REPUBLIC OF SOUTH AFRICA
DEPARTMENT OF AGRICULTURE
LMOs Act, 1997 (Act No. 15 of 1997)

DIRECTORATE BIOSAFETY
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APPLICATION FOR AN EXTENDED PERMIT FOR ACTIVITIES WITH GMO'S IN SOUTH AFRICA
CONTAINED USE AND TRIAL RELEASE

Directions for the applicant:

- Please consult the policy approved for extension permits, with particular reference to Section 7. (Available on the website of the department).
- Please complete all sections of this questionnaire. Please provide reasons if a particular section of this form is not completed ("not applicable" will not be accepted – one must provide reasons why a particular question is not applicable).
- Please provide one original and 11 copies of the application with confidential information for use by the regulatory bodies appointed in terms of the Genetically Modified Organisms Act, 1997 (Act no. 15 of 1997). This copy must be clearly marked: CONFIDENTIAL
- Please provide one hard and an electronic copy of the application containing no confidential information. This copy must be clearly marked: NON-CONFIDENTIAL, and will be made available for public scrutiny and placed on the website of the Department. This copy of the application must be submitted to the Registrar one day after placing of the public notices.
- In case of a trial release activity, please conduct a public notification in accordance with Regulation 6 of the GMO Act, and making use of the guideline document available on the website of the department. Copies of the public notification must be submitted with the application.
- Please note that the time period provided for comments or objections to be submitted in response to a public notification must have expired with at least 15 working days prior an Executive Council meeting, in order for the application to be considered in that particular meeting.
- Proof of payment of the correct fee stipulated under the GMO Act must accompany the application. Please note that payments can not be made at the Registrar's office.

PART I:

Please provide the following information:

Applicant / Party of Import

Contact person

Complete address

Previous authorisations (permit number) and a detailed report of the activities conducted under the most recent permit.

Characteristics of the GMO

- Designation of the transformed line
- Phenotype
- Construct
- Promoter
- Gene
- Enhancer
- Terminator (stop coding)
- Selectable marker

Mode of transformation for each GMO

Aim of trial and estimated duration of the activity

In the event of a trial release application; information pertaining to each trial site in terms of the following –

(i) Ordnance survey map of appropriate scale with site marked

(ii) GIS co-ordinates

(iii) Map indicating crops planted adjacent to the site and the distances involved

(iv) description in terms of –

- size
- volume seed to be planted (in kg)
- soil
- groundwater level
- topography
- flora and fauna
- climate, especially prevailing winds
- former use

- distance from the nearest human settlements, along with the size of such settlements
- distance from surface waters
- distance from environmentally and otherwise protected areas;
- history of the site

(v) description of the environment immediately surrounding the release site;

(vi) the barriers planned in order to segregate the experiments comprising the trial release from the surrounding environment;

(vii) the supervision and monitoring of the trial release

(viii) the contingency plans to deal with extreme conditions such as storms, floods and bush fires during the course of the trial release;

(ix) the provisions to remove or eliminate the GMO from the test site or any other place where it may be found upon completion of the trial release and to restore the test site and any such other place to its original form;

(x) the arrangements for transporting the GMO to the release site.

In the event of a contained use application; the type of facility, registration number of the facility and level of containment

Monitoring and accidents

(i) Indicate the methods and plans for monitoring of the GMO

(ii) Indicate any emergency procedures that will be applied in the event of an accident

Pathogenic and ecological impacts

(i) Submit an evaluation of the foreseeable impacts, in particular any pathogenic and ecologically disruptive impacts.

Risk management

(i) Please indicate any risk management measures that would be required during the activity.

What are the implications of the proposed activity with regard to the health and safety of the workers, cleaning personnel and any other person, that will be directly or indirectly involved in the activity? Please take into consideration the provisions of the Occupational Health and Safety Act, 1993 (Act No. 181 of 1993) and accompanied regulations.

Indicate the proposed health and safety measures that would be applied to safeguard employees during the proposed activity.

COMPLETE THE AFFIDAVIT. The affidavit is an inseparable part of the application form.

COMPLETE THE RISK ASSESSMENT DOCUMENT (PART II). The risk assessment forms an inseparable part of the application form and must be completed in the format provided below.

PART II
Risk Assessment

(In accordance with Annex III of the Cartagena Protocol ion Biosafety)

	Risk assessment details	
1.	Country Taking Decision:	South Africa
2.	Title:	<Text entry>
3.	Contact details:	<Standard contact address details: name, function (job title/designation), organization, address, phone, fax, email, website>
	LMO information	
4.	Name and identity of the living modified organism:	<Text entry – Identity of the living modified organism, and the differences between the biological characteristic of living modified organism and those of the recipient organism or parental organisms>
5.	Unique identification of the living modified organism:	<Text entry>
6.	Transformation event:	<Text entry>

