ACT Government
Health

REF: FOI:17-07

[redacted]

Dear [redacted]

Thank you for your application under the *Freedom of Information Act 1989* (the Act) received by ACT Health on 8 February 2017. You have requested access to documents relating genetically modified organisms and/or genetic engineering.

Under section 18 of the Act, an agency must take all reasonable steps to notify you of a decision on your application within 30 days. The 30 day period in relation to your request ends on 10 March 2017.

As Deputy Chief Health Officer, Population Health, I am an officer authorised under section 22 of the Act to make a decision in relation to your request. After conducting a search of the relevant records, ACT Health has identified 87 pages of documentation in its possession that meet the scope of your request. I have decided that the documentation will be released to you with some information redacted in accordance with provisions under the Act, as outlined in the Schedule of Documents attached to this letter.

My decision is appealable under the Act. This means that if you are dissatisfied with this outcome you have a right to seek a review under section 59 of the Act. This right of review extends to a review of the adequacy of the search for documents undertaken by ACT Health. If you wish to seek a review you should write to:

The Principal Officer
c/- FOI Coordinator
Ministerial and Government Services
ACT Health
GPO Box 825
CANBERRA ACT 2601

You have 28 days from the date of this letter to seek a review of the outcome or such other period as the Principal Officer permits.

Under section 54 of the Act, if you are concerned about the processing of your request or related administrative matters, you may complain to the Ombudsman, who may conduct an independent investigation into your complaint. There is no fee for this, and the contact details are as follows:

The Ombudsman
GPO Box 442
CANBERRA ACT 2601

If you have any queries concerning the processing of your request please contact the Freedom of Information Coordinator on (02) 6205 1340 or via email at HealthFOI@act.gov.au .

Yours sincerely

Andrew Pengilley
Deputy Chief Health Officer
Population Health
ACT Health

14 March 2017

FOI17-7 – [redacted]

FOLIO	ITEM	DATE	STATUS	REASON FOR EXEMPTION	Internet publication – YES/NO – if no, why not
1-6	GBC15 28 - Assembly - March 2015 - Operations of the Gene Technology Regulator - 4th Quarterly Report - 1 July - 30 September 2014	16/2/15	Full Release		
7-13	GBC15 70 - Assembly - May 2015 - Operations of the Gene technology Regulator 1st Quarterly Report 1 October 2014 - 31 December 2014	10/4/15	Full Release		
14-17	GBC15 261 Assembly - September 2015 - Operations of the Gene Technology regulator Quarterly Report 1 January to 31 March 2015	17/8/15	Full Release		
18-22	GBC15 353 - Brief to Minister - Seeking Chief Minister approval to amend the Gene Technology Act 2003	19/11/15	Full Release		
23-26	GBC15 389 - Assembly - February 2016 - Operations of the Gene Technology Regulator Quarterly Report 1 April to 30 June 2015 and Annual Report 2014-15	30/11/15	Full Release		
27	GBC15 353 - CM Signed agreement to amend Gene Technology Act and Single Pass Approval.pdf	1/12/15	Full Release		
28-31	GBC 16 62 Brief to Assistant Minister - Tabling of the Operations of the Gene Technology Regulator –Quarterly Report – 1 July to 30 September 2015	18/2/16	Full Release		

32-41	MIN 16 1181 - Email - Minister for Health - Proposed appointment to the Gene Technology Ethics and Community Consultative	14/10/16	Partial Release S 41 S34	Section 41 - Unreasonable disclosure of personal information Section 34(1)(b) - Documents affecting relations with Commonwealth and States/Territories.	
42-52	GBC 16 373 - Brief to Minister for Health - Seeking approval to amend the Gene Technology Act 2003	15/11/16	Full Release		
53-60	MIN16 1363 Letter Meeting request Regulation of new genetic modification (GM) techniques - Sales	23/11/16	Partial Release S 41	Section 41 - Unreasonable disclosure of personal information	
61-81	MIN16 1408 - Final Package.pdf	9/12/16	Partial Release S 41	Section 41 - Unreasonable disclosure of personal information	
82-83	MIN16 1363 signed completed package	19/12/16	Partial Release S 41	Section 41 - Unreasonable disclosure of personal information	

ACT Government Health

CORRESPONDENCE CLEARANCE

SUBJECT: **Min Brief - Office of the Gene Tech Regulator - 4th Quarterly Report - July - September 2014**

NUMBER: **COR15/1019** GBC 15/28 **DATE DUE:** .....

Director-General - Health Directorate: ..... Date: 16/2/15

Deputy Director-General, Strategy & Corporate: ..... Date: .....

Deputy Director-General, Canberra Hospital& Health Services: ..... Date: .....

Deputy Director-General, Health Infrastructure and Planning: ..... Date: .....

Senior Manager, Executive Coordination: ..... Date: 13/2/15

Senior Manager, Communications and Marketing: ..... Date: .....

Chief Information Officer, E-Health & Clinical Records: ..... Date: .....

Chief Finance Officer, Financial Management: ..... Date: .....

Exec Director, Business and Infrastructure: ..... Date: .....

Exec Director, Cancer, Ambulatory & Community Health Support: ..... Date: .....

Chief Health Officer, Population Health: ..... Date: 12/2/15

Exec Director, Critical Care: ..... Date: .....

Exec Director, People, Strategy & Services: ..... Date: .....

Exec Director, Medicine: ..... Date: .....

Exec Director, Mental Health, Justice Health, Alcohol & Drug Services: ..... Date: .....

Exec Director, Pathology: ..... Date: .....

Exec Director, Performance Information: ..... Date: .....

Exec Director, Policy & Government Relations: ..... Date: .....

Exec Director, HealthCARE Improvement: ..... Date: .....

Exec Director, Rehabilitation Aged & Community Care: ..... Date: .....

Exec Director, Surgery, Oral Health & Medical Imaging: ..... Date: .....

Exec Director, Women Youth & Children: ..... Date: .....

Manager, Canberra Hospital Foundation: ..... Date: .....

Director, Donate Life ACT: ..... Date: .....

Exec Director, Clinical Support Services: ..... Date: .....

Professional Leads: ..... Date: .....

Other: ..... Date: .....

c. to give policy advice in relation to licences issued under the *Gene Technology Act 2003* that relate to GM food plants;

d. to give advice on current developments and issues in relation to gene technology and its application to agriculture.

7. Sub-section 136A(1) of the Act requires the Regulator to prepare and give to the Minister after each quarter a report on the operations of the Regulator during that quarter.

8. The Minister must present a copy of the report to the Legislative Assembly within six sitting days after the Minister receives the report.

Government Commitment – Other

9. Under section 136A of the Act, you are required to present a copy of the report to the Legislative Assembly within six sitting days of receipt of the report.

Issues

10. A copy of the Report is at Attachment A.

11. Speaking notes have been prepared for your presentation and are at Attachment B for your information.

12. Key achievements for the July to September 2014 quarter (detailed in the Report) are outlined below.

a. Two organisations were issued with accreditation.

b. One licence was issued for Dealings involving the Intentional Release (DIR) of Genetically Modified Organisms (GMOs) into the environment.

c. Three licences were issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment.

d. 35 physical containment facilities were certified.

e. 48 instruments were surrendered.

f. 70 certifications, three DIR licence and 22 DNIR licences were varied.

g. Routine monitoring activities for this quarter exceeded the target rate and no significant risks to either human health or the environment were identified.

13. There was one audit and no investigations completed in the quarter. There were no non-compliances or breaches evident in the audit.

14. There were no audits or non-compliance issues in relation to activities undertaken in the ACT.

15. There are no specific ACT issues noted in the report.

Financial Implications

16. There are no financial implications.

Directorate Consultation

17. No Directorate consultation is required.

External Consultation

18. No external consultation is required.

Benefits/Sensitivities

19. There are unlikely to be any benefits or sensitivities related to the tabling of this Report.

Media Implications

20. No media interest is expected on this issue.

Recommendations

That you:

1. Note the information contained in this brief.

Noted / Please Discuss

2. Agree to present a copy of the Report to the Legislative Assembly during the sitting week commencing 16 March 2015.

Agreed / Not Agreed / Please Discuss

Simon Corbell MLA..... 18/2/15

Minister's Comments

Signatory Name:	Dr Paul Kelly	Phone:	6205 0883
Title:	Chief Health Officer		
Date:			
Action Officer:	Kirsty Whybrow	Phone:	6205 0178

Speaking notes for

the Minister for Health

Mr Simon Corbell

Presentation of the Quarterly Report on the Operations of the Gene Technology Regulator to the Legislative Assembly

March 2015

- I present the Quarterly Report of the Operations of the Gene Technology Regulator for the period 1 July to 30 September 2014 for tabling within today's Assembly.

- Under section 136A of the *Gene Technology Act 2003*, the Regulator must prepare and provide the ACT Minister for Health reports on the operations of the Regulator under the Act during that quarter as soon as practicable after the end of the quarterly reporting period.

- According to the reporting requirement of the *Gene Technology Act 2003*, the ACT Minister for Health must present a copy of the Quarterly Report of the Operations of the Gene Technology Regulator to the Legislative Assembly within six sitting days of receipt of the report.

- Key achievements for the 1 July to 30 September 2014 period are detailed in the report and include:
    - Two organisations were issued with accreditation.
    - One licence was issued for Dealings involving the Intentional Release of Genetically Modified Organisms into the environment.
    - Three licences were issued for Dealings Not involving the Intentional Release of Genetically Modified Organisms into the environment.
    - 35 physical containment facilities were certified.

- 48 instruments were surrendered.
- 70 certifications, three Dealings involving the Intentional Release licences and 22 Dealings Not involving the Intentional Release licences were varied.
- Routine monitoring activities for this quarter exceeded the target rate and no significant risks to either human health or the environment were identified.

- There was one audit and no investigations completed in the quarter. There were no non-compliances or breaches evident in the audit.
- There were no audits or non-compliance issues in relation to activities undertaken in the ACT.

ACT Government
Health

CORRESPONDENCE CLEARANCE

SUBJECT: **Assembly - May 2015 - Operations of the Gene technology Regulator 1st Quarterly Report 1 October 2014 - 31 December 2014**

NUMBER: **GBC15/70** **DATE DUE:**

Director-General - Health Directorate: Date: 10/4/15

Deputy Director-General, Strategy & Corporate: Date:

Deputy Director-General, Canberra Hospital & Health Services: Date:

Deputy Director-General, Health Infrastructure and Planning: Date:

Senior Manager, Ministerial and Government Services: Date: 10/4/15

Senior Manager, Communications and Marketing: Date:

Chief Information Officer, E-Health & Clinical Records: Date:

Chief Finance Officer, Financial Management: Date:

Exec Director, Business and Infrastructure: Date:

Exec Director, Cancer, Ambulatory & Community Health Support: Date:

Chief Health Officer, Population Health: cleared by D/CHO LMcN Date: 9.4.15

Exec Director, Critical Care: Date:

Exec Director, People, Strategy & Services: Date:

Exec Director, Medicine: Date:

Exec Director, Mental Health, Justice Health, Alcohol & Drug Services: Date:

Exec Director, Pathology: Date:

Exec Director, Performance Information: Date:

Exec Director, Policy & Government Relations: Date:

Exec Director, HealthCARE Improvement: Date:

Exec Director, Rehabilitation Aged & Community Care: Date:

Exec Director, Surgery, Oral Health & Medical Imaging: Date:

Exec Director, Women Youth & Children: Date:

Manager, Canberra Hospital Foundation: Date:

Director, Donate Life ACT: Date:

Exec Director, Clinical Support Services: Date:

Professional Leads: Date:

Other: Date:

ACT Government
Health

MINISTERIAL BRIEF

GPO Box 825 Canberra ACT 2601 | phone: 13 22 81
www.health.act.gov.au

UNCLASSIFIED

		TRIM No.: GBC15/70.
To:	Minister for Health	Date Rec'd Minister's Office 14/4/15
From:	Dr Peggy Brown, Director-General, ACT Health	
Subject:	Quarterly Report of the Operations of the Gene Technology Regulator – 1 October to 31 December 2014	
Critical Date:	Within six sitting days of receipt of the Report.	
Critical Reason:	Under section 136A of the *Gene Technology Act 2003*, the Minister must present a copy of the Quarterly Report of the Operations of the Gene Technology Regulator to the Legislative Assembly within six sitting days after the Minister receives the Report.	

- DG Health 10/4/15 (PB)
- CHO .../.../...

Purpose

1. To provide you with a copy of the Quarterly Report of the Operations of the Gene Technology Regulator (the Report) for presentation to the Legislative Assembly in accordance with the requirements of the *Gene Technology Act 2003*.

Background

2. The National Gene Technology Regulator (the Regulator), regulates gene technology using a nationally consistent legislative scheme.

3. The scheme is made up of the Commonwealth *Gene Technology Act 2000*, the Gene Technology Regulations 2001 and corresponding state and territory legislation. All Australian jurisdictions contributed to developing the scheme and related legislation.

4. The corresponding legislation in the ACT is the *Gene Technology Act 2003* (the Act). The object of this Act is to protect the health and safety of people, and to protect the environment by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

5. Sub-section 136A(1) of the Act requires the Regulator to prepare and give to the Minister after each quarter a report on the operations of the Regulator during that quarter.

6. The Minister must present a copy of the report to the Legislative Assembly within six sitting days after the Minister receives the report.

7. The Legislative and Governance Forum on Gene Technology is currently exploring a number of changes to the Commonwealth *Gene Technology Act 2000*, including discontinuing the requirement for quarterly reporting to the Commonwealth Minister. Further information on this issue will be provided once changes are finalised.

Government Commitment – Other

8. Under section 136A of the Act, you are required to present a copy of the Report to the Legislative Assembly within six sitting days of receipt of the Report.

Issues

9. A copy of the Report is at Attachment A.

10. Speaking notes have been prepared if required at Attachment B.

11. Key achievements for the October to December 2014 quarter (detailed in the Report) are outlined below:

    a. Three organisations were issued with accreditation;

    b. Three licences were issued for Dealings involving the Intentional Release (DIR) of Genetically Modified Organisms (GMOs) into the environment;

    c. Four licences were issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment;

    d. 11 physical containment facilities were certified;

    e. 34 instruments were surrendered;

    f. 66 certifications, one DIR licence and 21 DNIR licences were varied; and

    g. Routine monitoring activities for this quarter exceeded the target rate and no significant risks to either human health or the environment were identified.

12. There were no audits or investigations completed in the quarter.

13. There were no audits or non-compliance issues in relation to activities undertaken in the ACT.

14. There are no specific ACT issues noted in the Report.

Financial Implications

15. There are no financial implications.

Directorate Consultation

16. No Directorate consultation is required.

External Consultation

17. No external consultation is required.

Benefits/Sensitivities

18. There are unlikely to be any benefits or sensitivities related to the tabling of this Report.

Media Implications

19. No media interest is expected on this issue.

Recommendations

That you:

1. Note the information contained in this brief; and

Noted / Please Discuss

2. Agree to present a copy of the Report to the Legislative Assembly during the sitting week commencing 5 May 2015.

Agreed / Not Agreed / Please Discuss

Simon Corbell MLA..... ...../...../.....

Minister's Comments
5.5.15

Signatory Name:	Dr Paul Kelly	Phone:	6205 0883
Title:	Chief Health Officer		
Date:			
Action Officer:	Kirsty Whybrow	Phone:	6205 0178

Speaking notes for

the Minister for Health

Mr Simon Corbell

Presentation of the Quarterly Report on the Operations of the Gene Technology Regulator to the Legislative Assembly

1 October – 31 December 2014

April 2015

- I present the Quarterly Report of the Operations of the Gene Technology Regulator for the period 1 October to 31 December 2014 for tabling within today's Assembly.

- Under section 136A of the *Gene Technology Act 2003*, the Regulator must prepare and provide the ACT Minister for Health reports on the operations of the Regulator under the Act during that quarter as soon as practicable after the end of the quarterly reporting period.

- According to the reporting requirement of the *Gene Technology Act 2003*, the ACT Minister for Health must present a copy of the Quarterly Report of the Operations of the Gene Technology Regulator to the Legislative Assembly within six sitting days of receipt of the report.

- Key achievements for the 1 October to 31 December 2014 period are detailed in the report and include:
  - Three organisations were issued with accreditation.
  - Three licences were issued for Dealings involving the Intentional Release (DIR) of Genetically Modified Organisms (GMOs) into the environment.
  - Four licences were issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment.
  - 11 physical containment facilities were certified.
  - 34 instruments were surrendered.

