

State, Territory and Australian
Governments’
Response to the
Recommendations of the
Statutory Review of the
Gene Technology Act 2000
and the
Gene Technology Agreement 2001
2006

ISBN

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List of Acronyms and Abbreviations

AAT	Administrative Appeals Tribunal
Act	<i>Gene Technology Act 2000</i>
ANAO	Australian National Audit Office
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
CCI	Confidential Commercial Information
DIR	Dealing involving intentional release
DNIR	Dealing not involving intentional release
GM	Genetically modified
GMO(s)	Genetically Modified Organism(s)
GTA	Gene Technology Agreement (citation for the Inter-governmental Agreement on Gene Technology 2001 – also referred to the Inter-governmental Agreement; IGA)
GTCCC	Gene Technology Community Consultative Committee
GTEC	Gene Technology Ethics Committee
GTECCC	Gene Technology Ethics and Community Consultative Committee
GTMC	Gene Technology Ministerial Council
GTRAP	Gene and Related Therapies Advisory Panel
GTTAC	Gene Technology Technical Advisory Committee
IBC	Institutional Biosafety Committee
NHMRC	National Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NLRD	Notifiable Low Risk Dealing
OH&S	Occupational health and safety
Other regulatory agencies	Commonwealth agencies involved in regulating products (FSANZ, AQIS, NICNAS, APVMA, TGA)
OGTR	Office of the Gene Technology Regulator
OECD	Organisation for Economic Co-operation and Development
PC1-4	Physical containment levels 1-4 (PC4 provides the greatest degree of containment)
Prescribed agencies	Agencies that must be consulted by the Regulator when developing a RARMP (FSANZ, AQIS, NHMRC, NICNAS, APVMA, TGA)
RARMP	Risk assessment and risk management plan
Regulations	<i>Gene Technology Regulations 2001</i>
States	Australian States and Territories
Regulator	Gene Technology Regulator
Review	<i>Gene Technology Act 2000 and Gene Technology Agreement 2001 Review Panel</i>
TGA	Therapeutic Goods Administration
ToR	Term of reference

Foreword

The *Gene Technology Act 2000* is the Commonwealth's component of the nationally consistent regulatory scheme for gene technology in Australia. Its object is to protect the health and safety of people, and to protect the environment, by identifying risks posed or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms. The *Gene Technology Agreement 2001* provides a national gene technology regulation scheme.

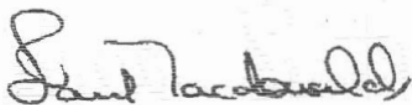
The Statutory Review of the *Gene Technology Act 2000* and the *Gene Technology Agreement 2001* (the Review) was conducted in 2005 and found that the Act and the national regulatory scheme have worked well over the past five years, and no major changes are required. The review panel recommended a number of changes intended to improve the operation of the Act at the margin.

The report on the Review was tabled in the Australian Parliament by the Hon. Christopher Pyne MP, Parliamentary Secretary to the Minister for Health and Ageing on 27 April 2006. The Gene Technology Ministerial Council (GTMC), comprising Australian, State and Territory representatives responsible for gene technology regulation, approved work to amend the legislation at their meeting on 27 April 2006.

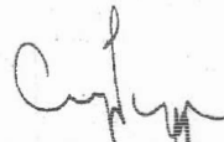
The majority of the recommendations have been agreed and the exceptions dealt with in the body of the response. The response, including some minor variations to facilitate the implementation of the recommendations, was prepared in consultations with State and Territory government officials through the Gene Technology Standing Committee Working Group and was approved by the GTMC at their meeting on 27 October 2006.

Implementation of the recommendations will provide an efficient and effective regulatory system for the application of gene technologies. This will ensure that the regulatory burden is commensurate with the risks and is based on a scientific assessment of risks undertaken by an independent Regulator.

The Australian Government intends to introduce the Gene Technology Legislation Amendment Bill into the Australian Parliament as soon as possible. States and Territories will use their best endeavours to introduce corresponding amending legislation into their Parliaments before 31 December 2007.



The Hon Ian Macdonald MLC
Chair
Gene Technology Ministerial Council
2 November 2006



Hon. Christopher Pyne MP
Parliamentary Secretary to the
Minister for Health and Ageing
14 November 2006

Acknowledgements

The State, Territory and Australian Governments' Response to the Recommendations of the Statutory Review of the *Gene Technology Act 2000* ('the Act') and the *Gene Technology Agreement 2001* ('the GTA') has been collaboratively prepared by the Australian, State and Territory Governments.

This work is a response to the recommendations made in the high quality review that was produced by the The *Gene Technology Act 2000* and *Gene Technology Agreement 2001* Review Panel

The Australian, State and Territory Governments acknowledge the Gene Technology Standing Committee and its working group, the Gene Technology Standing Committee Working Group, in providing input and shaping the drafting of the Governments' Response.

State, Territory and Australian Governments' Response to the Recommendations of the Statutory Review of the Gene Technology Act 2000 and Gene Technology Agreement 2001

Scope of the Act (Review Term of Reference 1)

1. *Review the scope of the Act to determine whether the policy objectives remain valid; and consider other issues, technologies or organisms that may be included in the scope of the Act, including:*
 - a) *consideration of economic, marketing and trade, cultural and social impacts, and re-examine how ethical issues are considered.*
 - b) *the definitions in the Act, including of the environment, and the need for the definition of other terms, including health.*
 - c) *consideration of the technologies and organisms covered by the Act.*
 - d) *consideration of a trait based or novel organism based regulatory scope.*

Recommendation 3.1:

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

Governments' response:

All governments agree to recommendation 3.1.

No legislative changes are needed to implement this recommendation.

The Review considered whether marketing and trade issues should be considered in assessing a genetically modified organism (GMO), but found no compelling case for inclusion of these factors. No relevant operational examples, including the assessment of market and economic impacts, were received during consultations.

Recommendation 3.2:

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

Governments' response:

All governments agree in-principle to recommendation 3.2.

No legislative amendments are needed to implement this recommendation.

The Review noted that a number of submissions suggested adopting a wider definition of ‘environment’, as described in the *Environment Protection and Biodiversity Conservation Act 1999*. This would require the Gene Technology Regulator (the Regulator) to have regard to economic, social and cultural impacts of GMOs.

