

SA'S SUBMISSION OF INFORMATION REQUESTED IN NOTIFICATION 2017-142 ON CONTAINED USE (ARTICLE 6)

A. BACKGROUND

Notification 2017-142, dated 13 December 2017, invited Parties and other Governments to submit practical guidance on specific measures for contained use of living modified organisms that effectively limit their contact with and impact on the external environment.

B. SA'S EXPERIENCE

South Africa has a well-developed regulatory system in the form of the Genetically Modified Organisms Act, 1997. The GMO Act provides for an administrative system through which authorizations for any activity involving GMOs are granted through the issuance of the relevant permit. Consequently, the contained use of LMOs is regulated under the GMO Act and implemented through provisions in the relevant regulation.

The GMO Act defines contained use as the development, production, cultivation, use, application, storage, movement, destruction or disposal of genetically modified organisms within a facility, installation or other physical structure, including a greenhouse, that are controlled by specific measures, including physical barriers or a combination of physical barriers together with chemical or biological barriers or both, that effectively limit contact of the genetically modified organisms with humans, animals, and the external environment and their impact on humans, animal and the external environment.

A contained use permit is required once the research is scaled up from basic research to product development, or when the containment level is above 2.

Contained use permit conditions compel permit holders to amongst others:

1. Store all transgenic material and materials associated or used in the contained use activities in the registered storage facility to prevent release of the organism or material associated with the contained use activities.
2. Keep accurate records of all activities pertaining to the management of the registered facility including the quantity of GMO/material by means of an inventory and their disposal at the end of the contained use period.
3. Store surplus genetically modified material in a secure place within the facility in closed bags/containers to ensure that the material is not dispersed and submit a declaration to the Registrar stating that the surplus material will be shipped back to the foreign supplier (if applicable apply for an export permit under GMO Act).

The Registrar responsible for the administration of the GMO Act (as delegated by EC) reserves the right-

- a) In the event of breach of these permit conditions or requirements, to take such steps that he or she may deem necessary to ensure the safe use of this GMO consignment at the expense of the permit holder and withhold the permit and any further authorisations.
- b) To amend permit conditions, if and when required.