- 66 certifications, one DIR licence and 21 DNIR licences were varied.
- Routine monitoring activities for this quarter exceeded the target rate and no significant risks to either human health or the environment were identified.

- There were no audits or investigations completed in the quarter.
- There were no audits or non-compliance issues in relation to activities undertaken in the ACT.
- There are no specific ACT issues noted in the Report.

ACT Government Health

CORRESPONDENCE CLEARANCE

SUBJECT: Assembly - September 2015 - Operations of the Gene Technology regulator Quarterly Report 1 January to 31 March 2015

NUMBER: GBC15/261 **DATE DUE:** .....

Director-General - Health Directorate: ..... Date: .....

Deputy Director-General, Strategy & Corporate: ..... Date: .....

Deputy Director-General, Canberra Hospital & Health Services: ..... Date: .....

Deputy Director-General, Health Planning and Infrastructure: ..... Date: .....

Senior Manager, Ministerial and Government Services: ..... Date: ..... MG 17/8

Senior Manager, Communications and Marketing: ..... Date: .....

Chief Information Officer, E-Health & Clinical Records: ..... Date: .....

Chief Finance Officer, Financial Management: ..... Date: .....

Exec Director, Business and Infrastructure: ..... Date: .....

Exec Director, Cancer, Ambulatory & Community Health Support: ..... Date: .....

AO Chief Health Officer, Population Health: ..... Date: 17/8

Exec Director, Critical Care: ..... Date: .....

Exec Director, People, Strategy & Services: ..... Date: .....

Exec Director, Medicine: ..... Date: .....

Exec Director, Mental Health, Justice Health, Alcohol & Drug Services: ..... Date: .....

Exec Director, Pathology: ..... Date: .....

Exec Director, Performance Information: ..... Date: .....

Exec Director, Policy & Government Relations: ..... Date: .....

Exec Director, HealthCARE Improvement: ..... Date: .....

Exec Director, Rehabilitation Aged & Community Care: ..... Date: .....

Exec Director, Surgery, Oral Health & Medical Imaging: ..... Date: .....

Exec Director, Women Youth & Children: ..... Date: .....

Manager, Canberra Hospital Foundation: ..... Date: .....

Director, Donate Life ACT: ..... Date: .....

Exec Director, Clinical Support Services: ..... Date: .....

Professional Leads: ..... Date: .....

Other: ..... Date: .....

ACT Government
Health

MINISTERIAL BRIEF

GPO Box 825 Canberra ACT 2601 | phone: 13 22 81
www.health.act.gov.au

UNCLASSIFIED

	TRIM No.: GBC15/261
To: Minister for Health	Date Rec'd Minister's Office 18/8/15

From: Ms Nicole Feely, Director-General, ACT Health

Subject: Quarterly Report of the Operations of the Gene Technology Regulator – 1 January – 31 March 2015

Critical Date: Within six sitting days of receipt of the Report.

Critical Reason: Under section 136A of the *Gene Technology Act 2003*, the Minister must present a copy of the Quarterly Report of the Operations of the Gene Technology Regulator for 1 January – 31 March 2015 to the Legislative Assembly within six sitting days after the Minister receives the Report.

- DG Health .../.../...
- CHO 13/08/15

Purpose

1. To provide you with a copy of the Quarterly Report of the Operations of the Gene Technology Regulator (the Report) for presentation to the Legislative Assembly in accordance with the requirements of the *Gene Technology Act 2003*.

Background

2. The National Gene Technology Regulator (the Regulator), regulates gene technology using a nationally consistent legislative scheme.

3. The scheme is made up of the Commonwealth *Gene Technology Act 2000*, the Gene Technology Regulations 2001 and corresponding state and territory legislation. All Australian jurisdictions contributed to developing the scheme and related legislation.

4. The corresponding legislation in the ACT is the *Gene Technology Act 2003* (the Act). The object of this Act is to protect the health and safety of people, and to protect the environment by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

5. Sub-section 136A(1) of the Act requires the Regulator to prepare and give to the Minister after each quarter a report on the operations of the Regulator during that quarter.

6. The Minister must present a copy of the report to the Legislative Assembly within six sitting days after the Minister receives the report.

7. The Legislative and Governance Forum on Gene Technology is currently exploring a number of changes to the Commonwealth *Gene Technology Act 2000*, including discontinuing the requirement for quarterly reporting to the Commonwealth Minister. Further information on this issue will be provided once changes are finalised.

Government Commitment – Other

8. Under section 136A of the Act, you are required to present a copy of the Report to the Legislative Assembly within six sitting days of receipt of the Report.

Issues

9. A copy of the Report is at Attachment A.

10. Speaking notes have been prepared for your presentation and are at Attachment B.

11. Key achievements for the January – March 2015 quarter (detailed in the Report) are outlined below:

a. No organisations were issued with accreditation;

b. Two licences were issued for Dealings involving the Intentional Release (DIR) of Genetically Modified Organisms (GMOs) into the environment;

c. One licence was issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment;

d. 17 physical containment facilities were certified;

e. 24 instruments were surrendered;

f. 49 certifications, four DIR licences and 10 DNIR licences were varied; and

g. Routine monitoring activities for this quarter exceeded the target rate and no significant risks to either human health or the environment were identified.

12. There were no audits or investigations completed in the quarter.

13. There were no audits or non-compliance issues in relation to activities undertaken in the ACT.

14. There are no specific ACT issues noted in the Report.

Financial Implications

15. There are no financial implications.

Directorate Consultation

16. No Directorate consultation is required.

External Consultation

17. No external consultation is required.

Benefits/Sensitivities

18. There are unlikely to be any benefits or sensitivities related to the tabling of this Report.

Media Implications

19. No media interest is expected on this issue.

Recommendations

That you:

1. Note the information contained in this brief; and

Noted / Please Discuss

2. Agree to present a copy of the Report to the Legislative Assembly during the sitting period commencing 15 September 2015.

Agreed / Not Agreed / Please Discuss

Simon Corbell MLA..... 24/8/15

Minister's Comments

Signatory Name:	Dr Andrew Pengilley	Phone:	6205 0883
Title:	A/g Chief Health Officer		
Date:			
Action Officer:	Kirsty Whybrow	Phone:	6205 0178

ACT Government Health

CORRESPONDENCE CLEARANCE

SUBJECT: Brief to Minister - Seeking Chief Minister approval to amend the Gene Technology Act 2003

NUMBER: COR15/13827 GBC15/353 **DATE DUE:**

Director-General - Health Directorate: Date: 19/11

Deputy Director-General, Strategy & Corporate: Date:

Deputy Director-General, Canberra Hospital & Health Services: Date:

Deputy Director-General, Health Planning and Infrastructure: Date:

Senior Manager, Ministerial and Government Services: Date: 11/11 MG 11/11

Senior Manager, Communications and Marketing: Date:

Chief Information Officer, E-Health & Clinical Records: Date:

Chief Finance Officer, Financial Management: Date:

Exec Director, Business and Infrastructure: Date:

Exec Director, Cancer, Ambulatory & Community Health Support: Date:

Chief Health Officer, Population Health: Cleared by D/CHO - LMcNeill Date: 30.10.15

Exec Director, Critical Care: Date:

Exec Director, People, Strategy & Services: Date:

Exec Director, Medicine: Date:

Exec Director, Mental Health, Justice Health, Alcohol & Drug Services: Date:

Exec Director, Pathology: Date:

Exec Director, Performance Information: Date:

Exec Director, Policy & Government Relations: Date:

Exec Director, HealthCARE Improvement: Date:

Exec Director, Rehabilitation Aged & Community Care: Date:

Exec Director, Surgery, Oral Health & Medical Imaging: Date:

Exec Director, Women Youth & Children: Date:

Manager, Canberra Hospital Foundation: Date:

Director, Donate Life ACT: Date:

Exec Director, Clinical Support Services: Date:

Professional Leads: Date:

Other: Date:

ACT Government
Health

MINISTERIAL BRIEF

GPO Box 825 Canberra ACT 2601 | phone: 13 22 81
www.health.act.gov.au

CABINET-IN-CONFIDENCE

		TRIM No.: GBC15/353
To:	Minister for Health	Date Rec'd Minister's Office 25/1/15
From:	Ms Nicole Feely, Director-General, ACT Health	
Subject:	Seeking approval to amend the *Gene Technology Act 2003*	
Critical Date:	15 January 2016	
Critical Reason:	To meet timeframes for Parliamentary Counsel to draft the amendments in early February 2016.	

- DG Health .../.../...
- A/g CHO .../.../...

Purpose

1. To seek your signature on a letter to the Chief Minister requesting agreement to amend the *Gene Technology Act 2003* to align it with recent changes to the Commonwealth Act.

2. To seek your agreement to include the amendment to the *Gene Technology Act 2003* on the 2016 Autumn Legislation Program.

Background

3. On 24 August 2015, the Department of Health advised ACT Health that the *Gene Technology Amendment Bill 2015* was passed without amendment by the House of Representatives on 19 August 2015 and the Senate on 20 August 2015.

4. In accordance with Clause 41 of the Intergovernmental Gene Technology Agreement (IGA) all jurisdictions where required should introduce appropriate amendments to their legislation to ensure that the regulatory system for gene technology remains nationally consistent.

5. In the ACT, the relevant legislation is the *Gene Technology Act 2013* (the GT Act). The aim of the GT 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 genetically modified organism.

6. The amendments required to the GT Act to bring it in line with the changes outlined in the *Gene Technology Amendment Bill 2015* are minor and non-controversial.

7. The Cabinet Office have confirmed that the amendments meet the exceptions to the normal bills process and require a single pass Cabinet Submission following approval by the Chief Minister.

8. If agreed it would be preferable, whilst not essential, to have the amendments to the *Gene Technology Act 2003* included on the 2016 Autumn Legislation Program, proposing to introduce the amendment during the June 2016 sitting period.

Government Commitment – Parliamentary Agreement

9. In accordance with Clause 41 of the IGA, all jurisdictions, where required, should introduce appropriate amendments to their legislation to ensure that the regulatory system for gene technology remains nationally consistent.

Issues

10. A draft letter to the Chief Minister (Attachment A) has been prepared for your consideration.

11. The draft letter seeks agreement to proceed with amendments to the GT Act to align with the *Commonwealth Gene Technology Amendment Bill 2015* and to add the amendment to the 2016 Autumn Legislation Program.

12. The amendments to the GT Act will:

    a. discontinue the requirement for quarterly reporting to the Minister (annual reporting will remain);

    b. clarify which dealings may be authorised by inadvertent dealings licences;

    c. update advertising requirements for public consultations;

    d. remove the requirement that the Gene Technology Regulator maintain a record of genetically modified product approvals made by other agencies (whilst retaining the requirement to record the Regulator's own approvals);

    e. amend licence variation requirements; and

    f. make technical amendments.

13. The amendments proposed are relatively minor amendments which draw on the practical experiences of the Gene Technology Regulator and are designed to improve the efficiency of the gene technology regulatory regime.

Financial Implications

14. There are no financial implications associated with this brief or the attached draft Cabinet Submission.

Directorate Consultation

15. The Parliamentary Counsel's Office and Cabinet Office were consulted in relation to these issues.

External Consultation

16. As the proposed amendments are required to bring the GT Act in line with the Commonwealth Act, no external consultation was deemed necessary in relation to this issue.

Benefits/Sensitivities

17. Amending the GT Act to align with the changes recently made to the Commonwealth Act will meet requirements under Clause 41 of the IGA.

Media Implications

18. No media interest is anticipated in relation to these issues.

Recommendations

That you:

1. Note the information contained in this brief;

Noted/Please Discuss

2. Agree to add the amendment to the *Gene Technology Act 2003* to the 2016 Autumn Legislation Program; and

Agreed/Not Agreed/Please Discuss

3. Agree to sign the letter to the Chief Minister at Attachment A.

Agreed/Not Agreed/Please Discuss

Simon Corbell MLA..... 27/11/15

Minister's Comments

Signatory Name:	Dr Andrew Pengilley	Phone: 6205 0883
Title:	A/g Chief Health Officer	
Date:	30 October 2015	
Action Officer:	Kirsty Whybrow	Phone: 6205 0178

Original Sent by Minister's Office
27/10/15

Simon Corbell MLA

DEPUTY CHIEF MINISTER

ATTORNEY-GENERAL
MINISTER FOR HEALTH
MINISTER FOR THE ENVIRONMENT
MINISTER FOR CAPITAL METRO

MEMBER FOR MOLONGLO

Mr Andrew Barr MLA
Chief Minister
ACT Legislative Assembly
London Circuit
CANBERRA ACT 2601

Dear Chief Minister

I am writing to seek your agreement to amend the *Gene Technology Act 2003* to align it with recent changes to the Commonwealth Act, and to add the amendment to the 2016 Autumn Legislation Program.

On 24 August 2015, the Department of Health advised ACT Health that the *Gene Technology Amendment Bill 2015* was passed without amendment by the House of Representatives on 19 August 2015 and the Senate on 20 August 2015.

In accordance with Clause 41 of the Intergovernmental Gene Technology Agreement (IGA), all jurisdictions, where required, should introduce appropriate amendments to their legislation to ensure that the Scheme remains nationally consistent.

In the ACT, the relevant legislation is the *Gene Technology Act 2013* (the GT Act). The aim of the GT 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 genetically modified organism.

The amendments required to the GT Act to bring it in line with the changes outlined in the *Gene Technology Amendment Bill 2015* are relatively minor amendments which draw on the practical experiences of the Gene Technology Regulator and are designed to improve the efficiency of the gene technology regulatory regime. The Cabinet Office has confirmed that the amendments meet the exceptions to the normal bills process and require a single pass Cabinet Submission.

I seek your agreement to draft amendment legislation in accordance with Clause 41 of the IGA.

Thank you for your consideration of this matter.

Yours sincerely

Simon Corbell MLA
Minister for Health
27.10.15

ACT LEGISLATIVE ASSEMBLY

London Circuit, Canberra ACT 2601 GPO Box 1020, Canberra ACT 2601
Phone: (02) 6205 0000 Fax: (02) 6205 0535 Email: corbell@act.gov.au
Twitter: @SimonCorbell Facebook: www.facebook.com/simon.corbell

CANBERRA

ACT Government Health

CORRESPONDENCE CLEARANCE

SUBJECT: Brief to Minister for Health - Operations of the Gene Technology Regulator (OGTR) Annual report 2014-15 and Quarterly Report April- June 2015

NUMBER: ~~COR15/14632~~ GBC15/389 **DATE DUE:** .....

Director-General - Health Directorate: ..... Date: .....

Deputy Director-General, Strategy & Corporate: ..... Date: .....

Deputy Director-General, Canberra Hospital & Health Services: ..... Date: .....

Deputy Director-General, Health Planning and Infrastructure: ..... Date: .....

Senior Manager, Ministerial and Government Services: ..... Date: 25/11/15 MG 24/11/15

Senior Manager, Communications and Marketing: ..... Date: .....

Chief Information Officer, E-Health & Clinical Records: ..... Date: .....

Chief Finance Officer, Financial Management: ..... Date: .....

Exec Director, Business and Infrastructure: ..... Date: .....

Exec Director, Cancer, Ambulatory & Community Health Support: ..... Date: .....

Chief Health Officer, Population Health: ..... Date: 7/12

Exec Director, Critical Care: ..... Date: .....

Exec Director, People, Strategy & Services: ..... Date: .....

Exec Director, Medicine: ..... Date: .....

Exec Director, Mental Health, Justice Health, Alcohol & Drug Services: ..... Date: .....

Exec Director, Pathology: ..... Date: .....

Exec Director, Performance Information: ..... Date: .....

Exec Director, Policy & Government Relations: ..... Date: .....

Exec Director, HealthCARE Improvement: ..... Date: .....

Exec Director, Rehabilitation Aged & Community Care: ..... Date: .....

Exec Director, Surgery, Oral Health & Medical Imaging: ..... Date: .....

Exec Director, Women Youth & Children: ..... Date: .....

Manager, Canberra Hospital Foundation: ..... Date: .....

Director, Donate Life ACT: ..... Date: .....

Exec Director, Clinical Support Services: ..... Date: .....

Professional Leads: ..... Date: .....

Other: ..... Date: .....

