opinion of the Authority, the local authority is likely to have an interest in the application;<br>– if the application is to conditionally release or release a GMO (i.e. if the GMO is not to be used in containment), publicly notify the application (in relation to an application for contained work, including contained field tests, ERMA may publicly notify the application if it considers that there is likely to be significant public interest). The public notice invites people to make submissions on the application. All submissions must be received by the date specified in the public notice, and this date must be no longer than 30 working days after the public notification was advertised. ERMA may also call a hearing to consider the application and any submissions made (The Authority is obliged to hold a hearing if the applicant has made a written request to the Authority for a hearing, or if a person who has made a submission stated in that submission that he or she wishes to be heard and has not subsequently advised that he or she does not wish to be heard); |

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| Assessment process for intentional releases of a GMO into the environment (continued) | • Consider the application and any submissions made in accordance with documented assessment methodology;<br>• Consider the following principles:<br>– safeguarding the life supporting capacity of air, water and ecosystems; and<br>– maintaining and enhancing the capacity of people and communities to provide for their own economic, social and cultural wellbeing, and for the reasonable foreseeable needs of future generations;<br>• Consider:<br>– the sustainability of all flora and fauna;<br>– the intrinsic value of ecosystems;<br>– public health;<br>– the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga;<br>– economic and related benefits and costs of using a particular new organism; and<br>– New Zealand's international obligations.<br>For applications to release a new organisms to the environment, the Authority must decline an application, if the new organism is likely to:<br>– cause any significant displacement of any native species within its natural habitat; or<br>– cause any significant deterioration of natural habitats; or<br>– cause any significant adverse effects on human health and safety; or<br>– cause any significant adverse effect to New Zealand's inherent genetic diversity; or<br>– cause disease, be parasitic, or become a vector for human, animal, or plant disease, unless the purpose of that importation or release is to import or release an organism to cause disease, be a parasite, or a vector for disease.<br>(For the purposes of conditional release, see above note on assessment process for intentional releases.) |

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| Consideration of ethical issues | • For ERMA's assessment process, no specific mention is made of ethical concerns, except in relation to provisions for Ministerial call in of applications. (The Minister may direct that he or she will decide an application if the Minister considers that the decision on the application will have significant cultural, economic, environmental, ethical, health, international, or spiritual effects, or have significant effects in an area in which the Authority lacks sufficient knowledge or experience.) However, it is possible that ethical concerns could be addressed when weighing up the positive and adverse effects of an application, especially as section 5 provides that persons exercising functions under the Act should recognise and provide for the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural wellbeing. However, harm (or adverse effects) would need to be established. |
| Public consultation on applications | • Refer to assessment process. ERMA must publicly consult on all applications for release into the environment for a period of no longer than 30 working days.<br>• ERMA may consult on applications for use of GMOs in contained settings if ERMA considers that there is likely to be significant public interest in the issue. |

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| Protection of confidential commercial information | • HSNO provides some specific protection for commercial in confidence information. In addition, the Official Information Act 1982 contains comprehensive provisions relating to the availability and protection of official information, for example, to protect information where the making available of the information would disclose a trade secret or would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information.<br>• Any information withheld by ERMA from any person in accordance with section 9(2)(b) of the Official Information Act 1982 may be considered by the Authority in reaching a decision. Where any person supplies any information to the Authority; and the information is likely to relate to an application for approval; and the relevant application has not yet been lodged formally with the Authority, the provisions of the Official Information Act 1982 do not apply to that information until the relevant application has been received by the Authority.<br>• Additionally, where any information is held by ERMA relating to any application made under HSNO in respect of a new organism that is also the subject of an innovative medicine application as defined under the Medicines Act 1981, or of an innovative agricultural compound application under the Agricultural Compounds and Veterinary Medicines Act 1997, and that information includes trade secrets or information that has commercial value that would be, or would likely to be, diminished by disclosure, the relevant provisions of those Acts, with the necessary modifications, apply to that information as if the information were confidential supporting information as defined under the relevant provisions of those Acts. |
| Conditions that may be applied | • There is no provision for conditions to be applied to full release applications.<br>• Controls may be imposed on conditional release, field test and other containment approvals in relation to GMOs. |

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| Monitoring, surveillance and enforcement powers | • The Ministry of Agriculture and Forestry (MAF) is the agency responsible for ensuring the new organisms provisions of the HSNO Act are enforced. Operationally, enforcement responsibilities are carried out by the Biosecurity New Zealand division of MAF. Both MAF and ERMA may appoint enforcement officers in accordance with the HSNO Act. The Chief Executives of Ministry for the Environment and ERMA also have functions, powers, duties, and protections of enforcement officers.<br>• Enforcement officers have powers of entry for inspection without consent to monitor the conditions in a premises or to determine the nature of any organism in the premises. Officers have extensive seizure powers and powers to take samples, open containers, conduct examinations and inquiries, and to require the production of documents. Enforcement officers can issue compliance orders to require persons to cease, or prohibit persons from commencing, anything which will, or is likely to, contravene the Act. |
| Penalties | • One of the key offences under the Act is manufacturing or developing a GMO in contravention of the Act (maximum penalty of NZ$500,000 or up to 3 months imprisonment and NZ$50,000 for every day on which the offence continues).<br>• Similar penalties for offences such as failing to comply with any controls in relation to an approval.<br>• A civil penalty regime also exists, whereby the State can take proceedings against persons breaching the regulatory regime for new organisms (including GM organisms), regardless of whether harm is caused (see section below). |

| Policy and Governance issues | |
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| Liability for contamination | • The HSNO Act provides for:<br>– a strict civil liability regime, available to victims for harm caused by activities in breach of the regulatory regime for new organisms (including GM organisms). This means that victims of such harm do not have to prove that the injurer was negligent.<br>– a civil penalty regime, whereby the State can take proceedings against persons breaching the regulatory regime for new organisms (including GM organisms), regardless of whether harm is caused. The maximum penalties are set at levels that create incentives to comply with the regime (for body corporates, the greater of NZ$10 million, 3 times the commercial gain from the breach, or if the commercial gain cannot be ascertained, 10% of the body corporate's turnover).<br>• New Zealand also has a common law liability regime — tort law — which operates in a similar fashion to Australian law. Legal action can be based on negligence, nuisance, the rule in Rylands v Fletcher[1] and breach of statutory duty. Liability rules generally provide compensation for property damage and certain types of economic loss. In New Zealand, personal injury is compensated via a state accident compensation regime. To establish the tort of negligence a plaintiff would need to show the existence of a duty of care, a breach of that duty, causation of damages, proximity, and damage.<br>• Additionally, where enforcement powers are exercised for the purpose of the management or eradication of any organism, the exercise of those powers causes verifiable loss as a result of the damage to or destruction of a person's property; or restrictions on the movement or disposal of a person's goods, that person is entitled to compensation for that loss. |

1 (1968) LR 3 HL 330

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| Expert committees | • The Act establishes an advisory committee, Nga Kaihautu Tikanga Taiao, to provide ERMA, on request, with information on Maori issues in relation to individual applications. The legislation also acknowledges the roles of Institutional Biological Safety Committees. Decision-making authority of IBSCs is delegated by ERMA to approve low risk containment work.<br>• ERMA has also appointed non-statutory advisory committees, to provide ERMA, on request, with information on ethical issues (Ethics Advisory Panel) and scientific issues (Expert Scientific Panel on Genetic Modification) in relation to individual applications.<br>• The Authority may also commission a report or seek advice from any person on any matters raised in relation to an application, including a review of any information provided by the applicant. |
| Research undertaken by Regulator | • It is not a statutory function of ERMA to conduct, or commission, research. However, the Authority may commission a report or seek advice from any person on any matters raised in relation to an application, including a review of any information provided by the applicant. |
| **Other** | |
| The precautionary principle | • Section 7 of the Act states that all persons exercising functions, powers and duties under this Act shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects. |
| Cost recovery | • ERMA applies partial cost recovery and levies charges for services such as searching the register, submitting applications, auditing and conducting public hearings.<br>• The Biosecurity Act 1993 empowers MAF to monitor new organisms approved by ERMA under HSNO for use in approved containment facilities and to recover costs for such work. |
| Moratorium | • The two year statutory restricted period (moratorium) on considering applications to release GMOs into the environment expired on 29 October 2003. |

## REGULATION OF GENE TECHNOLOGY IN JAPAN

**SUMMARY** — Controls on gene technology are essentially voluntary and different aspects of gene technology are overseen by different portfolios: Ministry of Agriculture Forestry and Fisheries oversee GMOs for use in agriculture; Science and Research Agency oversees experimentation in all research facilities other than University research facilities; MEXT (Ministry of Education, Culture, Sports and Science Technology) oversees experimentation in University research facilities; and in relation to GM products, the Ministry for Health, Labour and Welfare approves GM products such as pharmaceuticals, medical treatments and foods.

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| **For contained work with GMOs** | |
| Responsible agency | • Science and Research Agency — for experimentation in all research facilities other than University research facilities.<br>• MEXT (Ministry of Education, Culture, Sports and Science Technology) — for experimentation in University research facilities. |
| Guidelines (no legislation) | • Voluntary guidelines: 'Guidelines for rDNA Experimentation' (for experimentation in facilities other than university facilities) and 'Guidelines for rDNA Experimentation in University Research Facilities'. |
| **For intentional releases of GMOs in the environment** | |
| Responsible agency | • Ministry of Agriculture, Forestry and Fisheries (MAFF). |
| Guidelines (no legislation) | • 'Guidelines for application of recombinant DNA organisms in Agriculture, Forestry, Fisheries, the Food Industry and other related industries'.<br>• The system is based on administrative guidance with no underpinning legislation. |

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| Coverage of the guidelines | • The release, production and use in agro-industries of rDNA organisms in both open systems (without specific measures of containment) and simulated model environments (e.g. experimental applications of rDNA in a restricted area). |
| Assessment process for intentional releases of a GMO into the environment (field trials and general releases) | • Any person who wishes to utilise rDNA crop plants in agriculture must conduct safety assessments in accordance with the guidelines.<br>• Before organisms can be applied to open systems or a simulated model environment, the developer may request the approval of the MAFF to confirm that the safety assessments satisfy the requirements of the guidelines. Safety assessments undertaken by proponents are examined by scientific advisory committees underpinning MAFF.<br>• The guidelines set out how safety is to be confirmed. For example the guidelines set out: the way of conducting simulations (including requirements for facilities, experimental equipment, cultivation, storage, and transport); the information required for a safety evaluation of an organism (conducted by the proponent); and the institution of management systems including appointment of a safety officer, an operations administrator, a safety operations manager and a safe operations committee.<br>• When a safety assessment has been conducted in accordance with the guidelines, a person may request the Minister of Agriculture, Forestry and Fisheries to approve the safety criteria regarding safety assessment and procedures utilised to ensure compliance with the guidelines. |
| Consideration of ethical issues | • No reference to ethics in the guidelines. |
| Public consultation on applications | • Not required. |

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| Protection of confidential commercial information | • Information not available. |
| Conditions that may be applied | • The guidelines set out the requirements for various releases (e.g. education, handling, and reporting). |
| Monitoring, surveillance and enforcement powers | • The system is a voluntary one and as such there are no enforcement provisions. |
| Penalties | • No penalties as the system is a voluntary one. |
| **Policy and Governance issues** | |
| Liability for contamination | • Plaintiffs must seek redress for contamination by GMOs under general law. |
| Expert committees | • Information not available at this time. |
| Research undertaken by the Regulator | • There is no statutory provision for research to be undertaken on risks posed by GMOs.<br>• However, there are significant research budgets across various portfolios. |
| Other | |
| The precautionary principle | • No reference to the precautionary principle in the guidelines. |
| Cost recovery | • Information not available — but as the system is based on voluntary compliance with guidelines it is unlikely that there is a cost recovery regime. |
| Moratorium | • No moratorium. |

## REGULATION OF GENE TECHNOLOGY IN THE UNITED STATES

**SUMMARY** — Several pieces of legislation regulate GMOs: Federal Plant Pest Act—7 USC 7B; Federal Insecticide, Fungicide, and Rodenticide Act—7 USC 136; Federal Food, Drug and Cosmetic Act—21 USC 9; Toxic Substances Control Act — 15 USC 53.

- The system requires permits to be issued by the relevant regulatory authority. Depending on the nature of the GMO, permits may be required from more than one authority. In general: the US Department of Agriculture Animal and Plant Health Inspection Service (APHIS) has the broadest authority over transgenic plants and has responsibility for determining whether such a plant poses a threat directly or indirectly as a plant pest; the US Environmental Protection Agency (EPA) regulates microbial and plant pesticides, new uses of existing pesticides and novel micro-organisms; and the US Food and Drug Administration (FDA) is responsible for ensuring the safety of all food (by enforcing tolerances in food set by EPA), feed, and human and veterinary drugs.
- There is no statutory link between each of the regulators.

