Australian Government

Department of Innovation
Industry, Science and Research

2011 Review of the Gene Technology Act (2000)

Public Submission

By the Department of Innovation, Industry, Science and Research

And

The Commonwealth Scientific and Industrial Research Organisation

About the Innovation, Industry, Science and Research portfolio

The **Department of Innovation, Industry, Science and Research** strives to encourage the sustainable growth of Australian industries by developing a national innovation system that drives knowledge creation, cutting edge science and research, international competitiveness and greater productivity, leading to a more prosperous Australia.

The Department's policies and programs recognise the importance of science and technology to Australia's economic and social well-being. The Department promotes Australia's science interests by managing national funding of major research infrastructure, developing global science partnerships, providing advice on science and technology issues and fostering the Department's relationship with Australia's research agencies.

The Department also provides advice on major strategic research policy issues including collaboration (between researchers, between researchers and industry, between researchers and the public sector), research training, research workforce and quality, funding and accountability.

The Department funds indirect costs of research through the 'Sustainable Research Excellence in Universities' initiative, and distributes performance-based funding to universities through 'Mission Based Compacts' to align institutional activities with national priorities.

By backing Australia's science and research efforts and investing in significant infrastructure, Australia has the edge to compete at the forefront of international research.

The **Commonwealth Scientific and Industrial Research Organisation (CSIRO)** is Australia's national science agency and one of the largest and most diverse research agencies in the world. CSIRO is an Australian Government statutory authority constituted and operating under the provisions of the *Science and Industry Research Act 1949*. CSIRO's primary functions under the Act are to carry out scientific research to benefit Australian industry and the community, and to contribute to the achievement of national objectives.

CSIRO is accountable to the Minister for Innovation, Industry, Science and Research and is part of the Innovation, Industry, Science and Research portfolio. The CSIRO Board is responsible to the Australian Government for the overall governance, strategy and performance of the Organisation.

Executive Summary

1. The Department of Innovation, Industry, Science and Research (Department) and the Commonwealth Scientific and Industrial Research Organisation (CSIRO) considers that the *Gene Technology Act 2000* (the Act) is an efficient and effective mechanism for regulating genetically modified organisms (GMOs) in Australia. This submission contends that the Act provides a suitable level of protection of people and the environment, by identifying and managing the risks posed by, or as a result of, gene technology.

2. The Department and CSIRO also support the Office of the Gene Technology Regulator's (OGTR) work to harmonise and reduce overlaps with other relevant Commonwealth regulators. Avoiding duplication of regulatory procedures is critical to facilitate the development of, and commercial investment in, biotechnology applications. Inconsistencies between the Act and State and Territory based processes is an area of concern.

3. Development of the emerging bio-based industry sector (biofuels and other industrial biotechnology processes) will be fostered by a nationally consistent regulatory framework for GMOs and applications. Providing a consistent regulatory framework enables certainty for investments by industry to develop globally competitive bio-based industries. This will drive economic growth nationally, but particularly in rural and regional centres, stimulating employment and initiating precinct development in rural regions.

4. Opportunities exist to improve regulatory efficiency and enhance the ability of the legislation to support new and emerging biotechnology industries and applications. The Department therefore recommends the following:

    - Simplify the current regulatory scheme in Australia. The regulation of GMOs at a Commonwealth level works through the relatively successful integration of responsibilities by relevant agencies. However, an apparent disconnect between Commonwealth and state/territory schemes for the regulation of gene technology and the moratoria imposed by various States on the growing of certain genetically modified (GM) crops on a commercial basis, hampers innovation and creates uncertainty for businesses. This, in turn, creates a disincentive for investment.

    - Consider how the Australian regulatory framework can be amended to meet the challenges of industrial scale bio-based production. The Australian industrial biotechnology sector has noted that the current regulatory processes cannot effectively deal with certain aspects of industrial GMOs. Issues such as scale, containment and the organisms with multiple modifications may create problems for regulators in the future.

    - Consider how well placed the current Australian regulatory framework is to assess emerging biotechnology applications such as synthetic biology. Possible regulatory issues from synthetic biology applications could arise due to the regulatory lag in dealing with modified DNA that contains new bases. The current regulation is based on the difference between "original" and a "modified" gene, however, in the case of a new synthetic gene without a

natural counterpart the lack of a baseline comparison would pose challenges for the current regulator framework. In short, there is a risk of the technology outpacing the regulation.