ACT Government
Health

MINISTERIAL BRIEF

GPO Box 825 Canberra ACT 2601 | phone: 13 22 81
www.health.act.gov.au

UNCLASSIFIED

		TRIM No.: GBC15/389
To:	Minister for Health	Date Rec'd Minister's Office 30/11/15
From:	Ms Nicole Feely, Director-General, ACT Health	
Subject:	Annual and Quarterly Reports of the Operations of the Gene Technology Regulator to 30 June 2015	
Critical Date:	15 January 2016	
Critical Reason:	Under section 136 and 136A of the *Gene Technology Act 2003*, the Minister must present copies of Annual and Quarterly Reports of the Operations of the Gene Technology Regulator to the ACT Legislative Assembly within six sitting days after the Minister receives the Report.	

- DG Health .../.../...
- CHO .../.../...

Purpose

1. In regards to the Operations of the Office of the Gene Technology Regulator (OGTR); to provide you with a copy of the 2015 OGTR Annual Report (the Annual Report) and the OGTR Quarterly Report for April –June 2015 (the Quarterly Report) for presentation to the Legislative Assembly in accordance with the requirements of the *Gene Technology Act 2003*.

Background

2. The National Gene Technology Regulator (the Regulator), regulates gene technology using a nationally consistent legislative scheme. The Regulator requires organisations licensed to work with GMOs to remain accredited.

3. The scheme is made up of the Commonwealth *Gene Technology Act 2000*, the Gene Technology Regulations 2001 and corresponding state and territory legislation. All Australian jurisdictions contributed to developing the scheme and related legislation.

4. The corresponding legislation in the ACT is the *Gene Technology Act 2003* (the Act). 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 Genetically Modified Organisms (GMOs).

5. Under section 136 and 136A of the Act, you are required to present a copy of the Annual and Quarterly Reports to the Legislative Assembly within six sitting days of receipt.

6. A copy of the Annual Report for the twelve month period ending 30 June 2015 is provided at Attachment A.

7. A copy of the Quarterly Report for the 1 April to 30 June 2015 period is provided at Attachment B.

8. Speaking notes are provided at Attachment C.

Issues

9. There were no issues for the ACT identified in these reports.

Annual Report 2015

10. There are 168 accredited organisations, of which, five percent are based in the ACT.

11. Eighty nine certifications for physical containment facilities were approved and six per cent of these were located in the ACT. Six certified ACT facilities were inspected in 2014-15.

12. Field trials involving intentional release of GM crops were undertaken at five sites in the ACT but no ACT field trial site inspections were conducted in 2014-15.

13. During 2014–15, the regulated community demonstrated a high level of compliance with the gene technology legislation.

14. Eight incidents of noncompliance were assessed by the Regulator and found to present negligible risk to human health and safety or to the environment.

Quarterly Report 1 April-30 June 2015

15. One licence was issued for dealings involving intentional release of GMOs.

16. Two licences were issued for dealings not involving intentional release of GMOs.

17. Twenty six physical containment facilities were certified.

18. Twenty three per cent of current field trial sites and seven percent of post-harvest field trial sites were routinely monitored; this exceeded the target minimum rate of five percent of all field trial sites per quarter.

Financial Implications

19. Nil.

Directorate Consultation

20. N/A.

External Consultation

21. N/A.

Benefits/Sensitivities

22. Nil.

Media Implications

23. No media interest is expected.

Recommendations

That you:

1. Note the information contained in this brief; and

Noted/Please Discuss

2. Agree to present a copy of the 2015 Annual Report and the April-June 2015 Quarterly Report of the Operations of the Gene Technology Regulator to the Legislative Assembly during the February 2016 sitting period.

Agreed/Not Agreed/Please Discuss

Simon Corbell MLA..... 18/12/17

Minister's Comments

Signatory Name:	Andrew Pengilley	Phone:	50883
Title:	Ag Chief Health Officer		
Date:	17 November 2015		
Action Officer:	Cathy Watson	Phone:	75235

GBC 15/353

Simon Corbell MLA

DEPUTY CHIEF MINISTER

ATTORNEY-GENERAL
MINISTER FOR HEALTH
MINISTER FOR THE ENVIRONMENT
MINISTER FOR CAPITAL METRO

MEMBER FOR MOLONGLO

Mr Andrew Barr MLA
Chief Minister
ACT Legislative Assembly
London Circuit
CANBERRA ACT 2601

Dear Chief Minister

I am writing to seek your agreement to amend the *Gene Technology Act 2003* to align it with recent changes to the Commonwealth Act, and to add the amendment to the 2016 Autumn Legislation Program.

On 24 August 2015, the Department of Health advised ACT Health that the *Gene Technology Amendment Bill 2015* was passed without amendment by the House of Representatives on 19 August 2015 and the Senate on 20 August 2015.

In accordance with Clause 41 of the Intergovernmental Gene Technology Agreement (IGA), all jurisdictions, where required, should introduce appropriate amendments to their legislation to ensure that the Scheme remains nationally consistent.

In the ACT, the relevant legislation is the *Gene Technology Act 2013* (the GT Act). The aim of the GT 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 genetically modified organism.

The amendments required to the GT Act to bring it in line with the changes outlined in the *Gene Technology Amendment Bill 2015* are relatively minor amendments which draw on the practical experiences of the Gene Technology Regulator and are designed to improve the efficiency of the gene technology regulatory regime. The Cabinet Office has confirmed that the amendments meet the exceptions to the normal bills process and require a single pass Cabinet Submission.

I seek your agreement to draft amendment legislation in accordance with Clause 41 of the IGA.

Thank you for your consideration of this matter.

Yours sincerely

Simon Corbell MLA
Minister for Health
27.11.15

Agreed on behalf of CM; ie single pass Cabinet.
Michael Cook.
DCoS.
1/12.

ACT LEGISLATIVE ASSEMBLY

London Circuit, Canberra ACT 2601 GPO Box 1020, Canberra ACT 2601
Phone: (02) 6205 0000 Fax: (02) 6205 0535 Email: corbell@act.gov.au
Twitter: @SimonCorbell Facebook: www.facebook.com/simon.corbell

CANBERRA

ACT Government Health

CORRESPONDENCE CLEARANCE

SUBJECT: Brief to Assistant Minister - Tabling of the Operations of the Gene Technology Regulator –Quarterly Report – 1 July to 30 September 2015.

NUMBER: GBC16/62 **DATE DUE:**

Director-General - Health Directorate: Date:

Deputy Director-General, Strategy & Corporate: Date:

Deputy Director-General, Canberra Hospital & Health Services: Date:

Deputy Director-General, Health Planning and Infrastructure: Date:

Senior Manager, Ministerial and Government Services: Date: 18/2/16

Senior Manager, Communications and Marketing: Date:

Chief Information Officer, E-Health & Clinical Records: Date:

Chief Finance Officer, Financial Management: Date:

Exec Director, Business and Infrastructure: Date:

Exec Director, Cancer, Ambulatory & Community Health Support: Date:

Chief Health Officer, Population Health: cleared by CHO on 15/2/16 LMW Date: 16/2/16

Exec Director, Critical Care: Date:

Exec Director, People, Strategy & Services: Date:

Exec Director, Medicine: Date:

Exec Director, Mental Health, Justice Health, Alcohol & Drug Services: Date:

Exec Director, Pathology: Date:

Exec Director, Performance Information: Date:

Exec Director, Policy & Government Relations: Date:

Exec Director, HealthCARE Improvement: Date:

Exec Director, Rehabilitation Aged & Community Care: Date:

Exec Director, Surgery, Oral Health & Medical Imaging: Date:

Exec Director, Women Youth & Children: Date:

Manager, Canberra Hospital Foundation: Date:

Director, Donate Life ACT: Date:

Exec Director, Clinical Support Services: Date:

Professional Leads: Date:

Other: Date:

ACT Government
Health

MINISTERIAL BRIEF

GPO Box 825 Canberra ACT 2601 | phone: 13 22 81
www.health.act.gov.au

UNCLASSIFIED

		TRIM No.: GBC16/62
To:	Meegan Fitzharris MLA, Assistant Minister for Health	Date Rec'd Minister's Office 22/2/16
Cc:	Simon Corbell MLA, Minister for Health	
From:	Ms Nicole Feely, Director-General, ACT Health	
Subject:	Quarterly Report of the Operations of the Gene Technology Regulator – 1 July to 30 September 2015	
Critical Date:	Within six sitting days of receipt of the Report, March or April 2016 sitting period	
Critical Reason:	Under section 136A of the *Gene Technology Act 2003*, the Minister must present a copy of the Quarterly Report of the Operations of the Gene Technology Regulator for 1 July to 30 September 2015 to the Legislative Assembly within six sitting days after the Minister receives the Report.	

Purpose

1. To provide you with a copy of the Quarterly Report of the Operations of the Gene Technology Regulator (the Report) for presentation to the Legislative Assembly in accordance with the requirements of the *Gene Technology Act 2003*.

Background

2. The National Gene Technology Regulator (the Regulator), regulates gene technology using a nationally consistent legislative scheme.

3. The scheme is made up of the Commonwealth *Gene Technology Act 2000*, the Gene Technology Regulations 2001 and corresponding state and territory legislation. All Australian jurisdictions contributed to developing the scheme and related legislation.

4. The corresponding legislation in the ACT is the *Gene Technology Act 2003* (the Act). The object of this Act is to protect the health and safety of people, and to protect the environment by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.

5. Sub-section 136A(1) of the Act requires the Regulator to prepare and give to the Minister after each quarter a report on the operations of the Regulator during that quarter.

6. The Minister must present a copy of the report to the Legislative Assembly within six sitting days after the Minister receives the report.

7. The Legislative and Governance Forum on Gene Technology have recently made a number of changes to the Commonwealth *Gene Technology Act 2000*, including discontinuing the requirement for quarterly reporting to the Commonwealth Minister. Further information on this issue will be provided once the amended legislation takes effect.

Government Commitment – Other (and reason)

8. Under section 136A of the Act, you are required to present a copy of the Report to the Legislative Assembly within six sitting days of receipt of the Report.

Issues

9. A copy of the Report is at Attachment A.

10. Speaking notes have been prepared for your presentation and are at Attachment B.

11. Key achievements for the July to September 2015 quarter (detailed in the Report) are outlined below:

    a. Three licences were issued for Dealings involving the Intentional Release (DIR) of Genetically Modified Organisms (GMOs) into the environment;

    b. Two licences were issued for Dealings Not involving the Intentional Release (DNIR) of GMOs into the environment;

    c. 20 physical containment facilities were certified;

    d. 24 instruments were surrendered;

    e. 96 certifications, two DIR licence and 10 DNIR licences were varied; and

    f. Routine monitoring activities for this quarter exceeded the target rate and no significant risks to either human health or the environment were identified.

12. There were two audits completed in the quarter (Queensland University of Technology and RMIT, Melbourne). Neither audit revealed any non-compliances or breaches.

13. There were no investigations completed in the quarter.

14. There were no audits or non-compliance issues in relation to activities undertaken in the ACT.

15. There are no specific ACT issues noted in the Report.

Financial Implications

16. There are no financial implications.

Directorate Consultation

17. No Directorate consultation is required.

External Consultation

18. No external consultation is required.

Benefits/Sensitivities

19. There are unlikely to be any benefits or sensitivities related to the tabling of this Report.

Media Implications

20. No media interest is expected on this issue.

Recommendations

That you:

That you:

1. Note the information contained in this brief; and

Noted/Please Discuss

2. Agree to present a copy of the Report to the Legislative Assembly during the sitting week commencing 8 March 2016 or 5 April 2016.

Agreed/Not Agreed /Please Discuss

Meegan Fitzharris MLA..... 3/3/2016

Minister's Comments

Signatory Name:	Dr Paul Kelly	Phone:	6205 0883
Title:	Chief Health Officer		
Date:	15 February 2016		
Action Officer:	Kirsty Whybrow	Phone:	6205 0178

Min16/1181

Dal Molin, Vanessa (Health)

From: Hosking, Kim on behalf of CORBELL
Sent: Friday, 14 October 2016 9:31 AM
To: Dal Molin, Vanessa (Health)
Subject: FW: ACTION: LGFGT Out of Session paper 2016/001 - Proposed appointment of AHEC cross member for GTECCC [SEC=UNCLASSIFIED]
Attachments: GTECCC appointment of Cross member 2016 MS16-001661 - Signed Min Sub (D16-1082236).PDF; Attachment B - NHMRC letter re AHEC-GTECCC cross member1 (D16-1083137).PDF; Final - Attachment A - Draft LGFGT agenda paper 20161 v2.docx

FI.

Cheers,
Kim.

From: Gene Technology_Secretariat [mailto:Gene.Technology.Secretariat@health.gov.au]
Sent: Thursday, 13 October 2016 1:19 PM
To: Minister Gillespie DLO; CORBELL; Pengilley, Andrew (Health); Dale, Emm (Health); 'niall.blair@parliament.nsw.gov.au'; 'minister.health@health.vic.gov.au'; 'innovation@ministerial.qld.gov.au'; 'lea.diffey@dsiti.qld.gov.au'; 'officeofadgsd@dsiti.qld.gov.au'; 'directorgeneral@dsiti.qld.gov.au'; 'sarah.bloxsom@dsiti.qld.gov.au'; 'jeremy.rockliff@parliament.tas.gov.au'; 'Minister.vowles@nt.gov.au'; 'minister.health@health.sa.gov.au'; 'minister.lewis@dpc.wa.gov.au'
Cc: ogtrcommittees; COLEBATCH, Gillian; Gene Technology_Secretariat; BURGGRAAFF, Katrina; ARTHUR, Rowena; JACKSON-HOPE, Beth; BOOTH, Mark; SHAW, Gillian; philip.wright@dpi.nsw.gov.au; christine.long@nt.gov.au; Kelly, Paul (Health); directorgeneral@dsiti.qld.gov.au; fay.jenkins@health.sa.gov.au; John.Whittington@dpipwe.tas.gov.au; jeffrey.chapman@health.vic.gov.au; Kevin.Chennell@agric.wa.gov.au; BHULA, Raj; martin.blumenthal@dpi.nsw.gov.au; Pengilley, Andrew (Health); REDDEN, Carol; Dale, Emm (Health); lea.diffey@dsiti.qld.gov.au; officeofadgsd@dsiti.qld.gov.au; Sarah.Bloxsom@dsiti.qld.gov.au; Joanne.Cammans@sa.gov.au; Josie.doering@dpipwe.tas.gov.au; michael.ackland@health.vic.gov.au; mara.d.putnis@ecodev.vic.gov.au; Caroline.brown@dpipwe.tas.gov.au; modika.perera@agric.wa.gov.au; ESOBiosecurityandRegulation@agric.wa.gov.au; LAWLER, Damien; NOVELLI, Rob; BARBER, Greg; JAGADISH, Vidya
Subject: ACTION: LGFGT Out of Session paper 2016/001 - Proposed appointment of AHEC cross member for GTECCC [SEC=UNCLASSIFIED]

Dear Legislative and Governance Forum on Gene Technology (LGFGT) members

Please find attached the Out Of Session (OOS) paper 2016/001 – Proposed appointment to the Gene Technology Ethics and Community Consultative Committee (GTECCC).

The LGFGT are being asked to:

- **ENDORSE** the appointment of Professor Dianne Nicol as a member of the GTECCC, as nominated by the Australian Health Ethics Committee (AHEC); and
- **COMPLETE AND SIGN** the attached response form (last page of Attachment A) and return to the LGFGT Secretariat by 26 October 2016.

If you require any further information on the item please contact the Secretariat at gene.technology.secretariat@health.gov.au or call 02 6289 8984.

