

AUSTRALIAN DEMOCRATS'

ADDITIONAL COMMENTS

While supporting many of the observations and recommendations contained within the Chair's Report, the Australian Democrats do not sign off on the document. The Democrats provide these additional comments as detail of our concerns with the proposed regulatory system and to provide an overview of the sustainable and responsible manner in which genetic technology should be undertaken and applied.

The Democrats' concerns regarding the Gene Technology Bill 2000 are not limited to the comments listed below. We submit them as a contribution to the increasing public debate surrounding the Bill as it is considered by the Senate. The Democrats will continue to monitor further developments and seek to amend the Bill as seen appropriate when it is considered by the Senate.

1. *The Australian Democrats believe that an effective gene technology regulatory system must contain - not to the exclusion of others - two elements:*

- (i) community confidence;***
- (ii) independent public information and education.***

2. *Current Regulation of Gene Technologies*

2.1 *Domestic*

Six differing bodies, or schemes, regulate differing aspects of gene technology¹ at a Commonwealth level:

- (i) Australia New Zealand Food Authority (ANZFA), regulating genetically modified foods;**
- (ii) Therapeutic Goods Administration (TGA), regulating genetically modified therapeutic goods and human gene therapy under the Gene and Related Therapies Research Advisory Panel (GTRAP);**
- (iii) National Registration Authority (NRA) regulating agricultural and veterinary (agvet) chemicals;**

¹ It is recognised that concern was expressed in the Committee to the terminology used to describe the science and techniques developed to manipulate an organisms genome. While quotes, excerpts from Committee submissions, and past Democrat releases and statements on the subject use varying terms, 'gene technology' will be used generally in the following paper as it is the title of the Bill referring to genetic modification, genetic manipulation, genetic engineering and transgenic processes rather than drawing distinctions between the terms.

- (iv) National Industrial Chemicals Notification and Assessment Scheme (NICNAS) regulating use of industrial chemicals; Australian Customs Service (ACS) and the Australian Quarantine and Inspection Service (AQIS) overseeing the importation and exportation of genetically modified organisms and related products.²

The Australian Democrats have wide-ranging concerns about aspects of current gene regulation in many of these bodies, the current disparate regulation and artificial delineations in gene technology processes and products created by the current regulatory system.

The Gene Technology Bill 2000 will not act to address this disparity, but will rather add another tier to the current regulatory system.

Another area of inadequate protection for the Australian community includes biosafety regulation currently overseen by the Genetic Manipulation Advisory Council (GMAC).

2.1.1 *Australian Democrat concerns with current regulatory system:*

While the following statement does not address the specific issues surrounding recent controversial threats to public health and biosafety, such as those surrounding the Mt Gambier field trials, it outlines general long-held concerns about biosafety procedures in Australia even when stipulated disposal and buffer requirements are adhered to:

Australia's current voluntary system of biosafety regulation is not of an acceptable standard and the public can not be confident it is a reliable scheme or that it will deal with their concerns.

At present voluntary regulation of small and large scale genetic manipulation work in containment facilities and the release of genetically modified organisms into the environment under GMAC are inadequate. GMAC regulates such activities by the issue of non-statutory guidelines which specify the procedures to be followed by institutions and researchers intending to undertake genetic manipulation work and detail requirement for containment facilities. Proposals for genetic manipulation work are assessed on a case-by-case basis giving varied conditions under which organisms are to be modified and released.

The inadequacies of this system can be illustrated by the determination of buffer zone specifications under GMAC. Currently in Australia, 'refuge'³ and 'buffer' zones⁴ are not defined in GMAC's guidelines. Instead conditions are established on a case by case basis. The

² M Wooldridge, Gene Technology Bill 2000 *Explanatory Memorandum*, at page 7.

³ Refuge zones are expanses of farm land of traditional crops designed to prevent the development of pesticide resistant organisms.

