SUBMISSION TO THE
SENATE COMMUNITY AFFAIRS REFERENCES COMMITTEE

in the matter of the

Inquiry into the *Gene Technology Bill 2000*

Prepared by

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Submission by the
Australian Centre for Environmental Law (ACEL) - ANU
on the *Gene Technology Bill* 2000

If biologists were to achieve th[e] power [to produce intended mutations of genes], that would mark a new departure in the operation of the process of evolution. For the first time, an existing species of living creature would be able to create new species on its own initiative, by a conscious and purposeful act of planning. This power to direct our own evolution, and the evolution of any other species, would have greater effects on mankind's future than any power we have acquired so far.

-- Arnold Toynbee (1966) [*]

The Committee believes that the [Gene Technology] bill's provisions must ensure that a more comprehensive, independent and rigorous regulatory ststem for GMOs is established than exists at present.

-- Standing Committee on Primary Industries and Regional Services (2000) [**]

SUMMARY

In July 1999, Deutsche Bank, a leading international investment firm, issued a report highlighting that genetically modified products are fast becoming an economic liability.[1] By the end of 1999, more than 30 farm groups in the United States, including the American Corn Growers Association, were advising farmers not to grow genetically engineered crops.[2] These developments call into serious question the wisdom of the "Ministerial Introduction" contained in the recently released *Australian Biotechnology: A National Strategy*.[3] Indeed instead of delivering improved international "competitiveness and sustainability" for Australia, the policy decision to promote genetic modification, including of agricultural and food products, in Australia may have a profound opposite effect.

More importantly for the present Inquiry, however, the concerns of Deutsche Bank and the US farm groups emphasise the growing uncertainty about the risks to human health and safety and to the environment that are attendant on genetically modified

[*] A TOYNBEE, CHANGE AND HABIT (1966), pp 9-10.

[**] House of Representatives Standing Committee on Primary Industries and Regional Services, Work in Progress: Proceed with Caution -- Primary Producer Access to Gene Technology (June 2000), at 123. (available at: <www.aph.gov.au/house/committee/primind/gtinq/report/contents.htm>).

[1] FJ Mitsch & JS Mitchell, *Ag Biotech: Thanks, But No Thanks?* (Deutsche Bank, Equity Research, North America, July 12, 1999), pp. 17 - 20.

[2] BBC News, GM Crop Warning for US Farmers (24 November 1999)(available at: <http://news6.thdo.bbc.co.uk/hi/english/world/americas/newsid%5F535000/535387.stm>).

[3] Commonwealth of Australia, Australian Biotechnology: A National Strategy (2000), p. 4.

organisms (GMOs).[4] In order to address these risks in Australia, the *Gene Technology Bill* 2000 ('the *GTB* 2000') was introduced into Parliament on 22 June of this year. Unfortunately, as this submission demonstrates, in its current form the *GTB* 2000 is unlikely to provide effective protection against potential risks posed by GMOs and GM products for at least six paramount reasons.

Objectives of Government Action

First, two of the central goals of the Government underpinning this legislation will seriously undermine the purpose of the risk analysis and identification regime established by the Bill. The Government, in its overarching goals, seeks to "provide to industry a more streamlined and certain pathway for seeking an gaining approval" and will do this by pursuing "an efficient and cost effective approach".[5] However, the *raison d'être* of an assessment, including risk assessment, prior to the approval of regulated activity is not to streamline pathways. Indeed, it is just the opposite. As emphasised in *Prineas v Forestry Commission of New South Wales* the purpose of an assessment is "to ensure that government and semi- government bodies properly understand the environmental consequences of carrying out or not carrying out an activity".[6] It is designed to slow things down; to require that we take a "hard look" before doing something that may have irreversible catastrophic consequences.[7]

Object of the GTB 2000

Second, the object of the *GTB* 2000 is focussed only on the identification and management of risks. Effective regulation of risk, however, requires not only management, but more importantly, the reduction, minimisation and elimination of overall risk. Indeed "[i]n the twentieth century, the reduction of risks to life and health has become one of the government's most important taks".[8]

Failure to incorporate a precautionary approach

Despite widespread community support during consultations on the Bill for a requirement that the Regulator consider the precautionary principle in decision-making, the *GTB* 2000 fails to include any reference to precaution. This is in direct contravention of advice provided by **Environment Australia** in the *Inquiry Into Primary Producer Access to Gene Technology*. As Environment Australia emphasised:

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[4] See Parliament of the Commonwealth of Australia House of Representatives, Gene Technology Bill 2000 Explanatory Memorandum (circulated by authority of the Minister for Health and Aged Care), pp. 12-13.

[5] Id., at 14.

[6] (1983) 49 LGRA 402 at 417.

[7] Citizens Airport Environment Association Inc v Maritime Services Board (1993) 114 ALR 473.

[8] C Sunstein, *Forward*, in JD GRAHAM & JB WIENER, EDS, RISK VS. RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT (1995), p vii.