Governments agree that given the scope of the *Gene Technology Act 2000*, the Act should not be widened (see recommendation 3.1), and the definition of ‘environment’ should not be changed.

While governments agree with the policy intention underpinning the definition of what it is to ‘deal with’ a GMO, governments have agreed to a technical amendment to the definition (see recommendation 4.4).

Act Achieving Objects (Review Term of Reference 2)

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

Recommendation 4.1:

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

Governments' response:

All governments agree in-principle to recommendation 4.1.

No legislative changes are needed to implement this recommendation.

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

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

- provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation;
- provides an efficient and effective system for the application of gene technologies; and
- operates in conjunction with other Australian and State and Territory regulatory schemes relevant to GMOs and genetically modified (GM) products.

In assessing whether the object of the Act was being achieved, the Review also considered:

- the introduction of strict liability for contamination;
- establishment of a compensation fund;
- mandatory insurance for GMOs;
- third party appeals.

The Review concluded that specific provisions should not be introduced on strict liability, compensation funds, mandatory insurance and third party appeals.

The Review recommended a number of changes intended to improve the operation of the Act, at the margin, to which governments agree or agree in principle subject to minor variations to facilitate implementation.

Governments considered that more work could be done to enhance public understanding of the objects of the nationally consistent scheme for gene technology. Governments considered that enhancing public understanding is an issue on which the new Gene Technology Ethics and Community Consultative Committee (proposed in recommendation 5.2) could provide advice on the request of the Regulator or the GTMC.

Recommendation 4.2:

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

Governments' response:

All governments agree to recommendation 4.2.

The Australian Government intends to introduce legislation in relation to this recommendation. The provisions would enable the Minister responsible for the Act to issue a special licence following advice from the Chief Medical Officer, the Chief Veterinary Officer and/or Chief Plant Protection Officer that there is an emergency; and on advice from the Regulator and in consultation with the States. The Minister must not issue the licence unless the Regulator is satisfied that any risks posed by the dealings proposed by the licence are able to be managed. Consequential changes would also be made to the GTA.

An emergency is when there is an actual or imminent threat to the health and safety of people or to the environment. The licence would be in relation to an activity for a GMO which is intended to address the threat; including activities to minimise or eradicate the problem organism, its vectors, or to convey immunity in humans and/or animals.

Guidelines will be prepared, for approval by the GTMC, to ensure that this provision operates in parallel with relevant regulatory schemes.

Other regulatory systems contain provisions for the relevant minister to issue emergency licences, for example, the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Therapeutic Goods Administration (TGA), and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). This provision would improve consistency between regulatory schemes.

Recommendation 4.3:

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

Governments' response:

All governments agree to recommendation 4.3.

No legislative amendments are required to implement this recommendation.

There is currently no international consensus on data sets. The Regulator is participating in the Organisation for Economic Co-operation and Development (OECD) Working Group on Harmonisation in Regulatory Oversight of Biotechnology. This Working Group reports to the OECD Chemical Committee and the Working Party on Chemical, Pesticides and Biotechnology, and its papers are published by the OECD's Environment, Health and Safety Division. The Working Group has developed and made publicly available Consensus Documents, which summarise current information for use during the regulatory assessment of biotechnology products. The information is compiled and assessed on a species and trait basis. The aim of the documents is to allow information sharing on the key components of an environmental safety review to prevent any duplication of assessment efforts among countries. The Office of the Gene Technology Regulator (OGTR) has contributed actively to the development of these documents.

Recommendation 4.4:

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

Governments' response:

All governments agree to recommendation 4.4.

The Australian Government intends to introduce legislation to implement this recommendation.

The Regulator suggested some minor amendments to the Act that would improve the workability of the Act, but would not change its policy intention. The amendments are listed in Appendix 1.

Operation of the Act (Review Terms of Reference 3, 4, & 5)

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

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

Recommendation 5.1:

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

Governments' response:

All governments agree to recommendation 5.1.

No legislative changes are required to implement this recommendation.

This recommendation is already covered by the Act. Some of the current Gene Technology Technical Advisory Committee (GTTAC) members were appointed on the basis that they have expertise in public health environmental risk assessment. The areas of expertise in the Act do not align precisely with scientific disciplines and consequently, all the current members have nominated against multiple areas in the list of expertise. However, they have not identified public health or environmental risk assessment as their primary expertise. All GTTAC members were selected for appointment through a process that included a working group of State and Territory officials.

The Act requires that a Committee member must have skills or expertise in one or more of 19 specified areas (subsection 100(5)). However, appointments in each specific discipline are not required. GTTAC has a maximum membership of 20 and there are

currently 20 members. The Act provides that “the Minister must ensure, as far as practicable, that among members as a whole, there is a broad range of skills and experience in the areas mentioned in subsection 100(5)”.

Any need for specific additional public health or environmental risk assessment expertise in the current GTTAC could be addressed by the appointment of an ‘expert adviser’, in addition to the current membership (section 102).

Recommendation 5.2:

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

Governments’ response:

All governments agree to recommendation 5.2.

The Australian Government intends to introduce legislation to combine the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC) into one advisory committee, with the combined functions of the two committees. Consequential changes would also be made to the Act.

There is considerable overlap between the roles of the GTEC and GTCCC. The new committee would allow relevant skills to be distributed across its membership so that the committee is able to provide clear, balanced, appropriate and more coordinated advice.

The proposed name of the new, combined committee is the Gene Technology Ethics and Community Consultative Committee (GTECCC).

The GTMC will review the performance of this new advisory committee after 18 months, but before it has been operating for two years.

Recommendation 5.3:

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

Governments’ response:

All governments agree to recommendation 5.3.

The Australian Government intends to introduce legislation to implement this recommendation so that the functions of the new single statutory committee will include advice on community consultation and risk communication for commercial licence applications for dealing involving release (DIR). Consequential changes would also be made to the GTA.

The governments do not propose to mandate examination of each DIR commercial licence application. However, the Regulator may ask for advice in relation to particular types of releases that might be precipitated by such an application.

