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**Bio-safety:**  
**Experience of the Republic of South Africa**

Draft Discussion Paper

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## Introduction

Since the early 1970s recombinant DNA technology has enabled scientists to genetically modify plants, animals and microbes rapidly. Indeed, the term modern biotechnology has evolved to encompass three basically different technologies namely, traditional biotechnology (uses biological organisms or parts thereof to produce or modify chemical compounds); gene technology or genetic engineering (uses the properties of DNA to analyse and modify the genetic information); and reproduction biology (traditional breeding techniques, in vitro fertilisation and cloning of organisms).

To date biotechnology has led to advances in medicine with new biopharmaceuticals and diagnostics that offer amazing possibilities in the treatment of hitherto lethal and disabling diseases. This capacity to analyse and manipulate genes has been extended to other fields and promises to improve agricultural products as well as industrial processes.

Although modern biotechnology has demonstrated its utility, there are concerns in its application to agriculture about the potential risks to the environment and biodiversity. For the most, a potential problem is that the transgene may escape into wild and weedy relatives that may become more competitive and therefore, affect the biodiversity by replacing native flora. The demise being that once an organism is released, it cannot be recalled. As it reproduces, the genetic information it carries is replicated and can be dispersed into the surrounding environment through, it must be stressed, natural processes (pollen transfer, horizontal gene transfer).

In other words the source of a hazard is rarely the organism itself, when modified forms of familiar organisms are being reintroduced into environments in which they were already present. While some traits are recommended as safe (e.g.  $\beta$ -glucuronidase) others may be associated with certain hazards for instance, a gene conferring a selective advantage to its host). Thus depending on the nature of the novel trait, harm may occur if the genetic information transferred and expressed crosses geographical boundaries and taxonomic classes. It should be noted, however, that gene transfer frequencies are dependent on such factors as sexual compatibility between the donor and recipient species, flowering synchrony, sharing a common insect pollinator and distance.

During field trials of transgenic plants, biosafety regulators often enforce the use of containment measures such as fencing, netting or barrier rows to maintain reproductive isolation. This strategy for dealing with pollen flow is not much different from the isolation distances used in traditional breeding for maintaining genetic purity in cultivated crops.

The application of containment measures to commercial releases of transgenic crops may not be feasible. Some interpollination between cultivated species and wild or weedy relatives is to be expected. Since pollen flow is a natural process, gene dispersal is not the risk but rather the consequences of the possible plant-gene combinations that might be created.

Ultimately, under an effective biosafety regime genetically modified crops should not be given blanket approvals because of the intricate nature of gene expression. The biology of individual genes in individual crops in individual locations has to be assessed. The risks posed by GMOs to the environment and biodiversity should routinely be addressed on a case by case basis.

### **Government's role**

The GMO Act, 1997 (Act No 15 of 1997) which will come into effect early next year addresses environmental and human safety with regard to the application of biotechnology. The Act applies to all viable entities whose genetic material has been altered in some way.

### **What does the GMO Act provide for?**

The Genetically Modified Organisms Act promulgated in 1997 makes provisions for:

- An Executive Council - constituted of officials from the following government departments: Agriculture; Environmental Affairs & Tourism; Health; Arts, Culture, Science & Technology; Trade & Industry and Labour. These officials will make decisions on and monitor the development of GMOs in relation to impacts on the environment and the socio-economics of communities
- A Registrar - who will administer the Act
- An Advisory Committee - consisting of 8 scientists and 2 members of the public, appointed as the national advisory body on matters relating to GMOs
- An Inspectorate - officials with the authority to examine registered facilities
- Appeals - the Minister will appoint an appeal board should a person feel aggrieved by any decisions taken against them
- Regulations - prescribe a number of rules that must be adhered to. Failure to comply with the provisions of these regulations constitutes an offence:
  - All facilities developing or using GMOs will have to be registered within twelve months of implementation;
  - Activities classified as being of moderate to high risk will require permits;
  - Permits will be issued for imports/exports, greenhouse/field/clinical trials and commercial releases;
  - Risk assessments and environmental impact assessments are obligatory to determining the biosafety of all activities;
  - Contingency plans ought to be put in place and the Registrar immediately notified in the event of an accident;
  - Strategies put in place for effective management of waste;
  - Fees will be charged for all submitted applications.