> The precautionary principle has particular application to GMOs. Not only could direct damage be serious, but ongoing and extensive because of irreversibility. One released freely to the environment, a living organism, or a novel gene that has transferred to an unintended host, cannot be "recalled". A cautious and conservative approach to risk should be followed where there is insufficient scientific confidence of safety. Successful application of the principle will mean that Australia avoids expensive failures.[9]

The failure to adopt the precautionary approach in the *GTB* 2000 also flies in the face of claims made by the Government of Australian before the International Tribunal for the Law of the Sea in the Dispute Concerning Southern Bluefin Tuna that "[t]he precautionary principle must be applied by States in taking decisions about actions which entail threats of serious or irreversible damage to the environment . . .".[10]

Underpinning principles of Attachment B

The Discussion Paper states that the paramount object of the new regulatory system – protection human health and safety and the environment – will be underpinned by guiding "Policy Principles" outlined in Attachment B. These principles were apparently unilaterally agreed on, without public input, by the Commonwealth State Consultative Group on Gene Technology (CSCG). This is yet another failure of public consultation in the realm of GMOs. Moreover, the principles themselves are in large measure defective and will undermine "placing the health and safety of the public, and the environment, as the paramount concerns" of the proposed legislation.

In particular, we object to the following "regulatory framework" Policy Principles as inappropriate for and inimical to providing the highest standard of public health and environmental safety in connection with risks posed by GMOs:

- That "*the regulatory burden shall be kept to a minimum"*. This principle is especially inappropriate to legislation designed to provide a high level of protection for human health and safety, as well as the environment. Indeed, it is directly opposed to the recommendation put forward by the Australian public in the 1999 Consensus Conference, "Gene Technology in the Food Chain". This public Conference called for a far more regulated and precautionary regime than is currently supported by the Policy Principles developed by the CSCG working in splendid isolation.

- That "*a prime aim is to foster innovation*". This principle relates to the way in which cooperation across jurisdictions should be focused in administering the proposed legislation and developing policy guidelines. Of course, this

[9] Environment Australia, Environmental Issues Raised by the Release and Use of Genetically Modified Plants and Animals in Australia, 4 Submissions to the House of Representatives Standing Committee on Primary Industries and Regional Services Inquiry Into Primary Producer Access to Gene Technology (February 2000, Submission No 82), p 815, at 824.

[10] Australian Request for Provisional Measures, Southern Bluefin Tuna Cases (Australia v Japan), Annex 2 (Statement of Claim and Grounds on Which it is Based), p 28.

principle must be qualified by the need to ensure that such innovation is not harmful to human health, safety, or the environment.

- That "*prescriptive laws that attempt to predetermine what activities, technologies, or gene modifications*" are inappropriate in the new regulatory scheme. This is apparently true in all cases, even where prescriptive laws would be the most effective way to protect human health and/or the environment.

- That protection afforded by the law be at all times "*consistent with Australia's international obligations*". This principle is coupled with another that provides the new law "*shall be framed to minimise the creation of barriers to innovation or the market entry and exit of firms, and to minimise adverse impacts on Australia's international competitiveness*". Together, these principles raise the dangerous spectre that the object of protecting human health and the environment will be made subservient to GATT/WTO trade disciplines unfriendly to human safety and the environment.

- Additionally, in terms of market access, given the potentially catastrophic risks associated with GMOs, it is clear that the hurdle for access must be set high. Indeed, a missing policy principle in the Regulatory Framework of Attachment B is a requirement for the posting of a significant assurance bond as a condition precedent to receipt of a licence. This is especially necessary in light of the fact that "product liability remains the responsibility of the applicant" under the proposed regulatory framework.

In connection with the "regulatory processes" associated with the Policy Principles in Attachment B, we make the following objections:

- Effective protection of public health and safety from risks associated with GMOs is undermined by the requirement that GMO regulation be *"designed to minimise the costs of administration to Government, and the costs of compliance to individuals, businesses and organisations"*. Skimping and cutting corners in these areas is an invitation to disaster. The potential dangers to human safety and the environment require robust monitoring, enforcement and compliance requirements, with little consideration to cost.

- It is disappointing that policy principles provide that *"decision-making processes shall be based on rigorous scientific assessment"* alone. While scientific assessment is essential, it is not sufficient to protect human health and the environment in cases of scientific uncertainty – a condition likely to be present in most decisions. Effective protection requires application of the "precautionary principle" in the decision-making process. This is in line with the EPBC Act, as well as Australia's recent claims before the International Tribunal for the Law of the Sea that the precautionary principle is an obligation of every country under customary international law.

- The policy principles outline a set of criteria by which the proposed regulatory processes are to be measured. However, these criteria (such as "*efficient*", "*timely*", "*seamless*", and "*simple*") have very little to do with good outcomes

for human safety and environmental protection. Unfortunately, Appendix B fails to develop a set of *human health and safety* and *environmental* criteria by which to judge the proposed regulatory system.

Recommendation 6

The Policy Principles underpinning the proposed new legislation should be revisited in order to ensure that they support rather than undermine the protection of human health and safety and the environment. In reopening consideration of the Policy Principles, extensive public consultation should take place.

The scope of the legislation

The Discussion paper indicates that the proposed legislation will regulate all activities involving GMOs that are not currently covered by existing national regulatory schemes. This means that the new regulatory scheme will focus primarily on viable GMOs -- other than those resulting from human genetic manipulation – instead of GM products (including food, therapeutic goods, agvet and industrial chemicals, and imports).

Of course, it almost goes without saying that adding another new layer of bureaucracy, to the already variegated and complex regulatory structure cuts directly against the calls for the new regulation to be "efficient", avoid "unnecessary duplication", an provide a "streamlined" pathway for industry. Uncertainties about jurisdiction, bureaucratic rivalries, legislative interpretation, etc, all will ensure regulatory inefficiency, duplication and slow going. To avoid these problems, as a matter of sound policy, the new national regulatory system for GMOs should be a comprehensive and integrated regime covering all facets and activities involving genetic manipulation and the results of such manipulation.

