agriculture,
forestry & fisheries
Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

DIRECTORATE GENETIC RESOURCES
Private Bag X973, Pretoria, 0001
Harvest House Room 167,
30 Hamilton Street,
Arcadia, Pretoria, 0002
Tel: (+27) 12 319 6382, Fax: (+27) 12 319 6298,
E-mail: NompumeleloM@daff.gov.za

APPLICATION FOR AUTHORISATION TO EXPORT LMO'S FROM SOUTH AFRICA THAT ARE DESTINED FOR INTENTIONAL INTRODUCTION INTO THE ENVIRONMENT OF THE PARTY OF IMPORT

Information as required by the Cartagena Protocol on Biosafety and the national biosafety legislation:

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

2. Contact details of the Competent National Authority in South Africa

3. 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)?

4. Name and address of the Competent National Authority or government department engaged with issuance of import permits for LMOs within the Party of Import.

5. Name, address and contact details of importer within the Party of Import.

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

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

8. Port of exit within South Africa (name and city)?

9. The taxonomic status, common name, point of collection or acquisition, and characteristics of the recipient or parental organisms related to biosafety.

10. Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

11. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

12. A description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the LMO.

13. The regulatory status of the LMO within South Africa.

14. The intended use of the LMO in Party of Import and what was it used for in South Africa?

15. The quantity or volume of the LMO to be exported from South Africa?

16. A risk assessment report consistent with Annex III of the Cartagena Protocol on Biosafety.

17. Requirements for safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

18. Results and purpose of any other notifications by South Africa regarding the LMO to be transferred.

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

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

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

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

23. A import permit/letter of authority permitting import by Competent National Authority or government department engaged with issuance of import permits for LMOs within the Part of Import

Directions for the potential exporter:

(This page must be excluded from the documents to be submitted to the Party of Import)

- Please complete all sections of the form CLEARLY.
- In the event that the potential exporter is not able to compile or obtain a risk assessment report, please contact the registrar's office for further direction in this regard.
- A template of the affidavit is obtainable from the Registrar's office.
- Contact details of the competent national authority in SA is the following:
  Ms NL Mkhonza
  Registrar: Genetically Modified Organisms
  Private Bag X973
  Pretoria
  0001
  Tel: +27 12 319 6382
  Fax: +27 12 319 6298
  E-mail: NompumeleloM@daff.gov.za
- Please provide 1 original and 13 copies of the application with confidential information.
- Please provide an additional application containing no confidential information. The latter application will be made available for public scrutiny. **Non-Confidential Business Information copy (NON-CBI copy) - this is your application where you have deleted any information that you regard as confidential business information. Please take note that you must make reference to the specific section of the Promotion of Access to Information Act, 2000 whenever you "delete" information in this application**
- Every potential exporter must submit a notification to the competent national authority within the Party of Import.
  This notification shall contain of –
  - A letter indicating the intent of the potential exporter
  - Completed application form (Annexure A)
- Every potential exporter must inform the Registrar's office if a notification has been submitted to Party of Import. The document must contain the following:
  - The date that your notification has been submitted to the Party of Import.
  - Details of the competent national authority within the Party of Import
  - A copy of the notification
  - The correct fee in terms of the Genetically Modified Organisms Act, 1997
- Please take note that the Part of import may request additional information to the notification. In this event, a copy of the request from the Party of Import, as well as the documents provided in response to the request, must be submitted to the Registrar's office.
- The Party of Import 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 domestic regulatory framework of the Party of Import or acceding to the procedures specified in Article 10 of the CPB.

- If the Party of Import states that they wish to proceed according to their domestic regulatory framework or acceding to the procedures specified in Article 10 of the CPB, please contact the Registrar's office for further directions in this regard.
- Please take note that failure by the Party of Import to acknowledge receipt of a notification shall not imply its consent to the proposed import. If the Party of Import does not acknowledge receipt within 90 days, please contact the Registrar's office for further directions in this regard.
- A permit for exportation will only be issued once the Registrar has received written consent (original) directly from the Competent National Authority or government department engaged with issuance of import permits for LMOs within Part of Import to be submitted with export application
- LMO's exempted from requirement of an export permit under the GMO Act are not necessarily exempted from requirement of an export permit in terms of the Biosafety Protocol.
- ***All permits or letters submitted must be a certified copy of the original documentation if not submitted with the application.***
- A Party is a Party in terms of the Cartagena Protocol on Biosafety.
- **These procedures are also applicable for exports to non-Parties to the Cartagena Protocol on Biosafety**.

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. Centre(s) 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