⁴ Buffer zones are expanses of land designed to prevent cross pollination of genetically modified crops.

effectiveness of this practice is at the very least questionable as presently the production of transgenic Bt Cotton⁵ requires a 'refuge' of 10% traditional crop to prevent the development of pesticide resistant organisms. This requirement means that such zones are of highly variable distances depending on the size of the field which the cotton is grown in. It does not take into account generally accepted international set distances or findings such as those in the UK which have established that bees can carry pollen four kilometres from test sites⁶ by failing specifying a minimum distance for such zones.

The current regulatory arrangements not only fail to provide sufficient protection to consumer health and the environment but also fail to provide standard enforceable regulations which clearly specify to researchers, industry and primary producers the boundaries in which genetic technology applications may be used. The present practices do not insure industry or consumer confidence. Furthermore, case-by-case assessment of genetic manipulation applications will become more and more unsustainable as the 'biotechnology revolution' evolves in Australia and the frequency of such activities increases exponentially.

Institutional Biosafety Committees (IBCs) are internal committees which oversee the implementation of GMAC Guidelines in individual institutions and companies which use genetic manipulation techniques. These committees rely solely on the full and voluntary cooperation of research institutions and companies to report all manipulation activities for compliance with the guidelines which is clearly inadequate in light of the possible risks associated with this technology. Furthermore, IBCs under GMAC are granted commercial-in-confidence rights. This practice is inappropriate and inadequate to ensure accountability, consumer and environmental safety and additionally acts to undermine consumer confidence. I have called for a statutory, publicly accountable, transparent regulatory and independent testing system to be implemented which ensures the safety of the public interest.⁷

The Australian Democrats welcome the establishment of a public register under the Office of the Gene Technology Regulator.

However, the Democrats remain concerned about the extensive classification of information surrounding GMO trials and applications for release as commercial in-confidence.

⁵ Bt Cotton is a genetically modified cotton species produced by Monsanto which carries a gene (including Bt – Cry1Ac or Bt – Cry2A) derived from a bacterium, *Bacillus thuringiensis*, that produces a Bt toxin killing pests of the crop.

⁶ Nuttal N, 'Bees spread genes from GM crops', *The Times*, 15 April 1999.

⁷ N Stott Despoja, Submission to the House of Representatives Standing Committee on Primary Producer and Regional Services' Inquiry into primary producer access to gene technology, June 1999, at page 5.

2.2 *International - The Cartagena Biosafety Protocol of International Biodiversity Convention.*

While it is recognised that the Cartagena Biosafety Protocol exempts many areas of transboundary movement of living modified organisms, such as those contained in pharmaceuticals, it does provide governments wider discretion to restrict imports than is permitted under the World Trade Organisation's (WTO) Agreement on Sanitary and Phytosanitary Measures.

The International Biosafety Protocol provides the best international legal framework to date for responsible international regulation and trade of genetically modified organisms. Australia's endorsement and signage of the Protocol will provide appropriate foundations for effective domestic regulation of gene technologies and the first step towards achieving public assurance that the benefits of biotechnology will be secured without damage to health and safety or the environment.

3. *Gene Technology - promises & risks*

Gene Technology is a nascent science, in which the potential and pitfalls are still being determined. Any science or technology is a tool that can be applied by a community for positive or negative outcomes.

The Chair's Report recognises "the significant number of and qualifications of scientists opposed to, or very concerned about, gene technology, its applications and possible consequences."⁸

The Australian Democrats recognise the nature and potential power of gene technology, and that its precision is hindered by the relative novelty of the science.

It was stated in Senator Stott Despoja's submission to the House of Representatives Standing Committee on Primary Producer and Regional Services inquiry into primary producer access to gene technology, June 1999 that:

Genetic engineering is not at present a precise technology and the long-term consequences of the technology are poorly understood. Current manipulation techniques involve the insertion of genetic material randomly and do not provide a precise or chosen location for insertion. Further, the levels of expression depends to a large extent on the location of insertion and genes may move outside their intended spaces.