- The OGTR consider exploring and trialling new media alternatives as additional ways to engage with a broader range of stakeholders. Although public concern over the use of GMOs has decreased over time, there is a need to ensure that consultation seeks to actively solicit input beyond the most active interest groups and includes those who are: highly-interested; those who are affected; and those who have lower levels of interest. Mechanisms to seek input from the unengaged should also be considered.

- Consider how the notion of *benefits* could be included in the risk assessment of GMOs. Currently, the OGTR is required to assess the risks to human health and safety and the environment. A risk assessment process that included a reflection of the likely 'benefits' of GMOs, would allow for the consideration of potential environmental benefits such as the potential for GM technologies to mitigate climate change. Any such consideration of benefits would need to ensure that no additional regulatory burden was placed on applicants.

5. The CSIRO recommends that consideration be given to streamlining the Act as follows:

    - Allowing variations to a licence for 'Dealings involving Intentional Release'(DIRs) where the consideration of additional (limited) risks is permitted (Part 5 Division 7 Section 71 (2B));

    - Allowing Institutional Biosafety Committees (IBCs) to approve variations to Notifiable Low Risk Dealings (NLRDs) without the need to issue a new NLRD (Section 74, 75);

    - Remove excessive regulatory requirements surrounding the 'large-scale' (>25 litres) culturing of organisms which would be considered 'NLRDs' at small-scale (eg. review and expand the current low-risk host/vector in Part 1 Schedule 2 to include others with similar low-risk profiles; 'large-scale' culture should not be given a blanket definition of >25 litres), and;

    - Remove an orphan reference in 'Definitions' which is no longer appropriate as the current gene technology legislation no longer deals with human cloning and associated matters.

1. The effectiveness and efficiency of the regulatory scheme

1(a) The national scheme for gene technology regulation in Australia

6. A best-practice regulatory framework that is effective and efficient is critical to the support of productive and internationally competitive Australian industries. It will also encourage world-class science, research and innovation. The Australian Government has stated that it will ensure regulations are well-designed, enacted only where absolutely necessary and at a minimum cost to business.

Integrated Commonwealth System

7. The current scheme of gene technology regulation in Australia is complex. Live and viable genetically modified organisms (GMOs) are regulated in Australia by the Gene Technology Regulator (Regulator) under the Commonwealth *Gene Technology Act 2000* (the Act) and corresponding state and territory legislation. The Regulator is supported by the Office of the Gene Technology Regulator (OGTR). The regulatory system centres on a rigorous process of identifying and assessing risks to human health and safety and the environment based on scientific evidence.

8. Australia's gene technology regulatory system operates at the Commonwealth level as an integrated framework involving other agencies that have responsibility for regulating GMOs or GM products as part of a broader or different mandate:

- Food Standards Australia New Zealand (FSANZ) is responsible for examining the safety of GM foods under Standard 1.5.2 (*Food Produced Using Gene Technology*) of the Australia New Zealand *Food Standards Code*. Approval of GM foods or ingredients is given if FSANZ concludes the GM food is as safe as its conventional equivalent.

- The Australian Pesticides and Veterinary Medicines Authority (APVMA) operates the national system that evaluates, registers and regulates all agricultural chemicals (including those that are, or are used on GM crops) and veterinary therapeutic products. This is conducted under the *Agricultural and Veterinary Chemicals (Code) Act 1994* and the *Agricultural and Veterinary Chemicals Administration Act 1994*.

- The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) provides a national notification and assessment scheme to protect the health of the public, workers and the environment from the harmful effects of industrial chemicals under the *Industrial Chemicals (Notification and Assessment) Act 1989*.

- The Therapeutic Goods Administration (TGA) administers the *Therapeutic Goods Act 1989* that provides a national framework for the regulation of medicines, medical devices, blood and tissues in Australia, including GM and GM-derived therapeutic products, and ensures their quality, safety and efficacy.

- The Australian Quarantine and Inspection Service (AQIS) regulates the importation into Australia of all animal, plant and biological products that may pose a quarantine pest and/or disease risk under the *Quarantine Act 1908* and *Imported Food Control Act 1992*. Import permit applications must indicate the presence of a GMO and the OGTR authorisation.