The Review highlighted community consultation and risk communication for commercial release licence applications as important issues raised during consultations.

The new GTECCC will be able to provide general advice on community consultation and/or risk communication issues that arise from applications for a licence submitted to the OGTR (but not on the specific applications themselves), as mentioned in the response to recommendation 4.1.

Recommendation 5.4:

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

Governments' response:

All governments agree to recommendation 5.4.

The Australian Government intends to amend the *Gene Technology Regulations 2001* (the Regulations) to implement this recommendation.

The National Health and Medical Research Council's (NHMRC) inclusion as a prescribed agency reflected provisions in the Act (former sections 192B-D) to ban cloning of human beings and some work with embryos, which were repealed when the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* came into force.

However, advice in relation to gene therapy (the most likely area for overlap of responsibility between the NHMRC and the Regulator) will still be available through cross membership between GTTAC and the NHMRC's Gene and Related Therapies Advisory Panel.

Recommendation 5.5:

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

- *Require the Regulator to identify whether or not the GMO poses a significant risk to the health and safety of people or the environment as part of the preparation of the RARMP;*
- *Where the Regulator gives notice of a decision that a GMO may pose a significant risk that a second round of public consultation be required on any amendments that the Regulator makes to the RARMP after the initial round of public consultation currently required under section 52. This additional consultation period should be 20 working days.*

Governments' response:

All governments note recommendation 5.5.

The Australian Government intends to introduce legislation in relation to this recommendation. The provisions would repeal the requirement for the Regulator to assess whether a proposed dealing may pose a significant risk before developing and consulting on a risk assessment and risk management plan (RARMP) (section 49). It would add a new requirement that if the Regulator is satisfied that one or more of the dealings proposed to be authorised by the licence may pose significant risks to the health and safety of people or to the environment, the public notification of the RARMP makes a statement to that effect, and the minimum period for public submissions on the RARMP is extended by an additional 20 days to 50 days.

A diagram of timeframes for applications is at Appendix 2.

The Review recommended that a second round of public consultation, including submissions, should then take place after the Regulator has reviewed the RARMP following the initial round of public consultation.

Governments agreed that it was preferable to extend the consultation period rather than invoke two shorter consultations. The Regulator's decision-making process, in circumstances where there is substantive amendment to the RARMP, would allow for appropriate community involvement. For example, local council meetings and policy approval arrangements often operate on a monthly cycle. A 50-day period allows a substantive issue to be considered within a council's ordinary business cycle.

Recommendation 5.6:

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

Governments' response:

All governments agree to recommendation 5.6.

The Australian Government intends to introduce legislation in relation to this recommendation. The provision would define an application as a field trial application where the Regulator is satisfied that the principal purpose is to carry out experiments and that the applicant has proposed controls to restrict dissemination, persistence and release of the GMO and its genetic material (that is, that the GMO is contained and controlled within the trial site). The provision would also provide that the requirements to seek advice from the existing range of bodies (which include the States, the GTTAC, prescribed agencies, the Environment Minister and any local council that the Regulator considers appropriate) on the preparation of the RARMP apply only to commercial releases and not to field trial applications.

Governments consider that applications should not be assessed against arbitrary criteria to determine whether applications are for commercial releases or field trials. This would be determined by the Regulator based on the primary purpose of the application.

In considering how to split the current DIR category, governments noted that there should be broadly two types of releases. The purpose of one type of release is for commercial production of the GMO, the proponent thus wishing to use the GMO with as few restrictions as possible. These types of releases have been called 'commercial releases' and would need a wider range of environmental and ecological settings to be considered in any risk assessment.

The purpose of the other type of release is not commercial but to gain experimental data needed for the commercial release, including any data needed for regulatory purposes. For example, the Regulator may impose research conditions on releases that are limited and controlled to address uncertainty that would otherwise prevent larger scale releases of the GMO. These releases are proposed to be called field trials (to be called 'limited and controlled releases' in the legislation) and require less comprehensive assessments because they are limited in terms of time, spatial scale and location and have containment measures to restrict dissemination.

Governments note that the splitting of limited and controlled releases and commercial releases allows appropriate timeframes to be set for field trials and commercial releases. Governments' responses on the recommended timeframes are outlined under recommendation 5.7 and 5.8.

The different timeframes for each category reflect the different intensity of the evaluations to assess the health and safety of people and the environment, which is dependent on the features of the two types of releases.

Recommendation 5.7:

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

Governments' response:

All governments agree in-principle to recommendation 5.7.

The Australian Government intends to amend the Regulations to implement this recommendation, subject to the Australian Parliament passing legislation to split the DIR category to distinguish between field trial and commercial release licences.

A diagram of timeframes for applications is at Appendix 2.

These maximum timeframes may be reviewed in light of experience in their implementation, in accordance with the ongoing review functions of the GTMC and the Regulator. The timeframes are specified by regulation.

The Review considered that this will result in important efficiency gains for industry as the bulk of the DIR applications are for field trials.

Recommendation 5.8:

The Review recommends that the statutory timeframe for commercial DIR licences be extended to 255 working days (this is consistent with other relevant regulatory systems) to ensure that the Regulator has adequate time for assessment and public consultation.

Governments' response:

All governments except Queensland agree in-principle to recommendation 5.8.

The Australian Government intends to amend the Regulations to implement this recommendation, subject to the Australian Parliament passing legislation to split the DIR category to distinguish between field trial and commercial release licences.

A diagram setting out timeframes for applications is at Appendix 2.

These maximum timeframes may be reviewed in light of experience in their implementation, in accordance with the ongoing review functions of the GTMC and the Regulator. The timeframes are specified by regulation.

Recommendation 5.9:

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

Governments' response:

All governments except Queensland agree in-principle to recommendation 5.9.

The Australian Government intends to introduce legislation to implement the recommendation for variations to licences with specified restrictions. Subject to the Australian Parliament passing such legislation, the Australian Government also intends to amend the Regulations to provide for a 90-day timeframe for variations.