It is reasonable to expect that pleiotropy (the affect of a single gene product on more than one trait) and epistasis (the capacity for one gene to modify the expression of another gene which is not an allele⁹ of the first) will also

⁸ Chair's Report, *Preface*, at page 1

⁹ Alleles are different types of a gene for a particular trait which produce differing outcomes. To use the Mendelian example, one allele of a gene will produce a wrinkled seed whereas another allele of the same gene will produce round smooth seeds.

occur in transgenic crops, as they do in their traditional counterparts. These effects increase the complexity and difficulty of assessing the risks that transgenic crops may have on the environment, nutrition, consumer health, etc. This aspect of gene technology is presently poorly understood, poorly researched and does not appear to have been adequately assessed in proposed regulatory schemes. For example, the proposed substantial equivalence for gene food labelling would be unlikely to detect a predisposition in a food crop to accumulate heavy metals with its downstream health effects.

Two examples illustrate this concern:

- (a) The production or conferral of weediness to agricultural and non-agricultural species is one aspect of agricultural gene technology which holds the potential to cause significant cost to primary producers in Australia. Scientists have suggested that some transgenes may confer or enhance the ability of a crop species to become a weed¹⁰. The risk of transgenic crop weediness is similar to that presented by the introduction of non-indigenous plant species into an environment, but the relatively few that can cause significant ecological disruption and a significant cost to agriculture, for example, through increased herbicide use and environmental degradation.
- (b) Another concerning aspect of first generation agricultural gene technology is the insertion of virus genes into crop plants to protect them against disease. Experiments have shown migrating viruses can acquire the inserted genes and produce novel viruses with new properties. Work on inserting virus genes for resistance is advancing in many countries, including Australia, and is well funded compared to the research attempting to understand the potential dangers. Significantly, field tests of transgenic plants are presently not even independently monitored. This is a major concern to Australian agriculture and means that we must be concerned about the genes we are incorporating in the populations of cells and organisms and their relations.

These are valid concerns - gene flow to wild relatives has been recorded in quinoa, squash, carrot, maize, sorghum, sunflower, strawberries and sugar beet¹¹ and there have been 16 reported international cases of genetic exchange between crops resistant to herbicides, insects and viruses and wild relatives.¹² Such genetic pollution is now receiving recognition and serious consideration by international governmental regulatory agencies. It was concluded by the United Kingdom's

¹⁰ Rissler J & Mellon M, *Perils Amidst the Promise: Ecological Risks of Transgenic Crops in a Global Market*, Union of Concerned Scientists, Cambridge MA, 1993 at page 4 of 8.

<http://binas.unido.or.at/binas/Library/ucs/section5.2.html> accessed 1 June 1999.

¹¹ Gray AJ & Raybould A F, 'Reducing transgene escape routes', *Nature* Vol 392 16 April 1998 at page 654.

¹² Brookes M, 'Running Wild', *New Scientist*, 31 October 1998 at page 41

Advisory Committee on Releases to the Environment (ACRE), Department of the Environment, Transport and the Regions that cross-pollination between adjacent crops of fodder maize and sweet corn can occur.¹³

This is also a concern in Australia. The Genetic Manipulation Advisory Committee (GMAC) 1997-98 Annual report documents an incident where transgenic lupins modified for herbicide resistance were inadvertently released. In Australia no crossing occurs with other species in this genus and the possibility of genes entering the naturalised races of lupin are very low. However, similar release of a transformed subterranean clover is very likely and under selective pressures and over a period of time as short as several years the likelihood of an outcross is very likely (it is a matter of numbers...). This may have significant implications for Australian primary producers and the wider Australian community.

The consequences of this “imprecise” technology are likely to significantly affect primary producer access to the benefits of the technology. An assessment of the exact impact is difficult because the mechanisms are poorly understood and they are not being investigated. I am particularly concerned about the long term consequences to the environment and its ability to sustain viable and productive agriculture.

An open letter from World Scientists to all Governments concerning Genetically Modified Organisms Submitted to the UN Commission on Sustainable Agriculture in New York (April 24-May 5 2000) outlined further concerns by scientists from a plethora of disciplines about the potential risks and misuse of genetic technologies, corroborating at an international level the diversity of concerned expert opinion noted by the Chair's report.

