GENERAL NOTICES
ALGEMENE KENNISGEWINGS

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DEPARTMENT OF AGRICULTURE

PUBLICATION OF DRAFT BIOSAFETY POLICY FOR COMMENTS.

I, Angela Thokozile Didiza, Minister of Agriculture hereby publish the draft Biosafety Policy, 2005, for comment by the general public. Comments must be submitted in writing within 30 days of publication of this notice to:

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BIOSAFETY POLICY

1. Introduction

Biosecurity and biosafety are two risk management measures used to achieve biological compliance, i.e. identifying applicable rules and regulations for handling biological organisms, complying with the rules and regulations, obtaining the necessary approvals and permits, and following specified conditions and practices for specific organisms and activities. Genetically modified organisms are only one group of organisms subject to biological compliance.

Biosecurity refers to ensuring the security of biological materials to prevent theft, illicit use, or release. Biosafety focuses on reducing accidental exposure to and release of biological materials. Successful biosecurity and biosafety programs should be integrated to leverage common solutions.

Biosecurity has direct relevance to food safety, the conservation of the environment (including biodiversity), and sustainability of agriculture. Biosecurity is composed of three sectors, namely food safety, plant life and health, and animal life and health. One element contained in these sectors is the introduction and release of Genetically Modified Organisms (GMO's) and their products.

The White Paper on Science and Technology and the National Biotechnology Strategy of South Africa acknowledged that biotechnology can play a major role in addressing national imperatives such as reducing the impact of HIV/ AIDS, job creation, rural development, urban renewal, human resource development and regional integration.

However, the use of modern biotechnology for the development and possible deployment of Genetically Modified Organisms (GMOs) is also accompanied by definite potential risks, impacting on biosafety and biosecurity. Effective, efficient, improved and updated international frameworks and standards to support appropriate national action, as well as national frameworks to regulate, manage and control biosecurity for food and agriculture, including forestry and fisheries is essential. Policies and frameworks must however permit practical implementation, increase cost effectiveness and improve consistency across sectors.

Establishing credible and effective safeguards is thus critical for maximizing the benefits of biotechnology while minimizing its risks. It is in view of this that a biosafety policy, applicable to contained application as well as controlled and uncontrolled release of **GMO's** as it relates to the current and future application in agriculture and human and veterinary medicine, is required.

This policy will offer guidance for sustainable development by providing for mechanisms to ensure the safe use of biotechnology so as to strengthen the economy and enhance livelihoods without prejudice to public health or the environment.

2. Definitions/Glossary of terms

'Biosafety' or 'biological safety'

means the management of risks to human and animal health and safety, and to the conservation of the environment, as a result of activities with genetically modified organisms.

'Biosafety Clearing House'
means a clearing house mechanism as established under article 18 (3) of the Convention.

'Biosecurity'
encompasses all policy and regulatory frameworks (including instruments and activities) to manage risks associated with food and agriculture (including relevant environmental risks), including fisheries and forestry.

'convention'
means the Convention on Biological Diversity.

'environment'
means the aggregate of surrounding objects, conditions and influences that influence the life and habits of man or any other organism or collection of organisms;

'genetically modified organism'
means any living organism, the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both, and 'genetic modification' shall have a corresponding meaning;

'Living modified organism"
means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology, within the context of the Cartagena Protocol on Biosafety;

'Living organism'
means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

'Modern biotechnology'
means the application of: (a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

'monitoring'
means the maintaining of regular surveillance over, the checking of, the warning about or the recording of a situation or process;

'risk'
means the probability of causing or incurring a loss or damage or an adverse impact or a misfortune;

3. Problem statement

Biotechnology brings with it a number of potential risks. However, it should not be construed that because there is potential risk, that the risk will materialise. With our current knowledge, the potential risks associated with biotechnology can be categorised into human and animal health, the conservation of the environment, including biodiversity, socio-economics, public awareness, education and participation, national and global security, cross-sector regulation and regulatory management.

3.1 Human, animal and plant health

Potential risks associated with human, animal and plant health include eexpression levels of the protein at different growth stages as well as different organs, foreign protein levels in food derivatives, the potential for toxicity, pathogenicity and allergenicity. The source of the gene, nature of host organism, comparisons of the DNA and protein, feeding tests, skin tests and clinical trials are also important.

Other factors would include unexpected products and effects, changes in nutrition, composition, digestibility and digestion products. It is also important to evaluate gene expression in time, and compare the levels of expression in different tissues, at different locations and at different intervals in the growth cycle. Protein integrity is important.

