agriculture
Department:
Agriculture
REPUBLIC OF SOUTH AFRICA

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

DIRECTORATE BIOSAFETY
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APPLICATION FOR AUTHORISATION TO IMPORT LMO'S INTENDED FOR INTENTIONAL INTRODUCTION INTO THE ENVIRONMENT (TRIAL RELEASE) OF SOUTH AFRICA

A document containing the information requested in this form will serve as a notification in terms of Section 8 of the Cartagena Protocol on Biosafety, and may include additional requirements in terms of national biosafety legislation.

This document must be accompanied by (a) a cover letter, (b) completed application for the intended use of the LMO in SA (i.e. trial release or fast track application form) and (c) the correct fee in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997).

1. Name, address and contact details of the importer (contact point for further information).

2. Contact details of the Competent National Authority in the Party of Export.

3. Name, address and contact details of the exporter.

4. Common name, scientific name, commercial name or unique identifier code (OECD) of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organisms (LMO's)?

5. A complete list of the varieties/hybrids of the event.

6. The intended date/dates of the transboundary movement, if known?

7. Port of entry within South Africa (name and city)?

8. The regulatory status of the LMO within the Party of Export.

9. The intended use of the LMO in SA and what was it used for in the Party of Export?

10. The quantity or volume of the LMO to be imported into South Africa?

11. A risk assessment report consistent with Annex III of the Cartagena Protocol on Biosafety (see format below).

12. Methods and plans for safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures.

13. Results and purpose of any other notifications by the Party of Export regarding the LMO to be transferred.

14. Methods and plans used in South Africa for monitoring of the LMO.

15. Emergency procedures that will be applied in South Africa in the event of an accident with the LMO.

16. An evaluation of the foreseeable impacts, in particular any pathogenic and ecologically disruptive impacts of the LMO's.

17. A completed affidavit to declare that the information provided is factually correct.

Directions for the potential importer:
(This page must be excluded from the documents to be submitted to the Registrar's office)

- Please complete all sections of the form CLEARLY.
- A template of the affidavit is obtainable from the Registrar's office.
- Please provide 12 copies of the application with confidential information and an additional application containing no confidential information. The latter application will be made available for public scrutiny.
- Every potential importer must submit a notification to the competent national authority within SA.
  This notification shall contain of –
  - A letter indicating the intent of the potential importer
  - Completed import application form
  - Completed application form for the intended use of the LMO in South Africa
  - The correct fee in terms of the Genetically Modified Organisms Act, 1997 for the importation and intended use.
- Contact details of the competent national authority in SA is the following:
  Ms GE Christians
  Registrar: Genetically Modified Organisms
  Private Bag X973
  Pretoria
  0001
  Tel: 27 12 319 6382
  Fax: 27 12 319 6329
  E-mail: GillianC@nda.agric.za
- Please take note that the Registrar's office may request additional information to the notification.
- The Registrar's office has 90 days to acknowledge receipt of the notification in writing.
- The acknowledgement shall state –
  - the date of receipt of the notification;
  - whether the notification, prima facie, contains the information referred to in Article 8 of the CPB; and
  - whether to proceed according to the GMO Act or acceding to the procedures specified in Article 10 of the CPB.
- A permit for importation will only be issued once the Registrar has received the necessary clearance by the Executive Council.
- LMO's exempted from requirement of an import permit under the GMO Act are not necessarily exempted from requirement of an import permit in terms of the Biosafety Protocol.
- A Party is a Party in terms of the Cartagena Protocol on Biosafety.
- These procedures are also applicable for imports from non-Parties to the Cartagena Protocol on Biosafety.
- The procedures for imports indicated above are applicable until such time that the Competent National Authority, i.e. Registrar, through the Biosafety Clearing House, has indicated a simplified procedure, or the Registrar has indicated a revised procedure to be followed.

COMMON FORMAT FOR 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