Kind regards

Gene Technology Secretariat
Health Regulatory Policy Section | BPRB
Department of Health
GPO Box 9848
Canberra ACT 2601

ACT Government Health

Government Business

Minister for Health

GBC Number: **GBC16/373**

Brief to Minister for Health - Seeking approval to amend the Gene Technology Act 2003

Action Required:	No	Reply by Minister	No	Brief to D-G
	No	Brief to ACT Chief Minister	No	Reply by Email
	No	Brief to Minister	No	Action As Necessary (please advise)
	No	Verbal brief OK	No	Info Only
	No	Reply by ACT Chief Minister	No	Telephone response OK
	No	Departmental Response	No	Cabinet Submission

Comments for Cover Sheet:

15/11 To Vanessa Dal Molin 18/11 To Ministers Office

16/11 Jocko Anderson

R/A AF to Touch

Registry file number:

Action Required		DATE COMPLETED	Cleared
Complete registration & send to area Due Date 15/11/2016 at 1:14 PM	Resp.Of Government Business Coordination	15/11/2016	
Action Required		**DATE COMPLETED**	**Cleared**
PA to allocate to responsible line area Due Date 16/11/2016 at 8:44 AM	Resp.Of PA to Chief Health Officer	15/11/2016	
Action Required		**DATE COMPLETED**	**Cleared**
Draft Response prepared & forwarded to PA Due Date 18/11/2016 at 8:44 AM	Resp.Of PA to Chief Health Officer	15/11/2016	
Action Required		**DATE COMPLETED**	**Cleared**
To DDG for Clearance Due Date 21/11/2016 at 8:44 AM	Resp.Of PA to Chief Health Officer	15/11/2016	
Action Required		**DATE COMPLETED**	**Cleared**
Sign off Draft & return to GBC Due Date 22/11/2016 at 8:44 AM	Resp.Of PA to Chief Health Officer	15/11/2016	
Action Required		**DATE COMPLETED**	**Cleared**
QA & send to Senior Manager/Director-General Due Date 22/11/2016 at 12:44 PM	Resp.Of Government Business Coordination		
Action Required		**DATE COMPLETED**	**Cleared**
Package for ministers office Due Date 22/11/2016 at 2:44 PM	Resp.Of Government Business Coordination		
Action Required		**DATE COMPLETED**	**Cleared**
Sign off & send back to GBC Due Date 1/12/2016 at 2:44 PM	Resp.Of Departmental Liaison Officer		
Action Required		**DATE COMPLETED**	**Cleared**
Finalise & distribute Due Date 5/12/2016 at 2:44 PM	Resp.Of Government Business Coordination		

ACT Government
Health

CORRESPONDENCE CLEARANCE

SUBJECT: Brief to Minister for Health - Seeking approval to amend the Gene Technology Act 2003

NUMBER: ~~COR16/15174~~ G8C16 /373 **DATE DUE:** .....

Director-General - ACT Health: ..... Date: 8/11

Deputy Director-General - Corporate: ..... Date: .....

Deputy Director-General - Canberra Hospital & Health Services: ..... Date: .....

Deputy Director-General - Innovation: ..... Date: .....

Deputy Director-General - Quality, Governance and Risk: ..... Date: .....

Deputy Director-General - Population Health Protection & Prevention: ..... Date: 9/11/16

Executive Director - Area nan ..... Date: .....

Senior Manager - Area nar ..... Date: .....

Senior Manager, Ministerial and Government: ..... Date: .....

Senior Manager - Media and Strategic Communications: ..... Date: .....

Executive - Area nan ..... Date: .....

Manager - Area nar ..... Date: .....

Professional Leads: ..... Date: .....

Other: ..... Date: .....

ACT Government
Health

MINISTERIAL BRIEF

GPO Box 825 Canberra ACT 2601 | phone: 13 22 81
www.health.act.gov.au

UNCLASSIFIED

		TRIM No.: GBC16/373
To:	Meegan Fitzharris MLA, Minister for Health	Date Rec'd Minister's Office .../.../...
From:	Ms Nicole Feely, Director-General, ACT Health	
Subject:	To seek approval for a single pass Cabinet process to amend the *Gene Technology Act 2003*	
Critical Date:	9 December 2016	
Critical Reason:	To meet timeframes to allow the Bill to be introduced in March 2017.	

Purpose

1. To seek your signature on a letter to the Chief Minister requesting agreement to amend the *Gene Technology Act 2003* to align it with recent changes to the Commonwealth *Gene Technology Act 2000* as a single pass Cabinet process.

Background

2. On 24 August 2015, the Department of Health advised ACT Health that the *Gene Technology Amendment Bill 2015* (the National Bill) was passed without amendment by the House of Representatives on 19 August 2015 and the Senate on 20 August 2015.

3. In accordance with Clause 41 of the Intergovernmental Gene Technology Agreement (IGA), all jurisdictions should introduce appropriate amendments (where required) to their legislation to ensure that the regulatory system for gene technology remains nationally consistent.

4. In the ACT, the relevant legislation is the *Gene Technology Act 2003* (the GT Act). The aim of the GT 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 genetically modified organisms.

5. The amendments required to the GT Act to bring it in line with the changes outlined in the National Bill are minor and non-controversial.

6. The former Minister for Health, Simon Corbell, was briefed on this issue in November 2015 and approval was given by the Chief Minister for a single pass cabinet process, see Attachment A.

7. The amendments were originally due for consideration by Cabinet in early 2016 but were given a low priority and removed from the legislation program.

8. The Cabinet Office has advised that your confirmation and the Chief Minister's re-endorsement is required due to the length of time and change in government since the original brief.

Government Commitment – Parliamentary Agreement

9. In accordance with Clause 41 of the IGA, all jurisdictions, where required, should introduce appropriate amendments to their legislation to ensure that the regulatory system for gene technology remains nationally consistent.

Issues

10. Your agreement has been sought to have the amendments to the GT Act included on the Autumn 2017 Legislation Program.

11. The Cabinet Office have previously advised that the proposed amendments meet the exceptions to the normal bills process and only requires a single pass Cabinet Submission, subject to the approval of the Chief Minister. A letter to the Chief Minister seeking approval for a single pass process has been prepared for your consideration at Attachment B.

12. The amendments proposed are relatively minor amendments which draw on the practical experiences of the Gene Technology Regulator and are designed to improve the efficiency of the gene technology regulatory regime.

13. The amendments to the GT Act will:

a. discontinue the requirement for quarterly reporting to the Minister (annual reporting will remain);

b. clarify which dealings may be authorised by inadvertent dealings licences;

c. update advertising requirements for public consultations;

d. remove the requirement that the Gene Technology Regulator maintain a record of genetically modified product approvals made by other agencies (whilst retaining the requirement to record the Regulator's own approvals);

e. amend licence variation requirements; and

f. make technical amendments.

Financial Implications

14. There are no financial implications associated with this brief.

Directorate Consultation

15. The Parliamentary Counsel's Office and Cabinet Office were consulted in relation to these issues.

External Consultation

16. As the proposed amendments are required to bring the GT Act in line with the Commonwealth Act, no external consultation was deemed necessary in relation to this issue.

Benefits/Sensitivities

17. Amending the GT Act to align with the changes recently made to the Commonwealth Act will meet requirements under Clause 41 of the IGA.

Media Implications

18. No media interest is anticipated in relation to these issues.

Recommendations

That you:

1. Note the information contained in this brief; and

Noted / Please Discuss

2. Agree to sign the letter to the Chief Minister at Attachment B.

Agreed / Not Agreed / Please Discuss

Meegan Fitzharris MLA..... 1/12/16

Minister's Comments

Signatory Name:	Dr Paul Kelly	Phone:	6205 0883
Title:	Chief Health Officer		
Date:	9 November 2016		
Action Officer:	Kirsty Whybrow	Phone:	6205 0178

ACT Government
Health

MINISTERIAL BRIEF

GPO Box 825 Canberra ACT 2601 | phone: 13 22 81
www.health.act.gov.au

CABINET-IN-CONFIDENCE

		TRIM No.: GBC15/353
To:	Minister for Health	Date Rec'd Minister's Office 25/1/15
From:	Ms Nicole Feely, Director-General, ACT Health	
Subject:	Seeking approval to amend the *Gene Technology Act 2003*	
Critical Date:	15 January 2016	
Critical Reason:	To meet timeframes for Parliamentary Counsel to draft the amendments in early February 2016.	

- DG Health .../.../...
- A/g CHO .../.../...

Purpose

1. To seek your signature on a letter to the Chief Minister requesting agreement to amend the *Gene Technology Act 2003* to align it with recent changes to the Commonwealth Act.

2. To seek your agreement to include the amendment to the *Gene Technology Act 2003* on the 2016 Autumn Legislation Program.

Background

3. On 24 August 2015, the Department of Health advised ACT Health that the *Gene Technology Amendment Bill 2015* was passed without amendment by the House of Representatives on 19 August 2015 and the Senate on 20 August 2015.

4. In accordance with Clause 41 of the Intergovernmental Gene Technology Agreement (IGA) all jurisdictions where required should introduce appropriate amendments to their legislation to ensure that the regulatory system for gene technology remains nationally consistent.

5. In the ACT, the relevant legislation is the *Gene Technology Act 2013* (the GT Act). The aim of the GT 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 genetically modified organism.

6. The amendments required to the GT Act to bring it in line with the changes outlined in the *Gene Technology Amendment Bill 2015* are minor and non-controversial.

7. The Cabinet Office have confirmed that the amendments meet the exceptions to the normal bills process and require a single pass Cabinet Submission following approval by the Chief Minister.

8. If agreed it would be preferable, whilst not essential, to have the amendments to the *Gene Technology Act 2003* included on the 2016 Autumn Legislation Program, proposing to introduce the amendment during the June 2016 sitting period.

Government Commitment – Parliamentary Agreement

9. In accordance with Clause 41 of the IGA, all jurisdictions, where required, should introduce appropriate amendments to their legislation to ensure that the regulatory system for gene technology remains nationally consistent.

Issues

10. A draft letter to the Chief Minister (Attachment A) has been prepared for your consideration.

11. The draft letter seeks agreement to proceed with amendments to the GT Act to align with the *Commonwealth Gene Technology Amendment Bill 2015* and to add the amendment to the 2016 Autumn Legislation Program.

12. The amendments to the GT Act will:

    a. discontinue the requirement for quarterly reporting to the Minister (annual reporting will remain);

    b. clarify which dealings may be authorised by inadvertent dealings licences;

    c. update advertising requirements for public consultations;

    d. remove the requirement that the Gene Technology Regulator maintain a record of genetically modified product approvals made by other agencies (whilst retaining the requirement to record the Regulator's own approvals);

    e. amend licence variation requirements; and

    f. make technical amendments.

13. The amendments proposed are relatively minor amendments which draw on the practical experiences of the Gene Technology Regulator and are designed to improve the efficiency of the gene technology regulatory regime.

Financial Implications

14. There are no financial implications associated with this brief or the attached draft Cabinet Submission.

Directorate Consultation

15. The Parliamentary Counsel's Office and Cabinet Office were consulted in relation to these issues.

External Consultation

16. As the proposed amendments are required to bring the GT Act in line with the Commonwealth Act, no external consultation was deemed necessary in relation to this issue.

Benefits/Sensitivities

17. Amending the GT Act to align with the changes recently made to the Commonwealth Act will meet requirements under Clause 41 of the IGA.

Media Implications

18. No media interest is anticipated in relation to these issues.

Recommendations

That you:

1. Note the information contained in this brief;

Noted/Please Discuss

2. Agree to add the amendment to the *Gene Technology Act 2003* to the 2016 Autumn Legislation Program; and

Agreed/Not Agreed/Please Discuss

3. Agree to sign the letter to the Chief Minister at Attachment A.

Agreed/Not Agreed/Please Discuss

Simon Corbell MLA..... 29/11/15

Minister's Comments

Signatory Name:	Dr Andrew Pengilley	Phone: 6205 0883
Title:	A/g Chief Health Officer	
Date:	30 October 2015	
Action Officer:	Kirsty Whybrow	Phone: 6205 0178

Original Sent by Minister's Office
27/11/15

Simon Corbell MLA

DEPUTY CHIEF MINISTER

ATTORNEY-GENERAL
MINISTER FOR HEALTH
MINISTER FOR THE ENVIRONMENT
MINISTER FOR CAPITAL METRO

MEMBER FOR MOLONGLO

Mr Andrew Barr MLA
Chief Minister
ACT Legislative Assembly
London Circuit
CANBERRA ACT 2601

Dear Chief Minister

I am writing to seek your agreement to amend the *Gene Technology Act 2003* to align it with recent changes to the Commonwealth Act, and to add the amendment to the 2016 Autumn Legislation Program.

On 24 August 2015, the Department of Health advised ACT Health that the *Gene Technology Amendment Bill 2015* was passed without amendment by the House of Representatives on 19 August 2015 and the Senate on 20 August 2015.

In accordance with Clause 41 of the Intergovernmental Gene Technology Agreement (IGA), all jurisdictions, where required, should introduce appropriate amendments to their legislation to ensure that the Scheme remains nationally consistent.

In the ACT, the relevant legislation is the *Gene Technology Act 2013* (the GT Act). The aim of the GT 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 genetically modified organism.

The amendments required to the GT Act to bring it in line with the changes outlined in the *Gene Technology Amendment Bill 2015* are relatively minor amendments which draw on the practical experiences of the Gene Technology Regulator and are designed to improve the efficiency of the gene technology regulatory regime. The Cabinet Office has confirmed that the amendments meet the exceptions to the normal bills process and require a single pass Cabinet Submission.

I seek your agreement to draft amendment legislation in accordance with Clause 41 of the IGA.

Thank you for your consideration of this matter.

Yours sincerely

Simon Corbell MLA
Minister for Health
27.11.15

ACT LEGISLATIVE ASSEMBLY

London Circuit, Canberra ACT 2601 GPO Box 1020, Canberra ACT 2601
Phone: (02) 6205 0000 Fax: (02) 6205 0535 Email: corbell@act.gov.au
Twitter: @SimonCorbell Facebook: www.facebook.com/simon.corbell

CANBERRA

COPY

delivered to CM office 6/12/16

Meegan Fitzharris MLA

Member for Yerrabi

Minister for Health
Minister for Transport and City Services
Minister for Higher Education, Training and Research

Mr Andrew Barr MLA
Chief Minister
ACT Legislative Assembly
London Circuit
CANBERRA ACT 2601

Dear Chief Minister Andrew,

I am writing to seek your agreement to amend the *Gene Technology Act 2003* (the GT Act) to align it with recent changes to the Commonwealth *Gene Technology Act 2000* through a single pass Cabinet process.

On 24 August 2015, the Department of Health advised ACT Health that the Gene Technology Amendment Bill 2015 (the National Bill) was passed without amendment by the Australian Parliament.

In accordance with Clause 41 of the Intergovernmental Gene Technology Agreement, all jurisdictions, where required, should introduce appropriate amendments to their legislation to ensure that the Scheme remains nationally consistent.

In the ACT, the relevant legislation is the GT Act. The aim of the GT 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 genetically modified organisms.

The amendments required to the GT Act to bring it in line with the changes outlined in the National Bill are relatively minor amendments which draw on the practical experiences of the Gene Technology Regulator and are designed to improve the efficiency of the gene technology regulatory regime. The Cabinet Office previously advised that the amendments meet the exceptions to the normal bills process and require a single pass Cabinet Submission, pending your approval.

AUSTRALIAN CAPITAL TERRITORY LEGISLATIVE ASSEMBLY
London Circuit, Canberra ACT 2601, Australia GPO Box 1020, Canberra ACT 2601, Australia
Phone +61 2 6205 0051 Email fitzharris@act.gov.au

@MeeganFitzMLA MeeganFitzharrisMLA

You previously agreed to proceed with these amendments in December 2015, however the item was later removed from the legislative program. In view of the significant length of time and change in Government that has occurred since your original agreement, I now seek your re-endorsement to proceed with the drafting of amendment legislation as part of a single pass Cabinet process.

Thank you for your consideration of this matter.

Yours sincerely

Meegan Fitzharris MLA
Minister for Health
1/12/16

MIN16\1363

Hon. Meegan Fitzharris
Minister for Health
GPO Box 1020
Canberra
ACT 2601

Received
on
29 NOV 2016
MINISTERIAL AND
GOVERNMENT SERVICES

Friends of the Earth Australia

Meegan Fitzharris MLA

23 NOV 2016
16\123 - FE

Thursday, 17th November 2016

Dear Minister,

Meeting request re. regulation of new genetic modification (GM) techniques

I am writing to request a meeting with you regarding a variety of new GM techniques that the Office of the Gene Technology Regulator (OGTR) is proposing to deregulate through its Technical Review of the Gene Technology Regulations[8]. We appreciate that you are extremely busy and ask that you suggest some suitable times so that we can work around your availability.

DCa to respon
Please

Friends of the Earth is concerned that if s
there will be no monitoring or surveillar :ry -
to terror groups would be free to use th
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Reviews commissioned by the Austrian t
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that products derived from them requi .

Obviously the OGTR is a Federal regula ites.
The states also play a key role in the de gh
their role on the Legislative and Governance Forum on Gene Technology, on which you sit.

The international trade implications of these techniques not being regulated could be significant. Largely because of these concerns, the New Zealand Government announced earlier this year that it would regulate these techniques as genetically modified organisms (GMOs).

We believe that greater scrutiny of the potential health, environmental and market impacts techniques is required. We therefore request that you instigate a parliamentary inquiry into these techniques.

