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

DIRECTORATE GENETIC RESOURCES
Private Bag X973, Pretoria, 0001
Harvest House Room 422, 30 Hamilton Street,
Arcadia, Pretoria, 0002
Tel: 12 319 6382, Fax: 12 319 6329,
E-mail: NompumeleloM@daff.gov.za

APPLICATION FOR GENERAL RELEASE OF GENETICALLY MODIFIED ORGANISMS (GMO's) IN SOUTH AFRICA

PART I

1. BRIEF DESCRIPTION OF THE GENETICALLY MODIFIED PLANT.

Include specific and common names of the plant, the country of origin of the plant and a description of the genetically modified trait.

2. GENERAL RELEASE.

2.1 Detail specific instructions for the storage and handling of the plant, or viable plant parts.

2.2 When will general release be implemented?

2.3 Where will general release take place?

2.4 Detail the type of environment and the geographical areas for which the plant is suited.

2.5 Who will undertake the general release?

2.6 Estimate the amount of production of the genetically modified plant within South Africa per annum, or the amount of viable plant product to be imported into South Africa per annum.

3. DESCRIPTION OF ANY PRODUCT DERIVED FROM THE PLANT

3.1 Identify the part of the plant to be used for the product, the type of product, and the use of the product, the market sector in which the product will be marketed and the trade name of the product.

3.2 Specify the exact conditions of use of the product.

3.3 Provide information on the proposed labelling of the product for marketing.

3.4 State whether the benefits of the product are available in any other non-genetically modified form. If so, state why the genetically modified form should be approved for general release when other, non-modified products are available.

3.5 Detail specific instructions for the storage and handling of viable plant products that will avoid misuse or escape of the genetically modified plant into an environment for which it was not intended.

3.6 Detail the likelihood of the genetically modified plant or its products being exported from South Africa, particularly if such export could result in the introduction of the plant into its centre of origin.

4. BRIEF SUMMARY OF FIELD TRIALS UNDERTAKEN

4.1 Submit a list of previously authorised activities with the GMO in –
(a) South Africa
(b) Other countries.

4.2 Include information on the country, year, location and the authority from which permission was obtained to run the field trials.

4.3 Provide full data on the field performance of the genetically modified plant, including the efficacy of the introduced trait.

5. POLLEN SPREAD

5.1 Identify all methods of pollination applicable to the plant.

5.2 Identify pollinating agents and the distances to which pollen is known to spread.

5.3 Identify any plants in the area of general release that may become cross-pollinated with the genetically modified pollen.

5.4 Describe methods to be used to prevent the spread of genetically modified pollen to wild type plants.

6. SEED DISPERSAL

6.1 If seed is to be sold, state whether the seed is hybrid.

6.2 Describe methods to be used to limit the dispersal of genetically modified seed into the environment.

6.3 If seed dispersal will occur describe what volumes of seed are likely to be dispersed, how this seed will interact in the environment and what long term effects the seed is likely to have on the environment.

7. VEGETATIVE SPREAD OF THE GENETICALLY MODIFIED PLANTS

7.1 Describe methods of vegetative reproduction that are available to the plant.

7.2 Describe methods to be used to limit vegetative spread of the genetically modified plant into the environment.

8. FOREIGN GENES AND GENE PRODUCTS

8.1 Identify all foreign genes in the genetically modified plant.

8.2 Describe the gene products that are derived from the foreign genes.

8.3 Describe the biological activity associated with the foreign gene products.

8.4 Provide information on the rate and level of expression of the foreign genes and the sensitivity of the measurement of the rate and level. State whether expression is constitutive or inducible. Are foreign genes expressed throughout the plant or only in certain organs or tissues?

8.5 Provide protocols for the detection of the foreign genes in the environment including sensitivity, reliability and specificity of the techniques.

9. RESISTANCE

9.1 Detail whether the genetically engineered plant is able to initiate resistance, in any biotic component of the environment, to any biologically active foreign gene product.

9.2 Detail what methods are available to minimise the risk of resistance developing in the environment.

9.3 Detail how resistance will be managed during general release of the genetically modified plant.

10. HUMAN AND ANIMAL HEALTH

Please take cognisance of the requirements pertaining for food and feed safety, as contained in sections 5.1 and 5.2 of the guidelines for use of GMO's (available on website of DoA). You are required to follow these guidelines in compiling the information for your application.

