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 PC1
NLRD	minimal	No, dealings must be approved by IBC; OGTR notified	Yes PC2 (usually)
DNIR	≥ minimal	Yes, dealings must be approved by IBC; RARMP prepared, licence decision by the Regulator	Yes ≥ 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.

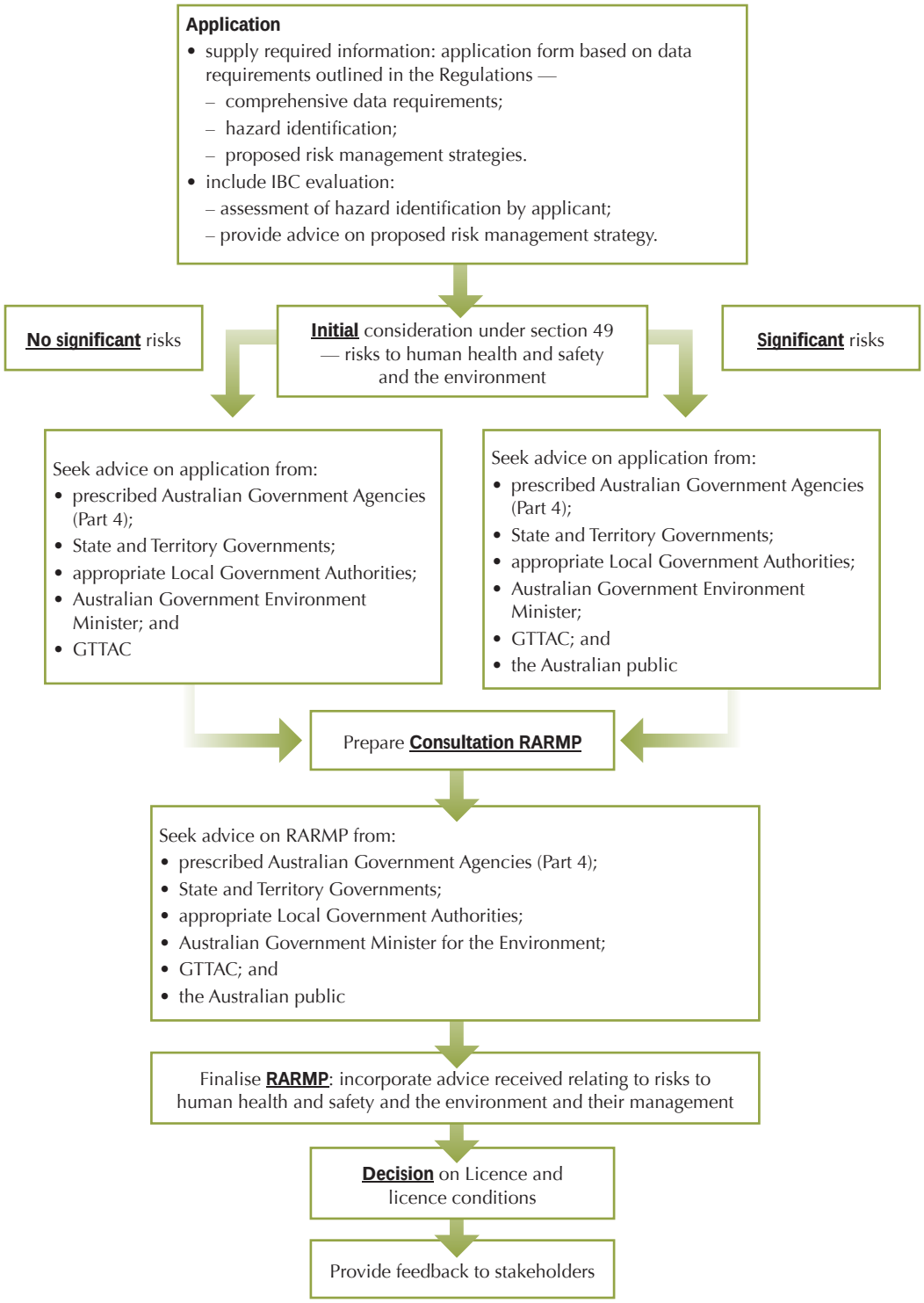
The risk management plan evaluates which of the risks to human health and safety and the environment posed by the dealing with the GMO require management, and considers how they may be able to be managed. This provides the basis for conditions that may be applied to the licence and draft conditions are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