4. Principles & Objectives of the Office of the Gene Technology Regulator

4.1 *Objectives of the Bill*

The Object of the Gene Technology Bill 2000 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.¹⁴

The Australian Democrats support these objectives, though consider that stipulation in regulation of relating principles is required to adequately ensure the protection of public health and safety and the environment.

¹³ Department of the Environment, Transport and the Regions *Advisory Committee on Releases to the Environment*, Advice for the Secretary of State, 23 June 1998: Genetically Modified maize in National List Trials Adjacent to an Organic Farm in Devon. <http://www.environment.detr.gov.uk/acre/advice01.htm>, accessed 8 March 1999

¹⁴ s3 at page 2.

The Chair's Report states at 3.76 that:

The Committee considers that while the protection of the environment is important, it should not detract from the paramount objective of protecting the health and safety of people. The Committee supports the placement of the OGTR in the Health and Aged Care portfolio.

The Australian Democrats maintain that environmental protection and public health and safety are synonymous and can not be conflicting objectives.

Furthermore, the Democrats maintain that the Commonwealth Environment Minister must play an active role in the regulation of gene technologies in Australia to ensure that the environment is appropriately considered in Office of the Gene Technology Regulatory (OGTR) decisions. In its current form, the Bill does not provide such involvement and, therefore, does not provide adequate protection for the environment.

4.2 *Role of the Environment Minister*

The Democrats note the commitment given on behalf of the government by the Environment Minister, Senator Hill to the Senate during the original passage of the Environment Protection and Biodiversity Conservation Act 1999 (EPBC Act) on 22 June, 1999 that "matters that affect the environment will be referred to the environment minister for assessment and advice by that independent regulator. That will ultimately be provided for through an amendment to this legislation (the EPBC Act), when it passes in conjunction with the law that is going to be put in place to set up the new GTR." This government commitment, provided immediately before the Senate vote on the EPBC Act legislation, has clearly not been met.

The Australian Democrats put on the Parliamentary record on June 2000 our concerns regarding the June 13 Federal Cabinet decision to minimise the role of the Environment Minister in gene technology regulation in Australia.

Under the proposed amendments [to the EPBC Act], which of course the Australian Democrats confirmed last year, we saw the environment minister—actually the environment minister, I should acknowledge, is on record as endeavouring to honour them—saying that he supported the role of the environment minister in relation to an environmental assessment of GMs before they were released. Under the EPBC Act a licence to deal with a GMO was required to be issued by the Gene Technology Regulator, the GTR. This application, if involving a deliberate release of a GMO into the environment—I think it is clause 43(b)—was required to be referred to the environment minister, who could then stipulate specific requirements to protect the environment if the minister believed that that release posed a significant risk of harm to the environment. The environment minister could accredit an assessment process for the GTR to pursue or direct an assessment on preliminary documentation if considered 'a controlled action under part 7 of the EPBC Act, clause 43(c)'.

With respect to the environmental assessment under clause 43(f), the environment minister could provide advice to the GTR which must be considered by the GTR when considering the licence application. Let us compare this now to the new proposal by cabinet which I think has no amendments to incorporate GMOs into the EPBC Act. The act that was designed to ensure the most comprehensive environmental assessment at a Commonwealth level has now been completely undermined—and with it, of course, the role of the environment minister in the approval of GMs and GMO releases. The new proposal, under the auspices of the health minister and the department, does not begin to make up for the ground lost by the rejection of the Democrats' original proposal. The draft substitute amendments to the Gene Technology Bill 2000 do not require the environment minister's input in matters of deliberate release to the environment, nor do they stipulate adherence to any advice that the minister may volunteer if he or she deems it appropriate to offer.

The Democrats are on record a number of times in the past week or so as saying that we regard the latest cabinet proposal as inadequate; and we will be seeking to rectify the situation when the bill is debated in this place. What is also questionable is the extent of the power of proposed amendments to the Gene Technology Bill 2000 without reciprocal amendments to the EPBC Act, putting the protection of the environment under the bill into further doubt. We know that consumers, through the health department's consultations on the Gene Technology Bill, are saying that they want environmental and health matters to be given equal weighting when discussing the release of GMOs. Yet basically it is a slap in the face to those people who participated in those public consultations.