Governments consider that in addition to an explicit power to allow a licence-holder to apply for a variation, restrictions on a variation should be that:

- a variation cannot turn a dealing not involving intentional release (DNIR) into a DIR;
- a variation cannot turn a field trial into a commercial release;
- the variation must be able to be assessed under the original RARMP;
- for a variation involving a new location of a field trial it can only be approved where the Regulator is satisfied that appropriate local councils have been consulted; and
- the Act should permit the regulations to prescribe other limitations.

Recommendation 5.10:

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

Governments' response:

All governments agree to recommendation 5.10.

The Australian Government intends to introduce legislation to implement this recommendation.

The Regulator was concerned that there is ambiguity about whether directions to comply with the Act or Regulations are applicable if there is not an immediate risk to health and safety of people or the environment.

Governments agree that the criteria the Regulator may have regard to, in deciding what directions are reasonable in the circumstances, should be drawn from the Regulator's May 2002 *Non-compliance Protocol*.

Recommendation 5.11:

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

Governments' response:

All governments agree to recommendation 5.11.

The Australian Government intends to introduce legislation to implement this recommendation.

The Regulator can use offence provisions or injunctions to deal with unapproved dealings with a GMO. However, these tools are not suited to a case where a person wishes to act cooperatively and to dispose of the GMO in accordance with the Regulator's requirements to protect health and safety of people and the environment.

Governments consider that except for provisions relating to initial consideration of and decision on licence (Divisions 3 and 4 of Part 5 and subsection 56(2)) of the Act, other provisions in the Act should continue to apply. For example, the licence may contain conditions, including the period of licence.

Regulatory Burden (Review Terms of Reference 6 & 7)

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

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

Recommendation 6.1:

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

Governments' response:

All governments agree to recommendation 6.1.

The Australian Government intends to amend the Regulations to implement this recommendation.

Research organisations stated to the Review that the current obligations in relation to exempt dealings represented an excessive administrative burden, given that this category of dealings poses negligible risks to people or the environment. The Review heard from GTTAC that exempt dealings do not need to be conducted in physical containment (PC) 1 facilities.

The Regulator intends to review the current list of exempt dealings to ensure there are none that require reclassification, in accordance with the ongoing review functions of the Regulator and the GTMC. The criteria used to assess any dealing subsequently included in the exempt category would be explained in the Explanatory Statement to any amending Regulations which listed that dealing.

Exempt dealings are those which:

- a) are listed in the Regulations (Schedule 2);
- b) do not involve genetic modification (other than a modification described in Schedule 2);
- c) do not involve an intentional release of the GMO into the environment.

The current requirement, that exempt dealings are conducted in PC1 facilities, would be removed.

A table outlining how the recommended arrangements compare with the current arrangements is at Appendix 3.

Recommendation 6.2:

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

Governments' response:

All governments agree to recommendation 6.2.

The Australian Government intends to amend the Regulations to implement this recommendation.

The Review heard that Notifiable Low Risk Dealing (NLRD) activities did not warrant the current regulatory burden. Currently, NLRDs must be conducted in facilities of the appropriate containment level under appropriate supervision. The adoption of the proposed recommendation will reduce the regulatory burden for NLRDs.

A table outlining how the recommended arrangements compare with the current arrangements is at Appendix 3.

Recommendation 6.3:

The Review recommends that the OGTR certification guidelines and the AQIS [Australian Quarantine Inspection Service] guidelines be harmonised as far as possible and that the OGTR and AQIS establish a system of single audits to meet the needs of both organisations as soon as practicable.

Governments' response:

All governments agree to recommendation 6.3.

No legislative amendments are required to implement this recommendation.

Work involving GMOs must be conducted in facilities certified for the purpose by the Regulator. The certification of facilities concerns the level of physical containment (PC) required by the facilities (categorised by the Regulator from PC1 to PC4; simplest level of PC to most sophisticated).

Certification for PC2 facilities remains an area causing difficulty and confusion for accredited organisations. Specific issues relate to the consistency of the requirements imposed by the Regulator, Australian Quarantine Inspection Service (AQIS) and the relevant Australian Standard and State occupational health and safety legislation.

The Review noted that the OGTR and AQIS requirements were addressing different risks, but believed there was scope for greater harmonisation. The Review therefore recommended that the OGTR and AQIS certification guidelines be harmonised as far as possible.

Governments note that the Regulator proposes to report to the GTMC on the implementation of this recommendation.

Recommendation 6.4:

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

Governments' response:

All governments agree to recommendation 6.4.

No legislative amendments are required to implement this recommendation.

The Review noted that the OGTR has already started work to review progressively the certification guidelines for all containment levels and facility types to ensure that they are outcome focussed.

Governments note that the Regulator proposes to report to the GTMC on the implementation of this recommendation.

Recommendation 6.5:

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

Governments' response:

All governments agree to recommendation 6.5.

No legislative amendments are required to implement this recommendation.

The OGTR is addressing these issues as part of its response to recommendations of the Australian National Audit Office (ANAO) Audit Report *Regulation by the OGTR* (No.7 2005–06).

Governments note that the Regulator proposes to report to the GTMC on the implementation of this recommendation.

Recommendation 6.6:

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

Governments' response:

All governments agree to recommendation 6.6.

No legislative amendments are required to implement this recommendation.

This recommendation is consistent with recommendation 6.1 on exempt dealings in removing administrative burden.

Governments note that the Regulator proposes to report to the GTMC on the implementation of this recommendation.

Interface with Other Systems (Review Terms of Reference 8 & 9)

8. *Examine the nationally consistent scheme for gene technology regulation in Australia and identify any need for, and ways to achieve, improvements in its consistency, efficiency and coordination.*

9. *Examine the interface between the Act and other Acts and schemes (either Australian Government or State and Territory) that regulate gene technology and gene technology products. Identify any discrepancies including regulatory gaps and areas needing consistency and harmonisation of provisions*

Note: recommendations in relation to harmonisation between AQIS and OGTR are dealt with under the section “regulatory burden”.

Recommendation 7.1:

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

Governments’ response:

All governments agree to recommendation 7.1.

No legislative amendments are required to implement this recommendation.

The Regulator has Memoranda of Understanding in place with the other regulatory agencies which have statutory responsibilities relevant to the regulation of GMOs and GM products across all Australian jurisdictions (including, APVMA, AQIS, NHMRC, NICNAS, TGA, and Food Standards Australia New Zealand).