There are a number of agencies under the US Department of Agriculture involved in the regulation of GMO-related matters:

- APHIS has responsibility for determining whether a genetically engineered organism is as safe for the environment as its traditionally bred counterpart and can be freely used in agriculture, and regulates field-testing, interstate movement, and importation of genetically engineered organisms through the Biotechnology Regulatory Services (BRS).
- The Agricultural Marketing Service (AMS) is responsible for administering plant variety and seed laws in the U.S., which also cover biotechnology-derived seeds, and for government activities regarding certification and labelling of agricultural seed for varietal purity for international trade.
- The Agricultural Research Service (ARS) is USDA's in house science agency. The agency's biotechnology research includes introducing new traits and improving existing traits in livestock, crops, and micro-organisms; safeguarding the environment; and assessing and enhancing the safety of biotechnology products.
- The Cooperative State Research, Education, and Extension Service (CSREES) administers the Biotechnology Risk Assessment Research Grants Program (BRAG) which supports the development of science-based information regarding the safety of introducing into the environment genetically-modified plants, animals, and micro-organisms.

**SUMMARY** — continued

- The Economic Research Service (ERS) conducts research on the economic aspects of the use of genetically engineered organisms, including the rate of and reasons for adoption of biotechnology by farmers.
- The Food Safety and Inspection Service (FSIS) is the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labelled and packaged including animals involved in biotechnology.
- The National Agricultural Statistics Service (NASS), as the fact finder for agriculture, provides information on the adoption of biotechnology crops (specifically corn, cotton, and soybeans).

| **Contained work with GMOs** | |
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| Responsible agency | • National Institute of Health (NIH). |
| Legislation | • There is no special regulatory system for ensuring the safe use of biotechnology in the laboratory or factory where the organism is not to be released into the environment (i.e. contained use). Voluntary guidelines — the NIH's Guidelines for Research Involving Recombinant DNA Molecules — are implemented by most users of the technology. |
| **Intentional releases of GMOs in the environment** | |
| Responsible agency | • The US Department of Agriculture Animal and Plant Health Inspection Service (for plant pests, plants and veterinary biologics).<br>• The U.S. Environmental Protection Agency (for microbial/plant pesticides, new uses of existing pesticides and novel micro-organisms). |
| Legislation | • Federal Plant Pest Act; Federal Insecticide, Fungicide and Rodenticide Act; National Environment Policy Act; Plant Protection Act; Federal Food, Drug and Cosmetic Act; Food Quality Protection Act; Endangered Species Act. |

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| Coverage of the legislation | • Field testing, moving, importing and commercial release of organisms and products altered or produced through genetic engineering which are plant pests or may become plant pests. Under the Plant Protection Act, APHIS regulates plants that may pose such a risk. Organisms and products that are known or suspected to be plant pests or to pose a plant pest risk, including those that have been altered or produced through genetic engineering are calle d 'regulated articles'.<br>• Intentional confined release into the environment of regulated articles require notification to the relevant authority under the relevant legislation.<br>• 'Genetic engineering' is defined as the genetic modification of organisms by recombinant DNA techniques. There is no definition of 'recombinant DNA techniques'.<br>• The Federal Food, Drug and Cosmetic Act, Food Quality Protection Act and Endangered Species Act are also considered by the EPA when evaluating the risks that biopesticides (including those that either are, or result from, GMOs or GM techniques) may pose to the environment or human health.<br>• The Federal Food, Drug and Cosmetic Act governs the FDA in assessing the safety of foods/ feeds from novel plant varieties (including genetically engineered plants); the Food Quality Protection Act imposes standard tolerances for allowable levels of pesticides in food; whereas the Endangered Species Act ensures that any pesticides (including those derived from GMOs or techniques) do not pose a risk to endangered species. |
| Assessment process for intentional release of a GMO into the environment (field trials) | • The developer submits a notification to the APHIS (notification to APHIS of an environmental release must be at least 120 days prior to release, but this can be extended if an environmental impact statement is required in addition to an environmental risk assessment, and in the case that additional information is subsequently required, the 120 day period will start upon the receipt of the additional information).<br>• Data must demonstrate that the plant is safe to release and is not itself a plant pest or potential noxious weed. |

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| Assessment process for intentional release of a GMO into the environment (field trials) (continued) | • The APHIS conducts an assessment. APHIS has a two tiered level of risk — lower risk GMOs (for example, plants that are altered with common agronomic traits such as pest or herbicide resistance) need only be notified to the agency, while other releases that pose an elevated risk (such as plants that produce pharmaceutical or industrial compounds and GMOs other than plants) require a permit.<br>• There are six criteria that a plant has to meet before being considered by APHIS for notification: it is either corn, cotton, potato, soybean, tobacco, tomato or any additional plant species that BRS has determined may be safely introduced; the introduced genetic material is stably integrated; the function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease; the introduced genetic material does not (1) cause the production of an infectious entity, (2) encode substances that are known or likely to be toxic to non-target organisms known or likely to feed or live on the plant species, or (3) encode products intended for pharmaceutical use; the introduced genetic sequences derived from plant viruses do not pose a significant risk of the creation of any new plant virus; the plant has not been modified to contain certain genetic material derived from an animal or human pathogen.<br>• Notifications are required to contain: specific information on the genetic trait introduced, including its origins; how the expression of the trait differs to the non-modified counterpart; information on proposed procedures and safeguards to prevent escape, dissemination and contamination; proposed method of final disposition.<br>• While there are no size restrictions on field trials, APHIS officials take into consideration the size of the field trial when they determine the significance of the impact on the environment.<br>• APHIS forwards the notifications on to relevant state agencies for comment within five days of receipt of the notification. State authorities can comment at their discretion, but comments from state authorities are not required for the progression of the assessment process. |

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| Assessment process for intentional release of a GMO into the environment (field trials) (continued) | • In assessing an application for a permit, the APHIS: must be satisfied that the benefits of the proposal outweigh the costs; may require the preparation of an environmental impact statement in addition to an environmental assessment; must seek public comment on a proposal if a person has submitted to the APHIS a petition to seek a determination that a particular GMO should not be regulated under the legislation; field trial results must be submitted to APHIS within 6 months of the termination of a field trial; . APHIS then makes a decision to approve the petition in whole or in part, or to deny the petition; and must consult Departments of Agriculture in the States where release is planned.<br>• If the GMO is also a plant pesticide (plant-incorporated protectant; PIP) then EPA approval is also required under the Federal Insecticide, Fungicide and Rodenticide Act as pesticide is broadly defined to include plants modified by biotechnology to resist disease. The EPA may also treat micro-organisms as subject to the Toxic Substances Control Act.<br>• A 'determination of non-regulated' status is issued by APHIS if the crop is not a plant pest allowing the crop to be released without restriction. EPA would also issue approval.<br>• In the case of PIPs or GM micro-organisms for pesticide use, the EPA does an evaluation to assess the risk: to human health and the environment; to non-target organisms; for potential gene flow. |
| Consideration of ethical issues | • The only matter considered by APHIS is whether the plant is a plant pest or has the potential to be a plant pest. Ethics, trade and social issues are not taken into account.<br>• However, under the National Environmental Policy Act the Council on Environmental Quality takes into account the scientific, economic, social, aesthetic, and cultural needs and interests of the nation. |

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| Public consultation on applications | • The APHIS only seeks public comment on a proposal if a person has submitted to the APHIS a petition to seek a determination that a particular GMO should not be regulated under the legislation. APHIS then makes a decision to approve the petition in whole or in part, or to deny the petition. A period of 60 days is given for public consultations on the petition.<br>• In conducting risk assessments, the data used by the EPA undergoes extensive public comment and peer review by scientific experts. |
| Protection of confidential commercial information | • Each of the relevant pieces of legislation provide for the protection of confidential commercial information.<br>• Proponents applying to APHIS for a permit must provide two copies of their application, one with confidential business information passages marked and the other with these passages removed. |
| Conditions that may be applied | • APHIS permits are subject to several conditions prescribed in the regulations, including: separation of the GMO from other organisms; treatment of material accompanying the GMO; compliance with measures prescribed by APHIS which are necessary to prevent the accidental or unauthorised release of the GMO; the requirement that the GMO be subject to the application of remedial measures determined by APHIS to be necessary to prevent the spread of plant pests; the maintenance of the GMO only in the areas prescribed in the permit; and inspectors must be allowed access, during regular business hours, to places where the GMO is located, and to records relating to the introduction of the GMO.<br>• In addition, the permit holder can be subject to any other conditions APHIS deems as necessary to prevent the dissemination and establishment of plant pests. Permit can be withdrawn if non-compliance with these conditions is identified.<br>• Unusual occurrences (to those specified in the application, such as higher rates of morbidity or mortality) and suspected accidental or unauthorised release of a regulated article must be notified to APHIS within the timeframes specified in the regulations. |

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| Monitoring, surveillance and enforcement powers | • Once permission for the cultivation of a transgenic crop has been granted, progress is monitored. The system does not rely on significant enforcement powers as the regulatory system is based on 'permits, testing and tolerance setting'.<br>• Any regulated article introduced not in compliance with the requirements shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary to prevent the introduction of such plant pests. (Under the Federal Plant Pest Act, the Secretary of Agriculture is authorised to order prompt removal from the United States or to seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of, in such manner as the Secretary deems appropriate, certain regulated articles which are believed to be infested or infected by or contain a plant pest.)<br>• Access shall be allowed for APHIS and State regulatory officials to inspect facilities and/or the field test site and any records necessary to evaluate compliance with the provisions.<br>• Field test reports must be submitted within 12 months of the start of a field trial and then every 12 months through the duration of a field trial. |
| Penalties | • Violations relating to plant pests can incur criminal or civil penalties.<br>• Any person who violates the regulations, or who forges or counterfeits any permit can be punished criminally by a fine not exceeding US$5000 or by imprisonment not exceeding 1 year, or both. Such violations may also be dealt with civilly with the maximum fine being US$1000. However, depending on the nature of the violation criminal penalties can range up to a fine of US$50,000 or a year in jail or both.<br>• Failure to adhere to BRS regulations, permit conditions and requirements can result in serious penalties, including fines up to US$500,000 per adjudication. |

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| Assessment process for unrestricted intentional release of a GMO into the environment | • When an applicant has field tested a transgenic crop and accumulated enough data to show that this crop is free from any risk (compared to its unmodified counterpart), the applicant can petition APHIS that the transgenic crop should no longer be considered a regulated article (and thus free from any monitoring or restriction). Depending on the product and its intended purpose, reviews by the FDA (if intended for food use) and the EPA may also be required.<br>• The petition is required to include data such as: a description of the biology of the plant before it was genetically engineered; extensive data from tests designed to detect differences between the GE plant and the original plant; characterisation of genetic changes; plant pest-risk characteristics; disease and pest susceptibilities; expression of gene products; new enzymes; effects on non-target organisms; changes in plant metabolism; weediness of the GE plant; impact on the weediness of relatives of the GE plant; impacts on agricultural practices or on other agricultural products; field-test reports for all trials conducted under permit or notification procedures involving the GE plant.<br>• Completed petitions are published on the Federal Register and public comment can be accepted for 60 days from the date of the publication on the Federal Register. |
| Assessment process for unrestricted intentional release of a GMO into the environment (continued) | • The administrator will, within 180 days of receiving a completed petition, either: approve the petition in whole or in part; or deny the petition.<br>• APHIS announces its decision on the Federal Register but he decision does not become final for another 30 days during which time APHIS may alter its decision should additional information become available. |
| Consideration of ethical issues | • Under the National Environmental Policy Act the Council on Environmental Quality shall have account of scientific, economic, social, aesthetic, and cultural needs and interests of the nation. |

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| Public consultation on applications | • Completed petitions are open to public comment for a period of 60 days. |
| Protection of confidential commercial information | • Each of the relevant pieces of legislation provide for the protection of confidential commercial information.<br>• Proponents applying to APHIS for a permit must provide two copies of their application, one with confidential business information passages marked and the other with these passages removed. |
| Conditions that may be applied | • After a petition for deregulation is granted, there are no restrictions on the GMO for which the petition was approved. |
| Monitoring, surveillance and enforcement powers | • None |
| Penalties | • No penalties apply, as once a regulated item has been petitioned and becomes a deregulated item, it can be freely moved and planted without BRS regulatory control and therefore is no longer subject to the APHIS or BRS regulations. |
| **Placing on the market GMOs intended for food or feed** | |
| Assessment procedure for placing on the market GMOs intended for food or feed | • Applicants should consult with the USFDA before submitting a notification for placing foods derived from novel plant varieties (including those genetically engineered) on the market.<br>• The consultation is a two-step process. Initial consultations should start early in the development of the novel food or feed and are designed to resolve potential safety, nutritional, and regulatory issues. Such issues may include, but are not limited to, significantly increased levels of plant toxicants or anti-nutrients, reduction of important nutrients, new allergens, or the presence in the food or feed of an unapproved food/feed additive. |

