



The Secretariat
Gene Technology Ministerial Council
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Re: Submission to the Review of the *Gene Technology Act 2000*

Agrifood Awareness Australia Limited (AFAA) welcomes the opportunity to make a submission to the independent review of the *Gene Technology Act 2000*.

Agrifood Awareness Australia Limited is an industry initiative, established in 1999, to increase public awareness of, and encourage informed debate about, gene technology. The organisation is supported by Avcare, the Grains Research and Development Corporation and the National Farmer's Federation and has project partnerships with a number of Research and Development Corporations.

Australia's gene technology regulation is one of, if not the, most rigorous, transparent, science-based systems in the world. We take this opportunity to congratulate the Office of the Gene Technology Regulator (OGTR) in successfully implementing this regulatory framework. We would also like to recognise the efforts of Australian agriculture, in particular, the Australian cotton industry, in working with the OGTR, to manage Australia's first genetically modified (GM) crop, cotton, which has delivered substantial benefits to Australia's cotton growers and regional cotton communities.

Agrifood Awareness Australia Limited also recognises that the intention of this framework – to develop a national gene technology system – has failed as a result of State-based moratoria which while justified on marketing grounds have been largely driven by politics. We challenge the Governments of Australia (Federal and State and Territory) to demonstrate leadership in this area and work to resolve this issue so that products approved by the OGTR have a clear and certain path to market.

We make the following comments (see attachment) in response to the Terms of Reference for the Review.

Yours sincerely,

Paula Fitzgerald
Executive Director

Gene Technology Act 2000 Review

TERMS OF REFERENCE

SCOPE OF THE ACT

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

AFAA Comments

The *Gene Technology Act 2000* was developed over a long period of time and with extensive consultation. Agrifood Awareness Australia Limited believes that the scope of the Act is comprehensive and should not be expanded.

The object of the Act is “to protect the health and safety of Australians and the Australian environment from risks posed by, or as a result of, gene technology by identifying those risks and managing them by regulating certain dealings with genetically modified organisms (GMOs)”. We believe the object and scope of the Act, with its science-based focus, is extremely comprehensive and that the policy objectives remain valid. It is critical for this technical focus to continue, free of political bias.

TOR 1a

- *Economic, marketing and trade* – Agrifood Awareness Australia Limited believes that a clear, transparent and predictable path to market must exist for GM products. This is currently not the case, with Australia’s rigorous science-based system unable to ‘deliver’ approved products to the marketplace as a result State-based moratoria.

The issues of economics, marketing and trade have had a large impact on the Australian agricultural gene technology debate and have resulted in a complete breakdown in Australia’s leading science-based approach.

The current system is unsustainable and presents complete uncertainty for Australian agricultural research and development investment. We believe that these issues need to be resolved by the agricultural and scientific communities and through Government (Federal, State and Territory) leadership.

We also note that while there are differing opinions on how to deal with the issues of economics, marketing and trade, the inclusion of these within the remit of the *Gene Technology Act* would not necessarily resolve the current Australian bans which while justified by governments on market grounds are primarily driven by politics. This situation has arisen as a result of the Policy Principle and AFAA believes this requires change (see comments at TORs 8&9).

Recently (19-22 June), Australian State Government leaders travelled to Philadelphia to participate in BIO – the annual, international biotechnology conference – to promote Australia as a centre of biotechnology excellence. If Governments are truly committed to promoting Australian biotechnology and capturing investment, then they must commit, as was the intention of the *Gene Technology Act 2000*, to a national gene technology scheme which allows product developers, after they have achieved OGTR-approval, to deliver their product to the marketplace. These same Government leaders must also recognise the outstanding record of the Australian agricultural industry in managing new technologies and products, as is clearly evident through the successful use of Australia’s first GM crop, cotton. We believe the current powers of State Governments to establish individual gene technology regulatory schemes for the risk assessment and commercialisation of GM crops must be removed.

- *Cultural and social impacts* – Agrifood Awareness Australia Limited believes that cultural and social aspects are dealt with through the Gene Technology Community Consultative Committee (GTCCC) particularly in its mandate to provide advice on “matters of general concern in relation to GMOs”. Also, we believe that cultural and social impacts are addressed by farming communities on a regular basis, when they make decisions about the adoption of agricultural commodities and technologies. Such decisions should remain with the agricultural community and should not be regulated by Governments.

We believe that it is imperative for Australia’s gene technology legislation to remain science-based, rather than incorporating value-based judgements. The incorporation of value-based judgements would weaken the OGTR’s science-based focus and also place significant additional and somewhat subjective data requirements on GM product developers.

- *Ethical issues* - Much gene technology research in Australia is already guided by animal and medical ethics committees. In addition, the Gene Technology Regulator has a Gene Technology Ethics Committee (GTEC) – comprised of professionals - from which she can draw expertise. AFAA believes that ethical issues are addressed in a comprehensive manner within the *Gene Technology Act*, however, we do not support Policy Principles based on ethical grounds (see comments at TORs 8&9).

TOR 1b

Agrifood Awareness Australia Limited supports the current definitions incorporated in the Act, as well as the interpretations of these by the OGTR, to deliver a sound, science-based regulatory framework.