The role of the environment minister and the role of the environment in terms of assessing the risks and benefits of GMOs has been completely undermined. The federal cabinet's decision of 13 June, which did decide to undermine the environment minister's role in the regulation process, can be construed as being in conflict with the objectives of the bill as it currently stands...¹⁵

The Australian Democrats maintain that amendment to the Bill and the EPBC Act must be undertaken to ensure the adequate protection of the environment from gene technologies and that operation of the OGTR is in keeping with the Bills objectives.

4.3 *Precaution: an approach or principle?*

¹⁵ N Stott Despoja, Matter of Public Interest: Genetically Modified Organisms, *Senate Hansard*, 21 June 2000 at pager 15318

The Chair's Report reflects, at 3.25, the wide variety of precautionary approaches and principles contained in international agreements, domestic law and environmental legal theory:

The differing forms of the precautionary principle also impacts on the scope of the principles application, with some conventions and statements limited to toxic substances control, while others include any government policy with the potential to cause environmental degradation.

Epidemiologist and biochemist, Dr Judy Carman, of the Public Health Association of Australia, commenting on the current use of caution and a precautionary approach in approval of genetically modified food products by the ANZFA in an interview with *the Age* stated:

“The precautionary principle that could be described as ‘unsafe until proven to be safe’, has been around for centuries to guide us in conditions of uncertainty. Yet ANZFA has officially adopted the opposite approach; that is, they permit 18.7 million Australians to eat GM foods based on a ‘safe until proven unsafe’ philosophy.”¹⁶

The ANZFA's current objectives do not incorporate the precautionary principle, despite the recommendations of public health and medical groups in the Senate Community Affairs References Committees' Inquiry into the Australia New Zealand Food Authority Amendment Bill 1999.

Attempts by the Senate minor parties to amend the Bill in the Senate to include a comprehensive precautionary principle were not supported by the Opposition and Coalition parties.

The absence of the precautionary principle in the ANZFA's objectives increases the exigency for its inclusion in the objectives of the OGTR.

The Chair's Report states at 3.72 and 3.73:

The Committee considers that the precautionary approach would be underpinned in the Bill if the precautionary principle appeared as one of the objects consistent with the way it appears in the Environment Protection and Biodiversity Conservation Act. The Committee does not support the precautionary principle being made a specific test in the licensing provisions.

The Committee considers that there is a balance between the risks to the community versus the rights of a company, and strongly considers that, in keeping with a precautionary approach, the onus of proving that GMOs are not harmful should rest with the proponents of the technology.

¹⁶ G Strong, 'GM-food tests 'inadequate'', *The Age* 28 October, 2000. <http://theage.com.au/news/2001029/A13301-2000Oct28.html>

The Australian Democrats do not consider the inclusion of a precautionary 'approach' as preferable to the precautionary principle and support the Chair's recommendation that the Objectives of the Bill contain the same words that appear in the EPBC Act 1999 in relation to the precautionary principle.

The Australian Democrats maintain that stipulation of specific preventative standards and safeguard measures is essential to the protection of public health and the environment, and to ensure public confidence in domestic gene technology regulation.

Furthermore, the Australian Democrats strongly question the adequacy of the regulatory system as stipulated by the Gene Technology Bill 2000; Gene Technology (Consequential Amendments) Bill 2000; Gene Technology (Licence Charges) Bill 2000 and related regulations to effectively review and assess declarations by parties with commercial interests in the technology that it is safe (as deemed in keeping by the Chair with a precautionary approach).

The Chair's Report states (at 3.64)

While there is clearly consensus on the need to ensure a cautious approach to the development and adoption of gene technologies, there is also acknowledgment of the need to ensure the continuation of research and development on the basis of current scientific understanding of potential risks: [The] Regulator's deliberations must be based on sound, consistent and reproducible scientific and technical data generated according to world best practice standards.¹⁷

The Australian Democrats, while supporting risk assessment and decision making based on reproducible scientific and technical data, believe that such scientific standards and assessment will not be able to be guaranteed under the proposed regulatory regime as the system does not provide for independent testing of such data in all cases.