9. Additionally, the States and territories also have regulatory responsibilities for GMOs. The Primary Industries Ministerial Council agreed in 2003 to issue a policy principle to recognise the rights of state and territory governments to designate zones for GM or non-GM crops for marketing purposes.

10. This means that the Regulator's decision to grant a commercial release licence for a GM crop must recognise any laws the states and territories make in respect of preserving the identity of GM and/or non-GM crops for marketing purposes. For example, when a state government implements a policy principle recognising a GM-free area, in granting any GM crop licence, the Regulator must respect this area as GM free and exempt it from any licence approval.

New bio-based industries

11. Regulatory reform of GMOs and applications will lead to improved economic and environmental outcomes for regional areas, and foster development of an Australian bio-based industry sector. Providing a consistent regulatory framework enables certainty for investments by industry to develop globally competitive bio-based industries. This will drive economic growth nationally, but particularly in rural and regional centres, stimulating employment and initiating precinct development in rural regions.

12. Australia's productivity can benefit from the bio-based future industries. In the future, a significant use of biotechnology will be outside food and pharmaceuticals. The bio-based industries utilise biomass as an industrial feedstock to produce energy, fuels, chemicals and materials. GM technology is applied for example in engineering improved plant or algal feedstocks, or microbes that can break down complex biomass (such as wood) into simple platform chemicals.

13. In 2010, the Department commissioned two scoping studies into the Australian bio-based industry. These studies found that internationally competitive and profitable bio-based products industries have the potential to generate a range of national benefits. Over 83,000 people work in the chemicals industry which contributes 1% Australia's GDP. A similar number of people are employed in forestry, pulp and paper industries. Bio-based manufacturing can modernise these industries, and promote sustainable development in the regional areas. It is estimated that in Australia, bio-based products could generate in excess of $20 billion annually in platform chemicals by 2020, in addition to income from renewable energy. Importantly, a local bio-based industry can replace some of the imported chemicals used within the manufacturing industry.

14. Furthermore, international studies show that replacing petrochemicals with biomass as industrial feedstock can significantly mitigate climate change, through reduction in the use of costly fossil fuels and reduction in greenhouse gas

emissions. These benefits were highlighted in a recent World Wildlife Fund (WWF) report, *Industrial Biotechnology: More Than Green Fuel In A Dirty Economy*? The report concluded that in order to solve the climate change crisis there is a need to alter policy perspectives from sole reliance on reduction in carbon emissions to developing industry sectors, such as industrial biotechnology, as part of a sustainable economy.

15. Currently, the bio-based industry sector avoids the creation of 33 million tonnes of carbon dioxide globally each year through various applications, without taking ethanol use into consideration, whilst globally emitting 2 million tonnes of carbon dioxide. The report concludes that 'full climate change mitigation potential of industrial biotechnology ranges between 1 billion and 2.5 billion tonnes of carbon dioxide emissions per year by 2030, compared with a scenario in which no biotechnology applications are available.'

16. Development of the emerging bio-based industry sector will require a regulatory framework that meets the challenges of industrial scale bio-based production. The industrial biotechnology sector has noted that the pathways for approval for GMOs essential for bio-product manufacture are anticipated to be problematic for the reasons described below.

17. Firstly, the industrial biotechnology sector has called for a simplification of the current GMO regulatory framework. The sector has noted that the interaction and potential overlap between Commonwealth and State regulations can be a hurdle to the establishment of local bio-based industries. While dealings with GMOs are regulated at the Commonwealth level, the permission to grow GM crops is a state issue. For example, if a GM crop is under consideration as a feedstock for a bio-based product, the decision of whether it can be grown in a particular area rests with the State jurisdiction. Therefore, consideration of the potential for harmonisation and simplification of the regulatory approval processes in such situations is warranted.

18. Secondly, industry representatives believe that the current regulatory processes may not have the capability to deal with certain aspects of industrial GMOs (note that these are also touched on in CSIRO's comments later in this submission):

    - Scale: according to industry, there is no capability to register for the *controlled release* on the very large scale (i.e. 100,000 litres) required by the chemicals industry for processing and/or manufacture using GM crops, crop waste, cell contents or whole organisms in the current regulatory framework.

    - Containment: unlike the pharmaceutical industry, industrial biotechnology processes are not necessarily produced in sterile or wholly-contained systems.