The Regulator will make arrangements to formalise the information exchange forums that are already in place.

Governments note that the Regulator proposes to report to the GTMC on the implementation of this recommendation.

Recommendation 7.2:

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

Governments' response:

All governments agree to recommendation 7.2.

No legislative amendments are required to implement this recommendation.

The Regulator is represented on the Standards Australia committee (AS/NZS 2243: Safety in Laboratories).

Changing Circumstances (Review Term of Reference 10)

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

Recommendation 8.1:

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

Governments' response:

All governments agree to recommendation 8.1.

No legislative amendments are required to implement of this recommendation.

The GTMC will determine a mechanism for the review of the Act.

The GTMC and the Regulator currently have ongoing review functions. The GTMC must oversee generally the implementation of the scheme and consider and, if thought fit, agree on proposed changes to the scheme (paragraphs 16(e) and (f)) of the GTA. The Regulator's functions include providing advice to the GTMC about the effectiveness of the legislative framework for the regulation of GMOs, including in relation to possible amendments of relevant legislation (paragraph 27(g)(ii)) of the Act.

IGA Achieving its Aims (Review Term of Reference 12)

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

Recommendation 9.1:

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

Governments' response:

No legislative amendments are required to implement recommendation 9.1.

Governments noted that the recommendation constitutes two separate elements:

- All governments reconfirm their commitment to a nationally consistent scheme for gene technology.
- Queensland, Tasmania, Western Australia and South Australia do not agree to a nationally consistent transparent approach to market considerations.

The GTMC agreed in April 2006 to refer the issue of market considerations to the Primary Industries Ministerial Council for consideration and advice by the end of 2007. This issue is also raised under recommendation 9.2.

Recommendation 9.2:

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

Governments' response:

All governments except Tasmania and Western Australia agree to recommendation 9.2.

No legislative amendments are required to implement this recommendation.

The GTMC agreed on 27 April 2006 to refer this issue to the Primary Industries Ministerial Council for consideration and advice, by the end of 2007, on a consistent and transparent framework for co-existence of both non-GM and GM crops which can be assessed for adoption by the States, who wish to do so, as each jurisdictions' moratorium ends or is reviewed.

Recommendation 9.3:

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

Governments' response:

All governments agree to recommendation 9.3.

No legislative amendments are required to implement this recommendation.

The GTA will be amended to implement this recommendation.

The Review found that the Act provides the flexibility to change the definition of a GMO through declaring that an organism is, or is not, a GMO. The Review also found that this flexibility will enable the regulatory scheme to keep pace with emerging trends. However, the requirement for regulations to be approved by the GTMC could inhibit the expeditious making of regulations to bring an organism under the scope of the Act.

The key element of this provision is that an emergency occurs where there is an actual or imminent threat to health and safety of people or the environment.

Governments noted that, in accordance with standard practice set out in the section 27(g)(ii) of the Act, the Regulator would provide advice on the making of such a regulation.

Guidelines will be prepared, for approval by the GTMC, to ensure that this provision operates in parallel with relevant regulatory schemes.

Appendix 1

TECHNICAL AND OTHER AMENDMENTS

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 [Institutional Biosafety Committee]

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.

Section 182 - 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 appealable 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.

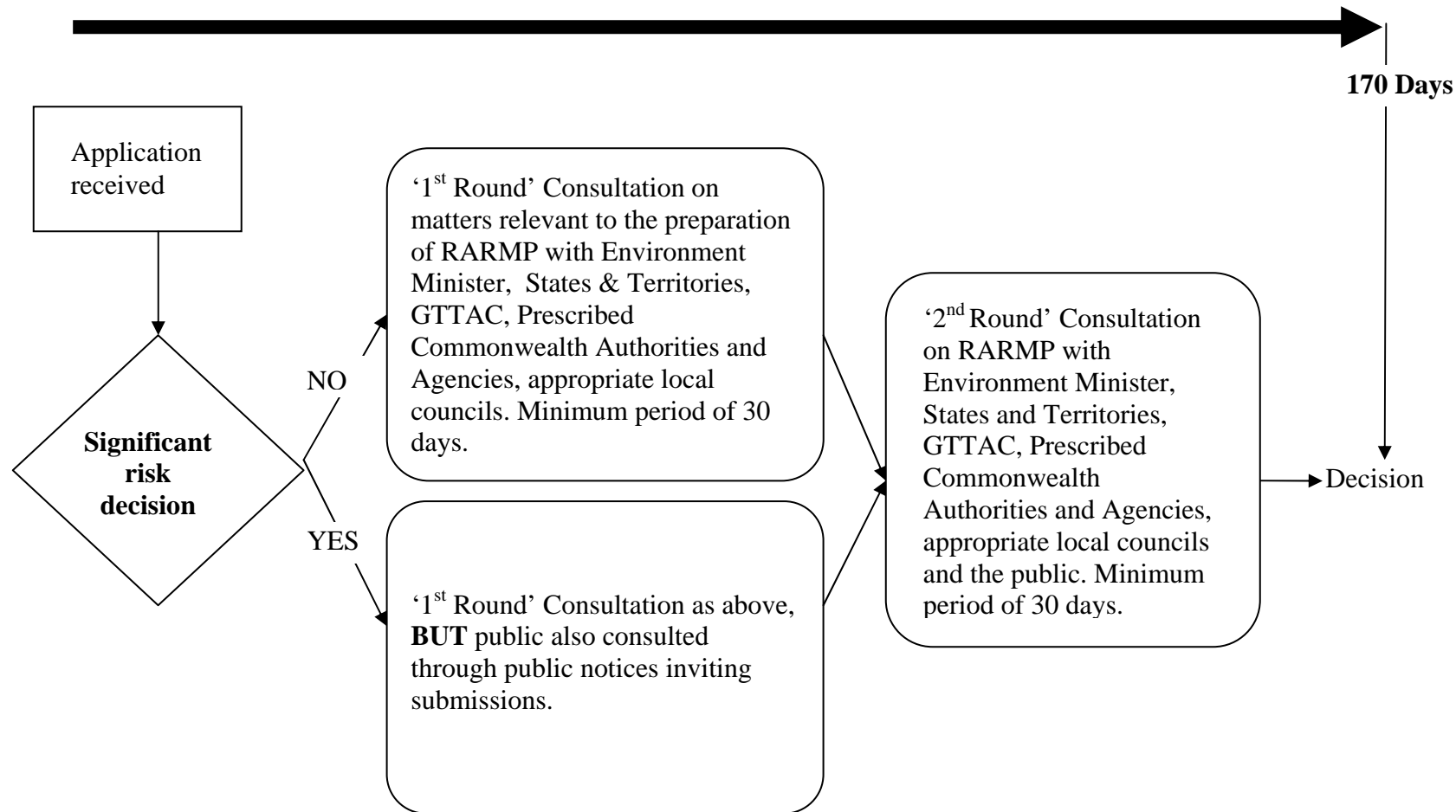
It is recommended that the definition be amended, as follows:

'Confidential commercial information' means:

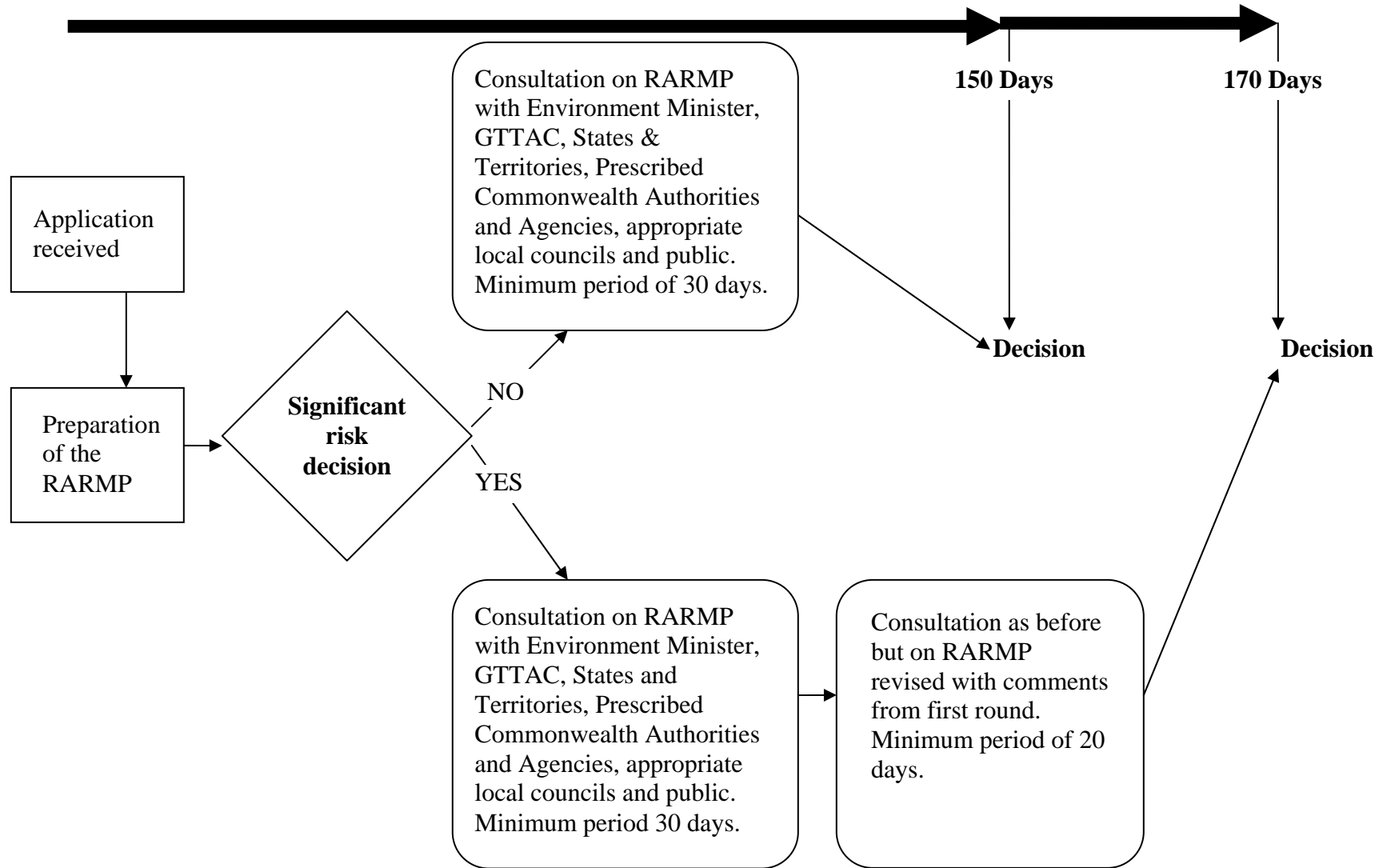
(a) information declared by the Regulator to be confidential commercial information under section 185; and/or,

(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.