The scheme of the proposed law should be to subject every activity, application and use of GMOs or products derived from GMOs to a unified regulatory control, administered by one independent regulator. The activities regulated should include: importation, export, deliberate release into the environment, placing on the market and contained use. All GMOs, as well as products thereof, should come within the ambit of the law.

This would include genetically modified fruits and plants; seeds; commodities such as soya bean, maize and corn, whether for human or animal consumption; fruits modified to be vaccines for humans or animals; transgenic fish; any organism intended for production of food enzymes or pharmaceuticals, or imported for sewage treatment; propagating material for breeding purposes/green house cultivation; and products from transgenics, such as flour from transgenic corn.

Recommendation 7

In order to promote regulatory effectiveness and efficiency, the regulation of all activities, applications and uses of GMOs and all products derived from GMOs should be subject to unified regulatory control by one independent regulator under

the proposed national regulatory system. The new regime should control the import, export, deliberate release, contained use, and placing on the market of GMO(s) and products thereof.

Definitions

As the Discussion Paper recognises, the scope of the legislation will be largely determined by the definitions of activities it is intended to cover. In order to achieve comprehensive and integrated regulatory coverage of all aspects and activities involving or related to genetic manipulation and its results and products, a far more comprehensive definition activities covered by the legislation is required. These would include such things as: 'activity', 'applicant', 'application, 'biological diversity', 'contained use', 'deliberate release or release', 'export and exporter', 'GMO', 'gene technology', 'import and importer', 'placing on the market', 'products derived from GMOs', 'protected disclosure' 'risk assessment', 'use', and 'written informed agreement'.

Recommendation 8

The definitions contained in the proposed national regulatory system should be greatly expanded in order to take account of the need for a comprehensive and integrated system. Additional terms requiring definition include: *'activity', 'applicant', 'application, 'biological diversity', 'contained use', 'deliberate release or release', 'export and exporter', 'GMO', 'gene technology', 'import and importer', 'placing on the market', 'products derived from GMOs', 'protected disclosure' 'risk assessment', 'use', and 'written informed agreement'.*

In the event that it proves politically impossible to expand the proposed regulatory system, the current definition of GMOs should be expanded. In addition to the proposed clauses (a) – (c), the proposed legislation should also cover, as GMOs, any biological entity capable of replication or transfer of genetic information, and includes plants, animals, bacteria and all other kinds of micro-organisms, cell cultures (prokaryotic or eukaryotic) created and propagated as such, viruses, and plasmids and other kinds of vectors, in which the genetic material has been altered in a way that does not occur naturally, by means of cell or gene technology.

Recommendation 9

The existing definition of GMOs in the Discussion Paper should be expanded to include: "any biological entity capable of replication or transfer of genetic information, and includes plants, animals, bacteria and all other kinds of micro-organisms, cell cultures (prokaryotic or eukaryotic) created and propagated as such, viruses, and plasmids and other kinds of vectors, in which the genetic material has been altered in a way that does not occur naturally, by means of cell or gene technology".

Relationship with other regulators

If, politically, the development of a comprehensive and integrated regulatory system proves unacceptable, as the Discussion Paper recognises, the new and independent Gene Technology Regulator (GTR) needs to be made a referral authority for other regulators. However, it is not enough for existing regulators to seek and take account of advice of the GTR on human and environmental safety in relation to applications for approval involving GMOs and GM products. Because the GTR is to be completely independent and its decisions must be based on scientific rigor, the GTR needs to be given the power to disallow applications for approval made to other regulators (or impose its own conditions), where the GTR believes that the safety of human health or the environment would otherwise be compromised.

Recommendation 10

The GTR should be empowered to disallow applications for approval made to other regulators (or impose its own conditions), if the GTR believes that the safety of human health or the environment would otherwise be compromised.

CHAPTER 3

The Gene Technology Regulator

We welcome the Discussion Paper's recognition of the need to ensure that the GTR has complete independence from the regulated community and the political process. This is especially important in light of the recent abolition of two other independent statutory authorities, the Commonwealth Environment Protection Authority and the National Parks and Wildlife Service.

Independence of the GTR

The Discussion Paper, however, fails to give adequate consideration to necessary disabilities in connection with eligibility to be the GTR. For instance, an individual with an interest (financial or otherwise) in a regulated entity should be precluded from holding the office of the GTR. Likewise, an individual who has worked for a regulated entity should be barred from holding the office of GTR until the expiration of an adequate amount of time to ensure propriety and the appearance of propriety in impartial decision-making. Disclosure of interest is clearly not sufficient in these areas.

Recommendation 11

In order to ensure independence and the appearance of independence of the GTR, the proposed national regulatory system should ensure that an individual with an interest in a regulated entity is barred from eligibility. Likewise, the expiration of a two-year period should be required before an individual who has been employed by a regulated entity is eligible to hold the office of the GTR.

The independence of the GTR is also undermined by the need to obtain the *approval* of the majority of States and Territories for the preferred candidate. Requiring the

political approval of a majority of States and Territories is hardly a recipe for independence. Indeed, in order to gain majority approval the preferred candidate may become inappropriately beholden to those supporting his or her appointment. Clearly, the preferable method of appointment would include extensive *consultation* with the States and Territories, but would not include the veto power over a proposed appointment.

Recommendation 12

The appointment of the GTR should require extensive consultation with the States and Territories, but should not require their approval.

Appointment of the GTR

Moreover, the process for appointment outlined in the Discussion Paper is not sufficient to ensure the adequate qualification of the GTR. It is clear that in making the appointment, the Governor General must only do so on the advice of ***both*** the Commonwealth the Minister for Health ***and*** the Minister for Environment. The two crucial objects of the proposed regulatory system are the protection of human health and safety and the environment. Accordingly, the Environment Minister should be included in the appointment process.