## **What is happening internationally?**

Many countries, particularly developed countries, have legislation regulating various aspects of genetically modified organisms. However, there is no binding international agreement that regulates movement of living modified organisms (LMO's) across national borders. The Biosafety Protocol that is being negotiated under the auspices of the Convention on Biological Diversity is aimed at regulating transboundary movement, handling and use of genetically modified organisms derived from modern biotechnology, that may have impacts on conservation and sustainable use of biodiversity. The development of a Biosafety Protocol is driven by the recognition that biotechnology, although potentially beneficial, raises concern that the new genetic combinations derived from modern biotechnology could manifest themselves in ways that could be risky to the environment.

South Africa has been an active participant in these negotiations, which are due to be concluded in January 2000. The Department of Environmental Affairs & Tourism is the lead department in these negotiations. The negotiation of the Biosafety Protocol has several issues of contention, mainly highlighting the tension between trade and environment. Of the 39 articles in the draft text of the Protocol, nine of these are yet to be resolved.

The South African position on the outstanding articles, and which was forwarded at the Informal Consultations between governments which were held in September 1999 with a view of bridging differences existing on the Protocol, is attached to this document. In line with the policy as stated in the White Paper on Biodiversity, South Africa has taken positions that seek to balance trade and environment concerns related to biosafety.

The major issues on which negotiating groups are not agreeing on revolve around the Articles on the Scope of the Protocol, the application of the advance informed agreement or AIA (the proposed regulatory mechanism of the protocol), and on the relationship with other international agreements.

The article on Scope, defines the scope of the protocol. The draft text of the Protocol excludes LMO's that "will not adversely affect biodiversity" ; as well as pharmaceuticals for humans; those in transit; and those destined for research. The more developed countries favours a scope as in the draft text whereas the developing world favours an inclusive scope covering all living modified organisms. South Africa's position favours inclusion of all LMO's.

The article on the application of the AIA procedure defines applicability and non -applicability of AIA procedures. The draft text excludes LMO's that are for food , feed and processing (termed commodities in the context of the negotiations). The more developed countries favour this articles as in the chair's text. The more developing countries, specifically the Africa Group, recently shifted their positions from requiring application of AIA on all transboundary movements of all LMO's to requiring it on only first transboundary movements. The developing countries in the proposal tabled in Vienna recently, suggested that any exclusions (e.g. pharmaceutical for

humans, LMO's in transit and LMO's destined for research in the protocol should be dealt with under this article and flexibility should there for countries to require AIA on some LMO's at domestic. South Africa's position is largely in line with the latest developing countries position.

The article on Relationship with International Agreements has trade issues underlying it, and it is widely known "secret" that it seeks to link the biosafety protocol to the World Trade Organisation which is perceived to have structured dispute resolution mechanism arising from trade. The draft text states that the Protocol shall not affect rights and obligations of Parties under existing agreements except if these would "cause serious damage or threat to biological diversity". There is a disagreement within the developed world on this, with some wanting it included and some wanting it deleted. Many developing countries wanted it out of the protocol. South Africa's has always maintained that its inclusion or exclusion is acceptable.

The negotiations of the Biosafety Protocol will be resumed in January 2000 and the goal is to finalise the Protocol. If and when South Africa signs and ratifies a Protocol on Biosafety, the infrastructure provided by the GMO Act will be the mechanism to effect obligations of the Protocol.

### **Public Participation**

Members of the public are expected to participate through representation on the Advisory Committee of the GMO Act. The Registrar keeps a register of all applications submitted which is accessible to the public. In addition, the regulations require applicants to notify the general public of planned trials and general releases by publishing such notifications in at least three local newspapers.