

Genetically Modified Organisms and Biosafety

Introduction

South Africa is far from an ideal country for crop production, with less than 15 % of its land being arable, as well as serious climatic constraints such as periodic droughts. The agricultural sector has experienced fundamental changes in recent years with regard to how genetic resources are being utilised through genetic modification technology for improved productivity. By means of genetic modification technology, desirable characteristics can now be introduced into plants in a more accurate and effective way. Currently, genetically modified maize, soya-bean and cotton have been approved for general use in South Africa. All activities related to GMOs are regulated by the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997). Amid findings that genetic modification technology can contribute significantly to poverty alleviation and improved productivity, concerns were raised by some governments, civil society and other role players around its safety to the environment and human health. This led to polarised debates globally that culminated in the Cartagena Protocol on Biosafety, which calls for the design and implementation of appropriate biosafety regulatory frameworks.

What is biosafety?

Biosafety is a term used to describe efforts to reduce and eliminate the potential risks resulting from biotechnology and its products. For the purposes of the Biosafety Protocol, this is based on the precautionary approach, whereby the lack of full scientific certainty should not be used as an excuse to postpone action when there is a threat of serious or irreversible damage. While developed countries, which are at the centre of the global biotechnology industry have established domestic biosafety regimes, many developing countries are still in the process of establishing their own national systems.

The Protocol defines Biosafety as 'Policies and procedures adopted to avoid risk to human health and safety and to the conservation of the environment as a result of the use of genetically modified organisms for research and commerce'.

How are GMOs regulated in South Africa?

Historical overview

Genetically modified organisms (GMOs) or Living Modified Organisms (LMOs) have been permitted in SA since 1992. In the absence of specific legislation to regulate activities with

- Affidavit from the applicant
- Acknowledgement and confirmation by the Party of Import to the intended introduction of the LMO to its environment; (NB failure by the Party of Import to acknowledge receipt of a notification shall not imply its consent to the proposed import)
- A permit for exportation shall only be issued if the Registrar of the GMO Act has received written consent (original) from the Party of Import or via the potential exporter. The export permit will contain at least the following information:
 - Identification of the LMO (relevant traits/characteristics of the LMO)
 - Volumes of the LMO to be transferred
 - Requirements for the safe handling, storage, transport and use
 - Contact details for further information on the exporter, the importer, and
 - A declaration that the transboundary movement is in accordance with the Protocol's requirements
 - Additional information may be requested by the competent national authorities, i.e. the Party of Import or Export.

Detailed procedures can be viewed and downloaded from the directorate's website at: <http://www.daff.gov.za/divisions/biosafety>

Important links

Convention on Biological Diversity: <http://www.biodiv.org> Public Understanding of Biotechnology (PUB): <http://www.pub.ac.za> Biosafety Clearing-house: <http://www.bch.bio-div.org> Department of Health: <http://www.doh.co.za> Department of Environmental Affairs (DEA): <http://www.environment.co.za> Department of Science and Technology: <http://www.dst.co.za>

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GMOs, a Committee was established to advise government, industry and the public on the safety of GMOs. This Committee was known as the South African Committee for Genetic Experimentation (SAGENE), and was responsible for the evaluation of the risk assessments, i.e. food, feed and environmental impact assessments of all applications requesting authorisation to conduct activities with GMOs. All activities approved were conducted according to a permit issued under an amendment of another closely related Act in government, viz. the Agricultural Pests Act, 1983 (Act No. 36 of 1983).

The Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) was passed by Parliament with the following objectives:

- To provide for measures to promote the responsible development, production, use and application of GMOs.
- To ensure that all activities involving the use of GMOs (including importation, exportation, transit development, contained use, storage, application, production, release and distribution) are carried out in such a way as to limit possible harmful consequences to the environment and human as well as animal 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 from activities involving the use of GMOs.
- To lay down the necessary requirements and criteria for risk assessments.
- To establish a Council for GMOs.
- To ensure that GMOs are appropriate and do not present a hazard to the environment.
- To establish appropriate procedures for the notification of specific activities involving the use of GMOs and to provide for matters connected therewith.

It should be emphasised that GMOs approved for use in South Africa have been tested thoroughly for safety with regard to humans, animals and the environment. As of 2003, GMO's commercially available in SA are:

- Insect resistant and/or herbicide tolerant maize
- Insect resistant cotton
- Herbicide tolerant cotton and soyabeans.

Since the implementation of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) in December 1999, all activities with GMOs in SA are conducted according to permits issued in terms of this Act. The GMO Act is administered by the Directorate Biosafety, within the Department of Agriculture, Forestry and Fisheries and makes provision for a Registrar, two regulatory bodies, i.e. the Advisory Committee and Executive Council, as well as inspectors. An illustration of how GMOs are approved in South Africa is available on the website of the Department of Science and Technology's programme for Public Understanding of Biotechnology (<http://www.pub.ac.za>).

What are the requirements of the Cartagena Protocol on Biosafety?

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted by the Conference of the Parties to the convention on 29 January 2000. The Protocol has

been signed by more than 157 countries, including South Africa, which became the 58th member by depositing its instrument of ratification on 14 August 2003. The Protocol came into force on 12 November 2003. The Protocol can be viewed or downloaded at <http://www.biodiv.org/biosafety>. The Protocol seeks to protect biological diversity from the potential risks posed by living modified organism resulting from modern biotechnology. The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, focusing specifically on transboundary movements. .

It establishes several procedures, which include the Advance Informed Agreement (AIA) that ensures that countries are provided with the information necessary to make informed decisions before agreeing to the import of GMOs into their territory. The Protocol also contains reference to a precautionary approach.

What is the Biosafety Clearing-house (BCH)?

The Protocol established a Biosafety Clearing-House (BCH) as part of the clearing-house mechanism 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 (see Article 20). The BCH website (<http://www.biodiv.org>), also contains a section devoted specifically to Frequently Asked questions about the Biosafety clearing-House.

What are the requirements in terms of the handling, transportation, packaging and identification of living modified organisms (GMOs)?

The Protocol provides for practical requirements that are regarded as contributing to the safe movement of LMOs. Parties are required to take measures for the safe handling packaging and transportation of LMOs that are subject to transboundary movement. The Protocol specifies requirements on identification by setting out what information must be provided in documentation that should accompany transboundary shipments of LMOs. This particularly applies to imports and exports of LMOs. It also leaves room for possible future development of standards for handling, packaging, transportation and identification of LMOs by the meeting of the Parties to the Protocol.

South Africa is required to take measures ensuring that LMOs subject to intentional transboundary movement are accompanied by documentation identifying the LMOs and providing contact details of persons responsible for such movement. The details of these requirements vary according to the intended use of the LMOs but require that certain basic requirements be fulfilled. These are:

- A letter indicating the intent of the potential importer/exporter
- Completed application forms
- Payment of appropriate fees in terms of the GMO Act
- Notification of the country of import into whose environment the LMO will be introduced intentionally