TOR 1c

We believe that the *Gene Technology Act* currently provides sufficient coverage for both organisms and technologies.

TOR 1d

AFAA believes the current trait based regulatory framework is the most appropriate system. We do not believe the Act should consider novel products created by other technologies.

ACT ACHIEVING OBJECTS

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

AFAA comments

TOR 2

Agrifood Awareness Australia Limited (AFAA) believes the object of the Act is being achieved and supports its focus on human health and safety and the environment. Further AFAA supports a national gene technology system which avoids duplication with existing agencies, and does not result in State and Territory Governments creating their own over-riding regulation denying access to the market for approved GM products.

OPERATION OF THE ACT

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

AFAA comments

TOR 3

As AFAA does not develop GM products and utilise the OGTR in a regulatory sense, we will not comment here on the structure of the organisation. We do believe however that the OGTR is effective in delivering a rigorous and transparent science-based regulatory framework.

Agrifood Awareness Australia Limited would like to commend the OGTR on its operations to date and the progress it has made since its inception in 2001. AFAA would like to see the OGTR build on this progress and in particular significantly enhance its public profile. A number of market research studies in Australia have highlighted a lack of public recognition of the OGTR and its activities and AFAA believes that this urgently needs to be addressed. We recommend that the OGTR consider the appointment of a dedicated, professional communication team to facilitate raising the organisation's profile and its role in regulating GM products. We also encourage the OGTR to consider more carefully its communication with lay audiences. For example, while the regulatory system may determine terminology for specific "dealings", such terminology requires explanation in the broader community. We believe for example, that the term "Deliberate International Release (DIR)" which applies equally to field trials and commercial releases, provides enormous confusion in the agricultural community. We recommend the OGTR consider the use of such words in its public communication.

TOR 4a

While AFAA does not develop GM products, we believe that the OGTR must be cost effective and decision-making must continue to be transparent. Further, as gene technology in Australia is still at an initial phase, AFAA believes the OGTR must continue to be Government funded, until such a time as a substantial number of products reach the market place and deliver return on investment.

TOR 4b

Agrifood Awareness Australia Limited believes the statutory advisory committees perform a very important role in Australia's gene technology regulation.

We commend the Gene Technology Advisory Committee (GTAC) on its scientific rigor and its role in evaluating, on a case-by-case basis, all GM products under development.

We believe that the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC) also play valuable roles in the regulatory system, particularly in enhancing two-way communication, and acknowledging community input.

We note with some concern the activities of GTEC, in particular the development of papers, about which GTEC appears to have facilitated little, if any, consultation. Also, we note that the GTCCC membership has not been renewed in nine months (since 8 October 2004) since the initial committee term expired. We believe this delay is primarily driven by politics, and again call on Federal, State and Territory Governments, particularly through the Gene Technology Ministerial Council, to demonstrate commitment to a national system.

We believe that to ensure a rigorous, science-based regulatory system, both GTEC and GTCCC should continue to discuss broad policy issues, but should not play a role in the case-by-base assessment of GM products. Further, we request that membership of both committees be expertise based and not overly representative of those campaigning against gene technology.

Going forward, we see a role for the OGTR to raise awareness of the existence of these committees to ensure greater community understanding of the roles and activities of these committees, and in turn build trust in the regulatory system.

TOR 4c

As AFAA does not utilise the OGTR we will not broadly comment in this area, other than to request some clarity around the OGTR's use of "stop clocks" which provide a degree of uncertainty in the community, and particularly, in rural Australia.

TOR 4d

AFAA supports wide consultation but believes this must be on an expertise-basis. AFAA therefore questions the OGTR's mandate to consult with local councils on applications of GM crop trials taking place in a council area. While AFAA supports wide consultation, we believe that to date this has not worked efficiently, primarily because the majority of councils have no expertise in gene technology – particularly in the science and an understanding of the regulatory process. As a result this consultation has generated a large amount of uncertainty in the community particularly in rural Australia and throughout the regional media. AFAA believes that this 'consultation' is therefore highly ineffective and needs to be significantly enhanced or removed.

TOR 5

Agrifood Awareness Australia Limited believes the *Gene Technology Act 2000* provides strong powers of enforcement for compliance which are both effective and appropriate and incorporating, in a worst case scenario, prison time and/or financial penalties for breaches to licence conditions.

Agrifood Awareness Australia Limited does not support the introduction of a strict liability regime for approved GM crops. We believe this is adequately covered through Common Law provisions. The Australian agricultural industry has managed the introduction of new technologies for centuries and while these are now increasingly covered through contractual arrangements, it has relied heavily on good agricultural practice, stewardship and communication – particularly between neighbours in farming communities. We see no precedent for introducing strict liability and believe this would only serve to increase community uncertainty about GM products, and compromise the science-based decision making of the OGTR, as are the aims of anti-GM campaigners. The reliance on Common Law is consistent with the approaches adopted in a majority of countries, including the United Kingdom, Canada and the United States, the latter of which are significant adopters of GM crops.