10.1 State whether the genetically modified plant or its products will enter human or animal food chains.

10.2 Detail the results of experiments undertaken to determine the toxicity of the foreign gene products (including marker genes) to humans and animals.

10.3 If the foreign gene products are toxic or allergenic in any way, detail how the general release will be managed to prevent contact with animals or humans that will lead to discomfort or toxicity.

10.4 What are the common/major allergens present in the recipient organism before modification?

10.5 What evidence is there that the genetic modification described in this application did not result in over-expression of the possible allergens indicated in 10.4 i.e. is the expression of the possible allergens in the non-GM counterpart substantially equivalent to that in the GM organism?

10.6 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.

10.7 Further to the question raised above, indicate the proposed health and safety measures that would be applied to safeguard employees during the proposed activity.

10 ENVIRONMENTAL IMPACT AND PROTECTION

11.1 Detail any long-term effect the general release of the genetically modified plant is likely to have on the biotic and abiotic components of the environment.

11.2 Provide data and information on ecosystems that could be affected by use of the plant or its products.

11.3 Specify what effect the general release of the genetically modified plant will have on biodiversity.

11.4 Specify the measures to be taken in the event of the plant or product being misused or escaping into an environment for which it is not intended.

11.5 If the foreign genes give rise to crops resistant to agrochemicals, provide information on the registration of the agrochemicals to be used on the crop.

12 SOCIO-ECONOMIC IMPACTS

12.1 Specify what, if any, positive or negative socio-economic impacts the genetically modified plant will have on communities in the proposed region of release. The information may include but is not limited to information on the impact on the following –

(a) The continued existence and range of diversity of the biological resources

(b) Access to genetics and other natural resources previously available
(c) Cultural traditions, knowledge and practices
(d) Income, competitiveness or economic markets and
(e) Food security

13 MONITORING AND ACCIDENTS

13.1 Indicate the methods and plans for monitoring of the GMO in the case of an accidental release in an approved region in terms of the stewardship program to be implemented

13.2 Indicate any emergency procedures that will be applied in the event of an Accident

14 PATHOGENIC AND ECOLOGICAL IMPACTS

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

15 WASTE DISPOSAL

15.1 Where only a portion of the genetically modified plant will be used for the product, how will the unused plant parts be disposed of?

16 RISK MANAGEMENT

16.1 Please indicate any risk management measures that users of this trait will have to adhere to with regard to commercial planting and use.

17. MONITORING PLAN

17.1 Please indicate a monitoring plan which encompasses but does not exclude the following: in addition to current prescripts of the application, a monitoring plan that addresses the following
(i) pollen spread,
(ii) seed dispersal,
(iii) vegetative spread of genetically modified plants,
(iv) foreign genes and products,
(v) resistance,
(vi) environmental impact and protection,
(vii) pathogenic and ecological impacts,
(viii) waste disposal and
(ix) risk management.
(x) Also refer to requirements in terms of Environmental Risk Assessment Framework for genetically modified organisms

18. POST MARKET MONITORING PLAN FOR THE EVENT INTENDED FOR GENERAL RELEASE

18.1 Please indicate a post market monitoring plan which encompasses but does not exclude the following, where applicable: in addition to current

prescripts of the application, a post market monitoring plan that addresses the following

(i) Insect resistance management
(ii) Direct and indirect impacts on non target organisms (NTO)
(iii) Weed resistance management
(iv) General observations
(v) Proposed actions (including training and education)
(vi) Reporting procedures
(vii) GPS co-ordinates and mapping
(viii) Also refer to requirements in terms of Environmental Risk Assessment Framework for genetically modified organisms

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

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

- Please complete all relevant sections of the questionnaire CLEARLY.
- Please provide 1 original and 15 copies (9 additional copies if application for a crop with no previous general release approval) 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).
  Please confirm with the Office of the Registrar with regard to submission of electronic applications
- Please provide an additional hard copy and electronic version of the application containing no confidential information. **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** This copy must be clearly marked: NON-CONFIDENTIAL, and will be made available for public scrutiny. This copy of the application must be submitted to the Registrar one day after placing of the public notices.
- 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
- Please provide an electronic and hard copy of a risk assessment conducted in accordance with Annex III of the Cartagena Protocol on Biosafety and in the format prescribed below.
- 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 submit all relevant documentation to the Registrar at the address indicated in the application form.
- The appropriate fee stipulated under the GMO Act must accompany the application. Please note that the Registrar's office does not accept cash.

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