Relevant acts, regulations & guidelines

Listed below are links to PDF documents of all the acts and regulations that are directly relevant to the regulation of GMOs in South Africa. Also included are direct links to the Department of Agriculture, Forestry and Fisheries' (DAFF's) biosafety resources including a link to their webpage, guideline documents and relevant application forms.

South African GMO related acts and regulations

DEPARTMENT OF AGRICULTURE, FORESTRY AND FISHERIES (DAFF)

Genetically Modified Organisms Act (GMO Act; Act No. 15 of 1997)

Genetically Modified Organisms Amendment Act (Act No. 23 of 2006)

Genetically Modified Organisms Act Regulations (No. R. 120 of 2010)

These pieces of legislation regulate all activities with GMOs, including confined research and development, field trials, general release and the import/export of any GMO. See GMO Act resources and guidelines below for more details.

DEPARTMENT OF HEALTH (DoH)

Foodstuffs, Cosmetic and Disinfectants Act (FCD Act; Act No. 54 of 1972)

Foodstuffs, Cosmetic and Disinfectants Act Regulations (No. R. 25 of 2004)

These pieces of legislation control the sale, manufacture and importation of foodstuffs, cosmetics and disinfectants to ensure their quality and safety. The Codex Alimentarius principles and guidelines are accepted as policy for the food/feed safety requirements of GMOs by the DoH. Regulation 25 relates to the labelling of GM derived foodstuffs. The DoH's guidelines for the food/feed safety assessment of GMOs are included in the "Guideline document for working with GMOs" (see DAFF guidelines below).

DEPARTMENT OF ENVIRONMENTAL AFFAIRS (DEA)

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

With regards to GMOs the NEMBA confers to the South African National Biodiversity Institute (SANBI) the responsibility to monitor and report on the potential environmental impacts of GMOs released into the environment in South Africa and also establishes a mechanism whereby the Minister of Environmental Affairs may request an environmental impact assessment (EIA), as outlined under the National Environmental Management Act (NEMA), for a particular GMO.

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

National Environmental Management Act Amendment Act (Act no. 8 of 2004)

National Environmental Management Act Regulations (No. R.385 of 2006)

List of Activities and Competent Authorities Identified in Terms of Sections 24 and 24d of the National Environmental Management Act, 1998

NEMA regulates products, activities and developments to ensure that they are socially, environmentally and economically sustainable. The environmental release of GMOs is one of the listed activities under this act, which may require an EIA as enabled under NEMBA. The DEA has provided general guidance with regards to the criteria that may trigger an EIA for a GMO, the general objectives of EIAs and the administrative procedure to follow should the trigger requirements be met (see DEA Guidance document below). To date the criteria for an EIA have not been triggered and consequently no EIAs have been conducted for any of the GMOs that have been released into the environment.

NOTE: An EIA should not be confused with an environmental risk assessment (ERA), which is done for all GMOs as required by the GMO Act.

DEPARTMENT OF TRADE AND INDUSTRY (DTI)

Consumer Protection Act (CPA, Act No. 68 of 2008; Section 24 (6) pertains to GMOs)

Consumer Protection Act Regulations (No. R. 293 of 2011; Section 7 pertains to GMOs)

The act aims to establish national norms and standards relating to consumer protection by, amongst others, ensuring access to information. Section 7 of the listed regulation outlines the labelling requirements for GMO goods.

DAFF's GMO Act resources and guidelines

Genetic Resources: Biosafety webpage

The website of the Biosafety division of the Directorate: Genetic resources that regulates GMO activities in South Africa.

Guideline document for working with GMOs

A guideline document providing guidance on various aspects of GMO regulation including risk assessment and risk management for different activities such as contained use, field trials or environmental release; food safety assessments; containment requirements for different activities with GMOs in facilities such as laboratories or greenhouses.

Permit application forms in PDF **or** Word **format for activities with GMOs in South Africa**

This includes the application forms for the registration of a facility; trial release; commodity clearance; contained use; general release; import for contained use; import for general release or commodity clearance; import for trial release into the environment; export for contained use or use as food, feed or processing; export for intentional release into the environment; commodity use for food, feed or processing; export time extension; GMO status certification for export and an affidavit.

Standard operating procedures with regard to regulation 4 **and** regulation 2(2) **of the GMO Act**

These SOPs outline the conditions for the registration of a facility and the conditions for exemption from the requirements for a permit for academic and research institutions respectively.

Guidelines for a public notifications

Outlines the public notification requirements for activities involving field trials, commodity clearance and general release.

Fees and banking details

Specifies the fees for permits for different activities with GMOs including the registration of a facility, permits for contained use, field trial applications, commodity clearance applications and general release applications.

Contact details of the Registrar: GMO Act

Other resources and guidelines

DoH

- The DoH accepted the Codex Alimentarius principles and guidelines on "Foods derived from modern biotechnology" as the official basis and guidelines for the food/feed safety assessment of GMOs in South Africa. An overview of the DoH's requirements is also included in the general "Guideline document for working with GMOs" under the GMO Act, under section 5.2.

DEA

- Environmental Risk Assessment Framework for Genetically Modified Organisms: A Guidance Document
- Risk analysis of contained use research and development activities with genetically modified aquatic organisms

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DST

- Bioeconomy Strategy

BIOSAFETY SOUTH AFRICA

- Procedure to register a facility for GM use

A brief outline of the process to be followed when registering a facility for GM use.

- Application for authorisation to import GMOs intended for a trial release in South Africa

A guide when applying for the import and trial release of GMOs.

- Risk Mitigating Strategies (RMS) for GM Products

An investigation of the conditions under which particular RMS may be beneficial to mitigating identified risks or decreasing regulatory requirements so that sound regulatory decisions can be made while harnessing the benefits of biotechnology.

- Current practice and potential impact of in-field separation strategies for GM and non-GM maize

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- Maize and Bacillus thuringiensis Cry protein allergenicity

- Late stage research and development, and regulatory roadmap

Late stage research and development, and regulatory roadmap for commercialising GM products in South Africa.