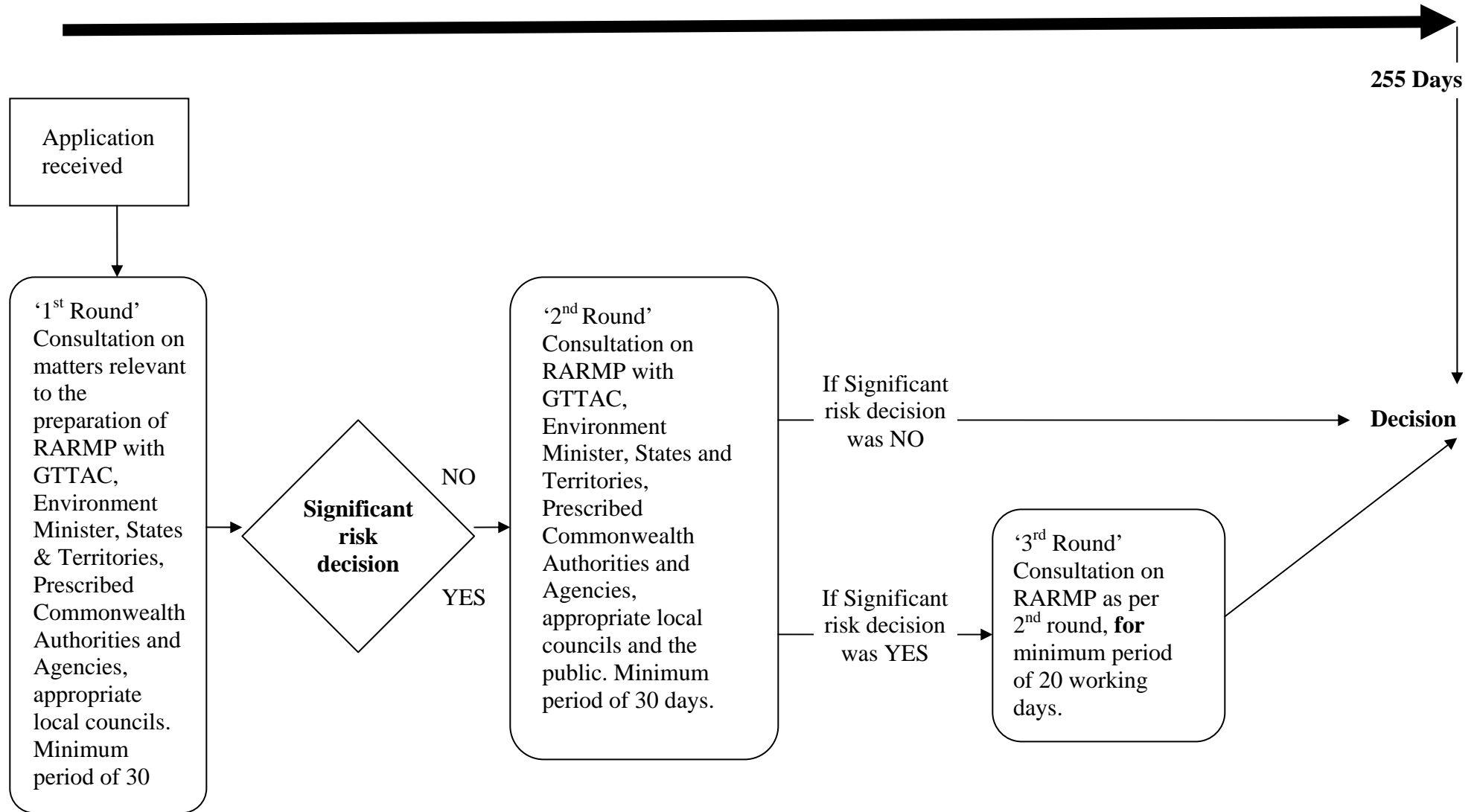
Current evaluation process for DIRs (covers 'field trials' and 'commercial releases')