Recommendation 13

In order to ensure adequate consideration is given to environmental concerns, the GTR should be appointed on the advice of both the Commonwealth the Minister for Health and the Minister for Environment.

The Ministerial Council

We strongly support the absence of a role of the Ministerial Council in considering, assessing or approving decisions made by the GTR. This is vital as safeguard on the independence of the GTR.

Public consultation on GMO policy

We are concerned, however, about transparency and the opportunities for public participation in relation to the development of policy by the Ministerial Council in relation to gene technology. At present, the Discussion Paper only provides for consultation "as requested" by the Ministerial Council with the Gene Technology Community Consultative Group (GTCCG). Clearly, the wider public should be consulted in the process given the important ramifications for the safety of human health and the environment.

Recommendation 14

The proposed national regulatory system should provide for wide community

consultation in connection with the formulation of gene technology policy by the Ministerial Council.

The Gene Technology Advisory Body (GTAC)

Ethics member

We support the establishment of GTAC to provide expert advice to the GTR. However, given the commitment in the Discussion Paper to take account of "ethical" concerns in decision-making, it is surprising that the proposed composition of GTAC fails to include an expert in ethics. In order to ensure ethical concerns are adequately accounted for, it is important that GTAC include an ethicist.

Recommendation 15

The provisions relating to the composition of GTAC ensure that an expert in ethics is a member of GTAC.

Independence of GTAC

Additionally, it is crucial to establish eligibility criteria for GTAC. For instance, as with the GTR, an individual with an interest (financial or otherwise) in a regulated entity should be precluded from siting on GTAC. Likewise, an individual who has worked for a regulated entity should be barred from GTAC until the expiration of an adequate amount of time to ensure propriety and the appearance of propriety in the provision of impartial advice. Disclosure of interest is clearly not sufficient in these areas.

Recommendation 16

In order to ensure independence and the appearance of independence of GTAC, the proposed national regulatory system should ensure that an individual with any interest in a regulated entity is barred from eligibility. Likewise, the expiration of a two-year period should be required before an individual who has been employed by a regulated entity is eligible to hold the office of the GTAC.

Appointment of GTAC

Finally, it is clear that the Commonwealth Minister for Environment *and* the Minister for Health be jointly responsible for the appointment of GTAC members. The two crucial objects of the proposed regulatory system are the protection of human health and safety and the environment. Accordingly, the Environment Minister should be included in the appointment process.

Recommendation 17

In order to ensure adequate consideration is given to environmental concerns, GTAC should be jointly appointed by the Commonwealth the Minister for Health and the Minister for Environment.

CHAPTER 4

A system of prohibitions and approvals

The proposal to base the national regulatory system on the prohibition of activities or use of GMOs unless otherwise approved (or exempted) is a generally accepted method by which to protect human health and the environment. It is of concern, however, that no approval will be necessary for an application that the GTR determines represents little or no risk. It is not clear from the Discussion Paper how and on what basis such a determination is to be made. Presumably, such an application would still be required to go through the complete risk assessment process before the GTR could exempt it from approval. This should be spelled out in the new legislation.

Recommendation 18

The proposed national regulatory system should provide that the full risk assessment process applies, including public notice and comment, before the GTR can make a determination that an application represents little or no risk.

Applying for a licence

Burden of proof

Given the potential catastrophic risks associated with the use, application or release of GMOs, it is imperative that the national regulatory framework clearly and expressly establishes that the applicant for a licence bears the burden of proof in connection with the application. In particular, the applicant must be required to demonstrate beyond reasonable doubt that granting the application will not result in damage or harm to human health and safety or to the environment.

Recommendation 19

The proposed national regulatory framework must clearly and expressly establish that the applicant for a licence bears the burden of proving beyond reasonable doubt that granting the application will not result in damage or harm to human health and safety or to the environment.

Information required to accompany application

The Discussion Paper fails to adequately set minimum standards for information that will be required to accompany applications. We appreciate that information required by the GTR will vary depending on the nature of the application. However, the proposed legislation should set out the general requirements for information, while leaving more detailed requirements for information to regulations (not guidelines as proposed by the Discussion Paper). At a minimum, the proposed law should require the following information:

- Information demonstrating the suitability of the applicant to hold a licence (including disclosure of all past compliance problems and breaches of health and environmental laws);
- information relating to the GMO(s), products anticipated to be developed there from, or products thereof;
- information relating to the conditions of release, contained use or placing on the market and, where appropriate, the receiving environment;
- information on the interaction between the GMO(s) or products thereof and the environment;
- information on monitoring, control, waste treatment and emergency response plans;
- in case of an application for contained use, an impact assessment report setting out the consequences of a release of the GMO(s) or anticipated GM products;
- a report on the impacts and risks posed by the GMO(s), products anticipated to be developed there from, or products thereof, to human and animal health, biological diversity and the environment in accordance with the regulations (to be developed);
- information on results from deliberate releases in the country and other countries of the GMO(s) or products thereof previously or currently carried out by the applicant;
- information on previous approvals or rejections of the GMO(s) or products thereof by any other country, where approval is sought;
- information on where and for what purposes the GMO(s) or products thereof will be marketed, together with detailed instructions for use and the proposed labelling and packaging, fulfilling the requirements specified in the regulations (to be developed).

