

## **NOTICE GIVEN UNDER CLAUSE 40 OF THE GENE TECHNOLOGY AGREEMENT**

The Gene Technology Agreement was signed by the following parties in 2001 and commenced on 11 September 2001:

The COMMONWEALTH OF AUSTRALIA and  
The STATE OF NEW SOUTH WALES;  
The STATE OF VICTORIA;  
The STATE OF QUEENSLAND;  
The STATE OF WESTERN AUSTRALIA;  
The STATE OF SOUTH AUSTRALIA;  
The STATE OF TASMANIA;  
The AUSTRALIAN CAPITAL TERRITORY and  
The NORTHERN TERRITORY OF AUSTRALIA

In response to the recommendations made in the document entitled '*Statutory Review of the Gene Technology Act 2000 and The Gene Technology Agreement*'<sup>1</sup>, the above-named parties:

- A. reconfirm their commitment to a nationally consistent scheme for gene technology; and
- B. agree to amendments to the Gene Technology Agreement contained in the Schedule to this notice.

Clause 40 of the current Gene Technology Agreement requires this notice to be given to and signed by all of the above-named parties.

The amendments contained in the Schedule to this notice will commence on the day the notice is signed by all of the above-named parties.

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<sup>1</sup> Published by the Commonwealth of Australia in 2006.

**This notice is signed on**                      **day of**                      **2008**    **by the following**  
**Parties**

The Honourable Kevin Rudd MP                      )  
Prime Minister of Australia                      )

The Honourable Morris Iemma MP                      )  
Premier of the State of New South Wales                      )

The Honourable John Brumby MP                      )  
Premier of the State of Victoria                      )

The Honourable Anna Bligh MP                      )  
Premier of the State of Queensland                      )

The Honourable Alan Carpenter MLA                      )  
Premier of the State of Western Australia                      )

The Honourable Mike Rann MP                      )  
Premier of the State of South Australia                      )

The Honourable David Bartlett MP                      )  
Premier of the State of Tasmania                      )

Mr Jon Stanhope MLA                      )  
Chief Minister of the Australian Capital Territory                      )

The Honourable Paul Henderson MLA                      )  
Chief Minister of the Northern Territory of Australia                      )

## SCHEDULE

### GENE TECHNOLOGY AGREEMENT

AN AGREEMENT made the                    day of                    Two Thousand and Eight,  
between –

The COMMONWEALTH OF AUSTRALIA ("the Commonwealth") and  
The STATE OF NEW SOUTH WALES;  
The STATE OF VICTORIA;  
The STATE OF QUEENSLAND;  
The STATE OF WESTERN AUSTRALIA;  
The STATE OF SOUTH AUSTRALIA;  
The STATE OF TASMANIA;  
The AUSTRALIAN CAPITAL TERRITORY and  
The NORTHERN TERRITORY OF AUSTRALIA  
(collectively called "the States and Territories").

#### RECITALS

The Commonwealth and the States and Territories, recognising that there are existing legislative 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 48.
5. In this Agreement, unless the context otherwise requires –
  - 'actual or imminent threat, in respect of the health and safety of people or to the environment, may include, but is not limited to, any of the following:
    - a) a threat from the outbreak of a plant, animal or human disease;
    - b) a threat from a particular plant or animal, such as a pest or an alien invasive species;
    - c) a threat from an industrial spillage;

'Commonwealth Act' means the *Gene Technology Act 2000* of the Commonwealth as amended from time to time;

'Confidential commercial information' means information that is declared by the Regulator under section 185 of the Commonwealth Act to be confidential commercial information and includes information in an application made under section 184 of the Commonwealth Act for such a declaration prior to the Regulator

deciding whether to make that declaration, as is provided for in section 185(3B) of the Commonwealth Act;

'Council' means the Ministerial Council established by Clause 20 and defined by section 10 of the Commonwealth Act;

'Emergency GMO regulation' means a regulation referred to in paragraph (c) of the definition of 'genetically modified organism' in the Commonwealth Act that is made because the thing, or class of things, declared to be a GMO poses an actual or imminent threat to the health and safety of people or to the environment;

'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 Act' means a State or Territory Act referred to in Clause 9 as amended from time to time;

'State or Territory Bill' means a State or Territory Bill referred to in Clause 9;