We also urge you to consider making a submission to the OGTR's review. The deadline for submissions has recently been extended to 16th December.

---

[8] The OGTR's discussion paper can be viewed here:
http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/regs-process-1

MIN16/1363

Hon. Meegan Fitzharris
Minister for Health
GPO Box 1020
Canberra
ACT 2601

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MINISTERIAL AND
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Friends of the Earth is concerned that if the OGTR deregulates these new GM techniques there will be no monitoring or surveillance. Anyone from amateur biohackers - to industry - to terror groups would be free to use them to genetically modify plants, animals and microbes. Entirely new diseases and poisons could be made. They could enter our food chain and our environment with no safety assessment and no labelling. The consequences could be catastrophic.

Reviews commissioned by the Austrian and Norwegian governments concluded that not enough is known about the risks posed by these new GM techniques. They recommended that products derived from them require comprehensive case-by-case risk assessments.

Obviously the OGTR is a Federal regulator, however trade is the responsibility of the states. The states also play a key role in the decision making around GM crop regulation through their role on the Legislative and Governance Forum on Gene Technology, on which you sit.

The international trade implications of these techniques not being regulated could be significant. Largely because of these concerns, the New Zealand Government announced earlier this year that it would regulate these techniques as genetically modified organisms (GMOs).

We believe that greater scrutiny of the potential health, environmental and market impacts techniques is required. We therefore request that you instigate a parliamentary inquiry into these techniques.

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---

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http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/regs-process-1

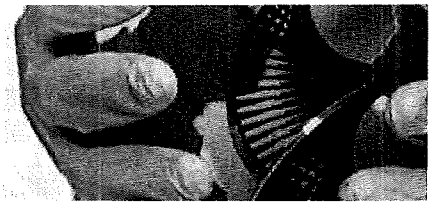
Additionally, we ask that you reaffirm your commitment to GM food labelling and the right of states to impose market based GM moratoria.

I have attached two factsheets and a report that outline our concerns in more detail. If you'd like any further information please do not hesitate to contact me.

Yours sincerely,

FACT SHEET
2 May 2016

GM 2.0



New Plant Breeding Techniques?

In recent years large agrochemical corporations such as Dow, Syngenta, Bayer and Monsanto and other players have been investing in a suite of risky new genetic modification (GM) techniques, which industry refers to collectively as 'New Plant Breeding Techniques' or 'gene editing'. Industry is arguing that these techniques are much more precise than older genetic engineering techniques - or even that they are not really genetic engineering at all - in order to attempt to circumvent regulation and public resistance to GMOs.

There is a global push to deregulate these techniques

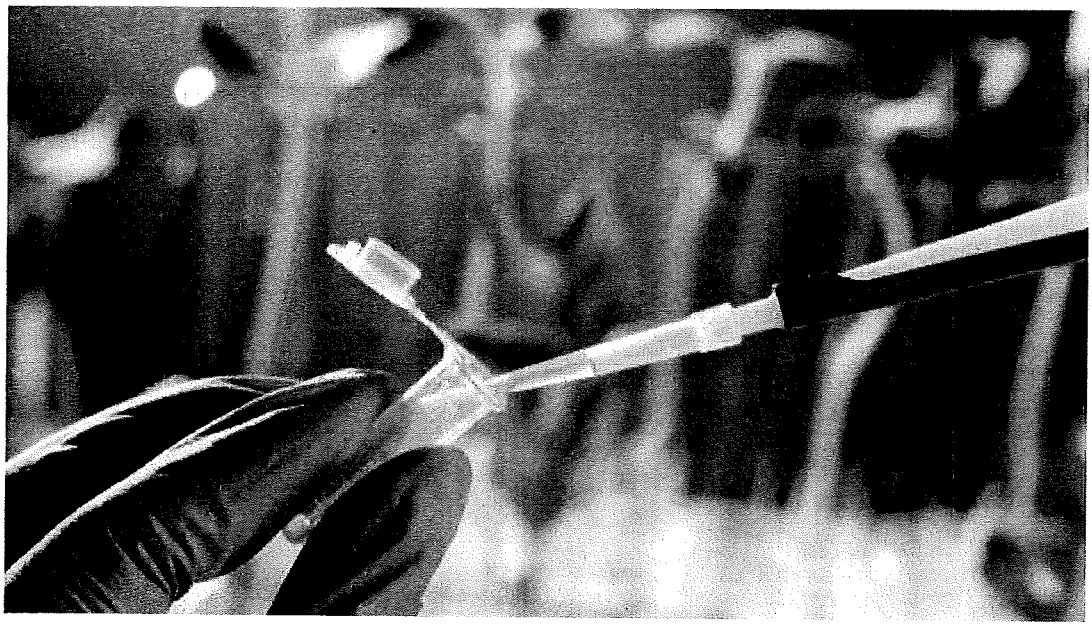
The GM giants are currently making a concerted push to have these emergent techniques escape GM laws in the United States, Europe and Australia. Industry is arguing that these techniques - which include oligo-directed mutagenesis (ODM) and site-directed nucleases (SDNs) such as zinc-finger nucleases (ZFN) and CRISPR - only result in small predictable changes to the genome and are therefore much more precise that earlier genetic engineering techniques. Interestingly, this is exactly the same argument they used when GM crops were originally introduced - and is equally untrue for these techniques.

Unfortunately, our regulators - the Office of the Gene Technology Regulator (OGTR) and Food Standards Australia New Zealand (FSANZ) - seem all too ready to allow products derived from these risky new techniques to go untested and unlabelled into our food chain.

These techniques pose unknown risks and need to be regulated

Austrian government agencies are among the few globally to consider the biosafety risks posed by new GM techniques. Their conclusion, over three separate, high-level reviews of the biosafety risks, is that there is insufficient knowledge regarding the risks posed by these techniques. On this basis, they argue that products derived from new GM techniques should be regulated in the same way as those created using older GM techniques and require a comprehensive case-by-case risk assessment.

The Norwegian Environment and Development Agencies also recently commissioned a review of these techniques. This concluded that further biosafety research needs to be performed before these techniques are commercialised.



FACT SHEET
2 May 2016

GM 2.0

Our regulators are failing us

The Australian Gene Technology Act defines gene technology as "any technique for the modification of genes or other genetic material". This would clearly include new GM techniques unless they were specifically exempted in the regulations. Unfortunately, our regulators - the Office of the Gene Technology Regulator (OGTR) and Food Standards Australia New Zealand (FSANZ) - are already working closely with industry to do just that.

On its website the OGTR professes a commitment to "accountability: through open and transparent processes". However, documents obtained by Friends of the Earth under Freedom of Information laws reveal that the assistant Health Minister Fiona Nash gave policy approval for drafting amendments to the Gene Technology Regulations on 8th July 2015 and that the agency has already issued drafting instructions to deregulate a number of these new GM techniques. This has occurred without any public input or consultation. Furthermore, it appears the agency has misled the Senate - claiming in Senate Estimates that drafting instructions have not yet been issued.

In 2012 and 2013 FSANZ convened an expert panel - comprised almost entirely of genetic engineers with gene technology patents - to look at whether these new GM techniques should be considered genetic engineering. Not surprisingly, the panel concluded that the majority of these techniques did not pose a significant food safety concerns and that they either be deregulated or undergo a simplified form of food safety assessment - conclusions strongly disputed by government agencies overseas. Furthermore, FSANZ appears to have deliberately misled the Senate by claiming it "is not aware that any members of the expert panel have potential conflicts of interest." Based on subsequent statements, it is clear that FSANZ was aware of these potential conflicts of interest

It's time our regulators stopped letting industry write the rules for them and put public health and our environment before private profit.

What needs to happen?

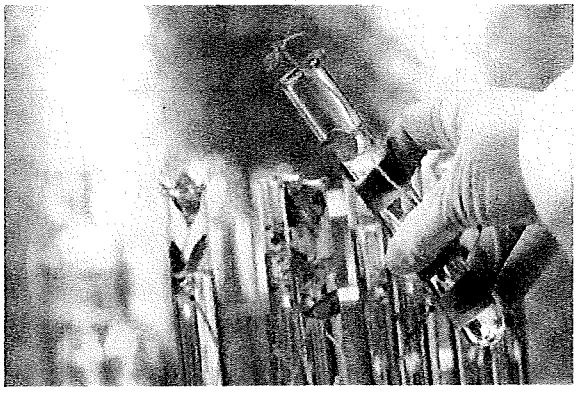
Friends of the Earth is calling for:

- These new GM techniques and the products derived from them to be subject to a comprehensive case-by-case risk assessment, including full molecular characterisation and independent safety testing to minimise any potential risks to human health and the environment;
- All products derived from new GM techniques to be labelled to protect choice for farmers, producers and consumers;
- The precautionary principle to be enshrined in both the Gene Technology Act and the Food Standards Australia New Zealand Act, given the experimental nature of these technologies and the risks associated with them;
- The Government to impose strict liability on all dealings with GMOs licensed by the OGTR, so that liability for GM contamination and the resultant losses and costs rests fully on the licensees and the owners of GM patents;
- A moratorium on the commercialisation of these new GM techniques until our regulatory system for GMOs is adapted to deal with the potential risks posed by them.

Find out more

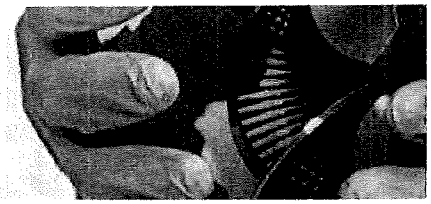
For more information find our report: *GM 2.0: Australian regulators engineering the truth* on our website (http://emergingtech.foe.org.au) or contact:

Louise Sales, Emerging Tech Project Coordinator,
Friends of the Earth, Mob: 0435 589 579;
Email: louise.sales@foe.org.au



FACT SHEET | 3 November 2016

GM 2.0 and its market impacts



There is currently a global push by the biotechnology industry to deregulate a variety of new genetic modification (GM) techniques - often referred to by industry as 'gene editing' or 'new plant breeding techniques'. These include techniques such as CRISPR, zinc finger nucleases and oligo-directed mutagenesis. However, if these techniques were to be deregulated in Australia before being approved in key export markets the market impacts could be catastrophic.

Key export markets have yet to decide whether to regulate these techniques as GM

The European Union has yet to make a decision on whether it will regulate these techniques as GM. The final word on the matter is likely to come from the European Court of Justice. It will rule in 18 months whether or not new GM techniques, including ODM, ZFN1, TALENs, and CRISPR-Cas, fall under EU GMO law.[1]

Australia's key trading partners have zero tolerance policies for unapproved GMOs

"There is no flexibility for unauthorised GMOs - these cannot enter the EU food and feed chain under any circumstances."

Markos Kyprianou, EU Commissioner for Health and Consumer Protection[2]

A survey of countries conducted by the Food and Agriculture Organisation (FAO) found that 73% of them have a zero tolerance for unapproved GM varieties.[3] The FAO found that between 2002 and 2012 there had been 200 cases of trade disruptions due to the presence of unapproved GMOs. The majority of the cases happened between 2009-2012, indicating increasing trade problems.

These techniques fall under Cartagena Protocol and Codex definition of modern biotechnology

All the new GM techniques involve *in vitro* nucleic acid techniques and so fall under the Codex Alimentarius and Cartagena Protocol definition of 'modern biotechnology'. Other countries could therefore reject shipments containing products derived from these new techniques that haven't been assessed for safety without fear of World Trade Organisation reprisals.

The risks of running ahead of market approval

Were Australia to clear new types of GM crops for growing before they were approved overseas, the costs for food exporters could be enormous and take years to recover from. There are numerous examples of costly market rejection and disruption due to the presence of unapproved GMOs. These include:

Triffid flax

When an unlicensed GM flax variety was found in a shipment to Japan in 2009, 35 countries closed their borders to Canadian flax exports, including 28 in the EU which accounts for 60 per cent of Canada's flax export market. A University of Saskatchewan study estimated the cost to the Canadian flax industry in the first year alone to be $29 million.[4]

Viptera corn

In 2015, the Swiss company Syngenta released a GM corn variety to market before it had been approved in key export markets, resulting in a Chinese import ban. The National Grain and Feed Association calculated the loss to farmers to be nearly US$3 billion.[5]

StarLink corn

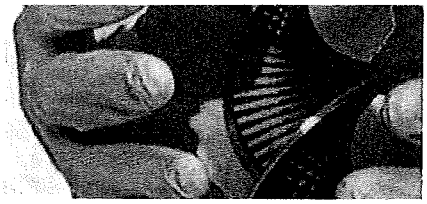
This was a massive supply chain contamination incident in 2000 involving a GM corn used for animal feed and not approved for human food use. It resulted in the largest food product recall in history and is estimated to have cost US companies US$1 billion.[6]

LibertyLink rice

In 2006, an unauthorised variety of GM rice was detected in US exports. According to the USA Rice Federation, "a robust long grain rice export market nearly vanished overnight".[7] The total cost to the US rice industry of the LibertyLink 601 contamination is estimated at around US$1 billion.

FACT SHEET | 3 November 2016

GM 2.0 and its market impacts



Regulatory standards don't necessarily reflect market realities

Regulatory standards have proven to be the minimum standards that food exporters must meet. Market requirements are often far more stringent than regulatory requirements. For example in Europe more than 40 GM foods have been approved for human consumption - but barely any are actually present in foods. This is because of the policy positions of food companies. Ultimately, food companies in overseas markets will determine whether new GM techniques are viewed as GM - not just governments.

Food companies are a long way from coming to a position on this and it could be some time before they do. Therefore, the prudent position from a food exporting perspective is to wait to see how the marketplace responds - not to commit supply chains to new GM products until there is certainty.

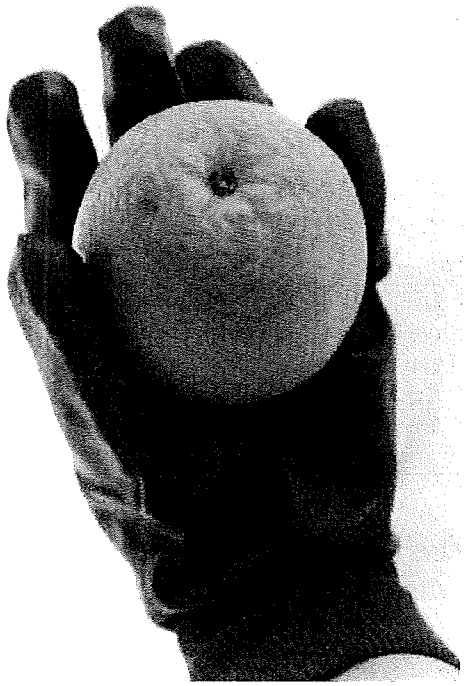
The New Zealand Government will be regulating these techniques as GMOs

It was in recognition of these potential market impacts that the New Zealand Government announced earlier this year that it would be regulating these new techniques as genetically modified organisms (GMOs). On making the announcement New Zealand's Environment Minister Dr Nick Smith stated:

> *"The rationale for our cautious approach is that New Zealand is an exporter of billions of dollars of food products and we need to be mindful of market perceptions as well as the science. We will continue to monitor global rules around the regulation of GMOs and adapt our system over time in line with international developments."*[8]

For more information contact:

Louise Sales, Emerging Tech Project Coordinator
Friends of the Earth
Ph: 0435 589 579
Email: louise.sales@foe.org.au



[1] GM Watch (2016) European Court of Justice will rule whether new GMO techniques fall under GMO law, 3/10/16, http://gmwatch.org/news/latest-news/17257

[2] *European Commission (2006)* GM FOODS - Commission requires certification of US rice exports to stop unauthorised GMO entering the EU: Press Release (IP/06/1120), 23 August 2006, http://www.reading.ac.uk/foodlaw/news/eu-06080.htm

[3] FAO (2014) The results of the FAO survey on low levels of genetically modified (GM) crops in international food and feed trade http://www.fao.org/fileadmin/user_upload/agns/topics/LLP/AGD803_4_Final_En.pdf

[4] Pilger, G. (2015) The great threat of 2015 facing farmers, *Country Guide*, http://www.country-guide.ca/2015/11/17/the-great-threat-of-2015-facing-farmers/47629/; Young, L. *et al.* (2015) Genetics, structure, and prevalence of FP967 (CDC Triffid) T-DNA in flax, *SpringerPlus* 4:146, http://link.springer.com/content/pdf/10.1186%2Fs40064-015-0923-9.pdf

[5] RT (2015) *Food fight: Indiana farmers sue seed company over millions in losses*, https://www.rt.com/usa/323493-Corn-farmers-sue-seed-corp/