At present, the ANZFA is responsible for assessment and approval of genetically modified organisms for farm production and public consumption.

The Australian Democrats have previously commented on the ANZFA's lack of testing facilities and the inadequacy of its reliance on applicant scientific data in the approval of genetically modified food products.¹⁸ This situation will not be rectified under the gene technology regulation system proposed.

The findings of a study conducted for the Public Health Association of Australia support this concern.

Scientists conducting the study examined procedures surrounding applications from US-based Monsanto for release of food produced from:

¹⁷ Submission No 42, p.4 (Floringene Limited and Nugrain Pty Ltd). See also, *Committee Hansard*, 23.08.00 p.184

¹⁸ Including, N Stott Despoja, Press Release 00/357: *Democrats call for ANZFA labs not just glossy PR*, 19 June 2000. <http://www.democrats.org.au/media/display.htm?id=659>

- (i) insect-protected corn line MON 810¹⁹;
- (ii) glyphosate-tolerant corn line GA21²⁰; and, or
- (iii) glyphosate-tolerant canola line GT73.²¹

The Public Health Association's review of the glyphosate-tolerant canola found that the canola when fed to laboratory rats, in one instance, caused liver enlargement up to 16%. However, this finding did not warrant further investigation by the applicant.

It is recognised that the percentage of modified DNA ingested by the rats in the mash preparation administered in the laboratory experiment was significantly higher than that which humans would ingest with the consumption of highly-refined canola oil. However, this raises further questions, including:

- (i) the scientific rigour of the tests conducted by applicants;²²
- (ii) the standard of current tests constructed to extrapolate valuable information regarding possible human health effects;
- (iii) the suitability of commercial interests to determine test models and procedures;
- (iv) the value of animal models to ascertain possible human health effects; and,
- (v) the right to cause animal distress for unusable test information.

These questions are sustained by the Public Health Association of Australia's review of the tests data submitted for application A346 for the insect resistant corn line MON810 finding:

- (i) the *Bt* protein (produced from the insertion of the *cryI(A)b* gene into the corn genome) designed to rupture the gut of lepidopteran insects had not been tested on humans; and,
- (ii) testing procedures did not include the ingestion of raw plants or waste material by other organisms in the human food chain and whether human ingestion of such organisms posed a health risk.

¹⁹ Australia New Zealand Food Authority Application A346, Food produced from insect-protected corn line MON 810. Draft risk analysis report at: http://www.anzfa.gov.au/documents/gen10_00.htm

²⁰ Australia New Zealand Food Authority Application A362, *Food derived from glyphosate-tolerant corn line GA21*, Draft risk analysis report at: http://www.anzfa.gov.au/documents/gen12_00.htm.

²¹ Australia New Zealand Food Authority Application A363, *Food produced from glyphosate-tolerant canola line GT73*. Draft risk analysis report at: http://www.anzfa.gov.au/documents/gen13_00.htm

²² Reports state that test replication for canola line GT73 was too small to constitute a statistically significant sample size. The composition of only two samples were analysed. Scientists from the Public Health Association of Australia stated "with such low numbers it is almost a foregone conclusion that a statistically significant difference will not be found between the GM food and the non-GM food". See G Strong, 'GM Food tests 'inadequate'', *The Age*, 28 October 2000 <http://www.theage.com.au/news/20001029/A13301-2000Oct28.html>.

The scientific data supporting Application A362 for 'Round-up ready' corn acknowledged that the line possessed a modified protein in which two amino acids differed from those found in non-modified corn. However, further details of these differing amino acids were not supplied on the grounds of commercial in-confidence.

4.3 *ECOLOGICAL SUSTAINABILITY*

The Australian Conservation Foundation's Gene Ethics Network recommended:

The Objects of the GT Bill 2000 should also be amended to include the principle of ecological sustainability, to ensure genetically engineered organisms do not contribute to the long-term destabilisation and decline of our food and fibre production systems, the natural environment and biological diversity.

