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STANDARD OPERATING PROCEDURES WITH REGARD TO REGULATION 4 OF THE GMO ACT

Approved by the

Executive Council for Genetically Modified Organisms

on 25 May 2006

within the framework of the Genetically Modified Organisms Act, 1997
(Act No. 15 of 1997)

PURPOSE OF THE DOCUMENT

This document shall provide standard operating procedures for the Registrar and Advisory Committee for implementation of Regulation 4 of the Genetically Modified Organisms (GMO) Act, 1997 (Act No. 15 of 1997).

BACKGROUND

Regulation 4 of the GMO Act requires the registration of all facilities, with facilities being defined as any place where organisms are being genetically modified under conditions of contained use.

Contained use means any activity in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers or in a combination of physical barriers together with chemical or biological barriers or both are used to limit contact thereof with the environment;

This implies that all facilities conducting activities in accordance with a contained use permit authorised by the Executive Council and any activity conducted in accordance with Regulation 2(2), must be registered in terms of Regulation 4 of the GMO Act.

No procedure in this document shall exempt any party from the provisions of any other legislation in SA.

STANDARD OPERATING PROCEDURE

(i) Facility description:

A facility, in accordance with the definition stipulated in the Regulations to the GMO Act and the definition of contained use, includes the following:

(a) laboratories (including laboratories within seed companies),

(b) growth rooms,

(c) greenhouses (glasshouses),

(d) store rooms
(d) GMO testing institutes, and
(e) facilities where GMO's are destroyed.

The following facilities must be registered in accordance with Regulation 4 of the GMO Act:

(a) All facilities conducting activities with any GMO, under authorisation of a contained use permit.
(b) All academic and research facilities conducting activities with any GMO, in accordance with Regulation 2(2).

(ii) Registration of facility:

To register a facility, the following documents are required:

(a) Completed application form
(b) Classification of the facility into a specific risk category / level.
(c) Locality map as required in terms of Regulation 4(3)
(d) The required fee.

All applications for the registration of a facility will be assessed by the Advisory Committee, who will in turn advise the Registrar on the applicability of the risk assessment, and any risk management measures that should be implemented by the facility.

A certificate of registration will only be issued once a recommendation has been received from the Advisory Committee.

(iii) Renewal of registrations:

Registration of a facility will be valid for a period of three years, provided that there is no change within the facility that significantly affects the risk category / level. Prior to expiry of the registration period, the facility must apply for a renewal of registration.

An application for renewal of a facility registration will be as follow:

(a) If there was **no** change in the facility that affects the risk category / level of the facility since its last registration: a notification letter to the Registrar requesting renewal of the facility.

(b) If there was change in the facility that affects the risk category / level of the facility since its last registration: you will have to follow the procedures as indicated in paragraph (ii) above.