3.2 Conservation of the environment

Any development, application and release of GMO's must be conducted in manner that will ensure the conservation and sustainable use of natural resources. Factors that could adversely impact the environment are unexpected persistence of the gene or transgene in the environment, volunteers, transgene products, susceptibility of non-target organisms, unpredictable gene expression or transgene instability, risks of horizontal gene transfer and potential ecological impacts.

3.3 Socio-economic factors

The socio, economical and cultural factors, including the value of biological diversity to indigenous and local communities, must be taken into account. Although these factors are not directly related to biosafety, it is an international obligation in terms of the Cartagena Protocol on Biosafety and of importance to support a sustainable agricultural sector, health sector, etc.

3.4 Public awareness, education and participation

Apart from establishing measures and procedures to obtain biosafety, one cannot disregard the importance of public acceptance of **GMO's** and **GMO** products, and also public confidence in the Government to ensure adequate safety in the development, application and release of **GMOs** in SA. Facilitating public awareness, education and participation is a requirement under the Cartagena Protocol on Biosafety, an international agreement to which SA is Party signatory to.

Access to information on the biosafety framework, as provided for by the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000), must be provided to third parties. Access to information will facilitate public assurance in the regulatory management of **GMOs.** Furthermore, a key factor influencing public acceptance of GMO's is the ability

of consumers to make an informed choice on whether they wish to consume a GMO product or not. In this regard, labelling plays an integral part.

Notwithstanding the right of access to information, the biosafety regulatory framework must also make provision for the protection of certain information classified as confidential information and is in accordance with the provisions of Chapter 4 of the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000).

3.5 National and global security

A plethora of national and international regulatory systems/agreements have evolved in response to the perceived risks of biotechnology products. Several international bodies/institutions are currently attempting to coordinate and regulate different aspects of food safety and environmental protection. International organizations seek to develop standards for health, safety, and labelling for GM foods, establish testing procedures to ensure that set standards are met, provide rules for allowable policies and create systems to manage disputes. Despite the substantial effort being undertaken, there is no common view on the goal of international regulation. While most agree that safety is the bottom line, few can agree on what that safety means or how to handle non-safety issues such as social, economic, or ethical concerns.

3.6 Cross-sector regulation

Activities with GMOs are accompanied with potential risks in various sectors, including agriculture, health, environment, labour, science and technology, and trade and industry. Bearing this in mind, the potential impact of a GMO activity on each sector has relevance. The national or even international agreements or legislative requirements pertaining to the sector must be taken into consideration to protect biosafety.

Notwithstanding the advantage of having a cross-sectoral approach in a biosafety framework, this should be managed effectively to ensure that legislative requirements in all sectors are effectively addressed. Existing legislation to take into consideration include the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), the Environmental Conservation Act, 1998 (Act No. 73 of 1998), the National Environmental Management Act, 1998 (Act No. 107 of 1998), the National Environmental Management Biodiversity Act, 2004 (Act No. 10 of 2004), the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), the Animal Diseases Act, 1984 (Act No. 35 of 1984), Agricultural Pests Act, 1983 (Act no. 36 of 1983), the Fertilizers, Farm Feed, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), the Medicines and Related Substances Amendment Control Act, 1997(Act No. 90 of 1997), Promotion of Access to Information Act, 2000 (Act No. 2 of 2000) and the Promotion of Administrative Justice Act, 2000 (Act No. 3 of 2000).

3.7 Regulatory management

Apart from establishing an effective biosafety regulatory framework, is the implementation of such a framework of critical importance to maintain biosafety. One requirement is sufficient capacity with regard to human resources to enable effective administration of such a framework. Elements that require attention are prescribed administrative procedures in terms of the Promotion of Administrative Justice Act (PAJA), 2000 (Act No. 3 of 2000) and the provision of information and data to third

parties through the Promotion of Access to Information Act (PAIA), 2000 (Act No. 2 of 2000).

4. Objectives

The objectives of this policy are the following.

1. To establish common measures, requirements and criteria for risk assessments, environmental impact assessments and assessment of the socio-economic impact to ensure that GMOs are appropriate and do not present a hazard to the environment, human, animal or plant health, taking into consideration the potential risks mentioned in paragraph 3 above.

2. In recognition of the constitutional right of access to information held by the State on matters pertaining to **GMOs,** promote and facilitate access to information not classified as confidential in terms of Chapter 4 of PAIA, public awareness, education and participation in the biosafety regulatory framework.