Recommendation 20

The proposed legislation should set out detailed general requirements for information to accompany all applications, while leaving more detailed requirements for information to regulations (not guidelines as proposed by the Discussion Paper).

Public notice of all applications

In order to give effect to the community's right to know about GMO activities taking place around them, it is vital that the proposed national regulatory system require that the public be given adequate notice of ***all applications*** received by the GTR. This is not provided for in the Discussion Paper.

Recommendation 21

*The proposed national regulatory system should require that the public be given adequate notice of **all applications** received by the GTR.*

Public register of application details, etc

It is also essential that the regulatory system establish a public register relating to licences. The register should be freely available to the public and at a minimum contain all information about licence applications, GTAC's report on assessment of risks (see **Recommendation 23**), reasons for licence decisions, the licence and conditions (if any), any variations of licences, and all monitoring data.

Recommendation 22

The proposed national regulatory system should establish a public register that includes all information about licence applications, the applicant's report on assessment of risks, reasons for licence decisions, the licence and conditions (if any), any variations of licences, and all monitoring data.

The Assessment Process

GTAC risk assessment report

In order to facilitate the assessment process, it is important that a risk assessment report be prepared. The Discussion Paper is silent on this matter. GTAC should be charged with the responsibility of providing the GTR with a report of an assessment of risks posed by the GMO or product(s) thereof in connection with all applications received by the GTR. The report should examine in detail the impacts and risks posed to human and animal health, the environment and biological diversity.

Recommendation 23

The proposed national regulatory system should require GTAC to provide the GTR with a risk assessment report that details the potential impacts and risks to human and animal health, the environment and biological diversity posed by the application.

The precautionary principle

The Discussion Paper outlines four matters that will guide and circumscribe the risk assessment process, including an appropriate risk assessment paradigm, clearly defined risk assessment standards and requirements, scientific objectivity, and case-by-case analysis. These matters are important as far as they go, but they are clearly insufficient in order to protect from risks in the case of scientific uncertainty. It is essential that the assessment process be based on a risk paradigm that involves the precautionary principle.

Recommendation 24

The proposed national regulatory system should integrate a precautionary approach into the three-step risk assessment paradigm. The paradigm should involve: (i) problem formulation, (i) exposure and effects analysis, and (iii) risk characterisation based on the need to err on the side of precaution in cases of scientific uncertainty.

Application and monitoring information presumed to be publicly available

The Discussion Paper fails to adequately consider the public's right to access information received by the GTR in connection with applications and monitoring information. The new regulatory system needs to strike a balance between the right of the public to all information on the risks associated with GMOs or products thereof, and the right of the applicant to protect its commercial interests from competitors.

There needs to be a presumption in the new system that all information required to be disclosed by an applicant or licence holder is to be freely available to anyone who seeks it. However, the applicant should be allowed ask the GTR to keep certain information confidential on the ground that its competitors may be able to acquire and use the information and harm the applicant's competitive business position.

The GTR would then decide whether confidentiality should be granted. Those claiming commercial confidentiality must bear the burden of proof beyond reasonable doubt. Applicants should not be able to claim commercial confidentiality unless they can prove:

- that the information has not already been disclosed anywhere in the world;
- another law, in Australia or in any other country, does not require disclosure of the information;
- keeping the information confidential *would not* create a significant public health/environmental risk;
- disclosure would cause substantial harm to the applicant;
- the information claimed to be confidential is not readily discoverable through

reverse engineering or other scientific means.

Further, and in any event, the GTR should always have the power to override the claim for confidentiality in the public interest, as when human lives or environmental damage are threatened.

Recommendation 25

The proposed national regulatory system should include a presumption that all information required to be disclosed in connection with an application is to be freely available to anyone who seeks it. An applicant can apply to the GTR to keep information confidential, but must bear the burden of proof, according to legislative standards, in establishing confidentiality.

Consultation during the risk assessment phase

Public participation in all cases

The Discussion paper attempts to draw an artificial distinction between contained experimentation and field trial or general release of GMOs in relation to public participation in the assessment process. The public is only to get a "look in" where field trials or general release is contemplated. This is entirely unacceptable. The public must have the right to be notified and participate in connection with all applications. It has the right to understand and have confidence in the so-called "contained" use of GMOs. After all, the release of GMOs from a contained environment (whether intentional, reckless, negligent or accidental) is likely to have much more catastrophic impacts on human health and the environment than field trials. This is, of course, because they have not been approved for release.

Recommendation 26

The proposed national regulatory system should ensure that the public is notified and has the opportunity to comment on all applications received by the GTR.

Matters to be taken into account

Impact on biological diversity

The Discussion Paper indicates that the GTR must consider risks to the environment in making a decision on a licence application. However, no mention is made about impacts on biological diversity. Because GMOs have the dangerous potential to greatly reduce or radically alter the wealth of biological diversity found in Australia, it is crucial that the GTR also specifically be required to consider risks posed to biological diversity.

Recommendation 26A

The proposed national regulatory system should require the GTR to specifically consider risks posed in biological diversity when making decisions on licence applications.

Public Comments

It is telling that the public comments received on applications as provided for in the Discussion Paper are entirely omitted from matters that must be taken into account by the GTR in making a decision on an application. Clearly, all public comments received on an application must be required to be considered by the GTR in making a decision.

Recommendation 27

Matters to be taken into account by the GTR in making a decision on a licence application must include all public comments received.

The precautionary principle

It is unacceptable that the proposed assessment process fails to incorporate the precautionary principle into matters to be considered in deciding whether or not to grant a licence. Given the potential for grave and irreversible harm that GMOs pose, it is irresponsible not to include an express requirement that the precautionary principle be considered in decision-making.