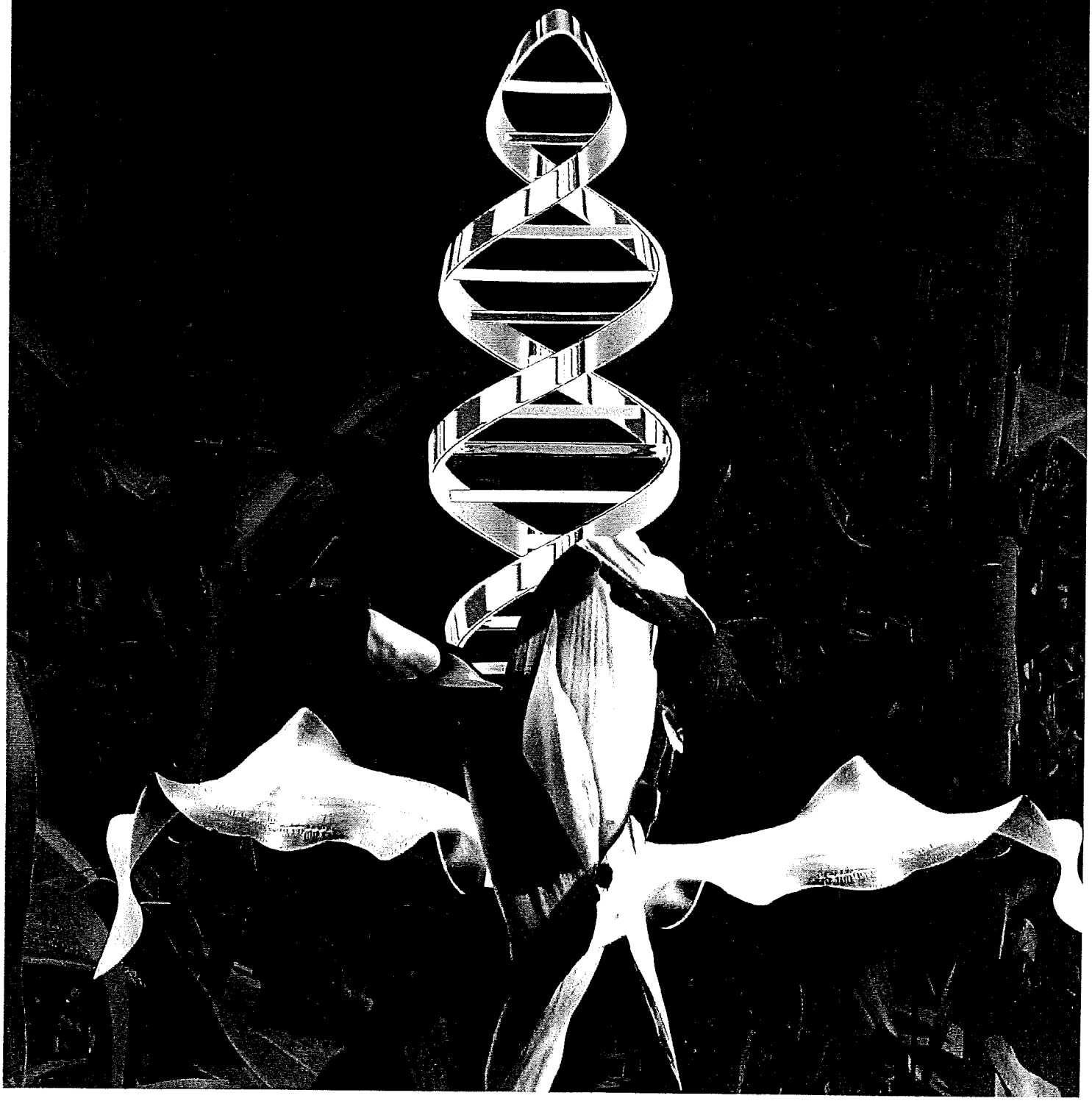
[6] Macilwain C. (2005). US launches probe into sales of unapproved corn. *Nature*, 434:423; CBS (2001) *The Starlink Nightmare*, 18/5/01, http://www.cbsnews.com/news/the-starlink-nightmare/

[7] USA Rice Federation (2013) Submission to the USTR on the Transatlantic Trade and Investment Partnership.

[8] Smith, N. (2016). GMO regulations clarified, 5/4/16, https://www.beehive.govt.nz/release/gmo-regulations-clarified-0

Friends of the Earth

GM 2.0
AUSTRALIAN REGULATORS ENGINEERING THE TRUTH



ACT Government Health

URGENT

CORRESPONDENCE CLEARANCE

SUBJECT: **Email - Legislative and Governance Forum on Gene Technology (LGFGT) Out of Session 2016/002 - Shortlist of Nominees for the Gene Technology Technical Advisory Committee (GTTAC)**

NUMBER: **MIN16/1408** **DATE DUE:** 9/12/16

Director-General - ACT Health:		Date:
Deputy Director-General - Corporate:		Date:
Deputy Director-General - Canberra Hospital & Health Services:		Date:
Deputy Director-General - Innovation:		Date:
Deputy Director-General - Quality, Governance and Risk:		Date:
Deputy Director-General - Population Health Protection & Prevention:		Date: 7/12
Executive Director - Area nan		Date:
Senior Manager - Area nar		Date: 7/12
Senior Manager, Ministerial and Government:		Date:
Senior Manager - Media and Strategic Communications:		Date:
Executive - Area nan		Date:
Manager - Area nan		Date:
Professional Leads:		Date:
Other:		Date:

ACT Government
Health

MINISTERIAL BRIEF

GPO Box 825 Canberra ACT 2601 | phone: 13 22 81
www.health.act.gov.au

UNCLASSIFIED

		TRIM No.: MIN16/1408
To:	Meegan Fitzharris MLA, Minister for Health	Date Rec'd Minister's Office 7/12/16
From:	Ms Nicole Feely, Director-General ACT Health	
Subject:	Appointment to the Gene Technology Technical Advisory Committee	
Critical Date:	9 December 2016	
Critical Reason:	In order to meet Commonwealth deadline.	

Purpose

1. To seek your agreement to:

   - the shortlisted nominees for appointment to the Gene Technology Technical Advisory Committee (GTTAC).
   - the proposed nomination of Professor John Rasko AO for appointment as Chair of GTTAC.

Background

2. The function of the GTTAC is to provide scientific and technical advice, on the request of the Gene Technology Regulator and the Legislative and Governance Forum on Gene Technology (LGFGT). As ACT Minister for Health, you are a member of the LGFGT.

3. The GTTAC can have up to 20 members, appointed by the Commonwealth Minister responsible for gene technology, Assistant Minister for Rural Health, the Hon Dr David Gillespie MP. Current appointments to the GTTAC expire on 31 January 2017.

4. On 1 September 2016, a Gene Technology Standing Committee (GTSC) selection working group, comprised of representatives from the Commonwealth, New South Wales, Victoria and Queensland, shortlisted 16 nominees for the 2017-20 triennium of GTTAC (shortlist at Attachment A).

5. In selecting nominees, the working group had regard to skills and experience required by the *Gene Technology Act 2000* (GT Act), as well as aiming to achieve a balance of gender concurrent with the mix of scientific expertise required, jurisdictional representation and a mix of new and returning members to provide continuity. Deliberations of the working group are outlined in Attachment A.

6. The proposed Chair for GTTAC is Professor John Rasko AO (nomination at Attachment B). Professor Rasko is the current Chair of GTTAC and the working group saw benefit in maintaining continuity in this key position at this time.

7. The working group was satisfied that there was adequate expertise on the shortlist in all categories required by the GT Act for GTTAC.

8. In September 2016, the GTSC agreed to refer the shortlist of nominees to the LGFGT and endorsed the reappointment of Professor Rasko as Chair of GTTAC.

9. A declaration of interests is being sought from all shortlisted nominees. None of the shortlisted nominees noted any conflicts in their nomination form beyond those that would reasonably be expected of professional people, some of whom work in gene technology.

Government Commitment – Parliamentary Agreement

10. Section 100 of the *Gene Technology Act 2000* requires the Commonwealth to consult with States, through the LGFGT, on appointments to the GTTAC.

11. In accordance with clause 23(d) of the intergovernmental gene technology agreement, this consultation is taking place through the LGFGT, of which you are a member.

Issues

12. It is recommended that you agree to the shortlisted nominees for appointment to the Gene Technology Technical Advisory Committee (GTTAC).

13. It is recommended that you endorse the proposed nomination of Professor John Rasko AO for appointment as Chair of GTTAC.

Financial Implications

14. Not applicable.

Directorate Consultation

15. Not applicable.

External Consultation

16. The Commonwealth Minister responsible for gene technology, Assistant Minister Gillespie, must consult all States and Territories before appointment members to the GTECCC.

Benefits/Sensitivities

17. Not applicable.

Media Implications

18. No media interest is expected in relation to this issue.

Recommendations

That you:

1. Note the information contained in this brief;

Noted/Please Discuss

2. Agree to endorse the proposed shortlist of nominees for appointment to GTTAC by completing the form at Attachment C.

Agreed/Not Agreed/Please Discuss

3. Agree to the nomination of Professor John Rasko AO for appointment as Chair of GTTAC by completing the form at Attachment C.

Agreed/Not Agreed/Please Discuss

Meegan Fitzharris MLA..... 9/12/16

Minister's Comments

Signatory Name:	Dr Paul Kelly	Phone:	50883
Title:	Chief Health Officer		
Date:	December 2016		
Action Officer:	Kirsty Whybrow	Phone:	50178

Attachment 2 A

Proposed members for Gene Technology Technical Advisory Committee (GTTAC)

A total of 16 nominees have been agreed by the Gene Technology Standing Committee (GTSC) for consideration for appointment to GTTAC. The *Gene Technology Act 2000* (GT Act) provides for a maximum of 20 members to be appointed to GTTAC.

Name	Position	Organisation, State
Dr Graham Bonnett	Research Director	CSIRO Agriculture and Food, QLD
Dr Orin Chisholm	Program Authority and Senior Lecturer in Pharmaceutical Medicine	School of Medical Sciences, University of New South Wales, NSW
Mrs Laura Fell ***proposed layperson***	Egg farmer	McLaren Vale, SA
Dr Tessa Gargett	Post-doctoral research scientist	Centre for Cancer Biology, University of South Australia, SA
Dr Richard Gordon	Senior Research Fellow	The University of Queensland, QLD
A/Prof John Hayball	Associate Professor	School of Pharmacy and Medical Sciences, University of South Australia, SA
Prof Robert Henry	Professor of Innovation in Agriculture; Director Queensland Alliance for Agriculture and Food Innovation	University of Queensland, QLD
Dr Thomas Higgins	Semi-retired and part-time Professor of Science and Technology	Queensland University of Technology, ACT
Dr Danny Llewellyn	Chief Research Scientist	CSIRO Agriculture and Food
Dr Rebecca McCracken	Senior Advisor Patents and Technical IP; Non-Executive Director	Rio Tinto; Epichem Pty Ltd
Dr Michael Michael	Laboratory Head	Flinders Centre for Innovation in Cancer, Flinders Medical Centre, SA
Dr Gabrielle O'Sullivan ***proposed GTECCC cross-member***	Executive Officer and member	Institutional Biosafety Committee, Royal Prince Alfred Hospital, NSW
Prof John Rasko AO ***proposed Chair***	Director; Program Head	Cell and Molecular Therapies Royal Prince Alfred Hospital; Centenary Institute, NSW
A/Prof Jason Smythe	Senior Business Development Manager; Adjunct Associate Professor	Faculty of Medicine, Monash University; Faculty of Science and Engineering, La Trobe University, VIC
Dr Robert Sward ***proposed GTECCC cross-member***	Director	BioBotanicals Consulting, VIC
Prof Paul Young	Professor of Virology and Head of School	School of Chemistry and Molecular Biosciences, University of Queensland, QLD

Proposed members for GTTAC – matrix of expertise

Nominees for the Gene Technology Technical Advisory Committee																			
Name	Previous Membership	Categories of Expertise																	
		A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
Dr Graham Bonnett	GTTAC	X	X				X				X					X				
Dr Orin Chisholm	New nominee	X									X		X	X						
Mrs Laura Fell ***proposed layperson***	GTTAC																			
Dr Tessa Gargett	New nominee	X										X							X	
Dr Richard Gordon	New nominee	X		X						X	X			X					X	X
A/Prof John Hayball		X		X	X		X						X		X			X	X	
Prof Robert Henry	New nominee	X	X	X			X						X		X	X				
Dr Thomas Higgins	New nominee	X		X									X			X				
Dr Danny Llewellyn	New nominee	X		X		X	X						X		X		X			
Dr Rebecca McCracken	New nominee	X		X	X			X		X	X	X	X		X		X	X	X	
Dr Michael Michael	GTTAC	X		X									X			X		X		
Dr Gabrielle O'Sullivan ***proposed GTECCC cross-member***	GTTAC				X				X		X		X				X		X	
Prof John Rasko AO ***proposed Chair***	GTTAC (Chair)	X			X				X	X	X	X	X					X	X	
A/Prof Jason Smythe	GTTAC	X		X	X			X	X	X	X		X		X		X	X	X	
Dr Robert Sward ***proposed GTECCC cross-member***	New nominee																			
Prof Paul Young	GTTAC	X			X												X		X	
	Totals	13	2	8	6	1	4	2	3	4	7	3	10	2	5	4	5	5	8	1

Categories of Expertise

A	Molecular Biology
B	Ecology
C	Plant, Microbial, Animal or Human Genetics
D	Virology
E	Entomology
F	Agricultural or Aquacultural Systems
G	Biosafety Engineering
H	Public Health
I	Occupational Health and Safety
J	Risk Assessment
K	Clinical Medicine
L	Biochemistry
M	Pharmacology
N	Plant or Animal Pathology
O	Botany
P	Microbiology
Q	Animal Biology
R	Immunology
S	Toxicology

Deliberations of the Gene Technology Standing Committee working group during shortlisting of nominees for the Gene Technology Technical Advisory Committee

Gender balance

- The working group had regard to the Commonwealth Government commitment to a gender diversity target whereby women hold 50 per cent of Government board positions overall, with at least 40 per cent representation of women and 40 per cent men on individual boards.
- The shortlist for GTTAC comprises 5 women (31%) and 11 men (69%) compared to the current membership of 6 women (37%) and 12 men (63%). Although this level of female representation is lower than the above targets, the working group considered the highly technical requirements for this committee and produced a shortlist that provided the highest calibre of scientific and technical expertise covering all the specific scientific disciplines prescribed by the GT Act and an appropriate gender balance.
- It is noted that in some prescribed fields there were as few as two candidates which impacted on how gender balance could be maintained.

Committee size

- The working group shortlisted 16 nominees for GTTAC, including a layperson. The GT Act provides for appointment of up to 20 members.
- The current GTTAC is made up of 19 members. In determining the number of nominees, the working group took into account the need for the committee to be effective and efficient and whilst ensuring sufficient scientific coverage.
- In shortlisting nominees, the working group had regard to skills and experience required by the GT Act, and was satisfied that the shortlist provides for a breadth of experience and expertise.

Chair

- Professor John Rasko was proposed as Chair. He is the current Chair of GTTAC.
- The working group noted that Professor Rasko has served two terms as a member of GTTAC and is completing his third term as Chair. The working group considered that it was important to have an experienced Chair to ensure GTTAC provides consistent and timely advice to support the new Regulator.

GTECCC cross-member

- The GT Act requires that GTTAC includes at least one person who is a member of the Gene Technology Ethics and Community Consultative Committee (GTECCC).
- The current GTTAC-GTECCC cross-member is GTTAC member Dr Gabrielle O'Sullivan, who has been in the role since she was appointed to GTECCC on 28 September 2015. The working group considered it appropriate to recommend Dr O'Sullivan for reappointment to GTTAC to continue as the GTTAC-GTECCC cross-member.
- The current membership of GTECCC will expire 18 September 2018, after which there will not be a cross member on GTTAC unless Dr O'Sullivan is reappointed to GTECCC at that time.
- To allow for some redundancy, the working group proposed GTECCC member Dr Robert Sward as a second cross-member, and that he be approached to ascertain his interest and willingness to be considered for this role.
- A second GTTAC-GTECCC cross-member would increase the likelihood that at least one cross-member would be reappointed to the new GTECCC membership after 28 September 2018 and be able to continue as the cross-member on GTTAC.

