



**DEPARTMENT OF AGRICULTURE**

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**STANDARD OPERATING PROCEDURES WITH REGARD TO  
REGULATION 2(2) OF THE GMO ACT**

Approved by the

Executive Council for Genetically Modified Organisms

on 13 October 2005

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

## **1. PURPOSE OF THE DOCUMENT**

This document shall provide standard operating procedures (SOP) for the Registrar, Advisory Committee and Executive Council for implementing Regulation 2(2) of the Genetically Modified Organisms (GMO) Act, 1997 (Act No. 15 of 1997).

## **2. BACKGROUND**

Regulation 2(2) of the GMO Act provides for an exemption from the requirement of a permit, as referred to in Regulation 2(1), for organisms that are used under conditions of contained use in academic and research facilities, and for those organisms specified in Table 3 of the Annexure to the Regulations. Table 3 lists GMO events that have obtained general release (or conditional general release) or commodity clearance authorisations.

## **3. STANDARD OPERATING PROCEDURE**

The procedures described below have been approved by the Executive Council as the standard operating procedures for activities with GMO's under Regulation 2(2).

### **3.1 First section of Regulation 2(2):**

*“2(2) Notwithstanding the provisions of subregulation (1), a permit referred to in the said subregulation shall not be required for organisms that are used under conditions of contained use in academic and research facilities, ...”*

The SOP for this section is as follow –

An import permit, or a permit authorising contained use, is not required for GMO's that are used in accordance with Regulation 2(2), provided that the following conditions apply:

- (a) The GMO will only be used within a research or academic facility;
- (b) The activity is for research or academic purposes only;
- (c) The confined area within the facility is a laboratory or growth room;

- (d) The confined area within the facility is a greenhouse (glasshouse), provided that the greenhouse (glasshouse) is not used for bulking-up or commercial production purposes;
- (e) The facility is registered in terms of Regulation 4 of the GMO Act;
- (f) The level of containment is not higher than 2, which has been verified by the Advisory Committee during registration of the facility;
- (g) The GMO will not be removed from the facility or released into the environment;
- (h) The responsible individual in charge of the facility implements the necessary measures to effectively contain the GMO at all times.

### **3.2. Second section of Regulation 2(2):**

*“2(2) Notwithstanding the provisions of subregulation (1), a permit referred to in the said subregulation shall not be required ...for those organisms specified in Table 3 of the Annexure”.*

Considering the various irregularities in Table 3 in its current format, the following SOP will be applicable to GMO's that have obtained commodity clearance and/or general (incl. conditional) release clearance.

- (a) Importation and exportation of GMO's approved as commodity (i.e. obtained commodity clearance approval) is still subject to a permit issued by the Registrar.
- (b) All activities, with the exception of exportation, with GMO's approved for commercial use, i.e. general release or conditional general release, are exempted from the requirement of a permit.

A list of the GMO's that have obtained commodity clearance or general (incl. conditional) release clearance is contained in the Annexure.

## Annexure

### A. General release (incl. conditional)

| Event                   | Crop    | Trait                                  | Company  | Year approved |
|-------------------------|---------|--|----------|---------------|
| BGRR                    | Cotton  | Insect resistant<br>Herbicide tolerant | Monsanto | 2005          |
| Bollgard II, line 15985 | Cotton  | Insect resistant                       | Monsanto | 2003          |
| Bt11                    | Maize   | Insect resistant                       | Syngenta | 2003          |
| NK603                   | Maize   | Herbicide tolerant                     | Monsanto | 2002          |
| GTS40-3-2               | Soybean | Herbicide tolerant                     | Monsanto | 2001          |
| RR lines 1445 & 1698    | Cotton  | Herbicide tolerant                     | Monsanto | 2000          |
| Line 531 / Bollgard     | Cotton  | Insect resistant                       | Monsanto | 1997          |
| MON810 / Yieldgard      | Maize   | Insect resistant                       | Monsanto | 1997          |

### B. Commodity clearance

| Event                              | Crop         | Trait                                  | Company         | Year approved |
|------------------------------------|--------------|--|-----------------|---------------|
| MON810 x NK603                     | Maize        | Insect resistant<br>Herbicide tolerant | Monsanto        | 2004          |
| MON810 x GA21                      | Maize        | Insect resistant<br>Herbicide tolerant | Monsanto        | 2003          |
| TC1507                             | Maize        | Insect resistant<br>Herbicide tolerant | Pioneer Hi-Bred | 2002          |
| NK603                              | Maize        | Herbicide tolerant                     | Monsanto        | 2002          |
| GA21                               | Maize        | Herbicide tolerant                     | Monsanto        | 2002          |
| Bt11                               | Maize        | Insect resistant                       | Syngenta        | 2002          |
| T25                                | Maize        | Herbicide tolerant                     | AgrEvo          | 2001          |
| Bt176                              | Maize        | Insect resistant                       | Syngenta        | 2001          |
| Topas 19/2, Ms1Rf1, Ms1Rf2, Ms8Rf3 | Oilseed rape | Herbicide tolerant                     | AgrEvo          | 2001          |
| A2704-12                           | Soybean      | Herbicide tolerant                     | AgrEvo          | 2001          |

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