Recommendation 28

Matters to be taken into account by the GTR in making a decision on a licence application must include the precautionary principle.

Ethical values and norms

Given the Discussion Paper's commitment to "providing a mechanism for considering ethical issues", it is strange to find ethical values and norms omitted from the matters that the GTR must take into account in making a decision on an application. Clearly, if the proposed national regulatory system is to be true to its objectives, ethical issues must be included in the calculus of decision-making.

Recommendation 29

Matters to be taken into account by the GTR in making a decision on a licence

application must include ethical values and norms.

Granting a licence

Assurance bonds

The Discussion Paper is non-committal about the need for assurance bonds. While money can never remedy death and disease or environmental harm, it is vital that a regime of adequate assurance bonds be established by the proposed national regulatory system. The effective use of assurance bonds finds ample precedent in the mining laws of various States and Territories.

Assurance bonds would help to facilitate the highest standard of care in the use, application or release of GMOs through the threat of forfeiture in the event of damage or harm caused by the applicant (either intentionally, recklessly, negligently or accidentally). It would also ensure "that product liability remains the responsibility of the applicant" in accordance with the Policy Principles outlined in Attachment B of the Discussion Paper. This is especially true in the event of insolvency.

Recommendation 30

The proposed national regulatory system should establish a requirement that an adequate assurance bond be posted by every applicant before a licence can be issued by the GTR.

Identification and labelling

The Discussion Paper is silent with respect to identification and labelling issues. While we appreciate the current responsibilities of ANZFA in relation to GM food labelling, it is important that the proposed regulatory system require all licence holders to identify and label all GMOs within the ambit of the new regime, in such a way that they can be traced.

Recommendation 31

The proposed national regulatory system should require all licence holders to identify and label all GMOs covered by the system in such a way that they can be traced.

Grounds for the decisions

In order to foster community confidence in decisions made by the GTR in relation to licence applications, it is necessary to ensure that the public is fully informed about the reasons for the GTR's decisions. In every case where a licence is granted or refused, the GTR must be required to provide public reasons. These reasons should be made freely available in the public register discussed above in connection with **Recommendation 22**.

Recommendation 32

The proposed national regulatory system should require the GTR to provide public reasons for all decisions the GTR makes in relation to applications.

New evidence and information

The new proposed regulatory system needs to establish a statutory obligation on all licence holders to provide new or additional evidence and information of any possible risks that become known to the applicant at any time. As discussed below in connection with **Recommendation 42**, breach of this obligation should entail criminal and civil penalties. If the new evidence or information warrants, based on the precautionary principle, the GTR must be empowered to suspend or revoke a licence.

Recommendation 33

The proposed national regulatory system should impose an obligation on all licence holders to provide new or additional evidence and information of any possible risks that become known to the applicant at any time.

Prior informed consent required for export

In order to maintain Australia's position in the international community as a respected and responsible environmental citizen, the proposed regulatory system should provide in cases where a licence is granted that there can be no export of GMOs or products thereof unless the Australian Quarantine and Inspection Service (AQIS) is satisfied that the country of import gives its prior informed consent. The exporter must provide the AQIS with a written informed agreement of the competent authority of the State of the importer before export is allowed. The new system should also establish an absolute prohibition on the export of any GMOs or products thereof that are banned in the country.

Recommendation 34

The proposed national regulatory system should provide in cases where a licence is granted that there can be no export of GMOs or products thereof unless the Australian Quarantine and Inspection Service (AQIS) is satisfied that the country of import gives its prior informed consent. The new system should also establish an absolute prohibition on the export of any GMOs or products thereof that are banned in the country.

State/Territory opt out

We support the comment in the Discussion Paper that "no State or Territory would be able to allow the release of a GMO where the GTR had determined on public health and safety [or] environmental grounds that the release must not proceed". We do, however, believe that the converse should be true.

A State or Territory should be able to refuse the release of GMOs on the grounds of protection of human health or safety or the environment, in the event it disagrees with the decision of the GTR. It is unacceptable to force States and Territories to harmonise their protection of health and the environment downwards to meet lower standards imposed by the proposed national regulatory scheme.

Of course, once a GMO is released and the "cat is out of the bag" it is, no doubt, unrealistic to expect mere laws to keep it out of a jurisdiction that does not want it. Still, States and Territories should have the choice to set health and environmental standards at levels higher than the Commonwealth and it is dangerous a precedent to refuse to allow them to do so.

Recommendation 35

Under the proposed national regulatory system States and Territories should have the choice to set health and environmental standards at levels higher than the Commonwealth and refuse the release of GMO within their jurisdiction on this basis.

The GTR's "delegates" – accredited organisations

We strongly oppose the accreditation of regulated entities to carry out the GTR's functions and duties under the proposed national regulatory system. Self-regulation in this context will undermine public confidence in the entire system. It defeats the purpose of an independent GTR It is clearly inconsistent with the Policy Principles in Attachment B to the Discussion Paper – ie "there *shall be no* conflict of interest in the decision-making and risk assessment process, which shall be at arm's length from specific interest groups". Accreditation as proposed in the Discussion Paper is akin to letting the wolf guard the sheep.

Recommendation 36

The proposed national regulatory system should not allow regulated entities to be accredited organisations charged with the responsibility of carrying out the GTR's functions and duties.

Moreover, the Discussion Paper is completely silent about the details (and adequacy) of what it terms "safety valves to ensure greater transparency, accountability and consistency in decision-making". Indeed, the Discussion Paper fails entirely to mention "safety valves" for the protection of human health and the environment.