Other deliberations

- The working group took advice from the OGTR in relation to the types of applications the GTTAC will advise on. It was noted GTTAC is being called upon increasingly to advise on Biomedical applications and to ensure to have a sufficient mix of scientific personnel who were comfortable within this discipline.
- Shortlisted nominees are from QLD (4), VIC (2), NSW (3), SA (4), WA (1) and ACT (2).
- The working group proposed Ms Laura Fell be reappointed as the layperson for GTTAC.
- Of the 16 shortlisted nominees, 8 are new nominees and 8 are current members of GTTAC.
- The shortlisted nominees have indicated specific expertise in all 20 categories specified in the GT Act and the GTSC working group was satisfied that there was adequate expertise in these categories among the shortlisted nominees.

B

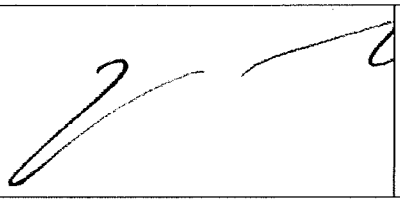
Australian Government

Department of Health

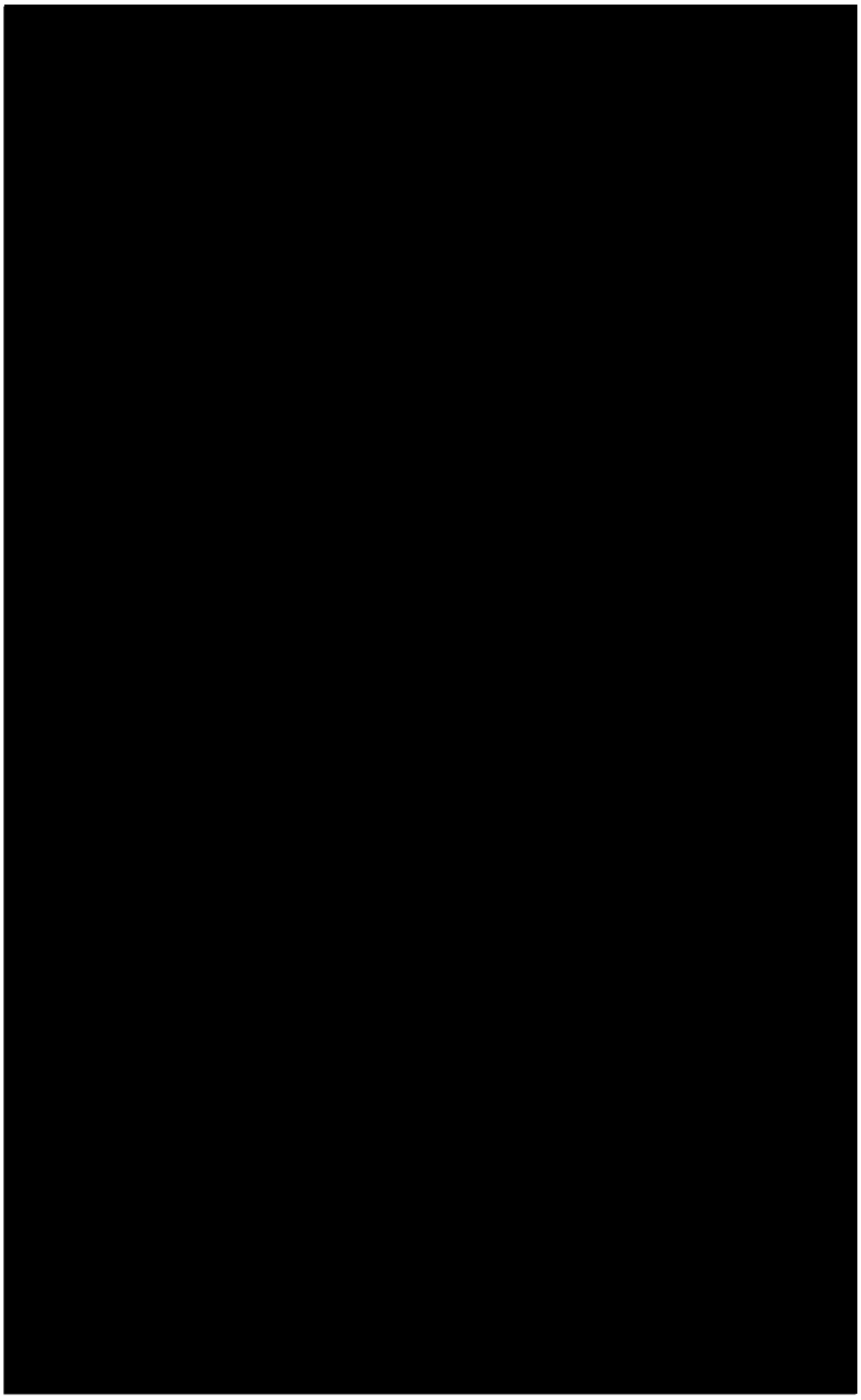
Office of the Gene Technology Regulator

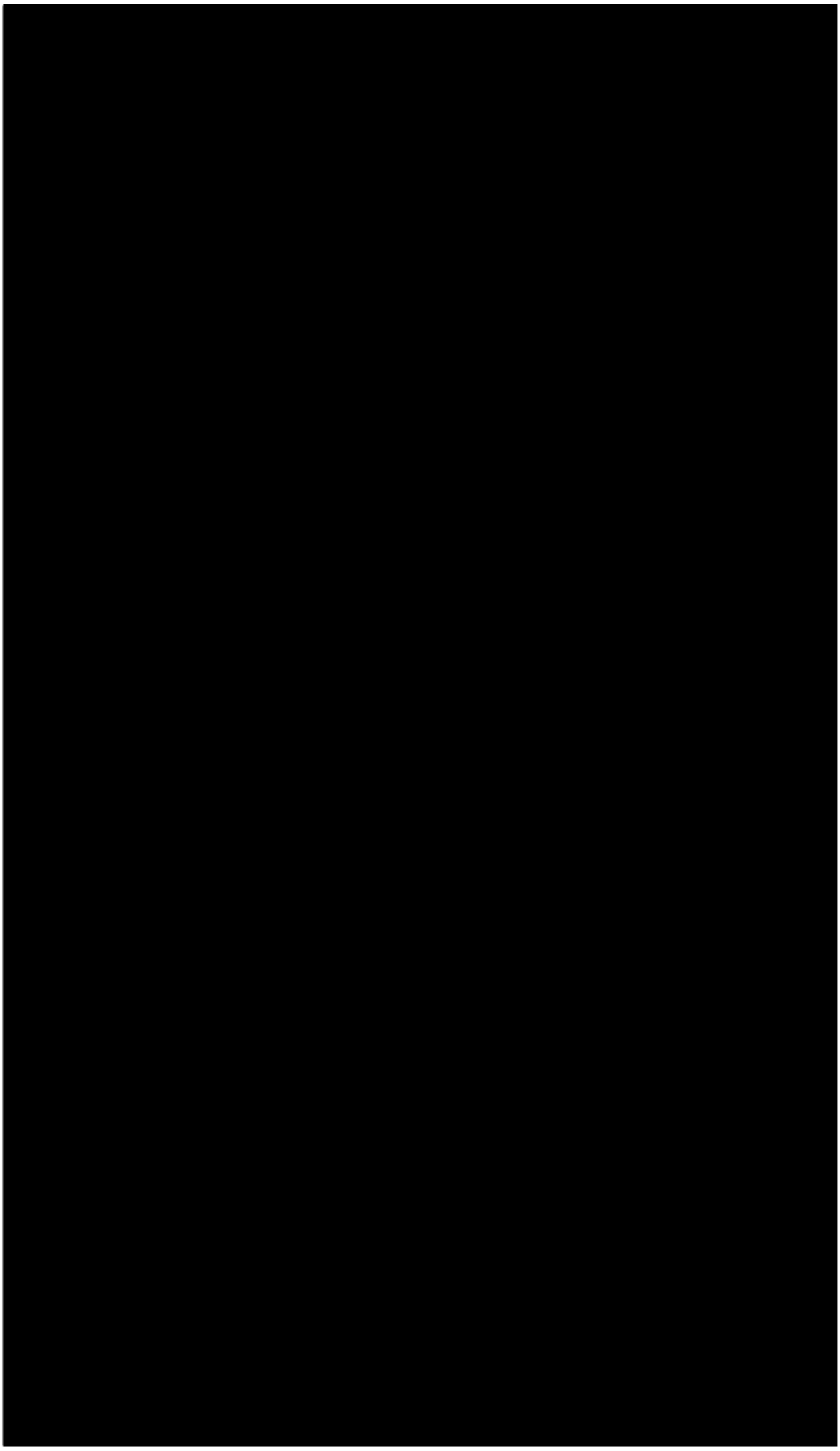
GENE TECHNOLOGY TECHNICAL ADVISORY COMMITTEE NOMINATION FORM

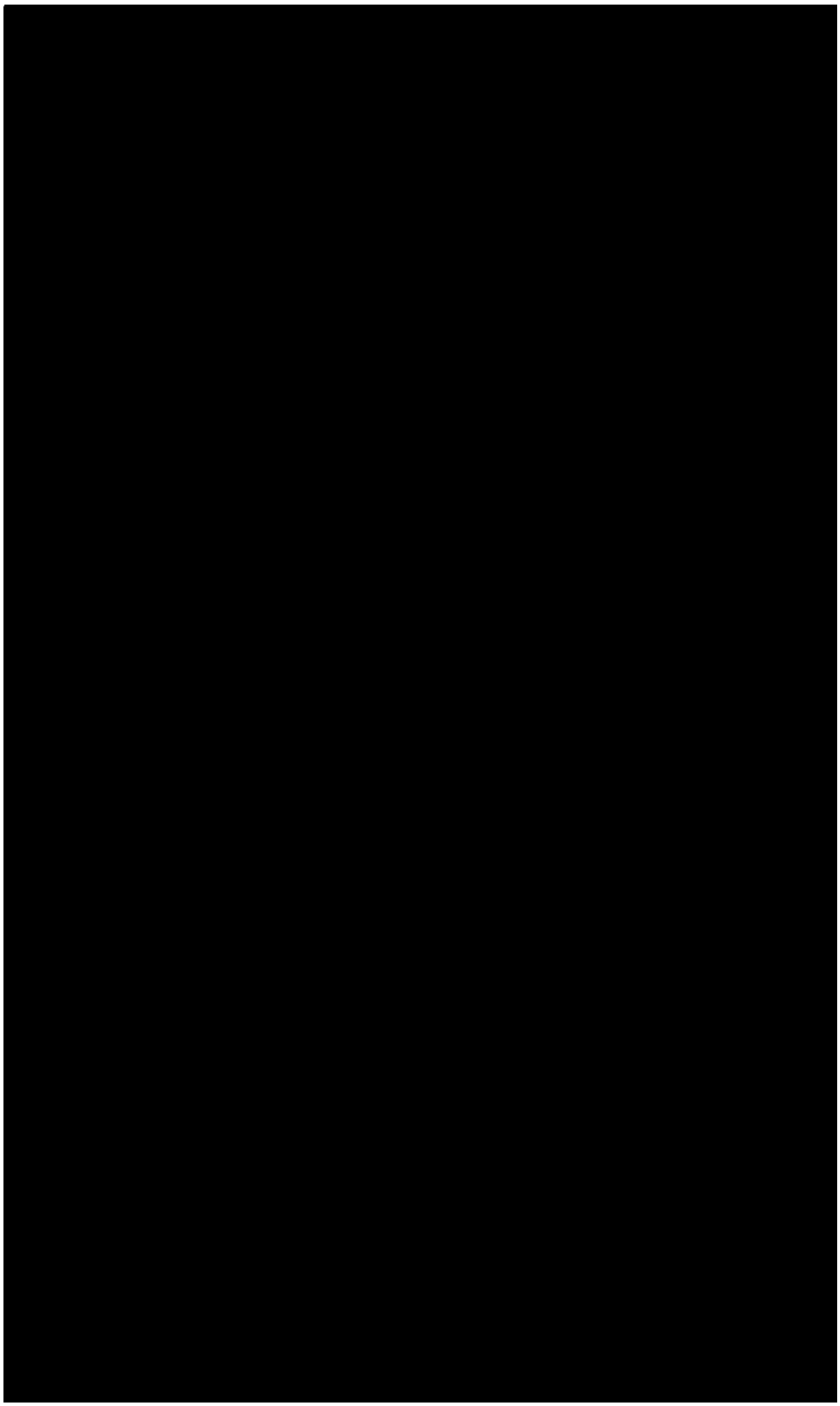
1. GENERAL INSTRUCTIONS	° Please complete all sections of this form. ° Additional pages may be attached if there is insufficient space on the form. ° Please DO NOT attach a separate *Curriculum Vitae* – all required information should be on the form. ° The Minister must appoint one of the members to chair the committee. If you would like to be considered for the role of Chair, please ensure you complete Part 8 of this form. CLOSING DATE FOR NOMINATIONS: 3 June 2016 Send the completed form to: Email: ogtrcommittees@health.gov.au (preferred) Mail: Committee Secretariat OGTR, MDP 54 GPO Box 9848 CANBERRA ACT 2601 Fax: 02 6271 4202			
	How did you hear about the call for nominations for membership to GTTAC? Email/committee			
2. PERSONAL DETAILS	SURNAME	Rasko AO		
	GIVEN NAME(S)	John Edward Joshua	TITLE	Prof
	DATE OF BIRTH	17-Sep-61	GENDER	M
	ADDRESS	Department of Cell & Molecular Therapies RPAH Level 2, Building 89, Missenden Road CAMPERDOWN NSW 2050		
	EMAIL	j.rasko@cenint.org		
	PHONE	+612 95656116		
	MOBILE	+61 0408 424 013		
	FAX	+612 95656101		