    - Extent of genetic modification: some industrial microorganisms or feedstock crops are extensively altered, with up to dozens of genetic modifications. Some industrial biotechnology stakeholders have expressed concern that these more complex modifications will result in timeframe blowouts for approvals. Timeframes have implications for investment in these new technologies and can add another burden to start up companies, or the commercialisation arms of universities.

19. The Department therefore recommends that the present review consider how the Australian regulatory framework can be amended to meet the challenges of industrial scale bio-based production.

Consideration of the benefits of GMOs

20. The focus of the Act is on protection of the community and environment from risks associated with GMOs. A risk assessment process that included a reflection of the likely 'benefits' of GMOs, would allow for the consideration of potential environmental benefits such as the potential for GM technologies to mitigate climate change and provide for safer technologies (eg. a crop strain that requires less water or pesticide). Any such consideration of benefits would need to ensure that no additional regulatory burden was placed on applicants.

1(b) Emerging trends and international developments in biotechnology

Synthetic biology may present more complex regulatory issues in the future

21. Synthetic biology (synbio) is: (1) the design and construction of new biological parts, devices, and systems, and (2) the re-design of existing, natural biological systems for useful purposes. Synbio combines methods for the chemical synthesis of DNA with computational techniques to design it. These methods allow scientists to construct genetic material that would be impossible or impractical to produce using more conventional biotech approaches.

22. Over the next 5-10 years many synbio products are likely to enter into markets. It is possible that anti-malaria drug artemisin will be one of the first to go into production. Artemisin is traditionally sourced from plants, but with the help of synthetic biology a yeast strain capable of synthesizing high amounts of artemisin precursor has been engineered. The new metabolic pathway is comprised of bacterial, yeast, and plant genes and is driving the yeast to produce a compound that can chemically be converted into artemisin via industrial-scale fermentation.

23. This ability to engineer microbial metabolism will have a big impact especially in the area of industrial biotechnology, such as the production of biofuels from various feedstocks. Importantly, in the future these fuels will be produced from grasses and non-food plant matter, rather than from crops such as corn. Synbio based biomaterials are in early developmental phase (e.g. synthetic silk), as are the development of multi-enzyme pathways to produce complex chemicals for the pharmaceuticals industry.

24. Possible regulatory problems from synbio applications could arise due to the inability of regulators to deal with modified DNA that contains new bases. As the regulation is based on the difference between "original" and "modified" gene, in the case of a new synthetic gene without a natural counterpart, the lack of a baseline comparison can become a problem. In addition, there might be a difficulty in classifying an organism that contains a mixture of genes from various

sources, especially in the case of a minimal host (e.g. 30% plant genes, 30% bacteria, 40% yeast).

In short, there is a risk of the technology outpacing the regulation.

25. The USA[1] and UK[2] reviewed their regulatory frameworks in regards to synbio, and the reports conclude that the likely first generation synbio products, synthetic microbes engineered to produce biofuels and drugs, will likely fit under the current regime. As the technology matures, however, it has the capability to produce complex organisms whose genomes have been assembled from a variety of sources, including artificial sequences designed and built in the laboratory. The regimes may have to be modified to take these into account.

26. Australia doesn't have current legislation or regulatory guidelines specific to synthetic DNA. It is expected that synbio will be regulated through the framework that includes the OGTR and other regulators with complementary responsibilities and expertise (such as the TGA, APVMA, AQIS, and FSANZ). It is unclear however at the moment how Australia's GMO regulation applies to synbio organisms. The Department recommends that the present review consider how the Australian regulatory framework can be amended to take into account the challenges of synbio that may arise in the future, in the same manner as USA and UK have done.

4. The consultation provisions of the Act

4(c) The stakeholders and methodology used to engage them

27. In 2010, the Department commissioned a public attitudes survey[3] which found that public concern over the use of GMOs has decreased over time. This may be due in part to a decade of successful operation of the Act in Australia, but the survey also found extremely low awareness of the OGTR as the regulator of GMOs.

28. Based on this, and previous surveys, public attitudes toward GM crops (and foods) can best be summarised as: a large amount of people have a small concern about GM crops and a small amount of people have a large concern. In 2005, public support of GM crops was roughly 54% rising to 69% in 2007 and dropping to 63% in 2010. From 2007 to 2010, there was a slight increase in those not aware of modifying the genes of plants to produce food crops (11% unaware in 2007 and 15% not aware in 2010). Those not aware of modifying the genes of plants to produce *non-food crops* remained fairly consistent, although moderately high (40% not aware in 2007 and 39% not aware in 2010).

