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Overview of the South African Regulatory Framework for GMOs

Introduction

A number of national and international regulations govern the use of genetically modified organisms (GMOs) in South Africa. The aim of these regulations is to ensure that any activities with GMOs are assessed with regards to their potential risks to human health & prosperity and the environment prior to undertaking any such activity. Furthermore it aims to ensure that approved activities are conducted in a controlled manner including, if necessary, strategies to mitigate and/or manage any potential risks. This document discusses the key regulations with regards to the use of GMOs in South Africa.

National Regulations

The Genetically Modified Organisms Act

The regulation of GMOs is principally governed by the Genetically Modified Organisms Act (GMO Act) and its subsequent amendments and their applicable regulations. Specifically the two relevant acts are:

- Genetically Modified Organisms Act 1997 (Act No. 15, 1997)
- Genetically Modified Organisms Amendment (Act No. 23 of 2006)

The act was put in place to regulate the prudent and responsible use of GMOs in South Africa. This encompasses the entire pipeline of GMO development including research and development (contained use and field trial activities), production (general release activities), import and export, transport, use and application of GMOs. Accordingly, the act aim to ensure that any activity with a GMO in South Africa is conducted so as to limit potential risks to the environment and to human and animal health and take socio-economic considerations into account. The GMO Act and its amendment and the relevant regulations monitor all activities with GMOs according to permits issued in terms of this act. A number of types of permits can be applied for relating to the particular GMO activity, including permits for import, commodity clearance, general release, field trials and contained use.

The GMO Act is implemented by the Directorate Biosafety of the Department of Agriculture, Forestry and Fisheries. The Registrar of the GMO Act administers the act. Two regulatory bodies namely the Executive Council and the Advisory Committee evaluate and decide on applications. The Advisory Committee is composed of independent scientists with various scientific backgrounds. This body then advises the Executive Council as to the level of risk associated with the activity and whether the permit for that particular activity can be issued. This may include risk management strategies that may need to be implemented should the permit application be approved. The Executive Council is the decision making body made up of representatives from a number of government departments. If the Executive Council is satisfied with the findings of the Advisory Committee and if other issues that may be brought up by the Executive Council are resolved, including for example trade issues or consideration of public comments, a permit for that particular activity may be issued by the Registrar. Inspectors ensure compliance to permits approved under the GMO Act. For a cartoon summary of the GMO application process see "Regulation overview" on this site or go to http://www.pub.ac.za/resources/docs/cartoon_gmo_approve.pdf.

The National Environmental Management Biodiversity Act

The National Environmental Management Biodiversity Act (Act no. 10 of 2004; NEMBA) confers to the South African National Biodiversity Institute (SANBI), as one of its functions the responsibility to monitor

and report on the environmental impacts of GMOs released into the environment in South Africa. This function is performed by the GMO Research and Monitoring unit of SANBI.

NEMBA also establishes a mechanism whereby the Minister of Water and Environmental Affairs may request an environmental impact assessment (EIA) of the GMO under the National Environmental Management Act (Act no. 107 of 1998; NEMA).

The National Environmental Management Act

NEMA provides established general principles for decision making with regards to activities that affect the environment and promotes co-operative governance. The Act and relevant amendments include:

- National Environmental Management Act (Act no. 107 of 1998)
- National Environmental Management Act Amendment Act (Act no. 8 of 2004)

The Department of Environmental Affairs (DEA) has provided general guidance with regards to the objectives of EIAs for GMOs, the criteria that may trigger an EIA and the administrative procedure to follow should the trigger requirements be met (This can be found in the document "Environmental Risk Assessment Framework for Genetically Modified Organisms: A Guidance Document" available from DEA). To date an EIA for a GMO has not been required under NEMBA and consequently an EIA under NEMA has not been conducted for a GMO.

If an EIA of a GMO is conducted under NEMA and the outcome of the EIA is that the particular activity is deemed acceptable the EC of the GMO Act nonetheless retains the authority to make a final decision on the granting of the permit. However; if the EIA concluded that the particular activity with a GMO poses an unacceptable level of risk then the EC may not instruct the Registrar to issue the permit (section 78 of NEMBA).

International Regulations

The Cartagena Protocol

South Africa ratified the Cartagena Protocol on Biosafety in 2003. This protocol is focussed specifically on regulating the transboundary movement of LMOs (living modified organisms), which are GMOs capable of transferring or replicating genetic material, to minimise the potential risks posed by LMOs by ensuring the safe transfer, handling and use of LMOs that may have negative effects on biodiversity or on human health. Included in the revisions made in the GMO Amendment Act of 2006 are changes to ensure compliance with the provisions of this protocol. Among these is the establishment of processes to ensure that the required information to make an informed decision on the import of a LMO is available prior to a decision on the import of a LMO. The Protocol has also established the Biosafety Clearing-House (BCH) as a mechanism to facilitate the exchange of information on GMOs to enable compliance under the Protocol. This includes information on scientific, technical, environmental and legal aspects on the transboundary movement of GMOs. Text of the protocol can be found at http://www.cbd.int/biosafety/.

Codex Alimentarius

South Africa is a member of the Codex Alimentarius Commission and accordingly follows the Codex principles and guidelines for the evaluation of the safety of food and feed derived from GMOs. This includes a safety assessment of the food considering aspects such as the possible allergenicity, toxicity, compositional analysis, evaluation of metabolites, possible effects of food processing, nutritional modifications and other considerations. Such an evaluation of food and feed safety is necessary when applying for a Commodity Import permit or a General Release permit in South Africa. The relevant Codex Alimentarius principles and guidelines documents can be found at http://www.codexalimentarius.net/.