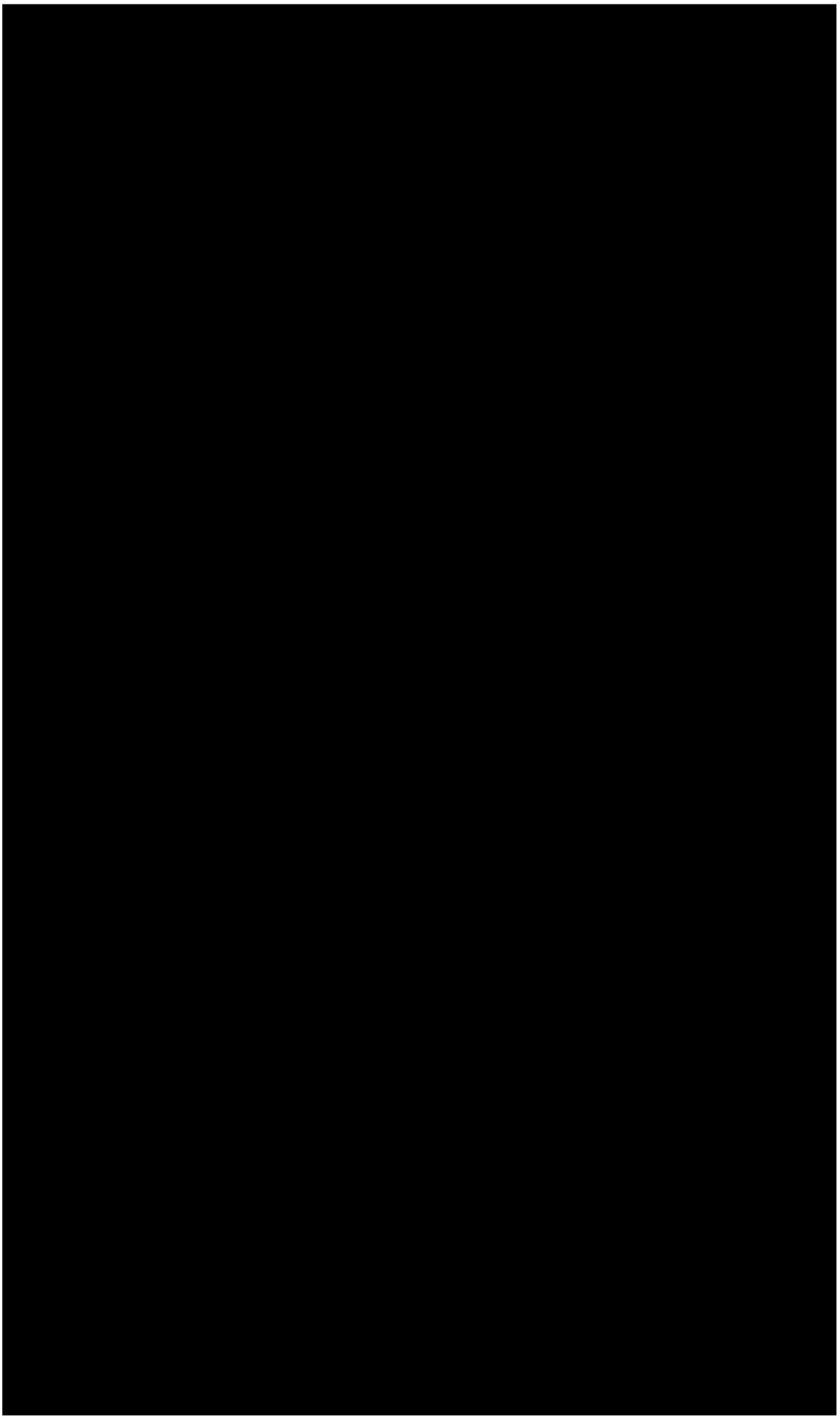
	SIGNATURE		DATE	3 June16

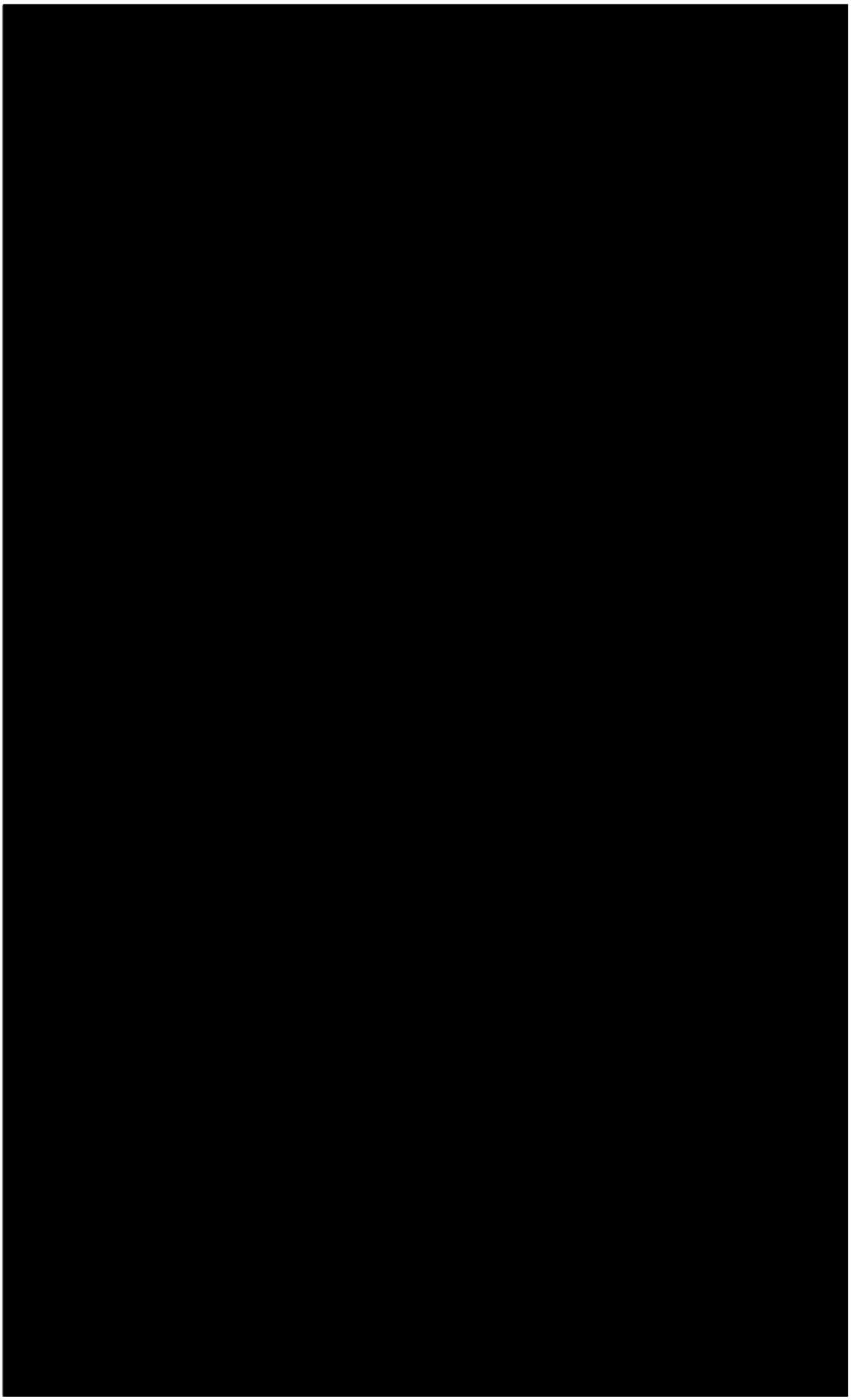
3. SKILLS AND EXPERIENCE	The *Gene Technology Act 2000* requires that, before making an appointment to GTTAC, the Minister must be satisfied that the person has skills or experience in one or more of the following areas. Please indicate those areas where you have skills and experience and briefly justify your claims in the space below.	
	☒ Molecular biology	☒ Clinical medicine
	☐ Ecology	☒ Biochemisty
	☐ Plant, microbial, animal or human genetics	☐ Pharmacology
	☒ Virology	☐ Plant or animal pathology
	☐ Entomology	☐ Botany
	☐ Agricultural or aquacultural systems	☐ Microbiology
	☐ Biosafety engineering	☒ Animal biology
	☒ Public health	☒ Immunology
	☒ Occupational health and safety	☐ Toxicology
	☒ Risk assessment	
	The Minister must also appoint a layperson as a member of the Committee, and is not required to be satisfied that the lay person has skills and experience in any of the areas listed above. If you wish to be considered for this position please indicate by ticking this box. You do not need to provide a justification for this. ☐ Lay person	

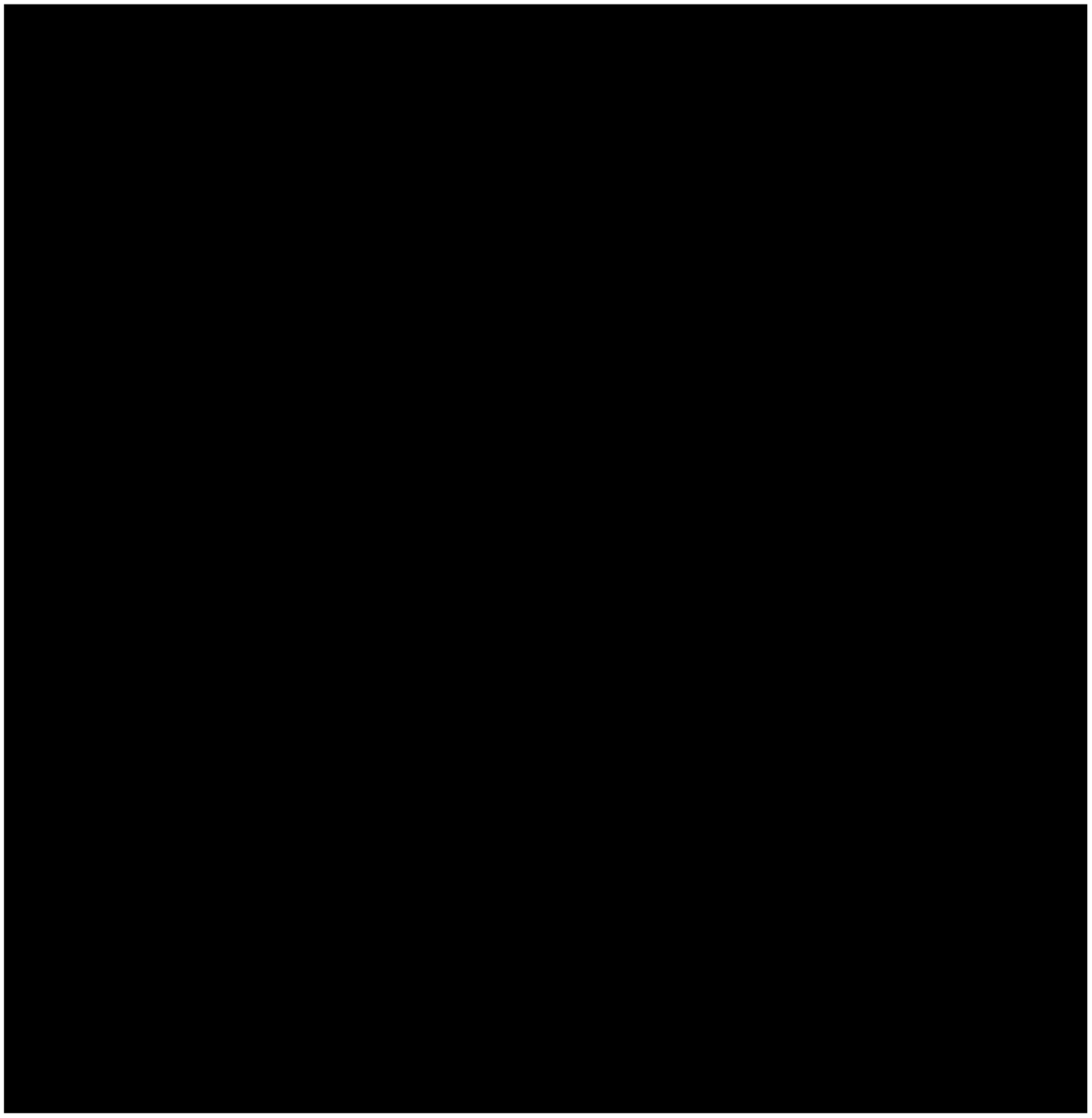


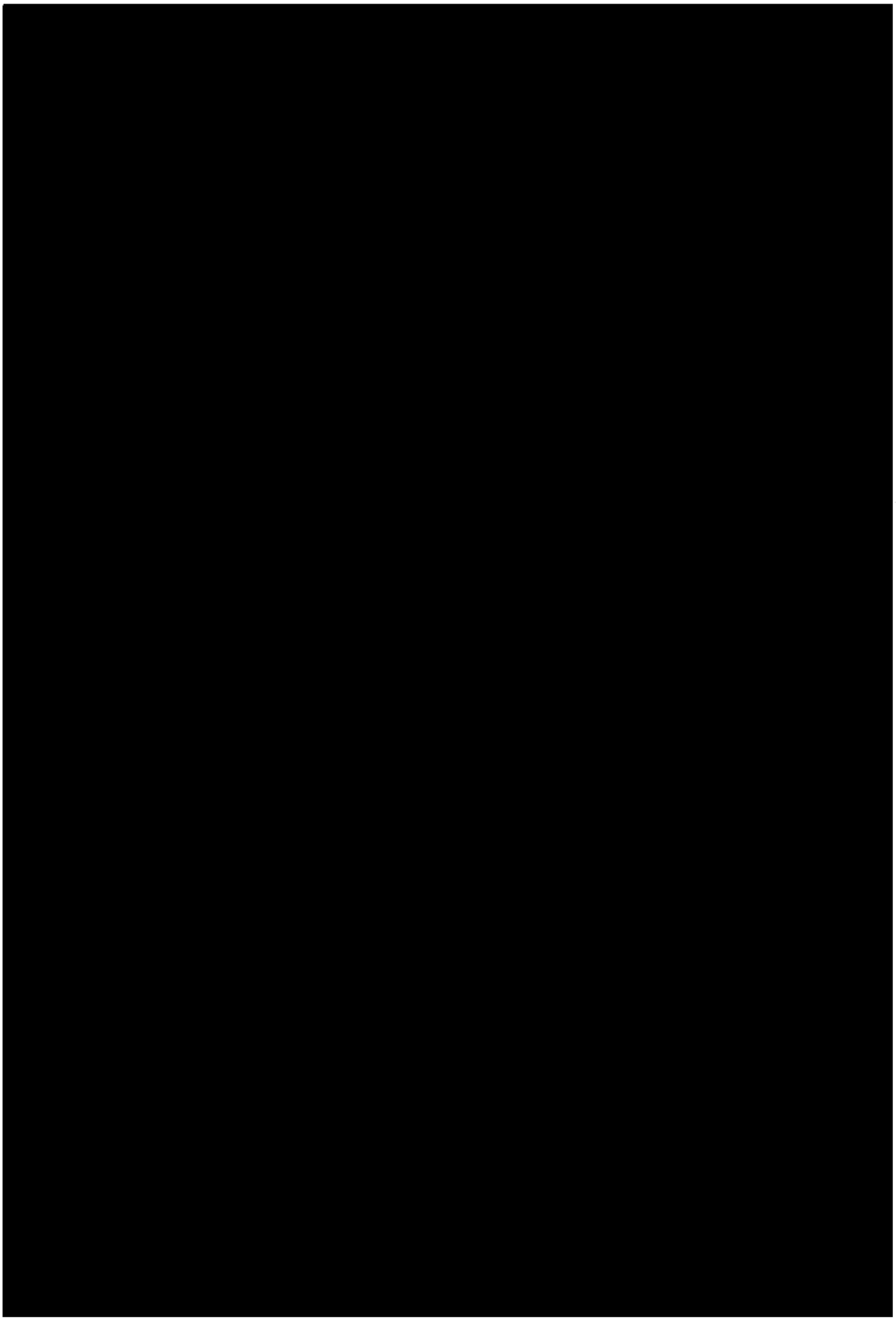












E-MAILED 9-12-16 MB

C

Australian Government

Department of Health

LEGISLATIVE AND GOVERNANCE FORUM ON GENE TECHNOLOGY

PLEASE REPLY BY 9 December 2016

TO: **Legislative and Governance Forum on Gene Technology Secretariat**

Email:gene.technology.secretariat@health.gov.au

FROM: ACT MINISTER FOR HEALTH

TEL:

MESSAGE:

I, MEEGAN FITZHARRIS,

for ACT MINISTER FOR HEALTH,

a member of the LEGISLATIVE AND GOVERNANCE FORUM ON GENE TECHNOLOGY,

(Please circle)

Noted	**NOTE** that the Gene Technology Standing Committee (GTSC) has agreed to refer for LGFGT consideration the shortlist of nominees for GTTAC and has endorsed the proposed Chair
Endorse/~~Not Endorse~~	**ENDORSE** the proposed shortlist of nominees for appointment to GTTAC
Agree/~~Not Agree~~	**AGREE** the nomination of Professor John Rasko AO for appointment as Chair of GTTAC

Signature Block:

Date: 9/12/16

Your reply by 9 December 2016 would be greatly appreciated

ACT Government
Health

CORRESPONDENCE CLEARANCE

SUBJECT: **Letter Meeting request Regulation of new genetic modification (GM) techniques - Sales**

NUMBER: **MIN16/1363** **DATE DUE:** .....

Director-General - ACT Health: ..... Date: 19/12

Deputy Director-General - Corporate: ..... Date: .....

Deputy Director-General - Canberra Hospital & Health Services: ..... Date: .....

Deputy Director-General - Innovation: ..... Date: .....

Deputy Director-General - Quality, Governance and Risk: ..... Date: 15/12/16 revised pic.

Deputy Director-General - Population Health Protection & Prevention: ..... Date: 9/12/16

Executive Director - Area nan ..... Date: .....

Senior Manager - Area nar ..... Date: .....

Senior Manager, Ministerial and Government: ..... Date: .....

Senior Manager - Media and Strategic Communications: ..... Date: .....

Executive - Area nan ..... Date: .....

Manager - Area nan ..... Date: .....

Professional Leads: ..... Date: .....

Other: ..... Date: .....

ACT Government
Health

Office of the Director-General

[redacted]

E-MAILED
22/12/16

Dear [redacted]

Regulation of new genetic modification (GM) techniques

Thank you for your letter of 17 November 2016 to the Minister for Health, Ms Meegan Fitzharris MLA regarding the regulation of new genetic modification techniques that the Office of the Gene Technology Regulator (OGTR) is proposing to deregulate. I am responding on her behalf.

As you have mentioned in your letter, the OGTR is a federal regulator. Whilst the ACT is involved in providing feedback to the OGTR on various issues, including the Review to which you refer, I believe it would be more appropriate for you to contact OGTR directly on 1800 181 030 or by email to ogtr@health.gov.au with your concerns.

Thank you again for writing about this matter.

Yours sincerely

Nicole Feely
Director-General

19 December 2016