3 Support and facilitate capacity building, with particular reference to regulatory management, risk assessment, risk management and risk communication, including the development of a roster of experts in biosafety.

4 Aim to cooperate with other developing countries, especially countries in the region with overlapping borders, in harmonizing regulatory oversight in biosafety. Special attention must be given to developments within the Southern African Customs Union (SACU) and the Southern African Development Community (SADC).

5. Policy *to* address the problem

5.1 Policy options

5.1.1 Preventative approach

A preventative approach would imply that activities related to **GMO's** are only approved in the absence of any scientific uncertainty and knowledge regarding the potential adverse effects of the GMO on the environment, human, animal or plant health, i.e. when there is zero risk.

5.1.2 Precautionary approach

This approach will be based on the precautionary principle as stated in various international documents, such as the Rio Declaration on Environment and Development, 1992 (Principle 15), the Cartagena Protocol on Biosafety and the World Trade Organisation 1993 Agreement on Application of Sanitary and Phytosanitary Measures (Article 5.7). The precautionary principle, as provided for in the Cartagena Protocol on Biosafety is as follow: "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of Import,

taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism.... in order to avoid or minimize such potential adverse effects".

This policy will aim to protect the environment, human, animal or plant health against uncertain or unidentified risks, allowing use of the technology only to the extent that its impacts are known or can reliably be predicted.

5.1.3 Coherent approach

This policy approach would promote the development of an implementable regulatory system for biosafety and guide its coordination with related regulatory mechanisms such as phytosanitary requirements, variety registration, etc. This policy will provide a basis for a scientific approach and case-by-case decisions, but also accommodating the differing interests of ministries of agriculture, health, science and technology, environment, or other sectors involved. Implementation of the regulatory system will also contain elements of precaution

Policy decisions regarding the relative roles played by the various ministries involved will shape biosafety implementation. The statutory nature of the biosafety regulations, whether issued as legislation or as advisory guidelines, will dictate the nature and extent of enforcement measures and the means for addressing non-compliance.

Existing regulatory agencies such as those for plant quarantine, animal quarantine and variety registration may have statutory authorities that apply to GMO's and that need, therefore, to be coordinated with biosafety regulation.

5.2 Recommended policy option

It is recommended that policy option 5.1.3, i.e. a coherent policy approach, be chosen as an approach for SA. This approach will enable a cross sector regulation of GMO activities through implementation of different legislation by different ministries. Implementation of this approach will also be supported through compliance with existing or anticipated national instruments.

One can only prevent a risk from being realised if all risks are eliminated prior to commencement of an activity. Bearing in mind that no activity can commence without zero risk, the preventative approach is not recommended. It would not only be very difficult to conduct any activity without potential risk being involved, this approach will limit SA in taking advantage of the benefits that this technology can offer.

While there is no controversy about the usefulness of the concept of precaution per se, there has been much debate about its nature, in particular whether it is a legal principle in addition to being a sound policy approach. Some argue that the concept of precaution has not attained the status of a principle of law, and hence does not as such constitute a legal obligation. It should be noted that although the precautionary principle has been reflected in a number of international agreements, including the Cartagena Protocol on Biosafety, countries utilize different formulations and differences remain as to the prcper scope of

application of the principle and its practical implications. The precautionary principle has also potential to cause conflicts with international trade rules. Bearing this in mind, following a pure precautionary principle is not recommended. However, it should be noted that elements of precaution is still essential and should be incorporated into the coherent approach.

5.3 Policy Instruments

In support of the coherent policy approach, the following instruments will be used for implementation of the recommended policy option.

(i) Genetically Modified Organisms Act, **1997** (Act No. **15 of 1997)**

The aim of the Genetically Modified Organisms (GMO) Act is to provide measures to ensure that all activities involving **GMO's** are conducted in a manner that will limit potential risks associated with such activities to the environment, human, animal or plant health; to give attention to the prevention of accidents and the effective management of waste; to establish common measures for the evaluation and reduction of the potential risks arising out of activities involving the use of genetically modified organisms; to lay down the necessary requirements and criteria for risk assessments, environmental impact assessments and assessment of the socio-economic impact; to establish a council for genetically modified organisms; to ensure that genetically modified organisms are appropriate and do not present a hazard to the environment; and to establish appropriate procedures for the notification of specific activities involving the use of genetically modified organisms

A multidisciplinary evaluation process shall be applied through the Genetically Modified Organisms Act (GMO Act). Proposed activities will be assessed on **two** levels. An Advisory Committee shall make a recommendation to the Executive Council, based on its evaluation of risk assessment data and other relevant information, on the biosafety merits of the proposed activity.

