Bayer CropScience

BioScience

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GTMC Secretariat
Department of Health and Ageing
MDP 138
GPO Box 9848
Canberra ACT 2609
Australia

Dear Sir/Madam,

Submission to the Senate Department of Health and Ageing on the 2011 Review of the *Gene Technology Act 2000 (the Act)*

Background

Bayer CropScience, a subsidiary of Bayer AG with annual sales of about EUR 6.5 billion, is one of the world's leading innovative crop science companies in the areas of crop protection, non-agricultural pest control, seeds and plant biotechnology. In Australia, the company employs about 270 people and has its head office in Melbourne. The Australian BioScience division of Bayer CropScience has been involved in research and development of genetically modified canola and cotton, developing better varieties to suit the requirements of Australian farmers.

Bayer CropScience has stated that it is currently committed to developing biotechnology products suitable to the Australian agricultural environment. Considering the moratoriums still existing in some states of Australia, Bayer CropScience only carries out small scale contained trials, however, a clear and predictable path to market must be provided for the industry to allow farmers to capitalise on the latest technologies.

Responses to Terms of Reference (TOR)

TOR 1

Examine and review the effectiveness and efficiency of the way that the regulatory scheme operates, taking account of developments since 2005-06 including:

TOR 1 a

the national scheme for gene technology regulation in Australia to identify any need for, and opportunities to achieve, improvement in its national consistency, efficiency and effectiveness and coordination; and investigate if the aims of the Agreement to determine these are being achieved;

It is our belief that the current Gene Technology Regulations in Australia are robust, contain a number of checks and balances and work well to serve the common good. The Act is very successful in its objective to protect the environment and the health and safety of people. It is stringent and has proper safeguards to ensure this. Moreover it has been well administered and applied in a practical way based on scientific principles with the necessary independence required for the Regulator to act impartially. These qualities of the present system must be preserved.

TOR 1 b

emerging trends and international developments in biotechnology and its regulation and whether the regulatory system stipulated by the Act, including definitions within the Act, is flexible enough to accommodate changing circumstances;

The Act currently captures a wide range of related technologies, including processes that do not include the incorporation of novel DNA or that mimic natural processes. With the advent of such new technologies, the definition of GMOs captured within the Act should be reviewed. We believe some of the new technologies are no different to conventional processes and pose no risk and do not need to be captured under the Act.

TOR 1 c

definitions and provisions within the Act to identify possible areas for enhancement in light of experience with the operation of the regulatory system.

- **Whether the object of the Act is being achieved and whether the regulatory framework stipulated in section 4 of the Act is operating effectively.**

We believe that the section as it currently governs the administration of the Act is appropriate. The current practices of the OGTR under this section have been practical, while also stringently ensuring the protection of human health and the environment. Any changes, either to this section or the current administration of the Act, by the OGTR to impose greater restrictions under this section, would have a serious potential to threaten or even prevent the introduction of any new technology.

- **The powers of the Act to ensure that they are sufficient to enforce compliance.**

The Act has the necessary provisions to ensure it has the power and ability to enforce effective administration of the Act. The OGTR currently has operated in a practical and appropriate way to ensure enforcement as explained in its "*Monitoring and Compliance Framework*" document.

Section 35 of the Act however, imposes strict liability on breaches of licence conditions. We believe this is inappropriate. Licences often deal with biological systems and instances will arise where breaches may occur through no fault of the licence holder and be trivial. However, under section 35 there is no defence for licence holders and the Regulator may be required to act without any recourse to any discretion in administering this section of the Act.

We believe that section 35 should be amended so that breaches of licence conditions may not be subject to strict liability provisions.

- **The consultation provisions of the Act to determine:**

a) **their effectiveness with respect to changes in communication modes, such as various social media tools; the costs and benefits, including the value of advice received; and the transparency and accountability that they provide;**

The public consultations carried out by the OGTR through the present methods are appropriate. However, we do not think it is necessary to specifically contact certain parties directly to canvass opinions, such as Local Councils. A public announcement through the OGTR website is an adequate means of notifying all of the public who might be interested in OGTR decisions.

b) **the functions and roles of the statutory advisory committees;**

The amalgamation of GTEC and GTCCC to form one advisory committee is appropriate. The purpose of the amalgamated committee should be to provide guidance to the OGTR without placing any statutory obligation on the decisions of the OGTR. The membership of this committee should not include any person associated with activities or organisations involved in public campaigns against GM technology.

c) **the stakeholders for various applications under the Act and the methodology used to engage them.**

Under the present Act, the requirement to consult with local government seems inefficient, redundant and costly in time and money. It cannot be seen what expertise local councils have in the field of environment and human safety, especially as technical input into these aspects already have adequate expert consultation and advice (e.g. through the two advisory committees).

The ability for Councils to provide comment and input is adequately catered for through the public consultation process which is required for applications made to the OGTR. The necessity for the OGTR to specifically approach each and every Council in which GMOs are proposed to be released is time consuming and costly for the Regulator and does not provide any added benefit to the approval process.

It is more important for the OGTR to directly consult those stakeholders who are likely to be directly affected by any proposed dealing. For example, for agricultural crops, the major representative farmer groups, such as the various State Farmers Federations, could be consulted as relevant stakeholders.

The interface between the Act and other Acts and schemes in Australia (Include all States and Territories) that regulate gene technology and its products; and identify any discrepancies, including regulatory gaps and areas needing consistency and harmonisation of provisions.