The Australian Democrats support the inclusion of ecological sustainable principles in the regulation and promotion of gene technologies in Australia.

5. **State 'opt-out' clause**

The Democrats believe that a successful gene technology regulatory system must allow choice for consumers. This choice is facilitated most effectively by an 'opt out' provision for states with clear interests and concerns primarily in the regulation of agricultural GMOs. An 'opt-out' clause provides domestic market differentiation and clear 'safehavens' for GM free production which consumers can clearly identify and place confidence in.

A state 'opt out' clause would not prevent industry pursuing isolated identity preserved production lines in States or Territories pursuing GMO production and processing, though allow for areas with natural geographic or other advantages to pursue GM-free products.

The Democrats have acknowledged that a moratorium would have to be carefully considered as a moratorium may hinder positive Australian innovation and ecological sustainable gene technology applications.²³

Section 99 provides that:

The Commonwealth shall not, by any law or regulation of trade, commerce, or revenue, give preference to one State or any part thereof over another State or any part thereof.

While the Australian Government Solicitor provided advice that there was:

²³ N Stott Despoja, Press Release 00/357 'Democrats call for ANZFA labs not just glossy PR', 19 June 2000. <http://www.democrats.org.au/media/display.htm?id=659>

...a significant possibility that Commonwealth legislation to regulate GMOs would be regarded as a law of trade and commerce for the purposes of section 99 and the opt-out provision in that legislation would infringe that constitutional limitation.²⁴

The Democrats acknowledge the legal advice supplied to the Tasmanian Government concluding that an 'opt out' provision for States and Territories from the regulatory system, as proposed under the OGTR, is in keeping with WTO requirements:

The advice obtained indicates that the opt-out as proposed in Principle 7(d) probably would not offend against section 92 of the Constitution. Section 92 of the Constitution requires that trade, commerce and intercourse between the States be free. In order for a law to discriminate against interstate trade it must be protectionist in the relevant sense, by placing a discriminatory burden on trade in order to protect trade within the State (*Cole v Whitfield (1988) 165 CLR 360* is authority for this proposition).

Accordingly, where a state has declined to allow release within its own territory of a GMO, that would apply to trade within the State and trade with other States, therefore the law would not be protectionist in the relevant sense.

In any event, legal authority exists for the principle that laws for the protection from a real danger or threat, or some other legitimate object of a State, not offend section 92, if the law is appropriate for the achievement of that objective.

Section 99

In order to offend section 99 of the Constitution, two elements must be made out. Firstly a law or regulation must be one of trade, commerce or revenue. Legal opinion obtained by Tasmania suggests that, as the laws in the *Gene Technology Bill 2000* are to regulate the safe release of GMOs within Australia, it is not a law that can be classed as 'trade or commerce' for the purposes of section 99.

World Trade Organisation Agreements

As yet no jurisprudence exists on GMOs in the context of World Trade Organisation (WTO) Agreements.²⁵

The Australian Democrats, therefore, maintain that a State and Territory 'opt out' provision is the most appropriate mechanism to ensure domestic and export market diversity while effectively containing the impact of gene technologies on the environment.

²⁴ IOGTR, Submission No.77 at page 159

²⁵ Tasmanian Government, Submission 89 at page 12-14.

6. The Gene Technology Regulator

This will be a position of great power, not only within the scientific community but also with immense responsibilities for the long-term safety of the Australian and world environment, given that GMOs, once released, may not be able to be recalled.²⁶

The Australian Democrats believe that, in order to maximise the likelihood of public confidence in Australia's gene technology regulatory system the Gene Technology Regulator should be required to possess the following characteristics and abilities:

(i) *Independence;*

The Regulator must be at arms length from Government its research wing the CSIRO and independent of sectoral interests (ie, not holding employment with sectoral interests a minimum of 5 years before assuming the position, and not being employed by a sectoral interest for more than 5 years in total).

The position must be of a fixed, non-renewable tenure to ensure independence.