The Executive Council shall include members from relevant government departments and the chairperson of the Advisory Committee. Each Council member shall consider respective policies and legislation within his/her sector. A decision will include consideration of the application, AC recommendation and public input. Permits shall be issued on instruction by the Council.

Compliance to permit conditions shall be monitored through the departmental inspection services and the Border Control Strategy within the Department of Agriculture.

The Department of Agriculture shall endeavour to build capacity with regard to human resources and skills in the Advisory Committee, Executive Council, Appeal Board, inspection services and office of the Registrar. This will include the development and maintenance of a roster of experts in the field of biosafety. The Department of Agriculture shall further promote public awareness and participation with regard to the regulation of GMO's and, as appropriate, work with the Public Understanding of Biotechnology (PUB) programme.

(ii) Transit Policy *of* GMO's

South Africa is one of the few African countries that have formally adopted the use of genetically modified crops. The majority of African countries, including SADC countries, have not formally adopted the use of modern biotechnology in their agricultural systems. The reasons for this vary, depending on the country. However, many African countries, including SADC countries, often accept food aid that contains GM material.

Distribution of food aid to Southern Africa often transits through SA, which has biosafety implications for SA. In view of the potential biosafety concerns related to transit movements of GMO's, the Executive Council approved a GMO transit policy. This policy requests for, inter alia confirmation letters from the recipient country indicating their willingness to accept food aid, while acknowledging that it may contain GMO's. The policy also makes provision for a notification letter in advance of the proposed activity, procedures with regard to handling and packaging and an undertaking by the donating country.

(iii) Environmental Conservation Act, 1998 (Act No. 73 *of* 1998)

The Environmental Conservation Act (ECA), 1998 (Act No. 73 of 1998) provides for the effective protection and controlled utilization of the environment. In terms of Section 21 of ECA, the Minister of Environmental Affairs and Tourism has identified activities in Schedule 1 of the Act as activities which may have a substantial detrimental effect on the environment. These activities are prohibited unless written authorization is issued either by the Minister of Environmental Affairs and Tourism or a competent authority. Such authorization is only considered after reports of the impact of the proposed activity on the environment has been compiled and submitted in the prescribed manner.

The genetic modification of any organism with the purpose of fundamentally changing the inherent characteristics of that organism is one of the activities listed. Bearing this in mind, the provisions of ECA must be taken into consideration by the Executive Council in their deliberations on any proposed GMO activity.

(iv) National Environmental Management Act, 1998 (Act No. 107 of 1998)

The National Environmental Management Act (NEMA), 1998 (Act No. 107 of 1998) provides for cooperative environmental governance by establishing principles for decision making on matters affecting the environment.

Section 2 of NEMA sets out the national environmental management principles, with the aim to ensure that all activities are conducted in a sustainable manner. This requires that risk assessment and risk management procedures be undertaken prior to the approval of any proposed activity with **GMOs.** Risk assessment and risk management procedures are incorporated into the provisions of the GMO Act.

Section 3 of NEMA calls for the appointment of two institutions, viz. (1) the National Environmental Advisory Forum (NEAF) that can advise and inform the

Minister of Environmental Affairs and Tourism regarding the application of the principles of risk assessment and management and (2) the Committee for Environmental Co-ordination (CEC) to promote the integration and achievement of the purpose and objectives of environmental implementation plans and environmental management plans (Section 11), of which one objective is the protection of the environment of the country as a whole.

(v) National Environmental Management Biodiversity Act, 2004 (Act No. 10 of 2004)

This National Environmental Management Biodiversity Act (NEMBA), 2004 (Act No, 10 of 2004) was enacted within the framework of NEMA and institutes special requirements for the introduction of three categories of living organisms, viz. alien species, listed invasive species and threatened or protected species.

The objectives of the Act are –

(a) within the framework of NEMA, to provide for—
  (i) the management and conservation of biological diversity within the Republic and of the components of such biological diversity;
  (ii) the use of indigenous biological resources in a sustainable manner; and
  (iii) the fair and equitable sharing among stakeholders of benefits arising from bioprospecting involving indigenous biological resources;
(b) to give effect to ratified international agreements relating to biodiversity, which are binding on the Republic;
(c) to provide for co-operative governance in biodiversity management and conservation; and
(d) to provide for a South African National Biodiversity Institute to assist in achieving the objectives of this Act.

In accordance with the provisions of NEMBA, the Department of Agriculture, through implementation of the GMO Act, must manage, conserve and sustain South Africa's biodiversity and its components and genetic resources during any activity with GMOs.