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| Assessment procedure for placing on the market GMOs intended for food or feed (continued) | • Final consultations involve the submission to the USFDA of a summary of the safety and nutritional assessment that has been conducted and, if necessary, a meeting of the applicant's scientists with FDA scientists to discuss the data and results contained in the submission.<br>• The safety and nutritional assessment should contain information on: the particulars of the GE food/feed and plant derivative; the intended use of the product (including if it is intended for feed use); the particulars of the introduced genetic material; the purpose or intended technical effect of the modification; the modification's expected effect on the composition or characteristic properties of the food or feed; the identity and function of expression products encoded by the introduced genetic material, including an estimate of the concentration of any expression product in the bioengineered crop or derived food/feed; allergenicity and toxicity; the basis for concluding that foods containing the expression products can be safely consumed; comparing the composition or characteristics of the bioengineered food to that of food derived from the parental variety or other commonly consumed varieties. |
| | • During the consultation process, the USFDA does not conduct a comprehensive scientific review of data generated by the developer. Instead, the USFDA considers, based on agency scientists' evaluation of the available information, whether any unresolved issues exist regarding the food derived from the new plant variety that would necessitate legal action by the agency if the product were introduced into commerce.<br>• During the early consultation process, an applicant may submit an early food safety evaluation. The evaluation is intended to be done prior to the stage of development where the new proteins might inadvertently enter the food supply. The information requirements are similar to the above safety and nutritional assessment. A guidance document on the evaluation process states that the evaluation is to be acknowledged within 15 days of receipt by the USFDA and a response to the applicant is given within 120 days of receipt (which is considered short). A response may: extend the review time for another 120 days; request further information; conclude that there is no safety risk and that it satisfies the requirements of the Federal Food, Drug and Cosmetic Act. |

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| Assessment procedure for placing on the market GMOs intended for food or feed (continued) | • Once the consultation process has been completed, the applicant should then submit a pre-market notification. This notification should be submitted to the USFDA at least 120 days before the planned commercialisation date. The USFDA has drafted a document on the proposed rules for pre-market notification. In this document, it is proposed that plants modified to contain a pesticide substance come under the USEPA's jurisdiction via the Federal Insecticide, Fungicide and Rodenticide Act. Food derived form plants whose genetic transformation has already been assessed by the USFDA will be exempt from the proposed regulation. Proposed information to be included in the notification includes: the particulars of the genetic modification; the identity and function of these substances; the level of these substances in the bioengineered food; dietary exposure to these substances; the potential that the food will be an allergen; and a discussion of other safety issues that may be associated with these substances. Information, data and results from earlier evaluations (such as in the early food safety evaluation) may be submitted as part of the notification. |
| Consideration of ethical issues | • No mention of ethical issues was found in the relevant guidelines or legislation. |
| Public consultation on applications | • The application for notification will become public when the USFDA files it, but there was no specific mention of public consultation during the consultative or notification process. |
| Protection of confidential commercial information | • The USFDA treats submitted information in accordance with the United States Freedom of Information Act, which contains provisions to exempt information related to 'trade secret' and commercial information. The proposed guidelines allow the applicant to submit two versions of the notification: one has the information deleted that the applicant considers exempt from public disclosure.<br>• The application for notification will become public when the USFDA files it. However, there is provision for USFDA to evaluate applicant claims for confidentiality according to the exemption criteria under the proposed notification guidelines. |
| Conditions that may be applied | • Not applicable. Once the GMO intended for food/feed use is found to be safe for human and animal consumption, it can be entered into the market without restriction. |

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| Monitoring, surveillance and enforcement powers | • If a bioengineered food/feed is commercialised without prior approval, the USFDA has the power under the Federal Food, Drug and Cosmetic Act to conduct inspections and investigations, collect samples and perform analyses, as well as to engage in publicity and public education.<br>• The Federal Food, Drug and Cosmetic Act states that all food additives receive USFDA approval before commercialisation. Foods/feeds derived from or containing genetically engineered plants (or products thereof) would be considered as food/feed additives by the proposed notification guidelines. |
| Penalties | • The Federal Food, Drug and Cosmetic Act contains provisions for penalties (criminal and civil), including seizure of the product or proceeds thereof.<br>• Penalties exist for contravening specified sections of the Federal Food, Drug and Cosmetic Act. These may include: imprisonment for not more than one year or fined not more than $1000, or both; imprisonment for not more than three years or fined not more than $10,000 or both if a person commits another violation while a conviction of him is pending, or the person commits a violation with the intent to defraud or mislead; a civil money penalty of not more than $50,000 for an individual and $250,000 for any other person, but not exceeding $500,000 for all violations in a single proceeding for any person who introduces or delivers, for commercialisation, an article of food/feed with unapproved food/ feed additives (this would include additives derived from or that are genetically engineered plants). |
| **Policy and Governance issues** | |
| Liability for contamination | • There is no strict liability regime for recovery by third parties; third parties must rely on the common law or remedies available under general environment protection legislation. |

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| Expert committees | • Information about committees is currently being clarified but there are no statutory committees that examine GMOs specifically. |
| Research | • The National Environmental Policy Act states that the President appoints members of the Council on Environmental Quality and that part of its role is to research and collect data on the environment and ecosystems and monitor emerging trends, and to have account of scientific, economic, social, aesthetic, and cultural needs and interests of the nation.<br>• There are government agencies that are able to research various aspects of GMOs.<br>For example:<br>• The Agricultural Research Service (ARS) is USDA's in house science agency. The agency's biotechnology research includes introducing new traits and improving existing traits in livestock, crops, and micro-organisms; safeguarding the environment; and assessing and enhancing the safety of biotechnology products.<br>• The Cooperative State Research, Education, and Extension Service (CSREES) administers the Biotechnology Risk Assessment Research Grants Program (BRAG) which supports the development of science-based information regarding the safety of introducing into the environment genetically-modified plants, animals, and micro-organisms. |
| **Other** | |
| Liability for contamination | • No reference to a strict liability regime or no-fault scheme was found. |
| The precautionary principle | • The legislation does not reference the precautionary principle. |

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| Cost recovery | • There is capacity for some cost recovery: for example, permit applications carry a charge but the services of inspectors during regular assigned hours and at usual places of duty are furnished without cost, whereas overtime for inspectors does carry a cost. |
| Moratorium | • No moratorium. |
| Other | The pre-market notification guidelines were made in 2001 and at the time of compiling this information, it did not appear that the guidelines had been enacted into legislation. |

## REGULATION OF GENE TECHNOLOGY IN CANADA

**SUMMARY** — Canada does not have a single piece of legislation that regulates GMOs. Most of the legislation applicable to biotechnology addresses specific product categories, and pertains both to biological and non-biological processes and products.

- The main agencies involved in the regulation of GMOs are Agriculture and Agri-Food Canada, Environment Canada and Health and Welfare Canada. The relevant legislation includes: Canadian Environment Protection Act 1999 (CEPA) (covers those uses not covered by other legislation); Feeds Act (feeds); Fertilisers Act (supplements); Health of Animals Act (veterinary biologics); Seeds Act (plants with novel traits); Pest Control Products Act (microbial pest control agents); and Food and Drugs Act (drugs, cosmetics, medical devices, and novel foods from both plant and animal sources); Plant Protection Act (importation of unapproved plants with novel traits).
- The release of novel substances (this includes GMOs) into the environment is governed by the above-mentioned Acts. There are also directives that provide guidelines for applying for the release of novel substances into the environment. In addition, there are directives for the release of novel plant and animal organisms for both confined and unconfined releases. The Canadian Food Inspection Agency, under the Agriculture and Agri-Food Portfolio, is the main agency responsible for the release of novel substance into the environment and is divided into Sections. One of the sections, the Plant Biosafety Office has carriage of assessing applications for the confined and unconfined release of novel substances (plant) into the environment. If the novel plants could be used as a feed (for livestock or laboratory animals), then the Feed Section of the Canadian Food Inspection Agency assesses the application for release. Applications for release of novel substances that could be used as food for humans are assessed by the Department of Health. Where necessary, approval for release of a novel substance may require approval from more than one authority/agency.

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| **Contained work with GMOs** | |
| Responsible agency | • Canadian Medical Research Council.<br>• Guidelines of the United States of America's National Institute of Health (NIH). |
| Legislation | • Contained research involving GMOs is not covered by CEPA.<br>• Laboratory research in Canada is covered by the US NIH's Guidelines for Research Involving Recombinant DNA Molecules. All scientists working with GMOs must adhere to the guidelines established by the Medical Research Council, as well as codes of practice established by their own institution. |
| **Intentional releases of GMOs in the environment** | |
| Responsible agency | • Environment Canada. |
| Legislation | • CEPA.<br>• Directive 2000–07: Conducting Confined Research Field Trials of Plants with Novel Traits in Canada.<br>• Seeds Act and amendments.<br>• Directive 95–03: Guidelines for the Assessment of Novel Feeds: Plant Sources.<br>• Feeds Act and amendments.<br>• Directive 94–08: Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits. |
| Coverage of the legislation | • Substances that are new (i.e. not on the list of Domestic Substances) cannot be manufactured or imported unless approval is granted from the Minister. |

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| Coverage of the legislation (continued) | • Substance is defined as any distinguishable kind of organic or inorganic matter, whether animate or inanimate, and includes any matter that is capable of being dispersed in the environment or of being transformed in the environment into matter that is capable of being so dispersed or that is capable of causing such transformation in the environment. 'Living organism' is defined as a substance that is an animate product of biotechnology.<br>• The Canadian Food Inspection Agency's Plant Biosafety Office is responsible for regulating the intentional introduction into the environment in Canada of plants with novel traits (PNTs). The procedures and guidelines for applying to release PNTs into the environment are outlined in Directive 2000–07.<br>• The Feeds Act governs the use of feed within Canada and ensures that it is safe to use. Novel feeds, including those with a novel trait require a notification of intended release to be approved by the relevant minister before they can be released. The Act and its Regulations refer to the release of novel feeds, including those with novel traits, for research purposes only.<br>• Directive 95-03 applies to novel feeds from plants, or parts or products thereof, that have not been previously used as livestock feed in Canada, and/or have a novel trait. The application requires information on the novel trait, techniques used, the breeding history, nutritional data, toxicology data and dietary exposure, allergy data, animal/livestock trial data, an environmental risk assessment, detection methods. The guidelines appear as though they can be used for applying for release of novel feed (plant source) for eventual commercialisation. |
| Assessment process for confined intentional releases of a GMO into the environment (field trials), including for experiments on GMOs intended for feed | • The Minister must be notified if someone wishes to manufacture or import a new substance that is not on the Domestic Substances List (if it is on the list no approval is necessary).<br>• Information relevant to the assessment must be provided to the Minister.<br>• All proposals undergo a single 60-day public consultation period where interested parties may bring forward additional scientific evidence to support or refute the Minister's decision.<br>• After taking into account any advice provided, the Minister must decide whether the substance is toxic or capable of becoming toxic. |

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| Assessment process for confined intentional releases of a GMO into the environment (field trials), including for experiments on GMOs intended for feed (continued) | • If the Minister decides that the organism is not toxic or capable of becoming toxic, the Minister can place the organism on the Domestic Substance Register but cannot impose any conditions.<br>• If the Minister decides that the organism is toxic or capable of becoming toxic, then the Minister can: (a) permit its manufacture or importation subject to any conditions the Minister may specify; or (b) can prohibit its import or manufacture.<br>• The final decision of the Minister must be published.<br>• Under Directive 2000–07 (which provides guidelines to the applicant on how to apply for the confined release of a PNT) the application for a confined research field trial: puts the onus on the applicant to ensure that the PNT will not negatively affect any other trial or non-PNT crops; requires the applicant to consider contingency plans in the event of accidental release of material or inadvertent breakdown of reproductive isolation. If the applicant intends on feeding the material from the confined research field trial to livestock for research purposes, the application is given to the Feed Section of the Canadian Food Inspection Agency. The applications are sent to provincial governments where the trials will occur, who then have 30 days to provide comment. The comments are considered by the Plant Biosafety Office when making a decision on the application. To ensure that the trials are for research purposes only: each trial site must be no larger than 1 Ha; there are no more than 10 trial sites per submission, per province; trial site locations are no larger than 5 Ha cumulative per submission, per province. The applicant is responsible for reproductive isolation or other isolation methods (such as bags and nets over flowering plant parts, harvest of plant before flowering, removal of flowers before pollen maturity). |