'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 the subject of an emergency dealing determination, 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 (except in respect of a licence application for a limited and controlled release to which section 50A of the Commonwealth Act applies), and on that assessment and plan following their preparation. This paragraph does not apply to an inadvertent dealings application to which section 49 of the Commonwealth Act applies;
- 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 Ethics and 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:
  - (i) ethical issues relating to gene technology, including the need for, and content of:

- A. codes of practice in relation to ethics in respect of the conduct of dealings with GMOs; and
    - B. policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons;
  - (ii) the need for, and content of, policy principles, policy guidelines, codes of practice, and technical and procedural guidelines in relation to GMOs and GM products;
  - (iii) community consultation in respect of the process for applications for licences covering dealings that involve the intentional release of a GMO into the environment;
  - (iv) risk communication matters in relation to dealings that involve the intentional release of a GMO into the environment;
  - (v) matters of general concern identified by the Regulator in relation to applications made under the Commonwealth Act; and
  - (vi) matters of general concern in relation to GMOs.
- g) 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;
- h) 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);
- i) 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

- j) to provide for the Regulator to maintain a publicly available record of all dealings in Australia that involves 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 and the Gene Technology Ethics and Community Consultative 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:
- a) the Bill or Bills submitted to its Parliament to obtain consistency with the *Gene Technology Act 2000 (Cth)* and the *Gene Technology Amendment Act 2000 (Cth)*, as introduced, and commencement of the associated Act(s) by 31 December 2001<sup>2</sup>; and
  - b) any other State or Territory Bill that is subsequently required to ensure the Scheme remains nationally consistent. The State or Territory will use its

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<sup>2</sup> Paragraph 9(a) is of historical relevance only.



best endeavours to ensure each such Bill is enacted in the form in which it was introduced.

10. The Bill or Bills referred to in Clause 9 will together, among other things:
  - a) confer functions and powers on the Regulator, the Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative 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 the subject of an emergency dealing determination, 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 (except in respect of a licence application for a limited and controlled release to which section 50A of the Commonwealth Act applies), and on that assessment and plan following their preparation. This paragraph does not apply to an inadvertent dealings application to which section 49 of the Commonwealth Act applies;
  - 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(i) 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 2A –EMERGENCIES**

13. 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 to permit the responsible Commonwealth Minister:
  - a) to make, amend, suspend or revoke an emergency dealing determination, in respect of certain dealings for the purposes of the Commonwealth Act, but only in circumstances where the responsible Commonwealth Minister has followed the relevant emergency dealing determination procedures set out in Part 5A of the Commonwealth Act; and
  - b) to extend the period of effect of an emergency dealing determination, but only where the responsible Commonwealth Minister has followed the procedure for extending an emergency dealing determination set out in Part 5A of the Commonwealth Act.
  
14. Unless the Council otherwise determines in accordance with Part 5 of this Agreement, an emergency GMO regulation may only be made under the Commonwealth Act to declare a particular thing, or class of things, to be a GMO for the purposes of the Commonwealth Act if:
  - a) the responsible Commonwealth Minister has received:
    - (i) advice from the Commonwealth's Chief Medical Officer, Chief Veterinary Officer or Chief Plant Protection Officer that the thing, or class of things, proposed to be specified in the regulation poses an actual or imminent threat to the health and safety of people or to the environment; and
    - (ii) advice from the Regulator that declaring that thing, or class of things, to be a GMO would help respond to the actual or imminent threat to the health and safety of people or to the environment posed by the thing or class of things;
  - b) the Minister agrees with the advice received under subparagraph (a)(i) and (ii); and
  - c) the States and Territories have been consulted regarding the making of the emergency GMO regulation.
  
15. The Ministerial Council will review an emergency GMO regulation within 6 months of the date it was made.
  
16. If, as a result of the review mentioned in Clause 15, the Ministerial Council determines by special majority that:
  
- 17.