The Act further asks for the establishment of a South African Biodiversity Institute (SANBI), which is tasked with monitoring of the impacts any GMO that has been released into the environment, including the impact on non-target organisms, ecological processes, biological resources and biological diversity of species used for agriculture. The Institute must report regularly to the Minister of Environmental Affairs and Tourism.

Part 3 of Chapter 5 of NEMBA, provides the Minister of Environmental Affairs and Tourism the right to, if there is reason to believe that the release of a GMO into the environment under a permit applied for in terms of the GMO Act may pose a threat to any indigenous species or the environment, no permit for such release may be issued in terms of the GMO Act unless an environmental assessment has been conducted in accordance with Chapter 5 of NEMA, as if such release were a listed activity contemplated in that Chapter. This must be

indicated to the Executive Council before the application for the relevant permit is decided. This provision is applicable for trial release or general release activities of GMOs. The Executive Council must take this provision into consideration prior to the issuance of any permit authorizing trial or general release.

Section 80 of NEMBA provides for measures to regulate bioprospecting, including the exportation of indigenous biological resources for the purpose of bioprospecting or any other kind of research. "Indigenous biological resources" includes any indigenous biological resources, including any exotic animals, plants or other organisms, altered in any way by means of biotechnology. The provisions of this section must also be taken into consideration by the Executive Council should an application for such a GMO be submitted for authorization.

(vi) Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972)

The Foodstuffs, Cosmetics and Disinfectants Act (FCDA), 1972 (Act No. 54 of 1972) regulates the safety of all foodstuffs in South Africa, including foodstuffs derived from genetically modified organisms.

Regulations on the labelling of foodstuffs derived from certain techniques of genetic modification have been published in January 2004. The phrase "foodstuffs obtained through certain techniques of genetic modification" in the Regulations means a foodstuff (a) composed of a GMO(s), (b) containing a GMO(s), (c) produced from and contain a protein or DNA resulting from such genetic modification and (d) produced from, but not containing, a GMO(s) or protein or DNA resulting from such genetic modification.

The Regulations makes provision for mandatory and voluntary labelling. Mandatory labelling is required for a foodstuff obtained through certain techniques of genetic modification if (a) the composition differs significantly from the characteristic composition of the corresponding existing foodstuff, (b) the nutritional value differs significantly from the characteristic nutritional value of the corresponding existing foodstuff, (c) the mode of storage, preparation or cooking differs significantly from that of the corresponding existing foodstuff, (d) the foodstuff contain an allergen from any products listed in the Annexure of the Regulations that causes allergy, (e) the foodstuff is derived from plant material containing animal nucleic acid(s) or protein(s) derived from a human or from an animal and (9 the foodstuff is derived from animal material containing animal nucleic acid(s) or protein(s) derived from a human or from a different taxonomic animal family.

The Regulations also makes provision for voluntary labelling of foodstuffs that have enhanced characteristics. One may claim an enhanced-characteristic of a foodstuff in terms of composition, nutritional value and reduced caution of allergenicity, provided that the claim has been validated and certified by a competent body which is accredited to the South African National Accreditation Services and the label adheres to certain requirements.

Voluntary labelling with regard to consignments that do not contain GMOs may occur provided that the claim can be substantiated in accordance with the

requirements of the identity preservation systems approved by the South African Bureau of Standards.

(vii) Promotion of Access to Information Act, 2000 (Act No. 2 of 2000)

To aim of this Act is to give effect to the constitutional right of access to any information held by the State and any information that is held by another person and that is required for the exercise or protection of any rights; and to provide for matters connected therewith.

The Department of Agriculture shall, in accordance with the GMO Act, institute measures to prevent the disclosure of information acquired by a person through the exercise of his or her powers or the performance of his or her duties in terms of the GMO Act.

The Department of Agriculture shall further withhold certain information, as determined by the GMO Act, for the period needed to protect the intellectual property right of any applicant under the GMO Act.

(viii) Promotion of Administrative Justice Act, 2000 (Act No. 3 of 2000)

To give effect to the right to administrative action that is lawful, reasonable and procedural fair and to the right to written reasons for administrative action as contemplated in Section 33 of the Constitution of the Republic of South Africa, 1996; and to provide for matters incidental thereto.

The Department of Agriculture shall provide measures to ensure effective management of information and documentation pertaining to activities under the GMO Act and the disclosure of decisions, including reasons for decisions, in accordance with the provisions of the Promotion of Administrative Justice Act (PAJA), 2000.