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| Assessment process for confined intentional releases of a GMO into the environment (field trials), including for experiments on GMOs intended for feed (continued) | • Under the Feeds Act and its amendments and regulations a written notification of the proposed release must be made to the Minister, including information such as: the particulars of the release; confinement and monitoring procedures; methods for safe disposal; contingency plans to mitigate adverse effects on humans and the environment in the event of accidental release; the particulars of the novel trait; any results from data or research done to identify risks to the environment or human health. The Minister for Agriculture and Agri-foods can then either authorise or refuse to authorise the release of the novel feed and shall consider the magnitude of exposure of the release, the effects on the environment and whether the novel feed is toxic. The application shall be accompanied with evidence (such as scientific research) to permit an assessment or evaluation of the safety and efficacy of the feed in respect of livestock and its potential effect on humans and on the environment.<br>• Directive 95-03 provides the guidelines for the completion of an application for the unconfined release of a novel feed from plant sources. Applications should contain: sufficient data about the novel trait; information about the modification history; characterisation of the DNA inserted, if any; nutritional data, allergenicity data; toxicology data; dietary exposure; laboratory animal/livestock feeding trial data; environmental risk assessment; method of detection. A decision is then made on the information provided in the application.<br>• The application procedure and information requirements for releasing of a novel feed of an animal origin is similar to that for a novel feed from a plant source and is outlined in the Feeds Act and regulations.<br>• There is a draft document that outlines the application requirements for notification of a release of biotechnology-derived livestock animals. This draft appears to apply to confined and unconfined releases. Information requirements include information: on the organism; on the organism's manufacture or import; on the introduction of the organism; on the environmental fate of the organism; on the organism's environmental effects; on potential adverse effects on human health; on test data that assists in the identification of hazards to human health and environment. If the organism is confined, information on the possible mechanisms for escape and possible dispersal is also required. |

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| Consideration of ethical issues | • In making a decision Ministers may only determine whether the substance is toxic or capable of becoming toxic. No specific mention of ethics or trade is made. However, the Minister may take into account factors such as, but not limited to social, economic and technical matters when determining preventative or control action in relation to a substance or in plans for virtual elimination of the substance. |
| Public consultation on applications | • All proposals for release of a GMO into the environment undergo a single 60-day public consultation period where interested parties may bring forward additional scientific evidence to support or refute the Minister's decision. |
| Protection of confidential commercial information | • An applicant may request that information be treated as confidential.<br>• The Minister must not disclose any information in respect of which a request for confidentiality has been made unless: it is in the public interest; or it is disclosed under an agreement between the Government of Canada and any other government of Canada or government of a foreign state etc, and the agency agrees to keep the information confidential. |
| Conditions that may be applied | • Where the Minister suspects that a living organism is toxic or capable of being toxic, the Minister for the Environment may permit the manufacture or import of the living organisms subject to any conditions that the Minister may specify. |
| Monitoring, surveillance and enforcement powers | • Enforcement officers may be appointed under the CEPA.<br>• Enforcement officers have the power to enter and inspect premises where a substance can be found, for the purposes of the Act. Officers have been given wide powers of inspection, including opening receptacles and packages, examining records, taking samples and conducting tests. CEPA also allows officers to act without warrants in emergencies. Officers may seize or detain anything which caused a contravention to occur, or which will provide evidence of the contravention; however, they can only do so if it is required for evidence, analysis or it is in the public interest to do so. |

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| Monitoring, surveillance and enforcement powers (continued) | • Officers may also issue environmental protection compliance orders to owners and managers and persons contributing to contraventions which must be complied with (orders can include reporting requirements, and to cease operating).<br>• Under Directive 2000-07, the Canadian Food Inspection Agency requires the applicant to keep records regarding the management of the site (including monitoring, harvesting, cleaning of harvesting machinery, transportation and storage of the plant material) and the records must be made available upon request. Regional Food Inspection officers have the power to inspect trial sites during the growing season at random and without notification.<br>• Under the Feeds Act and Seeds Act, there are provisions for inspections and inspectors to seize and detain articles, open packages and take samples, where an inspector believes on reasonable grounds that the Act or the regulations have been contravened. |
| Penalties | • A maximum fine of CA$1,000,000 or a prison term of 3 years exists (if convicted on indictment) for persons who contravene a provision of the Act or regulations, an order or direction under the Act or an obligation or a prohibition arising from the Act or regulations, or who knowingly provide false or misleading information.<br>• For summary conviction it is CA$300,000 or 6 months.<br>• If, in committing the offence, a person intentionally or recklessly causes a disaster that results in loss of the use of the environment, or shows wanton disregard for the lives or safety of other persons and thereby causes a risk of death or harm to another person, the maximum prison term increases to 5 years and there can be an unlimited fine imposed.<br>• Each day the offence is committed is a separate offence. The CEPA also sets down criteria which the Court must look at when sentencing, including harm caused, the costs of any remedial actions, intention, and any property, benefit or advantage to the offender. |

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| Penalties (continued) | • Despite the maximum amount of any fine under the legislation, a court may impose an additional fine equal to the court's estimation of the amount of property, benefit or advantage derived by the offender from their actions. Instead of convicting an offender, or in addition to other punishments, a court may make an order requiring the offender to do or refrain from doing certain action (e.g. requiring the offender to take any action to remedy or avoid harm, prepare and implement a pollution prevention plan, carry out environmental effects monitoring, compensate the Minister, pay an amount to environmental, health or other groups or to scholarships for students enrolled in environmental studies, or publish the facts relating to the incident).<br>• Penalties for contravening the Feeds Act or the Seeds Act include: a fine of up to CA$50,000 or six months imprisonment or both for an offence punishable by summary conviction; a fine of up to CA$250,000 or two years imprisonment or both. |
| **Placing GMOs (or products containing GMOs) on the market** | |
| Responsible agency | • Environment Canada.<br>• The Canadian Food Inspection Agency's Plant Biosafety Office is responsible for regulating the intentional introduction into the environment in Canada of plants with novel traits (PNTs). |
| Legislation | • Feeds Act and amendments.<br>• Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits. |
| Coverage of the legislation | • Directive 94-08 provides guidance regarding the submission of an application for the authorisation of the unconfined release of a PNT. An unconfined release involves the release of a PNT into the environment with no restrictions, with a view towards commercialisation. |

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| Application process for unconfined release of GMOs into the environment (usually for the purpose of commercialisation) | • The Minister must be notified if someone wishes to manufacture or import a new substance that is not on the Domestic Substances List (if it is on the list no approval is necessary).<br>• Information relevant to the assessment must be provided to the Minister.<br>• All proposals undergo a single 60-day public consultation period where interested parties may bring forward additional scientific evidence to support or refute the Minister's decision.<br>• After taking into account any advice provided, the Minister must decide whether the substance is toxic or capable of becoming toxic.<br>• If the Minister decides that the organism is not toxic or capable of becoming toxic, the Minister can place the organism on the Domestic Substance Register but cannot impose any conditions.<br>• If the Minister decides that the organism is toxic or capable of becoming toxic, then the Minister can: (a) permit its manufacture or importation subject to any conditions the Minister may specify; or (b) can prohibit its import or manufacture.<br>• The final decision of the Minister must be published.<br>• Directive 94-08 specifies that applications contain information that allows the Plant Biosafety Office to conduct an environmental risk assessment.<br>• The criteria for the assessment include: potential of the PNT to become a weed of agriculture or be invasive of natural habitats; potential for gene-flow to wild relatives whose hybrid offspring may become more weedy or more invasive; potential for the PNT to become a plant pest; potential impact of the PNT or its gene products on non-target species, including humans; potential impact on biodiversity. In considering the environmental safety, the Plant Biosafety Office may consult with scientific experts. |

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| Application process for unconfined release of GMOs into the environment (usually for the purpose of commercialisation) (continued) | • In addition, and before authorisation for release can be granted, information on the following is also required: the identity and origin of the PNT; the properties of the novel gene and gene products; the relative phenotypic expression of the PNT compared to a similar counterpart, where differences are anticipated; anticipated or known relative effects on the environment resulting from the release.<br>• The applicant can also submit other scientific research as part of the application. Upon becoming aware of new information regarding the environmental safety of the PNT (e.g. enhanced weediness characteristics), including the risk to human health (e.g. exposure to allergens) that could result from the release, the applicant must immediately provide the Plant Biosafety Office with the new information.<br>• The Plant Biosafety Office may maintain, change, or remove existing conditions respecting the release; impose additional conditions; or refuse or cancel the authorisation and require the applicant to stop the release and take any appropriate action necessary to eliminate from, or minimise the risk to, the environment.<br>• There is a draft document that outlines the application requirements for notification of a release of biotechnology-derived livestock animals. This draft appears to apply to confined and unconfined releases. Information requirements include information: on the organism; on the organism's manufacture or import; on the introduction of the organism; on the environmental fate of the organism; on the organism's environmental effects; on potential adverse effects on human health; on test data that assists in the identification of hazards to human health and environment. |
| Consideration of ethical issues | • In making a decision Ministers may only determine whether the substance is toxic or capable of becoming toxic. No specific mention of ethics or trade is made. However, the Minister may take into account factors such as, but not limited to social, economic and technical matters when determining preventative or control action in relation to a substance or in plans for virtual elimination of the substance. |

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| Protection of confidential commercial information | • An applicant may request that information be treated as confidential.<br>• The Minister must not disclose any information in respect of which a request for confidentiality has been made unless: it is in the public interest; or it is disclosed under an agreement between the Government of Canada and any other government of Canada or government of a foreign state etc, and the agency agrees to keep the information confidential. |
| Conditions that may be applied | • Where the Minister suspects that a living organism is toxic or capable of being toxic, the Minister for the Environment may permit the manufacture or import of the living organisms subject to any conditions that the Minister may specify.<br>• The Plant Biosafety Office may maintain, change, or remove existing conditions respecting the release; impose additional conditions; or refuse or cancel the authorisation and require the applicant to stop the release and take any appropriate action necessary to eliminate from, or minimise the risk to, the environment. |
| Monitoring, surveillance and enforcement powers | • Monitoring and enforcement powers are the same as those described above because unconfined releases are governed by the same legislation as confined releases. |
| Penalties | • Penalties that may be imposed in relation to unconfined release are the same as those described for the Feeds Act for confined releases because unconfined releases are governed by the same legislation as confined releases. |
| **Placing on the market GMOs for food or feed** | |
| Legislation | • Food and Drugs Act.<br>• Feeds Act and amendments and regulations.<br>• Directive 95-03. |

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| Coverage of legislation | • The Food and Drugs Act regulates the use of GMOs (derived from plant and animal sources) that are intended for use as novel foods.<br>• The Feeds Act governs the use of feed within Canada and ensures that it is safe to use.<br>• Directive 95-03 appears as though it can be used for applying for release of novel feed (plant source) for eventual commercialisation. |
| Application process for unconfined release of GMOs into the environment for use as feed for livestock and laboratory animals (usually for the purpose of commercialisation) | • Under the Feeds Act and its amendments and regulations a written notification of the proposed release must be made to the Minister, including information such as: the particulars of the release; confinement and monitoring procedures; methods for safe disposal; contingency plans to mitigate adverse effects on humans and the environment in the event of accidental release; the particulars of the novel trait; any results from data or research done to identify risks to the environment or human health. The Minister for Agriculture and Agri-foods can then either authorise or refuse to authorise the release of the novel feed and shall consider the magnitude of exposure of the release, the effects on the environment and whether the novel feed is toxic. The application shall be accompanied with evidence (such as scientific research) to permit an assessment or evaluation of the safety and efficacy of the feed in respect of livestock and its potential effect on humans and on the environment.<br>• Directive 95-03 provides the guidelines for the completion of an application for the unconfined release of a novel feed from plant sources. Applications should contain: sufficient data about the novel trait; information about the modification history; characterisation of the DNA inserted, if any; nutritional data, allergenicity data; toxicology data; dietary exposure; laboratory animal/livestock feeding trial data; environmental risk assessment; method of detection. A decision is then made on the information provided in the application.<br>• The application procedure and information requirements for releasing of a novel feed of an animal origin is similar to that for a novel feed from a plant source and is outlined in the Feeds Act and regulations. |

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| Application process for unconfined release of GMOs into the environment for use as feed for livestock and laboratory animals (usually for the purpose of commercialisation) (continued) | • There is a draft document that outlines the application requirements for notification of a release of biotechnology-derived livestock animals. This draft appears to apply to confined and unconfined releases. Information requirements include information: on the organism; on the organism's manufacture or import; on the introduction of the organism; on the environmental fate of the organism; on the organism's environmental effects; on potential adverse effects on human health; on test data that assists in the identification of hazards to human health and environment. |
| Consideration of ethical issues | • In making a decision Ministers may only determine whether the substance is toxic or capable of becoming toxic. No specific mention of ethics or trade is made. However, the Minister may take into account factors such as, but not limited to social, economic and technical matters when determining preventative or control action in relation to a substance or in plans for virtual elimination of the substance. |
| Protection of confidential commercial information | • An applicant may request that information be treated as confidential.<br>• The Minister must not disclose any information in respect of which a request for confidentiality has been made unless: it is in the public interest; or it is disclosed under an agreement between the Government of Canada and any other government of Canada or government of a foreign state etc, and the agency agrees to keep the information confidential. |
| Conditions that may be applied | • The Plant Biosafety Office may maintain, change, or remove existing conditions respecting the release; impose additional conditions; or refuse or cancel the authorisation and require the applicant to stop the release and take any appropriate action necessary to eliminate from, or minimise the risk to, the environment. |