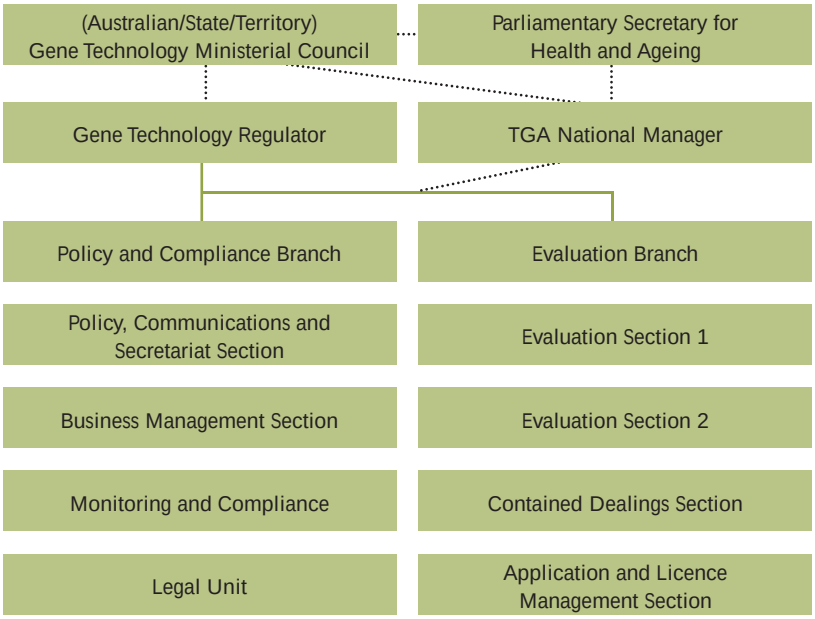
Since the *Gene Technology Act 2000* came into effect in June 2001 up until 29 March 2005, the Regulator has:

- 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	
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. • Competent authorities acknowledge the receipt of the notification. • The competent authorities then examine the conformity of the notification with the Directive. • 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. • The competent authority may modify, suspend or terminate the contained use if significant consequences may arise from risks posed.

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. • 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. • 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).

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. • 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. • The decision to reject or accept the application rests solely with the competent national authority and therefore is a national procedure. • The competent national authority approves the application if it considers that it complies with the Directive 2001/18/EC. • 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.

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. • 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. • The national authority issues an opinion in the form of an assessment report once the notification is received.

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. • In the event of issuing a favourable report, the member state informs other member states through the European Commission. • Member states examine the report and issue observations or objections. • If there are no objections, the member state that issued the assessment report authorises that the GMO be placed on the market. • When objections are raised a conciliation phase is entered so that issues can be resolved. • If objections still exist at the end of conciliation, the European Commission takes a decision by consulting the European Food Safety Authority. • A draft decision is then presented to the regulatory committee (composed of representative from member states). • If the committee gives a favourable opinion the Commission takes the decision. • If the committee's opinion is unfavourable, the report is referred to the Council of Ministers where a decision by majority is taken. • If the Council of Ministers does not act within three months, the decision is taken. • 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.

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. 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. • 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). • The application is sent to a competent authority in the member state. • The application is acknowledged in writing in 14 days.

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). • EFSA then informs other member states, the European Commission and makes the information in the application available to the public. • 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. • EFSA will give its opinion on the application within six months of receiving a completed application (excluding time required to provide additional information). • 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. • EFSA consults with the competent national authority of the member state and the competent authority has three months to make its own opinion known. • If the opinion is in favour of authorisation, conditions and restrictions in relation to marketing, monitoring or protection of environment/ecosystems may be made. • EFSA gives its opinion to the European Commission. • 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. • The European Commission informs the applicant of the decision made without delay. • 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.

Consideration of ethical issues	• This must form part of the application. • 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. • The application, supplementary information, opinions from competent authorities and monitoring reports are required to be made public. • 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. • Authorisations are valid for 10 years, subject to renewal. • 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. • 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.

Procedure for transborder movement of GMOs	**GMOs intended for deliberate release into the environment** • 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. • 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. • A decision to grant permission for transborder movement of GMOs is based on a risk assessment. • 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. **GMOs intended for direct use as food/feed** • 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. • The exporter shall respect the decisions taken by a Party on the import of GMOs. **Unintended movement of GMOs** • 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.

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.

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. • 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. • 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. • 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	
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. • 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	
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	
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). • 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: – any significant displacement of any native species within its natural habitat; – any significant deterioration of natural habitats; – any significant adverse effects on human health and safety; – any significant adverse effect to New Zealand's inherent genetic diversity; or – disease, be parasitic or become a vector for human, animal or plant disease, unless that is the purpose of the application.

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. • 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: – inform the Minister for the Environment and any government department or crown entity that is likely to express an interest in the application; – 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; – 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);

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; • Consider the following principles: – safeguarding the life supporting capacity of air, water and ecosystems; and – 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; • Consider: – the sustainability of all flora and fauna; – the intrinsic value of ecosystems; – public health; – the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga; – economic and related benefits and costs of using a particular new organism; and – New Zealand's international obligations. For applications to release a new organisms to the environment, the Authority must decline an application, if the new organism is likely to: – cause any significant displacement of any native species within its natural habitat; or – cause any significant deterioration of natural habitats; or – cause any significant adverse effects on human health and safety; or – cause any significant adverse effect to New Zealand's inherent genetic diversity; or – 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. (For the purposes of conditional release, see above note on assessment process for intentional releases.)

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. • 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.

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. • 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. • 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. • Controls may be imposed on conditional release, field test and other containment approvals in relation to GMOs.

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. • 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). • Similar penalties for offences such as failing to comply with any controls in relation to an approval. • 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	
Liability for contamination	• The HSNO Act provides for: – 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. – 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). • 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. • 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

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. • 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. • 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. • 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.

For contained work with GMOs	
Responsible agency	• Science and Research Agency — for experimentation in all research facilities other than University research facilities. • 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'. • The system is based on administrative guidance with no underpinning legislation.

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. • 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. • 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. • 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.

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. • 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.