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[1] http://www.synbioproject.org/process/assets/files/6319/nano_synbio2_electronic_final.pdf
[2] http://www.raeng.org.uk/news/publications/list/reports/Synthetic_biology.pdf
[3] [3] Ipsos-Eureka Social Research Institute, 2010. Methodology: Six focus groups followed by a broad public attitude survey, of n=1,024 with 501 responses being obtained from phone polling and 523 obtained from online polling.

29. Public attitudes to GM crops was more nuanced according to application. For example, public acceptance of modifying the genes of plants to produce food was 63%. This rose to 67% when recipients were asked if they support modifying the genes of plants to produce food by introducing the genes of a plant from the same species. There was also strong perceived value in genetically modifying food crops to make plants drought resistant (85% viewed this as valuable), to make plants able to grow in salty soils (81% viewed as valuable), to make food healthier (80% viewed as valuable), to make plants pest-resistant (79% viewed as valuable) and to make plants frost resistant (78% viewed as valuable).

30. The knowledge of GM crops being grown in Australia is mixed, with 46% stating they were aware of GM crops being grown in their state and 43% not knowing. State variations were notable, with Western Australia and Victoria having the highest levels of awareness (53% and 52% respectively). The three most cited GM crops that people believed were grown in their states, were canola, cotton and wheat, with canola being the most cited in all states except Queensland, where cotton was cited as the most grown crop.

31. There was general acceptability of genetic modification of non-food crops which increased slightly in the case of modifying genes of plants to produce non-food crops such as clothing and other textiles. Support for non-food crops to produce fuels was 68% with 58% supporting non-food crops in the production of plastics.

32. More than half of survey respondents considered that public consultation and participation improved regulation of gene technology. Attitudes towards the rigour and compliance with gene technology rules was less clear with more than half of respondents unsure or without a view.

33. Awareness of the OGTR was the lowest of all the regulators polled[4], with 8% awareness when both prompted and unprompted answers were combined. Of these respondents, 59% trusted the OGTR to regulate gene technology. This was down from 70% in 2007, but was of a similar level of trust to other regulatory agencies[5]. The survey concluded: "Trust in regulators has improved since 2007 and would be likely to improve still further if [the] OGTR [were] better known."

34. In view of the above, the Department recommends continued exploration and trialling of new media alternatives as additional ways to engage with a broader range of stakeholders. Furthermore, there is a need to ensure that consultation seeks to actively solicit input beyond the most active interest groups and includes those who are: highly-interested; those who are affected; and those who have lower levels of interest. Mechanisms to seek input from the unengaged should also be considered.

[4] Other agencies awareness rates were: Australian Pesticides Australian Pesticides and Veterinary Medicines Authority (APVMA) (22%), Biosecurity Australia (34%), Food Standards Australia New Zealand (FSANZ) (60%) and Australian Quarantine and Inspection Service (AQIS) (85%)
[5] Other agencies' results: AQIS 64%, FSANZ, 65%, Biosecurity Australia 67% and APVMA 72%.

5. The interface between the Act and other Acts and schemes

35. The Department supports the OGTR's efforts to avoid duplication of other regulatory procedures and supports the OGTR in continuing to work closely with other regulators. The Department considers this to be of critical importance in providing a regulatory system which facilitates the development of and commercial investment in biotechnology applications.

36. While the integrated Commonwealth system is supported, an apparent disconnect between Commonwealth and state/territory schemes for the regulation of gene technology and the moratoria imposed by various States on the growing of certain GM crops on a commercial basis, hampers innovation and creates uncertainty for business. This, in turn, creates a disincentive for investment.

6. Provision of recommendations for amendments to the Act and the Agreement

37. CSIRO considers that the current Act is providing a suitable level of security for the protection of both people and the environment. There is a high level of compliance with Gene Technology Legislation within all research organisation and companies, as evidenced by the lack of prosecutions by the OGTR in the 10 years of its existence. However CSIRO believes the following sections of the Act could be considered for amendment under the current Review.

38. Permitting variations to Dealings involving Intentional Release (DIRs) with limited additional risks (Part 5 Division 7 Section 71 (2B)):

    - Background: Currently the OGTR cannot vary a licence for a DIR to include new risks not previously covered in the original application. This poses difficulties for CSIRO and other organisations to obtain licences to conduct multiple DIRs at multi-user field sites. Resubmission of original DIRs to take into account new risks imposes a considerable additional workload on both CSIRO and the OGTR.