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| Monitoring, surveillance and enforcement powers | • Monitoring and enforcement powers are the same as those described in the above table because unconfined releases are governed by the same legislation as confined releases. |
| Penalties | • Penalties that may be imposed in relation to unconfined release of GMOs intended for feed use are the same as those described for the Feeds Act for confined releases because release of GMOs intended for feed use are governed by the same legislation as confined releases. |
| Application process for unconfined release of GMOs into the environment for use as food for human consumption (usually for the purpose of commercialisation) | • No novel food may be sold or advertised without first submitting a notification for the intention to do so to the decision maker.<br>• The notification requires the following information: details of the food, including information concerning its development; details of the method by which it is manufactured, prepared, preserved, packaged and stored; details of the major change, if any; information concerning its intended use and directions for its preparation; information concerning its history of use as a food; information relied on to establish that the novel food is safe for consumption; the estimated consumption level of the novel food.<br>• Upon receiving the information, the decision maker shall, within 45 days, notify the applicant that the information provided is sufficient if the food is safe, or request further information. Upon receiving the additional information, the decision maker shall notify the applicant within 90 days that the information was sufficient if the food is safe.<br>• The novel food must undergo numerous safety assessments before being approved for use as food. This may include using data from animal studies or trials regarding its toxicity and allergenicity.<br>• In evaluating GM foods for safety, government scientific evaluators may consider the following: how the food crop was developed, including the changes in the plant's/animal's molecular structure; how the GM food compares with its conventional counterpart; whether the GM food contains new toxins (to animals, humans and the environment); whether the GM food may cause allergies. |

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| Consideration of ethical issues | • No specific mention of this was found in the relevant legislation. |
| Protection of confidential commercial information | • No specific mention of this was found in the Food and Drugs Act or its regulations, or in the draft guidelines for notification for the intended release of biotechnology-derived animals. |
| Conditions that may be applied | • There was no mention of specific conditions required to be met other than those required when an application/notification for the novel food to be placed on the market is made. |
| Monitoring, surveillance and enforcement powers | • The Food and Drugs Act has provisions that allow an inspector from the Canadian Food Inspection Agency to conduct inspections. An inspector may, at any reasonable time, enter grounds where the inspector believes on reasonable grounds any article to which this Act or the regulations apply is manufactured, prepared, preserved, packaged or stored to: examine and take samples of articles; open and examine receptacles or packages; examine or make copies of documents that contain information relevant to the enforcement of the Act; seize and detain articles. |
| Penalties | • Persons who contravene the Food and Drugs Act: on a summary conviction for a first offence may face a fine of no more than CA$500 or a prison term no more than three months or both; for a subsequent offence, a fine no more than CA$1000 or a prison term of no more than six months or both; for a conviction on indictment, a fine no more than CA$5000 or a prison term no more than three years or both. |

| Policy and Governance issues | |
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| Liability for contamination | The CEPA provides for two types of action:<br>(1) Environmental Protection Actions.<br>Any Canadian citizen can apply for an investigation of an alleged offence in contravention of the legislation — this is called an 'Environmental Protection Action' (EPA). An EPA can only be bought if:<br>(a) the Ministers investigation was inadequate or non-existent; and<br>(b) there was an alleged breach of the Act; and<br>(c) the alleged breach is causing significant harm to the environment.<br>An EPA may not be bought if the alleged conduct was:<br>(a) taken to correct or mitigate harm or risk of harm to the environment or human plant or animal life;<br>(b) taken to protect national security; or (c) was reasonable and consistent with public safety.<br>Defences to an EPA include:<br>(a) due diligence;<br>(b) authorisation by another act of parliament;<br>(c) an officially induced mistake of law; and<br>(d) any other defences available under general law.<br>In addition, an action may be dismissed if it is not in the public interest. The only relief that is available if an EPA is successful is an injunction (stopping the defendant from doing something or forcing them to do something) or an order to the parties to negotiate a plan to correct or mitigate the harm to the environment etc, costs of the action. There can be no award of damages in the event of a successful EPA.<br>This action does not assist individuals affected by contamination to seek damages for loss suffered; rather it enables them to bring an action if there has been a breach of the Act, to stop the activity continuing. |

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| Liability for contamination (continued) | (2) Common law actions<br>The Act explicitly reiterates the common law right for a third party who has suffered damage to go to court to seek damages for such loss. The action that may be brought (and the damages able to be recovered) will depend entirely on the application of ordinary principles of law (for example, nuisance, negligence). The Canadian Environment Protection Act does not establish any statutory right to recover for loss or damage. There is a strict liability arrangement in the CEPA 1999 where the person who owns or has the charge, management or control of a substance immediately before an environmental emergency is liable:<br>– for restoring any part of the environment damaged by or during the emergency; and<br>– for costs and expenses incurred by a public department in respect of measures taken to prevent, repair, remedy or minimise the damage to the environment resulting from the emergency, including measures taken in anticipation of the environmental emergency; as the person's liability does not depend on proof of fault or negligence.<br>However, the person's strict liability may be reduced or nullified if the person can show that the emergency was caused by: an act of war; an exceptional, irresistible and inevitable natural phenomenon; a third party with the intent to cause damage; negligence or wrongful act of government, public department or authority. |
| Expert committees | • Canadian Biotechnology Advisory Committee (CBAC): is a non-statutory committee established by the federal government to provide advice to a Coordinating Committee of federal ministers on broad policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. CBAC is made up of 12 members drawn from the scientific, business, general public, ethics and environmental communities.<br>• The CEPA establishes a National Advisory Committee that can provide both technical and policy advice to the Minister on: proposed regulations for toxic substances; proposed regulations on environmental emergencies; a co-operative coordinated approach to the management of toxic substances; and any other matter of mutual interest.<br>• This Committee looks at all environmental issues not just biotechnology. |

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| Research | • The Minister for the Environment and Minister for Health must both undertake research and studies into environmental contamination arising from disturbances of ecosystems by human activity, and the role of substances in illnesses or health problems, respectively. The Minister for the Environment and the Minister for Health may collect or generate data and conduct investigations respecting any matter in relation to a substance when assessing whether a substance is toxic. |
| **Other** | |
| The precautionary principle | • The preamble to CEPA states that 'whereas the Government of Canada is committed to implementing the precautionary principle that, where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental damage.<br>• In giving advice and recommendations to the Minister, the National Advisory Committee shall use the precautionary principle. |
| Cost recovery | • Fees are attached to notifications to the relevant government departments for proposed use of novel plants, feed or food. The Canadian Government may also recover all costs of, and incidental to, taking reasonable measures to prevent releases that endanger the environment and public safety, or to remedy any dangerous situation or reduce or mitigate any danger to the environment or to human life that results, or may result, from the release of a toxic substance in breach of conditions (although there is a 5 year limitation period). |
| Moratorium | • No moratorium. |
| Other | • Canada is currently proposing a regulation under the CEPA (1999) that would allow Canada to implement the Cartegena protocol. However, living modified organisms that are pharmaceuticals for human use are excluded from the regulation.<br>• A novel feed from a PNT that could reasonably be expected to be released into the environment or used as food will not be authorised for livestock feed use until: the Plant Biosafety Office, CFIA, is ready to authorise the PNT for environmental release; the Novel Foods Section, Health Canada, is ready to provide notification of no objection for human food use of the novel food. |

## REGULATION OF GENE TECHNOLOGY IN ARGENTINA

**SUMMARY** — The Secretaria de Agricultura, Ganaderia, Pesca y Alimentos (SAGPyA)/Secretary of Agriculture, Livestock, Fisheries and Food is responsible for granting licences to dealings with GMOs. SAGPyA bases its decisions on the recommendation of an expert committee: Comisión Nacional Asesora de Biotecnología Agropecuaria (CONABIA)/The National Advisory Committee on Agricultural Biosafety.

- These rules are part of the general regulatory system governing the agricultural existing regulations in Argentina related to plant protection (Decree-Law of Agricultural Production Health Defense. N° 6704/66 and its amendments), seeds and phytogenetic creations (Seed and Phytogenetic Creations Law, N° 20.247/73 and its regulatory Decree), and animal health (Law of Veterinarian Products. Supervision of the creation and commercialisation. N° 13.636/49).

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| **Contained work with GMOs** | |
| Responsible agency | • CONABIA/SAGPyA. |
| Legislation | • Resolution N°31/03 of SAGPyA 11 July 2003 specifies the application procedure for the issue of licences for Experimentation on and/ or Release into the Environment of Genetically Modified Micro-organisms and/or their products for use in animals; the release of genetically modified animals are regulated by Resolution N°656 of SAGPyA 11 July 2003. |
| **Intentional releases of GMOs in the environment** | |
| Responsible agency | • CONABIA/SAGPyA. Commercial releases are also assessed by Health, Trade and Seed agencies. |
| Legislation | • Field trials are governed under Resolution N°57 of SAGPyA 18 July, 2003; commercial releases are also subject to SAGPyA Regulation No. 511/98 as well as general seed and health laws. |
| Coverage of the legislation | • The deliberate release of GMOs into the environment. |

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| Assessment process for intentional releases of a GMO into the environment (field trials) | • Information requirements for applications are based on the US Department of Agriculture's experience. CONABIA's technical staff make a preliminary review of the applications for completeness and data quality. The CONABIA committee then undertakes a risk assessment analysis. The risk assessment includes:<br>– assessment of the biosafety of the released organisms;<br>– assessment of the agro-ecological features of the site where they are intended to be released; and<br>– suitability of the person(s) responsible for conducting the field trial.<br>• Authorisations for field trials are then issued by SAGPyA based on CONABIA's recommendation.<br>• After at least one field trial and the safety of the GMO has been demonstrated, an applicant can apply for more flexible field trial conditions for that GMO referred to as 'flexibilización' (SAGPyA Resolution 131/98). After SAGPyA grants flexibilización, further releases into the environment of that GMO will only need the applicant to submit information on:<br>– the area sown;<br>– the date of sowing; and<br>– the site of release and the harvest date. |
| Procedure for the placing of GMOs or products containing GMOs on the market | • A flexibilización permit is also the first stage to get approval for a commercial release. In addition, seed commercialisation is subject to the following terms and conditions:<br>• National Service of Agrifood Health and Quality approval for use as food or feed. This is assessed by analysis of: (1) natural toxins; (2) new forms of toxins; (3) homology of the newly expressed proteins with other known allergens; (4) nutritional changes; (5) nutritional changes and nutritional characterisation resulting from processing methods; (6) modifications in the bioavailability of macronutrients and/or micronutrients; (7) characterisation of the modified foodstuff with regard to its safety for human and animal health. |

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| Procedure for the placing of GMOs or products containing GMOs on the market (continued) | • Approval for marketing by the National Division of Agrifood Markets of the Secretariat, which assesses the trade and marketing impacts. This assessment seeks to avoid any potential negative impact on Argentine exports.<br>• Compliance with the requirements set forth by the INASE for registration of the material in the National Cultivar Registry and in the Official Certification regulations.<br>• As with field trials the final approval is made by SAGPyA. |
| Consideration of ethical issues | • There is no specific mention made of consideration of ethical concerns. |
| Public consultation on applications | • There is no specific mention of public consultation on applications. Annual reports and details of GMOs approved are listed on CONABIA's web site. |
| Conditions that may be applied | • The Resolution provides that competent authorities may grant approvals subject to conditions. |
| Monitoring, surveillance and enforcement powers | • Monitoring of the field trials is the responsibility of the National Seeds Institute and of the National Service of Agrifood Health and Quality. The purposes of the monitoring are the on-site verification of compliance with the trial conditions as approved in the application and that the measures taken to avoid adverse effects on the environment have been followed. The fields are also inspected after the trials, in order to prevent any possible gene transfer from transgenic volunteer plants or harvest residues to other organisms. For field trials under flexibilización CONABIA will only recommend that inspections be made at harvest and of the measures taken for the final disposition of the material.<br>• At the end of the period for which the authorisation was granted, the applicant must submit to CONABIA a final report. CONABIA will not evaluate any further application from a public or private institution which had failed to present a final report. |

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| Penalties | • Not known at this stage. |
| Liability for contamination | • There is no mention of liability for contamination. |
| **Policy and Governance issues** | |
| Expert committees | • CONABIA is a multidisciplinary and inter-institutional group whose members are representatives of the public and private sectors working in Agricultural Biotechnology. |
| Research | • CONABIA requests that applicants perform research but does not conduct the research. |
| Other | |
| The precautionary principle | • The whole department operates under the 1992 Rio Declaration on Environment and Development version of the precautionary principle. |
| Cost recovery | • Not applicable. |
| Protection of confidential commercial information | • Parts of applications that contain trade secrets or confidential information are protected.<br>• There is no data exclusivity. |
| Moratorium | • Not applicable. |
| Other | |

## REGULATION OF GENE TECHNOLOGY IN CHINA

**SUMMARY** — The Ministry of Agriculture appears to be mainly responsible for the formulation and implementation of regulations in relation to biotechnology and biosafety.

