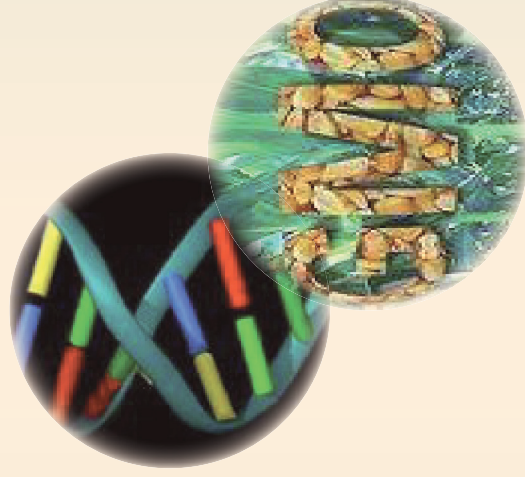


Bio-safety

- Trial release of GMOs (i.e. limited environmental release)
- General release of GMOs (i.e. unlimited environmental release)
- Time extension permits for approved GMO activities
- Registration of facilities where GMO activities are undertaken
- Commodity clearance and use of GMOs for food, feed and processing
- GMO Status certificates for exports

Bio-safety



Further information can be obtained from:

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Obtainable from:

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Bio-safety



Activities of the

Directorate Bio-safety



agriculture,
forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

Bio-safety

Bio-safety

Bio-safety

Background

The Directorate Biosafety manages the implementation of a bio-safety regulatory system focused on minimising potential risks associated with the impact of genetically modified organisms (GMOs) on the environment, human and animal health. This is achieved by focusing on the following core functions:

- Develop and implement policies and strategies to contribute to the safe use, handling and transfer of genetically modified organisms.
- Provide technical advice on matters relating to the application of genetically modified organisms in SA, the region and the rest of Africa.
- Facilitate a compliance system for assessing potential risks (scientific, economic, social and trade etc.) associated with the application of genetically modified organisms.
- Provide an administrative support system for the bodies established under the Genetically Modified Organisms Amendment Act, 1997.

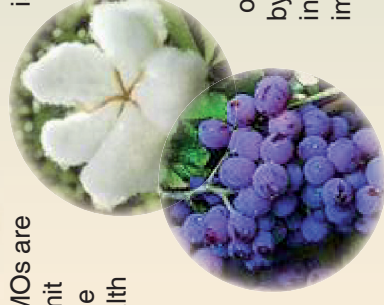
Legislation

The Directorate Biosafety administers the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) which regulates all activities involving GMOs through the issuance of relevant permits.

The main objectives of the Act are to:

- Provide measures to promote responsible development, production, use, application, import and export of GMOs

- Ensure that all activities involving GMOs are conducted in such a manner as to limit possible harmful consequences to the environment, human and animal health
- Ensure effective waste management
- Stipulate requirements and criteria for risk assessment
- Ensure that GMOs are appropriate and do not present a hazard to the environment
- Establish appropriate procedures for the notification of specific activities involving GMOs



In order to achieve these objectives the Act makes provision for the appointment of a Registrar; two regulatory bodies i.e. Advisory Committee and the Executive Council, as well as inspectors. Due to obligations under the Cartagena Protocol for Biosafety and to ensure effective streamlining of regulatory processes an amendment of the Act was undertaken resulting in the GMO Amendment Act, 2006 (Act No. 23 of 2006).



Competent National Authority to the Cartagena Protocol for Bio-safety

The Cartagena Protocol for Biosafety established under the Convention of Biological Diversity,

is an international agreement that aims to ensure an adequate level of protection in the field of safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology. South Africa acceded to the Protocol in August 2003. As the recognised Competent National Authority for South Africa, the Department of Agriculture, Forestry and Fisheries as represented by the Directorate Biosafety, is responsible for ensuring that all provisions relating to the Protocol are implemented.

How are GMO Activities regulated?

GMO applications are subjected to a scientific safety assessment conducted by an expert panel of scientists constituting the Advisory committee (AC). The AC is responsible for the evaluation of risk assessments of all applications as it relates to food, feed and environmental impact. Following the scientific assessment, the Executive Council, represented by officials from various government departments that have been appointed by the Minister, will decide whether or not to approve a particular GMO activity after consideration of the application, scientific recommendation of the AC and the public input received. GMO activities that are approved by the Executive Council are regulated by way of permits issued by the Registrar and accompanying permit conditions are monitored for compliance by inspectors of the Department of Agriculture, Forestry and Fisheries. The Directorate facilitates the following GMO activities:



- Importation / exportation of GMOs
- Contained use of GMOs (e.g. greenhouse trials)