(ii) *Contributor to public debate;*

The Regulator must be able to make public his or her views on any issue relating to gene technology and its regulation.

(iii) *Powerful 'watchdog'*

The regulator must be able to have the power to provide a Commissioner/Ombudsman of gene technology service. The regulator must possess wide ranging powers to commission research and surveillance and propose legislation to ensure public and environmental safety, monitor and enforce responsible application of gene technology.

7. Public Participation & the Community Consultative Committee

It is of course, impossible to neatly separate the technical, community, ethical and environmental aspects of the new technology. This was eventually recognised, even by the early biased GMAC, and specialists in most such issues were eventually appointed to GMAC. Thus the committee structure, or the committee responsibilities, proposed under the present Bill must be changed – either a single committee should be empowered to cover all aspects listed in the Bill or all three committees should consider and report to the Regulator on all applications for GM work.²⁷

²⁶ A Gibbs, submission 70 at page 2.

²⁷ A Gibbs, Submission No 70, at page 2.

The Gene Technology Technical Advisory Committee (GTTAC), The GT Community Consultative Committee (GTCCG) and the Gene Technology Ethics Committee (GTEC) are the engines of the new regulatory authority and will oversee public participation in the regulation of Australian gene technology.

they [the committees] will considerably diminish public involvement in gene technology regulation compared with the existing GMAC system²⁸

The Australian Democrats, therefore, conclude for the afore-mentioned reasons that the regulatory system, outlined in the Gene Technology Bill 2000, does not provide the protection that the community requires and as a result fails to provide community confidence, domestically or internationally, on which Australia's biotechnology research community and related agri-industries rely.

7. *Summary of Recommendations contained in the Chair's Report;*

The Australian Democrats support the recommendations contained in the Chair's Report with the following exceptions and comments:

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the relevant State and Territory animal welfare legislation and the NHMRC code of practice for the care and use of animals for scientific purposes, be examined to determine whether more stringent provisions need to be applied with respect to animals and genetic modification.

- (i) The Australian Democrats believe current animal welfare legislation and NHMRC codes of practice are inadequate to ensure the ethical scientific use of animals, as they are often not enforceable

The Australian Democrats support increasing regulation of genetic modification practices and testing involving animals, increasing animal welfare protection and translating the NHMRCs current voluntary 'guidelines' into law.

that an independent organisation conduct a national public education campaign to provide information on the benefits and risks of gene technology, drawing on, but not limited to, the expertise of scientists, primary producers, academics and consumer organisations.

- (ii) The Australian Democrats consider such a role as integral to an effective regulator. Rather than another independent entity provide such information, the Australian Democrats recommend that Bill be amended

²⁸ *Ibid.*

to ensure that the Regulator is first and foremost, the protector of public health and the environment, and instigator of public interest and independent information distribution.

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that an individual who has worked for a regulated entity be precluded from holding the office of Gene Technology until the expiration of a two-year period.

- (iii) The Australian Democrats consider this recommendation worthy of consideration and further examination.

In some cases the passing of two years, after a life career in a regulated scientific body, may not remove the shared knowledge, political and ethical values and vested interests established in a career of such standing.

Similarly employment in an industry does not guarantee sympathy with certain industry practices or directions.

The Australian Democrats further recommend:

- (iv) **That the Bill be amended to require that the Gene Technology Community Consultative Group is a Committee of equal standing and funding to the GTTAC and and GTEC.**
- (v) **That the Bill be amended to grant the Gene Technology Community Consultative Committee greater public participation powers.**
- (vi) **That the Regulator accept State and Territory self-determination to quarantine against genetically modified organisms or to 'opt-out' of the OGTR if deemed desirable and to facilitate dialogue and agreements between states to pursue GM-differentiated products.**
- (vii) **That the ANZFA is fitted with the independent laboratory facilities to review and test applications for release of genetically modified food products.**

Senator Stott Despoja
Deputy Leader Australian Democrats
Spokesperson for Biotechnology
Full Member of the Committee for
the purposes of the Inquiry

Senator Andrew Bartlett
Spokesperson for the Environment
Participating Member for this Inquiry