- Other interested government agencies include the State Environmental Protection Agency, the Ministry of Public Health, the Inspection and Quarantine Agency, the Ministry of Foreign Economy and Trade and the Ministry of Sciences and Technologies.
- All these agencies' views are represented on State Ministerial Council.
- Day-to-day regulation of GMOs is administered by the Office of Agricultural Genetic Engineering Biosafety Administration. However, in late 2005, the Chinese Government formed a new body to administer GMO regulation.
- The Ministry of Public Health is responsible for food safety in relation to GMOs intended for that purpose.
- The Ministry for Sciences and Technologies is responsible for biotechnology research.
- Genetic engineering work is classified into four classes of risk to human health and ecological environment: none; low; intermediate; and high.
- The risk classification is determined by the relevant agencies on the State Ministerial Council.

| **Contained work with GMOs** | |
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| Responsible agency | • This may depend on the classified level of risk for the type of work being done, but generally no or low risk, contained experimental work would normally require approval from the administration of the institution in which the work is conducted. However, higher risk work requires additional approval from the relevant departments under the State Council and the National Genetic Engineering Safety Committee. |
| Legislation | • Safety Administration and Regulation on Genetic Engineering Regulations (1993). |

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| Assessment process for contained work involving GMOs | • Institutions carrying out genetic experimental research should conduct evaluation on DNA donors, vectors, hosts and genetic engineered organisms. Factors considered should include pathogenicity, carcinogenicity, chemical resistance, transfer possibility, and effects on environment of target genes, vectors, hosts and genetically engineered organisms, and on determining biological control and physical control classes.<br>• For intermediate risk work, the institution's administration should consider the application and then submit the application to the relevant departments under the State Council for consideration. For high risk work, the application is submitted to the National Genetic Engineering Safety Committee for approval after being submitted to the relevant department under the State Council.<br>• Institutions carrying out genetic engineering work should go through the following application procedures: the chief of the planned genetic engineering project should evaluate the safety of the project and fill in the application form; the academic committee of the institution should conduct technical evaluation on the application; applications should be submitted along with technical documentation.<br>• Safety measures include: development of safety control measures appropriate for the class of risk; waste management procedures (GMOs should be killed and disposed of to prevent dissemination and environmental pollution); development of measures to prevent accidents; appropriate storage and transportation provisions; maintaining a written safety control record for a minimum of ten years; requirement for institutions taking immediate measures to restrict and alleviate harm if it is discovered that the institution's work is causing environmental damage or harm. |
| Consideration of ethical issues | • There was no specific requirement for ethical issues to be considered. |
| Public consultation on applications | • There was no specific mention for the requirement for public consultation. |

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| Conditions that may be applied | • No specific mention of the conditions to be applied were mentioned, but relevant administrative departments will issue warnings, stop operation, suspend financial support, confiscate illegal profits according to actual conditions of violations. |
| Monitoring, surveillance and enforcement powers | • Laws and regulations introduced in 2002 and 2003 contain provisions for monitoring and surveillance to ensure environmental safety from use of GMOs. |
| Penalties | • Relevant administrative departments will issue warnings, stop operation, suspend financial support, confiscate illegal profits according to actual conditions of violation when: the genetic engineering project begins operation without approval; equipment, apparatus, laboratories which do not fit in with regulations have been used; violation of safety operation regulations of genetic engineering work has occurred; violation of other rules under the regulations occur.<br>• Both individuals and the institution conducting the work can be liable for any damages resulting from the work.<br>• Responsible institutions of those violating any relevant legislation and causing one of the following results must immediately stop the violation and take measures to handle the pollution and compensate for losses: causing serious environment pollution; causing damage or harm to the public health; causing severe damage to ecological resources and ecological balance. Criminal charges can also be laid subject to the appropriate legislation. |
| **Intentional releases of GMOs in the environment** | |
| Responsible agency | • Departments under the State Council; Department of Agriculture; Department of Science and Technology; State Environmental Protection Administration; National Genetic Engineering Safety Committee. |

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| Legislation | • Safety Administration and Regulation on Genetic Engineering Regulations (1993).<br>• Regulations on Administration of Agricultural GMOs Safety (2001). |
| Coverage of the legislation | |
| Assessment process for intentional releases of a GMO into the environment (field trials and general releases) | • Institutions carrying out genetic engineering pilot experiments or industrial production should conduct safety evaluation on the physical barriers of the equipment and facilities of the culture, fermentation, separation and purification processes according to genetic engineered organisms safety class, to determine the safety class of pilot experiments or industrial production.<br>• Institutions carrying out the release of genetic engineered organisms should conduct evaluation on the safety of genetic engineered organisms, the purpose of the release, ecological environment conditions of the release site, releasing methods, monitoring means and control measures, to determine the safety class of the release. Approval for work classified as no risk should be obtained from the chief administrators of the institution; approval for work classified as low risk requires approval by relevant State Council departments; intermediate risk work also requires approval from relevant State Council departments with the application recorded by the National Genetic Engineering Safety Committee; applications for high risk work is examined by the relevant State Council departments and submitted for approval to the National Genetic Engineering Safety Committee.<br>• Institutions carrying out genetic engineering work should go through the following application procedures: the chief of the planned genetic engineering project should evaluate the safety of the project and fill in the application form; the academic committee of the institution should conduct technical evaluation on the application; applications should be submitted along with technical documentation. |

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| Assessment process for intentional releases of a GMO into the environment (field trials and general releases) (continued) | • Safety measures include: development of safety control measures appropriate for the class of risk; waste management procedures (GMOs should be killed and disposed of to prevent dissemination and environmental pollution); development of measures to prevent accidents; appropriate storage and transportation provisions; maintaining a written safety control record for a minimum of ten years; requirement for institutions taking immediate measures to restrict and alleviate harm if it is discovered that the institution's work is causing environmental damage or harm. |
| Consideration of ethical issues | • There was no specific requirement for ethical issues to be considered. |
| Public consultation on applications | • There was no specific mention for the requirement for public consultation. |
| Conditions that may be applied | • No specific mention of the conditions to be applied were mentioned, but relevant administrative departments will issue warnings, stop operation, suspend financial support, confiscate illegal profits according to actual conditions of violations. |
| Monitoring, surveillance and enforcement powers | • Laws and regulations introduced in 2002 and 2003 contain provisions for monitoring and surveillance to ensure environmental safety from use of GMOs. |

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| Penalties | • Relevant administrative departments will issue warnings, stop operation, suspend financial support, confiscate illegal profits according to actual conditions of violation when: the genetic engineering project begins operation without approval; equipment, apparatus, laboratories which do not fit in with regulations have been used; violation of safety operation regulations of genetic engineering work has occurred; violation of other rules under the regulations occur.<br>• Both individuals and the institution conducting the work can be liable for any damages resulting from the work.<br>• Responsible institutions of those violating any relevant legislation and causing one of the following results must immediately stop the violation and take measures to handle the pollution and compensate for losses: causing serious environment pollution; causing damage or harm to the public health; causing severe damage to ecological resources and ecological balance. Criminal charges can also be laid subject to the appropriate legislation. |
| Assessment process for intentional releases of a GMO for commercialisation | • Use of finished genetic engineering products (intended for release) should be accompanied by biological tests for the purposes of a safety evaluation, which will determine the possible impact of the product on the public health and the ecological environment.<br>• For work classified between no risk and intermediate risk, applications should be submitted to the relevant departments under the State Council for approval and to the National Genetic Engineering Safety Committee for their record.<br>• For releases classified as high risk, the application should be examined by the relevant departments under the State Council and submitted to the National Genetic Engineering Safety Committee for approval. |

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| Assessment process for intentional releases of a GMO for commercialisation | • Institutions carrying out genetic engineering work should go through the following application procedures: the chief of the planned genetic engineering project should evaluate the safety of the project and fill in the application form; the academic committee of the institution should conduct technical evaluation on the application; applications should be submitted along with technical documentation.<br>• Safety measures include: development of safety control measures appropriate for the class of risk; waste management procedures (GMOs should be killed and disposed of to prevent dissemination and environmental pollution); development of measures to prevent accidents; appropriate storage and transportation provisions; maintaining a written safety control record for a minimum of ten years; requirement for institutions taking immediate measures to restrict and alleviate harm if it is discovered that the institution's work is causing environmental damage or harm. |
| Consideration of ethical issues | • There was no specific requirement for ethical issues to be considered. |
| Public consultation on applications | • There was no specific mention for the requirement for public consultation. |
| Conditions that may be applied | • No specific mention of the conditions to be applied were mentioned, but relevant administrative departments will issue warnings, stop operation, suspend financial support, confiscate illegal profits according to actual conditions of violations. |
| Monitoring, surveillance and enforcement powers | • Laws and regulations introduced in 2002 and 2003 contain provisions for monitoring and surveillance to ensure environmental safety from use of GMOs. |

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| Penalties | • Relevant administrative departments will issue warnings, stop operation, suspend financial support, confiscate illegal profits according to actual conditions of violation when: the genetic engineering project begins operation without approval; equipment, apparatus, laboratories which do not fit in with regulations have been used; violation of safety operation regulations of genetic engineering work has occurred; violation of other rules under the regulations occur.<br>• Both individuals and the institution conducting the work can be liable for any damages resulting from the work.<br>• Institutions responsible for violating any relevant legislation and causing one of the following results must immediately stop the violation and take measures to handle the pollution and compensate for losses: causing serious environment pollution; causing damage or harm to the public health; causing severe damage to ecological resources and ecological balance. Criminal charges can also be laid subject to the appropriate legislation. |
| **Policy and Governance issues** | |
| Liability for contamination | • Institutions are responsible for any clean-up requirements and providing compensation for losses.<br>• Criminal charges can also be laid subject to the appropriate legislation. |
| Expert committees | • National Genetic Engineering Safety Committee.<br>• National Agricultural GMO Biosafety Committee participates in biosafety management. |
| Research | • At the national level, the Ministry of Agriculture, the Chinese Academy of Sciences, the State Forestry Bureau and the Ministry of Education are the major authorities responsible for agricultural biotechnology research.<br>• Under the Ministry of Agriculture, there are three large academies: the Chinese Academy of Agricultural Sciences; the Chinese Academy of Tropical Agriculture; and the Chinese Academy of Fisheries. |