The Advisory Committee, Executive Council, Appeal Board, inspectorate, Registrar and any other person performing functions or duties in terms of the provisions of the GMO Act, shall take appropriate measures to facilitate compliance with the provisions of PAJA.

(ix) Animal Diseases Act, 1984 (Act No. 35 of 1984)

The aim of this Act is to provide for the control of animal diseases and parasites, and to provide for measures to promote animal health.

In terms of this Act no person shall import into or convey in transit through the Republic of South Africa any animal, parasite or contaminated or infectious thing except under the authority of a permit and in compliance with any condition imposed in such permit. Furthermore, no person shall, except under a permit and in compliance with the conditions which are prescribed conduct any trial with any vaccine, serum, toxin, anti-toxin, antigen or other biological product which consist of, or originates wholly or partially of, or from, any micro-organism, or of or from any glands, organs, fluids, or any other part, of an animal or parasite.

(x) Agricultural Pests Act, 1983 (Act no. 36 of 1983)

The aim of the act is to provide for measures to prevent and control the importation of plant pests and to provide measures for the national control thereof.

In terms of the provisions of this act no person shall import into the RSA any controlled goods which inter alia include plants, plant products, organisms, exotic animals, infection things except under the authority of a permit and in compliance with the relevant import requirements imposed in such a permit. These import requirements shall be established through a pest risk analysis to ensure that it is technicallyjustified and is not used as unjustified barriers to free trade."

(xi) Fertilizers, Farm Feed, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 *of* 1947)

This Act provides for the appointment of a Registrar of Fertilizers, Farm Feeds and Agricultural Remedies; for the registration of fertilizers, farm feeds, agricultural remedies, stock remedies, sterilizing plants and pest control operators. This Act also regulates or prohibits the importation, sale, acquisition, disposal or use of fertilizers, farm feeds, agricultural remedies and stock remedies.
This will include the registration of veterinary vaccines for use in animals, which may contain **GMOs.**

(xii) Medicines and Related Substances Amendment Control Act, 1997(Act No. 90 of 1997)

This Act in general makes provision for the prohibition on the sale of medicines that are subject to registration and are not registered; to provide for procedures that will expedite the registration of essential medicines, and for the re-evaluation of all medicines after five years; to provide for measures for the supply of more affordable medicines in certain circumstances; to require labels to be approved by the council; to prohibit bonusing and sampling of medicines; to further regulate the control of medicines and Scheduled substances; to provide for the licensing of certain persons to compound, dispense or manufacture medicines; to provide for generic substitution of medicines and regulate the purchase and sale of medicines by wholesalers.

(xiii) Conservation *of* Agricultural Resources Act, 1983 (Act No. 43 of 1983)

The provisions of this Act will have to be taken into consideration when considering activities with **GMO's,** as it provides for measures to control the utilization of the natural agricultural resources within the Republic, in order to promote the conservation of the soil, the water sources and the vegetation and to combat weeds and invader plants; and for matters connected therewith.

(xiv) National Biosafety Clearing House

Article 20 of the Cartagena Protocol on Biosafety requires the establishment of a Biosafety Clearing House (BCH), as part of the Clearing House mechanism under Article 18, paragraph 3, of the Convention. The purpose of the BCH is to (a) facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMO's and (b) assist Parties to implement the Protocol. The Biosafety Clearing House is a website that will enable parties, as well as members from the public, to access information pertaining to inter alia decisions taken by different States, contact details of the Competent Authorities and Focal Points in the different States and risk assessment data, to name only some of the information that is available on the website.

South Africa is obliged to, through the Department of Agriculture who is the BCH focal point; submit the information as required in the relevant provisions of the Protocol to the central portal of the BCH. Article 23 of the Protocol further also requires that SA provide for measures to promote and facilitate public awareness, education and participation in the decision-making process of all activities with **GMO's.**

To fulfil these requirements, the Department of Agriculture will endeavour to establish a national BCH (website). The aim of this website would be to increase transparency, awareness, education and participation in the regulatory **process,** facilitate the efficient management of information and reduce administration. This website should also enable direct transfer of the required information to the central portal of the BCH by the BCH focal point.

It is also envisaged that the national BCH will facilitate adherence to the Promotion of Administrative Justice Act, 2000 (Act No. 3 of **2000)** and the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000), through an efficient system of public participation and information sharing during the decision-making process.