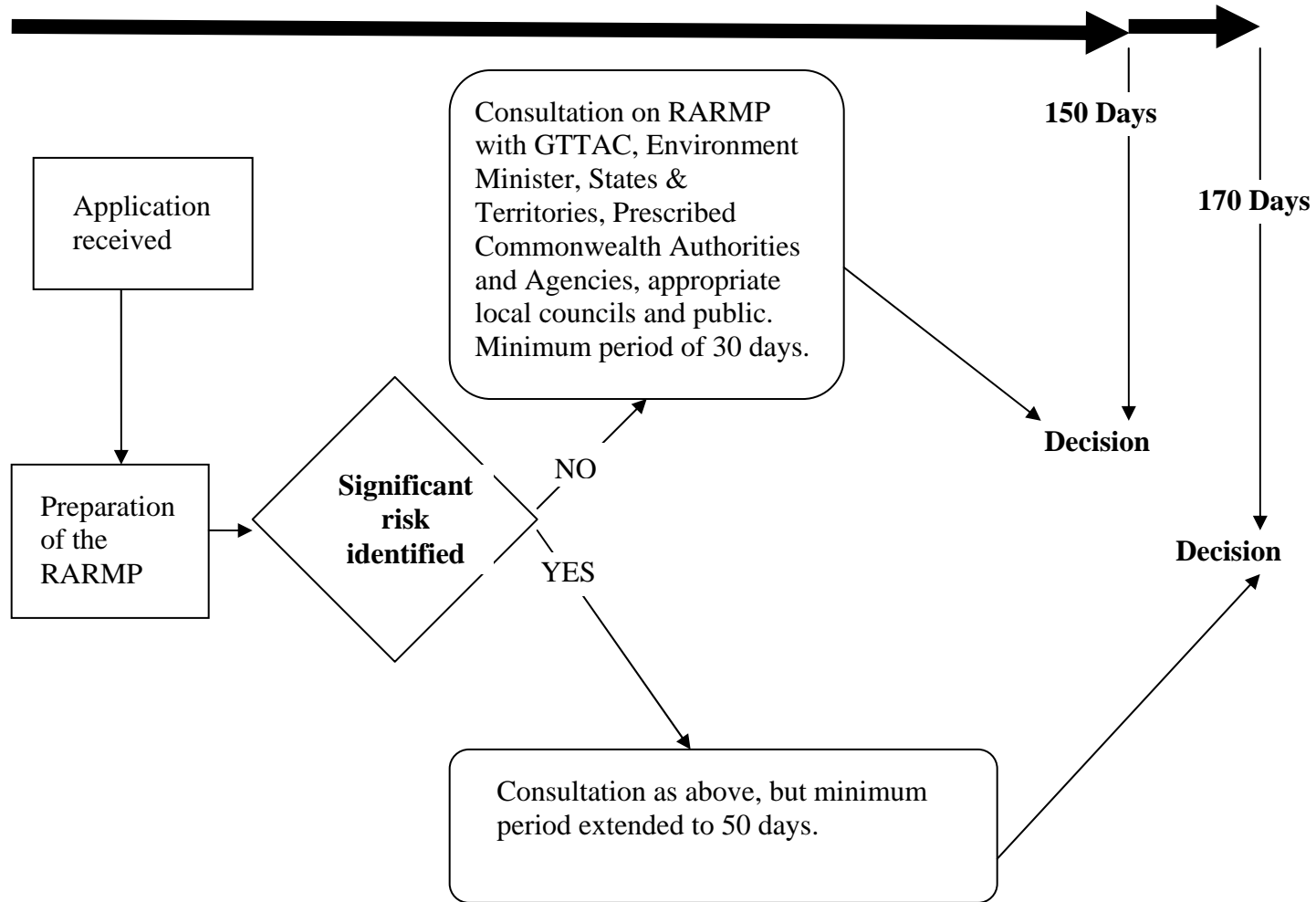
Review Recommendation for Field Trials



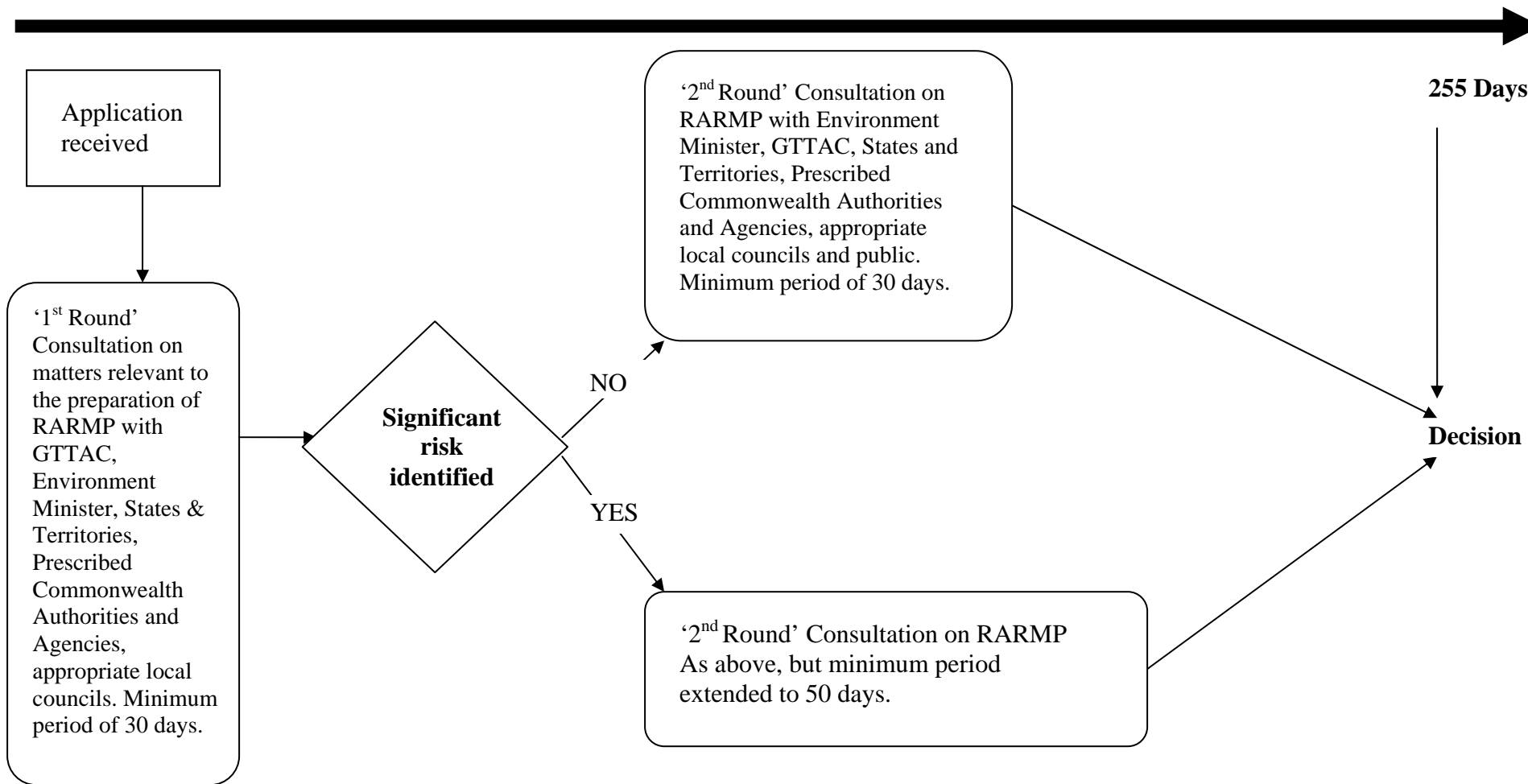
Review Recommendation for Commercial Releases



All Governments proposal for Field Trials



All Governments proposal for Commercial Releases



Comparison of Recommendations Concerning Contained Work

CURRENT	PANEL RECOMMENDATIONS
<p>DNIR</p> <ul style="list-style-type: none"> • Containment in facility level stipulated in DNIR licence - commensurate with assessed risk. Usually PC2/PC3 	<p>No change</p>
<p>NLRD</p> <ul style="list-style-type: none"> • Must be authorised by IBC and notified to OGTR within 14 days of IBC authorisation • Containment in at least PC2 facility unless otherwise authorised by Regulator 	<p>Rec 6.2</p> <p>IBC required to keep and provide a list of these low risk dealings in their organisation’s annual report to OGTR</p> <p>No change to containment requirement</p>
<p>EXEMPT</p> <ul style="list-style-type: none"> • Must notify IBC of work • Organisation/IBC must provide list of exempt dealings in annual report to OGTR • Must be contained in minimum PC1 facility 	<p>Rec 6.1</p> <p>No legislative requirements beyond a listing of dealings in this category in the Regulations *</p>

* Note: Recommendation goes further than reclassification changes proposed in Regulator’s parallel review of Gene Technology Regulations. Implementation would require the Regulator to conduct risk assessments on revised list of exempt dealings to determine which might still require PC1 containment.

LEVELS OF CONTAINMENT

- PC1 Non-pathogenic organisms not capable of infecting humans (for example, work with tissue culture).
- PC2 Organisms that may infect people if not handled in a proper facility with good laboratory practice (for example, work with cancer genes, HIV).
- PC3 Organisms that will infect people and cause harm if allowed to escape (for example, experimental insertion using airborne chimera viruses).
- PC4 Organisms that will cause serious harm/kill anyone who comes in contact with the organism (*for example, Ebola*).