Recommendation 37

The proposed national regulatory system should make effective provisions for "safety valves" in the system to ensure that human health and the environment receive paramount protection.

The Discussion Paper also briefly mentions "standards" to be "developed by the GTR and approved by Ministers" for accreditation under the new system. Clearly, stringent and enforceable standards need to be included in the proposed legislation if the unsound practice of accreditation is allowed to proceed. It is insufficient to rely on informal "standards" that do not have the force of law and which cannot be enforced by third parties.

Recommendation 38

In the unsound event that accreditation of regulated entities is permitted under the proposed regulatory system, stringent and enforceable standards governing accreditation should be established by regulation under the new law.

Review or renewal of licences

The Discussion Paper fails to outline requirements for the review or renewal of licences. It is unacceptable that licences will be issued in perpetuity without an established system for review or renewal. Review and renewal procedures are common in licensing regimes across Australia. There are included as a necessary means to ensure protection of public health and safety and the environment.

Recommendation 39

The proposed national regulatory system should include provisions for the mandatory review or renewal of all licences granted by the GTR. The review or renewal should take place at intervals of not more than 3 years.

CHAPTER 5

Monitoring of compliance

Public access to monitoring data

The Discussion Paper outlines five different methods for monitoring compliance. However, no mention is made about the right of the public to access data compiled as a result of such monitoring. Accordingly, the new regulatory system needs to require that monitoring data be included in the public register discussed in connection with **Recommendation 22**.

Recommendation 40

The proposed national regulatory system should provide for public access to all monitoring data.

Protected disclosures

"Whistleblowers" should receive protection under the new regulatory scheme. They should be protected against victimisation, sacking or other punishments so long as any disclosure is made in good faith and on reasonable belief of risks posed by the GMOs or products thereof. The disclosure must be made to the GTR.

Disclosure to the media should also be permitted, but subject to more stringent conditions. There must be clear and convincing grounds, and the disclosure must be necessary to avert an imminent and serious threat to human or animal health, the environment or biological diversity.

Recommendation 41

The proposed national regulatory system should include provisions for protected disclosures by "whistleblowers" to the GTR and, subject to stringent conditions, the media.

Liability and remediation

Criminal and civil penalties

In order to be effective, the liability provisions involving criminal and civil penalties must impose strict liability for breach of the new law. The penalties imposed should be sufficiently large to ensure compliance. Criminal and civil penalties should be provided for, including penalties for Directors and Officers, in cases of:

- unauthorised use of GMOs;
- use of GMOs in breach of conditions imposed by the GTR;
- failure to provide information, including new or additional information, whether intentionally, recklessly, negligently or accidentally;
- provision of false or misleading information, whether intentionally, recklessly, negligently or accidentally;
- the release of GMOs from a contained environment, whether intentionally, recklessly, negligently or accidentally;
- bribing or threatening a person to refrain from making a protected disclosure to the GTR or, if justified, the media;

Strict liability for harm at common law

We strongly disagree with the Discussion Paper's indication that the new legislation should not affect the common law avenues for redress. Given the potential for vast

and irreversible harm, the new legislation should impose strict liability for harm in civil actions.

Strict liability should attach to any person or entity responsible for any damage caused to human health or the environment by the introduction of a GMO or product thereof. Strict liability should also attach to officers of a corporation unless they can show that they did all that was possible to prevent the activity in relation to the GMO or product thereof.

If more than one person is responsible, then liability should be joint and several. Liability would attach if a plaintiff proved that one or more persons proceeded against could have caused the damage. Liability should not be limited to personal injury, damage to property and financial loss. It should also extend to damage caused to the environment and to biological diversity. The person or entity responsible must bear the costs for reinstatement, rehabilitation or clean-up measures and for loss or damage caused by taking preventive measures.

Recommendation 42

The proposed national regulatory system should impose statutory strict liability in civil actions for all harm caused by the introduction of a GMO or product thereof, including damage to the environment and biological diversity.

Open standing in action to recover damages to the environment of biological diversity

Of course, in order to reflect legislative "best practice", standing to maintain a strict liability action at common law should be expanded. In addition to the traditional standing requirements for individualised harm to person and property, the new regulatory system should provide that "any person" may bring an action to recover damage caused to the environment or biological diversity from the introduction of a GMO or product thereof. Any damages recovered in such an action should be awarded to an "Environment Compensation Fund" which would be spent on environmental remediation.

Recommendation 43

The proposed national regulatory system should provide that "any person" may bring an action to recover damage caused to the environment or biological diversity from the introduction of a GMO or product thereof. Damages recovered in such an action should be awarded to an "Environment Compensation Fund", to be spent on remediation.

Remediation

The Discussion Paper indicates that the GTR will have the ability to issue clean up orders to contain an unauthorised release or repair damage caused by GMOs. It is also vital that the GTR be empowered to take immediate remedial action to protect the

public and environment and recover costs form the individual(s) or entity(ies) responsible for the release or damage (regardless of whether the release or damage is intentional, reckless, negligent, or accidental).

As discussed in connection with **Recommendation 30**, the proposed national regulatory system should also establish a requirement that an adequate assurance bond be posted by every applicant before a licence can be issued by the GTR. This would help ensure that the GTR is able to recover remediation costs.

Recommendation 44

The proposed national regulatory system should provide that the GTR be empowered to take immediate remedial action to protect the public and environment and recover costs form the individual(s) or entity(ies) responsible for the release or damage (regardless of whether the release or damage is intentional, reckless, negligent, or accidental).