| **Other** | |
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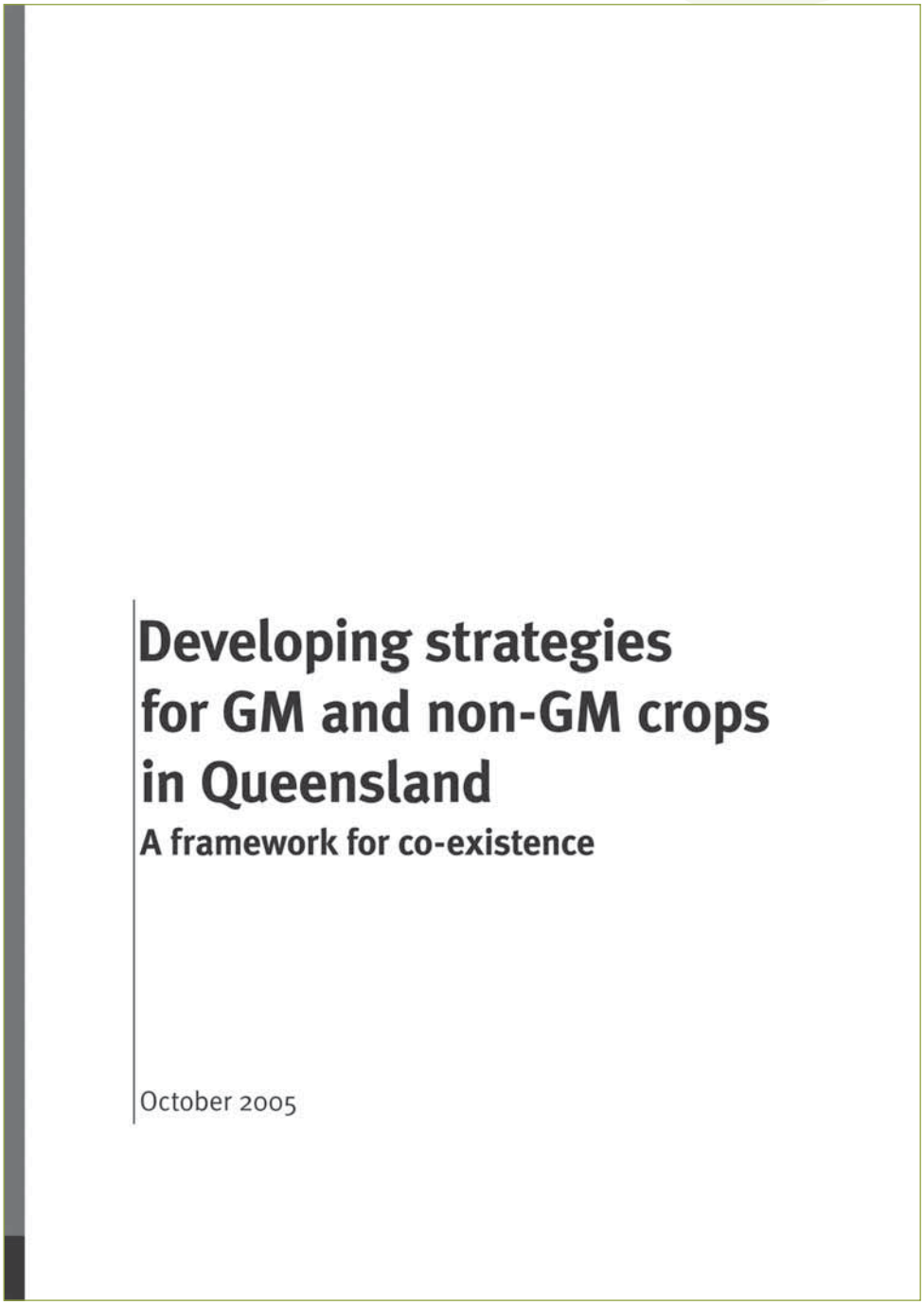
| The precautionary principle | • No specific mention of the precautionary principle was found in any of the information found on the Chinese gene technology regulation regime. |
| Cost recovery | • Institutions whose work with GMOs has caused environmental damage are responsible for taking remedial action and for compensation costs. |
| Protection of confidential commercial information | No reference was found to this. |
| Moratorium | No specific mention of a moratorium was found; however, China introduced more restrictive biosafety regulations in 2002. |
| Other | • China has ratified the Cartegena protocol on biosafety.<br>• As of 2003, China was in the process of introducing new/updating existing laws and regulations governing work involving GMOs. The information in this table may soon be superseded.<br>• GM labelling guidelines took effect from 2002.<br>• Information was sourced from http://www.ebnic.org (http://www.ebnic.org/detailsc.htm#hapter%20Two:%20Safety%20Classes%20and%20Safety%20Evaluation) and http://www.china.org.cn/english. Institute of Developmental Studies working paper 195, Jikun Huang and Qinfang Wang, Biotechnology policy and regulation in China (2003). |

# APPENDIX 9

## Developing strategies for GM and non-GM crops in Queensland: a framework for co-existence



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The Department of Primary Industries and Fisheries (DPI&F) seeks to maximise the economic potential of Queensland's primary industries on a sustainable basis.



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# Summary

With the advent of genetically modified (GM) crops in agriculture comes the risk of unintentional mixing of harvested GM and non-GM material that may compromise the integrity of products in the market-place. To achieve the full commercial potential of industries that utilise GM crops, participants in supply chains may need to consider the implementation of effective and rigorous strategies that focus on maintaining product integrity.

The concept of co-existence is not new to Australian primary producers. Co-existence strategies for harvested products may be applied in the same way for GM and non-GM crops as for any other harvested product.

This framework was produced by the Queensland Government to provide a basis for the development of effective co-existence strategies for agricultural cropping industries. The document identifies six fundamental principles that will assist industry to actively prepare for any new commercial release of GM crops. These co-existence principles include measures that:

1 offer freedom of choice to farmers, supply chain participants and consumers;
2 are transparent and enable consultation;
3 are based on science and practical process management;
4 minimise impacts on others;
5 can be assessed on a case-by-case basis; and
6 can be monitored and reviewed.

It is intended that the co-existence strategies developed from these principles will enable participants along the supply chain to competitively meet the requirements of their chosen markets, and give consumers the ability and freedom to select products according to their preference.

# 1 Introduction

Scientific innovation has always been a driving force behind advances in agriculture and food production. Gene technology, in particular, offers exciting opportunities for the agriculture sector. Benefits are clearly seen in the cotton industry, where modified varieties have resulted in significant environmental, economic and production gains. However, one of the key concerns of both supply chain participants and consumers is the risk of unintended mixing of the harvested products from genetically modified (GM) and non-GM crops and the integrity of the final product.

The Queensland Government is strongly supportive of the national gene technology regulatory scheme, which imposes a stringent, science-based licensing regime to protect the environment, and health and safety, of people. It is acknowledged that for industry to realise the full commercial potential of GM crops, marketing and trade implications of the technology also need to be considered.

To achieve the potential of GM crops, participants along the entire supply chain may need to implement effective and rigorous strategies that focus on maintaining product integrity at all stages, from pre-farm gate activities to processing and export. The concept of co-existence is not new to Australian primary producers, and may be applied to the co-existence of harvested products of GM and non-GM crops in the same way as for any other harvested product.

In this publication, co-existence is defined as the ability to grow and manage along the supply chain both GM and non-GM crops in a way that avoids unwanted mixing and delivers products below predetermined market thresholds.

The Queensland Government has developed this framework to guide in the development of effective co-existence strategies. This document provides a number of fundamental principles that will assist both government and industry to actively prepare for any new commercial release of a GM crop.

The co-existence strategies developed using these principles will enable participants along the supply chain to competitively meet the requirements of their chosen markets, and ensure consumers have the ability and freedom to select products according to their preferences.

# 2 Context

## 2.1 Australia's gene technology regulatory system

The national regulatory scheme for gene technology was introduced with the enactment of the Commonwealth *Gene Technology Act 2000* (CGTA) which came into force on 21 June 2001. As required by the Commonwealth legislation and the Queensland *Gene Technology Act 2000*, all gene technology research and its products are regulated to identify and manage any risks to human safety and the environment. The scheme is a scientifically-based risk assessment process overseen by the independent Gene Technology Regulator. All applications involving laboratory work or the release of genetically modified organisms (GMOs) into the Australian environment, including GM crops, are evaluated on a case-by-case basis and are subject to stringent public safety and environmental risk assessment.

## 2.2 Status of GM crops in Queensland

GM crops have been grown in Queensland since 1996, with the commercial release of insect resistant cotton. Since that time, GM cotton has become widely accepted by the industry and the community due to its reduced need for insecticide input and environmental benefits. No other GM crop is currently grown in Queensland, although trials are underway for papaya, pineapple and sugarcane (Table 1).

## 2.3 Market risk

One area not addressed by the national scheme is the economic implications associated with the marketing of GM products and the potential impacts on export markets, should the integrity of supply chains be compromised (e.g. the presence of GM material in consignments marketed as non-GM products could affect market access). In considering market risk, the Primary Industries Ministerial Council (PIMC) determined on 7 May 2002 that risks to agricultural production and trade should be self-regulated by industry and be supplemented by government monitoring. However, this process was not adopted, as some states chose instead to implement moratoria on the commercial release of GM crops (specifically canola).

Despite the fact that the PIMC determination was not implemented by a number of states, the Queensland Government is of the view that industry self-regulation is both desirable and necessary.

*Table 1. Current status of dealings with GM crops in Queensland.*

| Crop | Genetic modification | Current status | Organisation | Comments |
|---|---|---|---|---|
| Cotton | Insect resistance and herbicide tolerance | Commercially released plus ongoing field trials of new varieties | Monsanto Australia Ltd, CSIRO, Hexima Ltd, Dow AgroScience Australia Pty Ltd | Grown commercially by the majority of the industry. Large scale field trials underway |
| Papaya | Delayed fruit ripening, disease resistance | Field trials only | University of Queensland | Early stage, small-scale trials |
| Pineapple | Black heart tolerance and synchronising flowering | Field trials only | Department of Primary Industries and Fisheries | Early stage, small-scale trials |
| Sugarcane | Altered sugar content | Field trials only | University of Queensland, BSES Ltd | Early stage, small-scale trials |

## 2.4 Threat of litigation

A commercial reality of not segregating GM and non-GM crops is the risk of litigation. Although the inclusion of civil liability provisions for potential damage caused by GMOs were considered during the development of the CGTA, these options were ultimately rejected in favour of reliance on common law. The decision by the Queensland Government to introduce legislation that mirrors the Commonwealth *Gene Technology Act 2000* is confirmation that both the State and Commonwealth Governments agree that common law is adequate and appropriate for issues related to liability. This approach is consistent with that adopted in the United Kingdom, New Zealand, Canada and the United States, and would also be appropriate and adequate in shaping co-existence strategies developed under this framework.

The allocation of the costs of segregation and co-existence to individuals or entities is a contentious issue that is attracting considerable interest. ACIL Tasman (2004) reported that the introduction of canola into Australia in the 1970s and from the introduction of GM crops overseas has highlighted that the costs of segregation would fall mostly on GM users and handlers for the period in which GM crops remain the minor proportion of the total crop handled.

## 2.5 Co-existence through segregation

Marketing issues and the risk of litigation associated with the production of GM crops can be alleviated by development of co-existence systems aimed at maintaining segregation and identity preservation of products along supply chains within tolerances acceptable to particular markets. In the past, industry has implemented numerous management systems to ensure co-existence of different conventional production systems so that producers retain access and remain competitive in both domestic and international markets. In Australia and overseas, industry experience to date indicates that segregation thresholds for conventional commodity crops are being consistently met and that product handling systems would be technically and commercially capable of meeting a range of GM tolerance demands.

When conventional canola was first grown in Australia, grain handlers took extensive steps to manage its introduction. It is now, however, routinely handled in the grain supply chain to meet market grain purity specifications. For many years a tolerance of up to 0.6 percent of canola in wheat and malting barley has been specified in Australia's National Agricultural Commodity Marketing Association standards and the bulk handling companies which manage the storage. Handling of these grains indicate that this level is routinely met (ACIL Tasman 2004).

There are a number of other crops that are grown in Australia with quite specific product integrity and segregation requirements for the needs of individual customers. For example, pesticide residue-free grain is required by some of Australia's major wheat markets, including Japan and Korea. Furthermore, the organic sector achieves a price premium for their harvested products by the implementation of a completely closed system that enables segregation from those of conventionally-grown crops.

Australian growers, harvesters and exporters have been successfully segregating many bulk agricultural commodities for several years. Recently, this segregation capacity has extended to GM commodities. For example, GM cotton seed has been co-marketed and exported with other oilseed crops since 1997. The success of this segregation to meet market requirements has been demonstrated by the fact that there have been no reports of the presence of GM cotton seed in wheat, canola or other export grains, even though the seed is handled through the same bulk facilities. The access and competitive position that Australia maintains in export markets is evidence of the ability of agricultural industries to meet the requirements of markets by responding to and delivering on product specifications.

In the international context, GM corn co-exists with non-GM corn varieties in Spain (PG Economics 2004) and highlights the fact that such production systems can operate in parallel. There has been no evidence of loss of market share as a result of the cultivation of genetically modified crops.

### 2.6 Ethical practice

The Queensland Government has recognised that for Queensland to be a leader in biotechnology it needs to progress the development of robust and workable standards relating to safety and bioethics. In achieving this end, the Queensland Biotechnology Code of Ethics declares the fundamental ethical framework and legislative controls that will guide the development of biotechnology in Queensland. The Queensland Government believes that the general principles of the code are applicable to all dealings involving the use of GMOs, and therefore, the principles are relevant to this co-existence framework.

# 3. The Framework

## 3.1 Scope

The Queensland Government believes that the development of co-existence strategies may not be necessary for all agricultural industries and will only occur when the marketplace demands that the distinction be made for commercial/economic reasons. For example, although the cotton industry has not identified a need to adopt co-existence measures, other agricultural industries may require such measures. The degree to which measures for segregation should be employed may ultimately depend on the importance of the industry (planted area, production, economic value) and market requirements (product integrity, demographic use).

However, if required, co-existence measures should also be:

- non-discriminatory;
- science-based; and
- process management based.

Producers and those overseeing the integrity/purity of crops should be consistent in their behaviour towards the unintended presence of all unwanted material, including GM material.

It is unrealistic and scientifically impossible to expect or maintain 100 percent purity along the supply chain. The Queensland Government does not believe a GM-free standard can be achieved for any crop and supports the adoption of threshold levels for unintended presence of unwanted material.

The maintenance of thresholds is standard industry practice. For example, the Australian Oilseeds Federation has set an impurity threshold limit of 0.9% GM canola in non-GM canola consignments.

## 3.2 Objectives

The objective of this framework is to maximise economic returns to participants along supply chains by:

- allowing GM crops to be grown and managed either separately from, or combined with non-GM crops along the entire supply chain if appropriate;
- allowing supply chain participants to meet the requirements of their chosen market, recognising that these requirements will ultimately be determined by consumer preference and regulatory requirements;

- minimising the risk of unintended presence in the supply chain;
- enabling farmers to utilise technologies most appropriate to their chosen farming system; and
- enabling the production of GM crops with minimal unintended effects on the activities of other operators and on the environment.