    - Proposed Change: CSIRO requests that the Act be altered to allow for variations to DIRs be permitted where the consideration of additional (limited) risks is permitted.

39. Notifiable Low Risk Dealings (Section 74, 75)

    - Background: The Act currently precludes the ability of Institutional Biosafety Committees (IBCs) to make variations to Notifiable Low Risk Dealings (NLRDs). During the course of scientific research IBCs often need to add or remove facilities, people and/or classes of genes used. It is a major administrative load for IBCs to have to re-submit a new NLRD each time a minor modification is needed.

- Proposed Change: CSIRO request that there be provision within the Act to allow variations on NLRDs to be approved by IBCs without the need to issue a new NLRD.

40. Large scale cultures

CSIRO considers that there are excessive regulatory requirements surrounding the 'large-scale' (>25 litres) culturing of organisms which would be considered 'NLRDs' at small-scale:

- Background: If an organism is mentioned in Part 1 Schedule 2 of the Gene Technology Regulations then small scale culturing is considered as an 'exempt' dealing and large scale (>25 litres) fermentations are classified as NLRDs. However, if the organism is not listed in Part 1 Schedule 2, small-scale culture is an NLRD, and a large-scale culture requires a license (DNIR). An application for a DNIR represents a very large step-up in regulatory burden in terms of time and effort in preparing paperwork, and involves a 90 working day turnaround of the application by the OGTR, compared with the application for an NLRD. CSIRO questions whether this increase in regulatory burden is justified and believes that this depends on the design of the large-scale facility.

  CSIRO feels that additional risks, if any, from growing organisms at large scale can be mitigated by the appropriate design of the large-scale facility. Rather than using a blanket definition of 25 litre volume above which dealings are considered sufficiently high-risk as to warrant a DNIR License, the design of the facility should be taken into account. For example, the CSIRO's Recombinant Protein Production facility at Clayton can contain and sterilise large spills (e.g. 400-1000 litres). Not all large – scale Certified Facilities are designed to this level. CSIRO strongly believe that individual facilities should be certified with a particular specified threshold culture volume (say, 400-litres in the case of the facility at CSIRO, Clayton), below which cultures of organisms which are presently defined as NLRDs at <25 litre scale are also considered NLRDs, not DNIRs.

- Proposed change:

  1) 'Large-scale' cultures should not be given a blanket definition of >25 litres. If individual large scale facilities can demonstrate that larger scale cultures of organisms which are presently defined as NLRDs at <25 litre scale can be carried out with minimal elevated risk, they should also be considered NLRDs, not DNIRs.

  2) The list of low-risk host/vector systems mentioned in Part 1 Schedule 2 should be reviewed and expanded to include others with similar low-risk profiles (e.g. *Candida tropicalis,* an organism that CSIRO often use as a host that has no history of causing disease in other than immunocompromised patients in a hospital setting).

41. Changes to definition

Although the *Prohibition of Human Cloning for Reproduction Act 2002* and the *Research Involving Human Embryos Act 2002* are under review, it would still be possible for the following proposed change to occur without adversely affecting review outcomes:

- Background: The *Prohibition of Human Cloning for Reproduction Act 2002* legislates for a prohibition on human cloning and amends (Ss. 3-26 and Schedule 1: 16 Jan 2003) the *Gene Technology Act 2000* by repealing certain sections. The repealed sections of the *Gene Technology Act 2000* were the following:

  192B Cloning of human beings is prohibited;

  192C Certain experiments involving animal eggs prohibited; and

  192D Certain experiments involving putting human and animal cells into a human uterus prohibited.

  Nevertheless, an orphan reference to the purpose of these sections remained embedded in section 10, Definitions. This is no longer appropriate as the Gene Technology Act no longer deals with human cloning and associated matters.

- Proposed change: That section 10 (Definitions) be amended by excluding all of subitem (d) between the words *a human being* and *or* (highlighted in bold):

  genetically modified organism means:

a) an organism that has been modified by gene technology; or

b) an organism that has inherited particular traits from an organism (the *initial organism*), being traits that occurred in the initial organism because of gene technology; or

c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;

but does not include:

d) a human being, **if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy**; or

e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.