CHAPTER 6

Community input into policies underpinning the regulatory system

We strongly support the Discussion Paper's recognition of the need to ensure wide public consultation, including consideration of and responses to public submissions, on the development of GMO standards, and codes of practice. We also support the establishment of the Gene Technology Community Consultative Group and Community Forums.

However, the level of public consultation provided for the formulation of policy designed to drive the regulatory system is insufficient as discussed in **Recommendation 14**. Wide opportunities for all members of the Australian public should be available to participate in the development of policy.

Public "involvement" in GTR decisions

The Discussion Paper outlines inadequate and insufficient opportunities for public ***participation*** in connection with licensing decisions made by the GTR. As outlined in **Recommendation Recommendations 21, 22 and 25**, the proposed national regulatory system must provide for public notice of *all* applications received by the GTR. It must also establish a public register where any interested citizen can presumptively obtain all application details and information related to applications.

Likewise, as discussed in connection with **Recommendations 26 and 27**, the proposed national regulatory system must ensure that the public has the right to comment on all applications received by the GTR and that the GTR takes public comments into account in making decisions on licences.

GTR Reporting Requirements

Explicit recognition of EPBC Act requirements

The Discussion Paper fails to outline annual reporting requirements required by the *Environment Protection and Biodiversity Conservation Act* 1999 (EPBC Act). The new legislation should explicitly require that the GTR's annual report contain an account of:

- how the GTR's actions, including decisions, accorded with the principles of ecologically sustainable development;
- how the outcomes specified by the GTR in an Appropriations Act contribute to ecologically sustainable development;
- the effect of the GTR's actions, including decisions, on the environment and biological diversity;
- the measures the GTR is taking to minimise the impact of actions on the environment; and
- the mechanisms the GTR has established for reviewing and increasing the effectiveness of those measures.

Recommendation 45

The proposed national regulatory system should explicitly include annual reporting requirements for the GTR established by the *Environment Protection and Biodiversity Conservation Act* 1999.

Naming violators

The Discussion Paper mentions the ***option*** of naming individuals or entities that have breached the law or licence conditions in the GTR's annual report as a method of enforcement. In order to protect the public's confidence in the regulatory system, the naming of violators should be made mandatory.

Recommendation 46

The proposed national regulatory system should provide for the mandatory "naming" of all individuals and entities that have breached the law of licence conditions in the GTR's annual report.

Database of approvals

The Discussion Paper indicates that the GTR will maintain a public database of "approvals". Clearly, the database (or public register as has been described in this submission) must be much more comprehensive as discussed in connection with **Recommendation 22.** It should include all information about all licence applications, the applicant's report on the assessment of risks, reasons for licence decisions, the licence and conditions (if any), any variations of licences, and all monitoring data.

Moreover, as discussed in **Recommendation 25**, all information should be presumed to be publicly available unless an applicant proves beyond reasonable doubt that it should be treated as confidential in accordance with the criteria outlined in connection with **Recommendation 25.**

Review of GTR decisions

The Discussion Paper indicates that third parties will be entitled to appeal GTR decisions, including decisions on licence applications. Beyond that, what the Discussion Paper proposes unfairly discriminates against third parties and raises limited standing provisions reminiscent of the 19th Century. It certainly does not represent regulatory "best practice" on the cusp of the 21st Century.

Merits appeals and third parties

The Discussion Paper states that the new legislation will describe a statutory right of appeal to the Administrative Appeals Tribunal (AAT) under the *Administrative Appeals Tribunal Act* 1975. However, this right is to be limited and exercisable only by applicants for licences. For members of the public that comprise third parties, this limitation is clearly discriminatory, against principles of natural justice, and against the public interest.

While the AAT might not be the appropriate tribunal to consider merit appeals (indeed the Commonwealth might consider the establishment of a specialist environment court to hear these appeals, as well as all other environmentally related appeals), it is certain that third parties should be allowed the right to apply for review of a decision on the merits.

Recommendation 47

The proposed national regulatory system should provide for the right of third parties to apply for review of a decision by the GTR on the merits. Failure to do so is discriminatory, against principles of natural justice, and against the public interest.

Judicial review and third parties

The Discussion Paper limits the rights of third parties to review to judicial review in the Federal Court under the *Administrative Decisions Judicial Review Act* 1977. It also imposes draconian standing limitations. As discussed in connection with **Recommendation 47** this limitation on merits appeals is unacceptable. Moreover, as discussed in **Recommendation 48**, third party judicial review and merits appeals should be based on "best practice" open standing provisions.

Open standing for third parties in merit appeals and judicial review

We are deeply concerned that the Discussion Paper seeks to entrench standing requirements in connection with third party appeal rights that represent a retrograde and backward looking development. The Discussion Paper limits standing to "special interests" defined in terms of the requirements of the 19th Century.

A review of environmental standing provisions around the world (which can be provided on request) establishes that the "best practice" trend is toward open standing. Indeed, even the Commonwealth most recent piece of environmental legislation, the EPBC Act, creates limited open standing for any individual or organisation (whether incorporated or not) that has been involved in conservation or environmental issues over the previous two-year period. While this is not a complete open standing provision – as it should be, it does at least represent 20th Century thought about access to justice; something that the Discussion Paper fails to do. Accordingly, we strongly advocate that the new regulatory scheme provide open standing to third parties in merit appeals and judicial review.

Recommendation 48

The proposed national regulatory system should provide for open standing provisions for third parties in connection with merit review and third party appeals.