- a) the emergency GMO regulation should be revoked -- the emergency GMO regulation, and all State and Territory regulations that mirrors the emergency GMO regulation, will be revoked in accordance with Clause 41; or
  - b) certain amendments should be made to the emergency GMO regulation – those amendments will be made to the emergency GMO regulation, and all State and Territory regulations that mirrors the emergency GMO regulation, in accordance with Clause 41.
18. Apart from the circumstances specified in Clause 16, the Commonwealth must not revoke or amend an emergency GMO regulation unless the States and Territories have been consulted regarding the proposed revocation or amendment.
19. The Ministerial Council, prior to determining that an emergency GMO regulation should be revoked under Clause 16, and the Commonwealth, prior to revoking an emergency GMO regulation under Clause 17, must obtain advice from:
- a) the person mentioned or referred to in paragraph 14(a)(i), who gave advice in relation to the making of the regulation, that the thing or class of things specified in the regulation no longer poses an actual or imminent threat to the health and safety of people or to the environment; and
  - b) the Regulator that declaring that thing, or class of things, to be a GMO is no longer required to help respond to the actual or imminent threat to the health and safety of people or to the environment posed by the thing or class of things.
20. The Ministerial Council, prior to determining that an emergency GMO regulation should be amended under Clause 16, and the Commonwealth, prior to amending an emergency GMO regulation under Clause 17, must obtain advice from:
- a) the person mentioned or referred to in paragraph 14(a)(i), who gave advice in relation to the making of the regulation, that the amendments are required to the emergency GMO regulation because the thing or class of things specified in the regulation continues to pose an actual or imminent threat to the health and safety of people or to the environment; and
  - b) the Regulator that the amendments are required to the emergency GMO regulation to help respond to the actual or imminent threat to the health and safety of people or to the environment posed by the thing or class of things specified in the emergency GMO regulation.

### **PART 3 – THE GENE TECHNOLOGY MINISTERIAL COUNCIL**

- 20 There is established a Council of Ministers to be known as the Gene Technology Ministerial Council.
- 21 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.
- 22 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.
- 23 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 (excluding the making of an emergency GMO regulation under Clause 14 or the amending or revoking of an emergency GMO regulation under Clause 17) for the purpose of the Scheme;
  - c) approve, by special majority, any extension of an emergency dealing determination;
  - d) approve the appointment (and, if necessary, the dismissal) of the Regulator, and of the chairpersons of the Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee, and advise the responsible Commonwealth Minister on the appointment of the members of those bodies;
  - e) ensure co-ordination with other Ministerial Councils on matters relating to gene technology and, in particular, harmonisation of regulatory processes relating to GM products;
  - f) oversee generally the implementation of the Scheme;
  - g) consider and, if thought fit, agree on proposed changes to the Scheme;
  - h) initiate a review of the Scheme in accordance with Part 6; and
  - i) perform any other function conferred on the Council by this Agreement.
- 24 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.
- 25 The Council will meet at such times and places as a majority of the Council determines.

- 26 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).
- 27 The quorum for a Council meeting will be at least half of the members of the Council.
- 28 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 Council agreement or resolution referred to in Clause 16, paragraph 23(c) or Clause 40, which will be determined by a special majority).
- 29 Subject to Clause 28, 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.
- 30 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.
- 31 The Council may invite a representative of another Ministerial Council to attend and participate in a meeting of the Council as an observer.
- 32 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**

- 33 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 34, 35 and 36.
- 34 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.
- 35 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 34(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.
- 36 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.
- 37 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.
- 38 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**

- 39 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 (including with any emergency dealing determinations made, amended, suspended, revoked or extended under the Commonwealth Act and any emergency GMO regulation made, amended or revoked under the Commonwealth Act).
- 40 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. For the avoidance of doubt, this Clause does not apply to:
- a) the making, amending, suspending, revoking or extension of an emergency dealing determination;
  - b) the making, amending or revoking of an emergency GMO regulation; or
  - c) a regulation or determination made by a State or Territory to mirror an emergency dealing determination or emergency GMO regulation made under the Commonwealth Act.
- 41 Where the Council approves an amendment to legislation (or an extension of an emergency dealing determination) forming part of the Scheme (under Clause 16, paragraph 23(c) or Clause 40), all Parties will (unless otherwise agreed by the Council) introduce appropriate amendments to their legislation to ensure that the Scheme remains nationally consistent.
- 42 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).
- 43 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**

- 44 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.

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

- a) the Regulator;
- b) the Gene Technology Technical Advisory Committee and the Gene Technology Ethics and Community Consultative Committee; and
- c) such scientific, consumer, health, environmental, and industry groups as the Parties consider appropriate.

#### **PART 7 - AMENDMENT OR VARIATION OF AGREEMENT**

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

47 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**

48 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**

49 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.