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GUIDELINE FOR SUBMISSION OF TIME EXTENSION REQUESTS FOR CURRENT PERMITS ISSUED UNDER THE GENETICALLY MODIFED ORGANISMS ACT, 1997 (ACT NO. 15 OF 1997)

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1. DEFINITIONS

Activity: any activity with genetically modified organisms but is not limited to the importation, exportation, transit, development, production, release, distribution, use, storage and application of genetically modified organisms only.

Applicant: any person in control of facilities and activities involving genetic modification of organisms and includes “user”.

Advisory Committee: regulatory body established by Section 10 of the GMO Act.

Commodity clearance: authorisation to use a genetically modified organism as a food or feed, or for processing, but excludes the planting of the genetically modified organism as a release into the environment.

Contained use: 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.

Executive Council: the decision making body established by Section 3 of the GMO Act.

Extension permit: a permit issued for activities relating to genetically modified organisms for which a permit had been issued previously.

General release: a release of genetically modified organisms into the environment by whatever means, where the organisms is no longer contained by any system of barriers.

Genetically modified organisms: an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both.

The GMO Act: Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), as amended by Genetically Modified Organisms Act, 2006 (Act No. 23 of 2006) including the regulations.

Permit: a permit referred to in section 5(a) of the GMO Act and includes a written authority

Registrar: a person appointed under section 8 of the GMO Act

Trial release: the deliberate release of genetically modified organisms into the environment in the open under conditions where the degree of dissemination of the genetically modified organism is limited by chemical or physical barriers or by built-in-barriers which prevent the survival of such organisms in the environment.

Acronyms and Abbreviations

AC: Advisory Committee
DAFF: Department of Agriculture, Forestry and Fisheries
EC: Executive Council
GMO: Genetically modified organisms

2. INTRODUCTION

In South Africa all activities with genetically modified organisms (GMO's) are regulated by the Genetically Modified Organisms Act 1997 (Act No 15 of 1997) as amended by Genetically Modified Organisms Act, 2006 (Act No. 23 of 2006).

The GMO activities regulated through permits include: imports, exports, contained use, trial release, general release and commodity Clearance. Permits for imports, exports, contained use, and filed trial release are issued for a specified timeframe, however there are certain instances where the GMO activity cannot commence or be completed within the specified timeframe as stipulated in the permit.

Regulation 3 (11) of the GMO Act, makes provision for the Registrar as authorised by the Executive Council (EC), to issue an extension permit for an activity for which a permit has been issued previously.

3. PURPOSE

This document aims to provide guidance for applicants with regards to extending the timeframe for the following previously approved activities[a] in terms of the GMO Act: imports, exports, contained use and trial release. This guideline does not apply to clinical trials.

4. APPLICABLE FEES

Tariffs for the extension of permits for the following activities are payable:

- Contained Use
- Trial Release

Revised tariffs are published annually on the 1st of April and are obtainable from the Office of the Registrar[b] as well as from DAFF website[c].

[a] The guideline does not make provision to change the scope or contents of the activity

5. APPLICATION PROCEDURE

5.1 Contained use and trial release permits

5.1.1 Activities not yet commenced

For activities that did not commence as stipulated in the permit due to various conditions e.g. unavailability of material, severe weather resulting in damage to field trials, etc; the applicant may request a 12 months extension from the office of the Registrar. Such a request must be made 30 days before the permit expires.

The applicant must submit the following documents:

- The prescribed application form
- Proof of payment
- Affidavit

5.1.2 Activities already commenced

If an activity will extend past the timeframe stipulated in the permit, the applicant may request a 12 months extension from the office of the Registrar. Such a request must be made 90 working days before the permit expires.

The applicant must submit the following documents to the Office of the Registrar[b]:

- 9 copies of the prescribed application form
- 9 copies of comprehensive annual report pertaining to activities for which an extension permit is applied for.
- Proof of payment
- Affidavit

5.2 Import permit of GMOs that have general release and/or commodity clearance approval

5.2.1 Quantity of the stipulated material imported partially

If an applicant could not import the entire quantity of the material stipulated in the permit within the stipulated timeframes, the applicant may request a 30-day extension from the office of the Registrar. Such a request must be made 7 working days before the permit expires.

The applicant must submit an official letter to the Office of the Registrar. The letter must include the following:

- Applicant's details
- Permit number
- Reasons for requesting the extension

If an applicant could not import the required quantity of the material within the 30-day extension, the applicant shall submit a new import application as prescribed.

5.2.2 No material imported

If an applicant could not import any quantity of the material stipulated in the permit within the stipulated timeframes, the applicant shall submit a new import application as prescribed.

5.3 Addition of new sites for trial release

Addition of a new site falls out of the scope of an application for a time extension; it would require the submission of a new application for a particular category of activity.

6. ASSESSMENT OF APPLICATIONS

6.1 The Office of the Registrar shall refer applications for extension of contained use and trial release permits request to the Executive Council (EC) for consideration. Upon consideration, the EC may approve or reject an application.

6.2 Applications for extension of an import permit shall be considered by the Registrar.

N.B This document is solely a guideline and does not preclude the Executive Council, or the Office of the Registrar to request additional information.

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