In the Inter-governmental Agreement (IGA) it is stated that:

the Scheme should:

B *(a) provide an efficient and effective regulatory system for the application of gene technologies;*

(b) operate in a seamless manner in conjunction with existing Commonwealth and State regulatory schemes relevant to genetically modified organisms and products derived from such organisms (for example, the schemes that regulate food, therapeutic goods, agricultural and veterinary chemicals and industrial chemicals);

(c) be nationally consistent, drawing on power conferred by the Commonwealth, State and Territory Parliaments; .

The current situation is that the scheme does not provide an efficient and effective regulatory system for the application of gene technologies. While the Office of the Gene Technology Regulator (OGTR) approves applications based on environmental and health grounds, any approval at the OGTR level can be effectively "vetoed" by State Governments, based on grounds that a particular dealing could adversely affect trade and market access.

At present, 4 out of 6 States have imposed moratoriums of various forms within their respective jurisdictions. Moratoriums in two States, apply to all GM crops (SA and Tasmania). In at least one State (SA), after obtaining OGTR approval, it is necessary to apply for approval from the State government. This is regardless of whether the OGTR approval is for a small scale research trial or for large scale commercial releases. Separate OGTR and State approvals must be obtained.

This separation of OGTR function and States function has created a two-tiered system which is unpredictable and unclear for any company wishing to invest in and develop a biotechnology product. It is a significant disincentive for future investment in this field in this country.

While the OGTR regulatory system is backed up by best regulatory practices, to a large extent, the States systems are in the main prohibitory legislation and do not have the transparency nor a process by which best regulatory practices are apparent. State legislations are all different in scope, jurisdiction and administration. Thus, it cannot be said that the present scheme has in any way achieved a, b and c above.

In the Commonwealth Governments own document titled Australian Biotechnology 2000, A National Strategy one of the goals stated on page 7 (Government's Vision for Australian Biotechnology) is "To enhance the economic and community benefits of biotechnology through an internationally competitive environment for investment and enterprise development". Under the current prevailing situation this goal will never be achieved.

Coordination and clear delineation of responsibilities between Federal regulatory agencies should also be improved. Our experience shows the areas of overlap between regulatory jurisdictions occur in the following areas – an insecticide resistance plant which needs assessment by the OGTR and the APVMA. It would be more efficient and save on costs for both companies and regulatory agencies if duplication could be avoided.

The regulatory burden and whether compliance costs for organisations working in gene technology are reasonable and justified compared to benefits achieved and if the regulatory requirements for classes of approval under the Act are commensurate with the level of risk.

Experience gained during the years that Bayer CropScience has been working under the GT Act would suggest that the cost of compliance imposed on applicants is often excessive. While the mandate of the OGTR is that of safeguarding the environment and human health, experience has shown that often risk management requirements are so stringent that excessive costs are imposed which are disproportionate to the level of risk posed.

Cost savings can also be had by both applicants and the OGTR if measures to avoid duplication of assessment and data submission with other Australian and overseas regulatory agencies are implemented.

At least where human health is concerned there is a lot of potential for regulatory assessments to be harmonised with overseas agencies. Harmonisation is part of an international trend for regulatory processes and occurs in the areas of drug and pesticide approvals where assessment of human health occurs. Following this trend, where risk considerations for human health is often universal, the OGTR may not need to conduct a risk assessment in each and every case requiring the complete regulatory package, provided similar assessments for similar risks have been carried out already. Harmonisation with overseas regulatory authorities could mean that the OGTR may access these assessments and streamline processes, minimising duplication when the risks are universal. This has great potential for cost savings for both the OGTR and applicants, without compromising on safety.

Within Australia there are also instances where similar data packages have to be submitted to different Australian regulatory agencies (refer also to section under TOR 1c). This adds costs at least in terms of duplication, servicing and time taken to obtain approval. Regulatory systems should be streamlined, central, uniform and avoid duplication.

Instances have arisen in the past where a GM product approved overseas in one country has been detected in Australia. Shipments of grain, for example, containing the unapproved product, which often occurs at very low levels, would then have to be rejected. This is inefficient and extremely costly for all involved. The Act should be amended to allow reference and adoption of "Annex 3: Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material" in Foods of the "Codex Guidelines for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Plants" (Codex Plant Guideline, CAC/GL 45-2003), to allow the OGTR to deal with low level presence of unapproved products.

TOR 2

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

A Federal system which is consistent and predictable nation-wide and solves the current impasse whereby OGTR approvals can be vetoed at State level (with its multiplicity of ad hoc legislation) is essential. Such a system would give surety to researchers and developers of agricultural biotechnology and would give a measure of comfort to the public that the environmental safety, human health, etc are properly assessed and regulated by a world class regulatory system.

The recommendations of this submission, contained within the other parts to this submission, are summarised in this section. The general recommendation is that the Act remains the same in the bulk of its provisions except for the following amendments.

1. The scheme must deliver a system for the regulation of gene technology that is consistent nationwide and that provides a single system that incorporates regulatory best practice. It must dismantle the present two-tiered system operating at the Federal and State level.

2. The Act must ensure there is no overlap of regulatory function or jurisdiction with other State or Federal regulatory Acts – as it currently does with Acts administered by the APVMA and State moratorium legislations.

3. Include a subsection to preclude from membership of the Ethics or Community Consultative Committees, such persons as has shown through their records active anti-GM campaign activities.

4. Delete reference to strict liability in section 35. No other strict liability provision is required other than that found in section 33.

5. Allow and facilitate within the Act the ability for the OGTR to adopt harmonised risk assessment/risk management procedures with other creditable regulatory agencies worldwide.

6. The Act should be amended to allow reference and adoption of "Annex 3: Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material" in Foods of the "Codex Guidelines for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Plants" (Codex Plant Guideline, CAC/GL 45-2003).

Yours sincerely,

Submitted on behalf of Bayer CropScience