7.	Introduced or Modified Traits:	Choose the trait from the following list: A. <u>Abiotic environmental tolerance</u> - Altered photoperiod sensitivity - Cold or heat tolerance - Drought or water tolerance - Other abiotic environmental tolerance B. <u>Altered growth, development and product quality</u> - Altered ripening or flowering - Coloration - Fertility restoration - Growth rate or yield - Male sterility - Nutritional composition (inc. allergenicity) - Other growth, development and product quality - Selectable marker genes and reporter genes - Uptake or degradation of environmental pollutants **Chemical tolerance** - Herbicide tolerance - Other chemical tolerance **Medical products** - Animal vaccines - Development of transplant organs - Other medical products - Production of pharmaceuticals **Pest resistance** - Bacterial resistance - Fungus resistance - Insect resistance - Nematode resistance - Other pest resistance - Virus resistance and <text entry for other, not on the list>
8.	Techniques used for modification:	<Controlled vocabulary for common techniques - Please select techniques used for the transformation: plasmid carried by *Agrobacterium tumefaciens*, biolistic methods, breeding, electric shock (poration), osmotic shock> *and* <text entry – for other, not on the list>
9.	Description of gene modification:	<Text entry>
		Characteristics of modification
10.	Vector characteristics (Annex III.9(c)):	<Text entry - Characteristics of the vector, should include its identity, if any, and its source or origin, and its host range >
11.	Insert or inserts (Annex III.9(d)):	<Text entry - Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced>
		Recipient organism or parental organisms (Annex III.9(a)):

12. Taxonomic name/status of recipient organism or parental organisms:	<Controlled vocabulary: agreed international standards> *and* <text entry – for other, not on the list>
13. Common name of recipient organism or parental organisms:	<Controlled vocabulary with thesaurus> *and* <text entry – for other, not on the list>
14. Point of collection or acquisition of recipient or parental organisms:	<Text entry >
15. Characteristics of recipient organism or parental organisms related to biosafety:	<Text entry >
16. Centre(s) of origin of recipient organism or parental organisms:	<Text entry - Describe the exact location and give geographical coordinates>
17. Centres of genetic diversity, if known, of recipient organism or parental organisms:	<Text entry - Describe the exact location and give geographical coordinates>
18. Habitats where the recipient organism or parental organisms may persist or proliferate:	<Text entry - Description of the habitat where the organisms may persist or proliferate>
Donor organism or organisms (Annex III.9(b)):	
19. Taxonomic name/status of donor organism(s)	<Controlled vocabulary: agreed international standards> and <text entry for other, not on the list>
20. Common name of donor organism(s):	<Controlled vocabulary with thesaurus> and <text entry for other, not on the list>
21. Point of collection or acquisition of donor organism(s):	<Text entry - the exact location and geographical coordinates>
22. Characteristics of donor organism(s) related to biosafety:	<Text entry - Relevant biological characteristics of donor organisms>
Intended use and receiving environment	

23. Intended use of the LMO (Annex III 9(g)):	<Text entry - Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms>
24. Receiving environment (Annex III.9(h)):	<Text entry - Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment>
	Risk assessment summary
25. Detection/Identification method of the LMO (Annex III.9(f)):	<Text entry - Suggested detection and identification methods and their specificity, sensitivity and reliability>
26. Evaluation of the likelihood of adverse effects (Annex III.8(b)):	<Text entry - An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism>
27. Evaluation of the consequences (Annex III.8(c)):	<Text entry - An evaluation of the consequences should these adverse effects be realized>
28. Overall risk (Annex III.8(d)):	<Text entry - An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized>
29. Recommendation (Annex III.8(e)):	<Text entry - A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks>
30. Actions to address uncertainty regarding the level of risk (Annex III.8(f)):	<Text entry - details about any further information that has been requested where there is uncertainty regarding the level of risk, as well as any information on risk management strategies and/or monitoring of the LMO in the receiving environment>
	Additional information
31. Availability of detailed risk assessment information:	<Text entry - Please indicate whether more details on the risk assessment are available and how they can be accessed>
32. Any other relevant information:	< Text entry - any other information that is relevant to the risk assessment. e.g. information of non CBI nature that was included in the original application but is not included in this form>
33. Attach document:	*Not applicable to applicant* <Specific types of entry: option to choose a file from the local source and 'upload' a copy to the BCH server>
34. Notes:	<Text entry>

AFFIDAVIT/VERKLARING/STATEMENT

(moet ingevul word in teenwoordigheid van 'n Kommissaris van Ede / to be completed in the presence of a Commissioner of Oaths)

Ek/I……

ID-Nommer/Number…… Ouderdom/Age ……..

Woonadres/ Residing address …….

Werkadres/working address ……..

Tel ……..(w) ……(h) ……(cell)

Verklaar onder eed in afrikaans / bevestig in afrikaans -
Declare under oath in English / confirm in English –

……
……
……
……

Ek is vertroud met die inhoud van bostaande verklaring en begryp dit. Ek het geen beswaar/het beswaar teen die aflê van die voorgeskrewe eed. Ek beskou die voorgeskrewe eed/bevestiging as bindend vir my gewete.
I am familiar with, and understand the contents of this declaration. I have no objection/have objection to taking the prescribed oath. I consider the prescribed oath as binding to my conscience.

Plek/Place: …….. Datum/Date: ……..

Tyd/Time: ……

Handtekening/Signature: ……

Ek sertifiseer dat bostaande verklaring deur my afgeneem is en dat die verklaarder erken dat hy/sy vertroud is met die inhoud van hierdie verklaring and dit begryp. Hierdie verklaring is voor my beëdig en verklaarder se handtekening/merk/duimafrduk is in my teenwoordigheid daarop aangebring.
I certify that the above statement was taken from me and that the deponent has acknowledge that he/she knows and understands the contents of the statement. The statement was sworn to/affirmed before me and deponents signature/mark/thumb print was placed thereon in my presence.

Te/At: ……op/on ……om/at ……

……
Kommisaris van Ede/Commissioner of Oaths
(inligting i.v.m. fisiese en posadres moet verskaf word, bv. Stempel van die polisiestasie
details to be provided on physical and postal address e.g. stamp of police station)

……
Magsnommer /Rang/Naam – drukskrif
Force number/Rank/Name - print