(xv) International agreements

South Africa shall not enter into bilateral, regional and multilateral agreements and arrangements regarding genetically modified organisms, unless such agreements and arrangement provides for the same or higher level of protection than that provided for by the national biosafety framework and international agreements to which South Africa is party to. Special attention should be given to the agreements and arrangements that impacts directly or indirectly on the Southern African Customs Union (SACU) and the Southern African Development Community (SADC), including activities of the SADC Advisory Committee on Biotechnology and Biosafety (SACBB), to which SA is a member. The SACBB is an independent body of experienced specialists from the SADC region and has, since their inauguration in 2003, advised SADC policy makers and produced guidelines on biotechnology and biosafety for the region.

The Department of Agriculture shall, in consultation with other relevant departments and stakeholders, and taking into consideration developments within SACU and SACD, develop a strategy on regional cooperation on biosafety.

International agreements pertaining to biosafety include, but are not limited to, the Cartagena Protocol on Biosafety, the World Trade Organisation, the International Plant Protection Convention and Codex Alimentarius.

(a) The Cartagena Protocol on Biosafety

Biosafety is one of the key issues addressed by the Convention on Biological Diversity. The Convention recognized that although the concept of biosafety refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology, modern biotechnology has a great potential for the promotion of human well-being, particularly in meeting the critical needs for food, agriculture and health care. Bearing in mind the requirement of Article 8(g) of the Convention for Parties to take biosafety measures at national level, and the request for development of an internationally legally binding instrument to address the issue of biosafety in Article **19(3),** the negotiations of the Cartagena Protocol on Biosafety (CPB) that started in Denmark in **1997,** culminated in adoption of the CPB at an extended session of the Extraordinary Meeting of the Conference of the Parties (ExCOP) to the Convention of Biological Diversity (CBD) in Montreal, Canada in January **2000.**

The Protocol, which sets mechanisms and procedures to control the transboundary transfer, handling and use of living modified organisms, entered into force on **11** September **2003.** Parties to the CPB are obliged to observe provisions relating to the advanced informed agreement, risk assessment, risk management and information sharing. Article **20** of the Cartagena Protocol on Biosafety establishes a Biosafety Clearing House (BCH) as part of the clearing-house mechanism under Article **18,** paragraph **3,** of the Convention, in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and to assist Parties to implement the Protocol.

The Protocol became binding on South Africa on **12** November 2004, **90** days after ratification on **14** August 2004. In order to comply with the obligations of Parties to the Protocol, South Africa had to review its existing national biosafety framework, i.e. the Genetically Modified Organisms Act, **1997** (Act No. **15** of **1997)** to accommodate the provisions stipulated in the Protocol. The GMO Amendment Act will include actions to facilitate compliance with the provisions of the Protocol.

(b) The World Trade Organisation

The three main WTO Agreements of relevance to the domestic regulation of biotechnology and biosafety are: the General Agreement on Tariffs and Trade **1994** (GATT), the Agreement on Technical Barriers to Trade (TBT Agreement), and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). These agreements share the common purpose of ensuring that measures that affect the trade in products do not discriminate on the basis of a product's country of origin, and that these measures are no more trade restrictive than is necessary to achieve the purpose for which they were designed. Each agreement has detailed rules, and a growing body of practice that develops these disciplines further.

(c) International Plant Protection Convention (IPPC)

The International Plant Protection Convention aims at international cooperation in controlling pests of plants and plant products. The 1997 Convention introduces significant changes, particularly in respect of the elaboration and adoption of international phytosanitary standards, and explicitly reflects WTO principles. Phytosanitary measures are to be technically justified on the basis of conclusions reached using an appropriate pest risk analysis or other comparable evaluation, and they are not to be applied in such a way as to constitute either a means of arbitrary or unjustified discrimination or a disguised restriction, particularly on international trade

The Intergovernmental Committee for the Cartagena Protocol has urged ICPM to ensure that the standards to be developed are in harmony with the objective and all relevant requirements of the Cartagena Protocol. International standards adopted under the IPPC are the standards, guidelines and recommendations recognised as the basis for phytosanitary standards applied by WTO Members under the SPS Agreement.

(c) Codex Alimentarius

The Codex Alimentarius Commission is a FAO/WHO body which sets standards, general principles, guidelines and recommended codes of practice in relation to food safety. At its 26th session in 2003, the Commission adopted Principles and Guidelines on foods derived from biotechnology. These are overarching principles on the risk analysis of foods derived from modern biotechnology and guidelines for food safety assessment of foods derived from recombinant-DNA plants and microorganisms. However, it does not address environmental, ethical, moral and socio-economic aspects of the research, development, production and marketing of these foods.