REGULATORY BURDEN

6. Examine whether compliance and administrative costs, including information requirements, for organisations working in gene technology are reasonable and justified compared to benefits achieved and possible alternatives to legislation.
7. Review the system of approvals and the application of regulatory requirements commensurate to the level of risk.

AFAA Comments

TORS 6 & 7

Agrifood Awareness Australia Limited believes that the costs of gene technology regulation should not be prohibitive for potential technology developers (both large and small organisations) and that any costs should be relevant to the potential risk and unnecessary costs should not be placed on the technology developer. For example, laboratory-based research presents potentially significantly less risk to human health and safety and the environment, than field trial research. We believe such differences should be reflected in the regulatory requirements.

We also believe that regulations must be science-based and not based on emotions or driven by politics. Crops developed utilising gene technology undergo much greater assessment than their conventionally-bred counterparts. It is essential that assessments remain science-based and needless regulations are not imposed on GM crops.

INTERFACE WITH OTHER SYSTEMS

8. Examine the nationally consistent scheme for gene technology regulation in Australia and identify any need for, and ways to achieve, improvements in its consistency, efficiency and coordination.
9. Examine the interface between the Act and other Acts and schemes (either Australian Government or State and Territory) that regulate gene technology and gene technology products. Identify any discrepancies, including regulatory gaps and areas needing consistency and harmonisation of provisions.

AFAA Comments

TORS 8&9

In the introduction of the Senate Community Affairs Report “A cautionary tale: Fish don’t lay tomatoes” (see

http://www.aph.gov.au/Senate/committee/clac_ctte/completed_inquiries/1999-02/gene/report/index.htm), the then Interim Office of the Gene Technology Regulator

(IOGTR) in discussing why Australia needs a national regulatory framework for genetically modified organisms noted, “A national, uniform regulatory system is fundamental to the development of an industry based upon gene technology in Australia”. While State and Territory Governments across Australia have attempted to develop such an industry, their efforts in the agricultural biotechnology area have largely failed and will continue to do so, as a result of their own, individual legislation.

Australia currently does not have a nationally consistent scheme for gene technology regulation. We have an outstanding, science-based federal regulatory system and now, a series of inconsistent mini-regulatory schemes operating across most States of Australia in the form of moratoria – regulation which bans the commercial productions of some OGTR-approved crops, and which imposes regulation on the small scale trial of these same OGTR-approved products which have been deemed to pose no greater risk to human health or the environment than their conventional equivalent.

Australian agricultural and scientific community leaders need to come together to agree to a path forward for GM products, particularly in relation to issues of markets and trade. However, a path forward will not be found, until such a time as Australian Governments, particularly State and Territory Governments, truly support a national scheme for GM products and do not look for “opt out” options, particularly through Policy Principles.

Agrifood Awareness Australia Limited does not support the ability of the Gene Technology Ministerial Council to introduce Policy Principles that distract from the rigorous, science-based regulatory system. We do not support State-based moratoria, driven predominantly by politics and we question the legitimacy of the State-based moratoria in relation to our World Trade Organisation (WTO) obligations. Further, we do not support Policy Principles in relation to ethics as such considerations can be dealt with through the GTEC. Agrifood Awareness Australia Limited recommends the removal of the Policy Principles from the *Gene Technology Act 2000*.

CHANGING CIRCUMSTANCES

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

AFAA comments

TOR 10

The adoption of GM crops continues to grow with an estimated 81 million hectares of GM crops grown in 2004 by 8.25 million farmers in 17 countries – both developed and developing nations. While an increase in the commercial production of GM crops has been stalled in Australia as a result of State-based moratoria, we believe the current Act is sufficient to accommodate changing circumstances in gene technology developments. However we recommend that this should be re-visited within five to ten years.

CHANGES TO THE LEGISLATION

11. Recommend amendments to the Act (including consideration of those recommendations made by State or Territory Parliamentary Committees), or alternatives to legislation, which improve the effectiveness, efficiency, fairness, timeliness and accessibility of the regulatory system.

AFAA Comments

TOR 11

Agrifood Awareness Australia Limited believes that the Act delivers a world-class, rigorous science-based and transparent system for the regulation of gene technology. However, we believe that the intention of the Act – to provide a path to market for approved GM products – has failed. We do not believe that OGTR decisions should be the subject of, or be overruled by, political, emotive or anti-gene technology forces. We challenge Australian Governments to demonstrate leadership and commit to a science-based decision making process.

IGA ACHIEVING ITS AIMS

12. Investigate whether the Intergovernmental Agreement on Gene Technology is achieving the aims listed in its Recitals.

AFAA Comments

TOR 12

We believe the IGT has failed in its aim. In its Recitals, it notes that the Scheme should “provide an efficient and effective regulatory system for the application of gene technologies”. As it currently stands, gene technology is only allowed to be applied in research, as no clear path to market exists and State Government bans have prevented commercial applications of gene technology.

Agrifood Awareness Australia Limited calls on the agricultural and scientific communities to develop a path forward, and for Australian Governments to demonstrate leadership in this area and commit to a national system which does allow the “application” of gene technology – from product development through to the marketplace.