## 3.3 Principles

The Queensland Government believes that co-existence of GM and non-GM crops is achievable and that the development of any crop-specific co-existence system developed by industry and government should include consideration of the following six principles:

### 3.3.1 Freedom of choice

The Queensland Government supports the right of producers to choose production systems and supply chains that best suit their needs for an identified market. Furthermore, the Queensland Government advocates that consumers have the right to access the products of their choice.

For the producer, gene technology has the potential to develop crops with superior agronomic performance and with benefits to the environment through a reduced need for chemicals, water inputs, and fuel. For the consumer, GM crops may result in the production of foods with augmented health benefits or with other desirable traits.

Systems have been in place for many years to segregate commodities on the basis of product characteristics, food safety or legislative requirements. Quality assurance systems enable the delivery of standardised and certified products to the marketplace using environmentally responsible protocols. These systems can be employed or adapted to meet the requirements for the co-existence of products derived from GM and non-GM cropping systems. Segregation of GM and non-GM cotton or cotton seed (Australia's only broad-scale GM crop) is not undertaken in Australia. However, an example of a segregation strategy for canola is provided in Figure 1.

Within any market or industry, a number of supply chains may exist, with their requirements determined by a combination of consumer preference and regulatory standards. Based on market demand, individual supply chains can fall broadly into one of three categories:

1 Non-discriminating markets, where specifications do not require GM and non-GM material to be differentiated, hence the products may be combined for marketing purposes.
2 Markets for non-GM crops, where regulatory authorities or commercial customers accept products combined below a specified threshold for the unintended presence of GM material in non-GM material. For example, European and Australian regulations specify a threshold of up to one percent impurity with GM product, whereas Japan specifies a threshold of up to five percent impurity.
3 Identity-preserved markets, where the preservation of unique characteristics of a product considered desirable by a customer or consumer is guaranteed (i.e. product integrity), such as a specific product or a product based on a production system.

Therefore, measures implemented to meet market requirements will vary according to each individual supply chain and the market being targeted.

### 3.3.2 Transparency and consultation

Consistent with the principles developed in this framework, agricultural industry sectors have the opportunity to contribute to the development of specific industry co-existence guidelines that:

- define the needs of each supply chain equitably;
- ensure transparency to participants within and between other supply chains; and
- communicate clearly the production system and the supply chain requirements.

All stakeholders should have the opportunity to contribute to the development of industry initiatives and to work cooperatively in developing, implementing, and monitoring these initiatives. Adopting a cooperative approach involves:

- clearly communicating production system and supply chain requirements;
- helping to resolve debates on industry issues;
- assisting industry-wide communication through the dissemination of information on industry initiatives; and

- a commitment or statement of intent by industry to adopt the specific strategies developed for a particular industry.

### 3.3.3 Practicality

Co-existence measures should be based on science and practical process management. Measures that may be implemented to ensure development of effective co-existence strategies would need to:

- be based on customer requirements;
- be flexible, practical and cost effective;
- be science-based and supported by risk assessment; and
- incorporate relevant regulatory requirements.

### 3.3.4 Minimising impacts

Participants in one supply chain are responsible for implementing measures that prevent their activities and products from unduly interfering in the operation of another supply chain. To be equitable, either through act or omission, measures implemented by one supply chain should not impose material demands or costs onto other supply chains or other participants within a supply chain.

There is a clear requirement for all participants in a supply chain to work together to prevent, as practicably as possible, the presence of unwanted material from exceeding the levels determined by the market and/or regulators.

### 3.3.5 Case-by-case assessment for co-existence

Appropriately detailed plans should be developed to address identified risks associated with the introduction of GM crops into a particular agricultural industry sector. The interests of the majority of producers will be protected from the introduction of this co-existence framework, but will also allow the adoption of new technologies by those producers who wish to do so.

As required, specific co-existence strategies should incorporate the following elements:

- marketing standards;
- risk management strategies;
- inter-relationships between various cropping systems;
- the crop management plans developed by technology providers;
- systems that provide for traceability or identity preservation, with these systems varying in rigour in accordance with product, market and regulatory requirements;
- access to sampling and testing regimes, with the aim of confirming, or providing evidence, that market and regulatory requirements are being met;
- provision for remedial action as required;
- market dynamics that reflect changing product specifications, together with changing supply and demand scenarios; and
- education of supply chain participants to ensure understanding of the co-existence framework and associated industry initiatives.

Implicit in the development of case-by-case guidelines is the recognition that each agricultural industry has specific growing, harvesting, storage, marketing and export characteristics, and, therefore, requires a separate industry response. In addition, different traits (e.g. herbicide tolerance, insect resistance, nutritional enhancement) will also raise different industry management issues.

### 3.3.6 Development, monitoring and review

To ensure that the objectives of the co-existence framework are met, industry and the Department of Primary Industries and Fisheries, Queensland (DPI&F) will work together to develop specific co-existence strategies. Both parties will monitor and review practices, attitudes and market requirements relevant to specific circumstances.

Any consideration of market impacts will be done in a transparent, independent and consistent fashion. Issues arising in all dimensions of the scope of this framework – marketing, environmental, agronomic and technological – will change over time. As such, industry, with input from DPI&F, will need to ensure that it constantly monitors and periodically reviews the measures that are in place.

# 4 Application of Framework

In collaboration with the DPI&F, each agricultural industry is responsible for the development, assessment and monitoring of specific co-existence guidelines for GM and non-GM crops arising from this framework.

Use of the framework to develop co-existence strategies is voluntary, and no regulatory controls are envisaged or proposed. Market forces will ultimately determine the level to which strategies would be implemented.

For further information on this framework and its implementation contact the DPI&F Call Centre on 13 25 23

# 5. References

The following people and reports were consulted and referred to in the formulation of this framework:

ACIL Tasman (2004). Genetically Modified Canola: Market Issues, Industry Preparedness and Capacity for Segregation in Victoria.

Avcare. National Association for Crop Production and Animal Health.

Gene Technology Grains Committee (2002). A strategic framework for maintaining co-existence of supply chains. December 2002.

Hudson, David. Agricultural Consultant.

National Farmers Federation Limited – Biotechnology Position Statement 2003

PG Economics Ltd (2004). Co-existence of GM and non-GM crops: current experience and key principles. Graham Brookes PG Economics Ltd, Dorchester, UK. October 2004. http://www.pgeconomics.co.uk/pdf/Coexistencekeyprinciplesdocument.pdf

**Figure 1 – Industry segregation along the supply chain for GM canola***

*Grain is sampled as required along the supply chain to classify grain and ensure product integrity is maintained. The primary sampling points usually occurs where ownership transfers (quality and weight is assessed for payment).*

| Supply Chain | Supply Chain Activities | Industry arrangements to ensure physical separation | Quality Assurance Systems |
|---|---|---|---|
| Pre-farm Gate | Seed cultivation<br>Seed retail<br>Seed wholesale | • Seed growing requires stringent separation distances to maintain purity. This is already a routine activity for seed growers.<br>• Seed merchants, as with conventional varieties, clearly label bags of seed including batch numbers.<br>• Retail agronomists trained by GM companies work with farmers to gain compliance with technology agreements. | OECD<br>ASF<br>CISP<br>TSS |
| On Farm | Receival of seed<br>Storage of seed<br>Transport to seeder<br>Planting harvest<br>Transport off farm | • GM seed is made available only to farmers who have signed technology user agreements. These agreements require growers to undertake training and keep detailed records.<br>• Growers are required to institute separation distances (i.e. buffers) between GM and conventional crops.<br>• Growers test grain samples before and during harvest for purity.<br>• Harvest contractors required to verify cleanliness of headers. Headers may require additional cleaning. Potential for dedicated GM headers if GM crop usage expands.<br>• Transport off farm requires levels of machinery hygiene similar to those required for header contractors. | Graincare<br>Great Grain<br>SQF 1000$^{CM}$<br>SQF 2000$^{CM}$<br>Tech. Developers<br>CISP<br>TSS |
| Bulk Grain Handling | Receival of grain at regional delivery site<br>Transfer to storage<br>Transfer to truck/rail<br>Transport to central delivery site<br>Receival of grain at central delivery site<br>Transfer to storage<br>Transfer to truck/rail<br>Transport to crusher | • Each truck is sampled and directed to appropriate delivery point at country silos.<br>• Country silos also test samples brought in by farmers prior to truck departure from farm or even prior to harvest beginning.<br>• Dedicated trains to be used initially for any rail transport of GM crops.<br>• Rail operators to use existing internal procedures and protocols to maintain separation ensuring wagon hygiene practices would be maintained. | ISO 9001<br>HACCP<br>SQF 2000$^{CM}$<br>CISP |
| Processing (and Export) | Receival of grain<br>Transfer to storage<br>Oil extraction (press)<br>Filter/purify<br>Transfer to storage<br>Transfer to truck<br>Transport to refinery | • Dedicated storage, testing and quality assurance protocols are used for all incoming grain.<br>• Canola oil to food customer within labelling requirements.<br>• Canola meal (of known GM status) delivered to stock feed customer.<br>• Export — QA and hygiene practices maintained and export documentation to accompany each shipment (as with conventional crops). | ISO 9001<br>HACCP<br>SQF 2000$^{CM}$<br>CISP |

** Chart and information has been adapted from ACIL Tasman (2004) Genetically Modified Canola: Market Issues, Industry Preparedness and Capacity for Segregation in Victoria; and Gap Analysis in relation to Quality Management for the Supply Chain Management of Genetically Modified products. Tasmania Quality Assured (for AFFA).*

*Descriptions for quality assurance systems are provided by the relevant organisations on following page.*

# Quality Assurance Systems

*OECD* – the Organisation for Economic Cooperation and Development Seed Scheme for the Varietal Certification of Planting Seed Moving in International Trade is the principal international genetic quality management program for sowing seed traded on the global seed market.

*ASF* – the Australian Seeds Federation released guidelines for managing adventitious presence in the production, processing and marketing of canola seed. The Guidelines identify management processes required to maintain seed purity. ASF has also implemented Codes of Practice for the labelling and marketing of seed and the use of seed treatments.

*TSS* – Technology Stewardship Strategies are based on best practice management principles and aim to ensure growers are sufficiently trained to enable the sustainable and lawful use of GM canola technology in a manner that increases productivity and does not adversely affect other production systems or the environment. These strategies form the basis of recommendations for farmers to use the prescribed technology in conjunction with the recommendations of regulators such as the Office of the Gene Technology Regulator and the Australian Pesticides and Veterinary Medicines Authority.

*CISP* – The Gene Technology Grains Committee developed the Canola Industry Stewardship Principles to ensure different canola production systems and supply chains co-exist. The Principles are science-based and represent best practice management in the grains industry. The Principles are designed for use as a reference at appropriate points along the supply chain – from the supply of seed to the end use of the resulting grain products (e.g. in foods and feeds).

*Graincare* – an on-farm code of practice that has been developed by the Grains Council of Australia to provide a simple, cost effective quality assurance program for growers. The four management sections of the Code include training, internal audit and corrective action, quality records and document control.

*Great Grain* – the Great Grain Program is an on-farm quality assurance program that has been developed by Quality Wheat CRC, Pulse Australia and the Australian Oilseeds Federation to provide a coordinated approach to the implementation of on-farm quality management practices in the grains industry. It has been specifically designed to cater for identity preservation and segregated markets as well as addressing food safety, quality to the customer and legislative requirements.

*SQF 2000CM* – developed by the Western Australian Department of Agriculture in 1994 to increase the marketability and market access of WA produce. The system provides the tools for enterprises to demonstrate compliance with food safety standards and customer quality requirements. It has been widely adopted in Australia and overseas.

*SQF 1000CM* – developed by the Western Australian Department of Agriculture in 2000 following the success of SQF 2000CM and in response to demand for a less complex approach to food safety and quality. It is designed for use by primary producers that do not supply products directly to the consumer but rather to a packing shed or for further processing.

*Australian Oilseeds Federation Codes of Practice* – developed to standardise hygiene, cleaning procedures and minimise contamination of product.

*HACCP* – Hazard Analysis Critical Control Point is a system that identifies, evaluates and controls hazards which are significant to food safety. It is widely used throughout Australian agribusiness to address quality issues.

*ISO 9001:2000 Quality Management System* – widely recognised as the original reference standard for quality systems. The Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of quality management systems to enhance customer satisfaction by meeting customer requirements.

*Technology developers* – Monsanto and Bayer have developed stewardship programs and specific on-farm crop management plans to support the effective integration of GM canola varieties into farming systems and their sustainable use. These systems include contracts and audit/compliance provisions (including financial incentives). The Regulator, by imposing licence conditions, may also enforce aspects of the crop management plans.