(xvi) Capacity building

The Department of Agriculture will support and facilitate capacity building within the section responsible for administration of the GMO Act to ensure effective regulatory management and providing assistance to the bodies appointed in terms of the Act and the Minister of Agriculture.

The Department of Agriculture will, in co-operation with other Departments and relevant institutions, support and facilitate capacity building with regard to risk assessment, risk management and risk communication, within the bodies appointed in terms of the Act. This will include the development of a roster of experts in biosafety.

5.9 Summary of stakeholder inputs as well as responses to expressed suggestions and objections.

This section will be completed after the public consultation period has elapsed.

5.10 Institutional implications.

The Department of Agriculture, through the relevant Directorate, will be responsible for the regulation of all activities with GMO's, through the GMO Act.

The office of the Registrar will be responsible for the activities related to the management of the national BCH, including submission of the required information to the central portal of the BCH.

5.11 Financial implications.

Remuneration of the personnel in the office of the Registrar, including remuneration of the bodies appointed in terms of the GMO Act, will result in financial implications to the Department of Agriculture. This will be included in the budget of the relevant Directorate within the Department of Agriculture.

Activity	Estimated costs	Available	Shortfall
Implementation of current GMO Act	R600 000	R600 000	Nill
Implementation of GMO Amendment Act	R600 000	R600 000	Four unfunded positions
Establish national Biosafety Clearing House	R80 000	R80 000 within D: ICT	Nill
Capacity building within structures of GMO Act	R200 000	R200 000	Nill
Strategy on regional cooperation on biosafety	R150 000	R150 000	Nil

5.12 Communication implications.

The different ministries involved will be consulted to facilitate effective implementation of the recommended policy.

5.13 Legislative and regulatory implications.

This policy will underpin the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), including any amendments to this Act or accompanied Regulations.

6. Indicators of performance

6.1 The biosafety regulatory framework is in accordance with national, regional and international requirements.

6.2 All activities with GMO's are conducted in accordance with the provisions of the GMO Act.

6.3 Increased public awareness, education and participation in the biosafety regulatory framework, by providing access to information on activities conducted with GMOs in SA and information about the means of access to the central portal of the BCH, through the national BCH.

6.4 Measures established to facilitate public consultation in the decision making process.

6.5 Increased capacity in the field of GMOs with regard to risk assessment, risk management and risk communication for the bodies appointed in terms of the GMO Act, including the office of the Registrar.

6.6 Harmonization in regulatory oversight in biosafety with developing countries, especially countries in the region with overlapping borders.

6.7 Long term monitoring of GMO stability and the influence of GMOs on biodiversity through the provisions of NEMBA.

7. Timetable and implementation

Activity	Time frame	Key role players
Implementation of current GMO Act	Ongoing	DoA, DEAT, DoH, DST, DoL, DTI
Promulgation of GMO Amendment Bill	September 2005	DoA
Amending the Regulations of the GMO Act	January 2006	DoA, DEAT, DoH, DST, DoL, DTI
Implementation of GMO Amendment Act	March 2006	DoA, DEAT, DoH, DST, DoL, DTI
Establishment of a National Biosafety Clearing House	September 2005	DoA,
Capacity building within structures of GMO Act	Ongoing	DoA, DEAT, DoH, DST, DoL, DTI
Strategy on regional cooperation on biosafety	March 2006	DoA, DEAT, DoH, DST, DoL, DTI

8. Reference documents

8.1 Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997)
8.2 Genetically Modified Organisms Amendment Bill
8.3 Cross Border Control Strategy
8.4 GMO Transit Policy
8.5 Environmental Conservation Act, 1998 (Act No. 73 of 1998)
8.6 National Environmental Management Act, 1998 (Act No. 107 of 1998)
8.7 National Environmental Management Biodiversity Act, 2004 (Act No. 10 of 2004)
8.8 Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972)
8.9 Promotion of Access to Information Act, 2000 (Act No. 2 of 2000)
8.10 Promotion of Administrative Justice Act, 2000, (Act No. 3 of 2000)
8.11 Animal Diseases Act, 1984 (Act No. 35 of 1984)
8.12 Fertilizers, Farm Feed, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947)
8.13 Agricultural Pests Act, 1983 (Act No. 36 of 1983)
8.14 Medicines and Related Substances Amendment Control Act, 1997(Act No. 90 of 1997)
8.15 Conservation of Agricultural Resources Act, 1983 (Act No. 43 of 1983)
8.16 Cartagena Protocol on Biosafety

9. Policv owner

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