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

DIRECTORATE BIOSAFETY
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APPLICATION FOR CONTAINED USE OF GENETICALLY MODIFIED ORGANISMS (GMO's) IN SOUTH AFRICA

1 DETAILS OF THE FACILITY WHERE THE WORK IS TO BE CARRIED OUT

- Name and address of the organisation
- Department involved
- Contact details
- Has the facility been registered for work with GMO's? If so, provide the registration number.

2. DETAILS OF THE PERSON RESPONSIBLE FOR CARRYING OUT THE WORK

- Title, Initials and Surname
- Position within company
- Contact details

3. TITLE OF THE PROJECT

4. PURPOSE OF THE ACTIVITY TO BE UNDERTAKEN

5. COMPLETE RISK ASSESSMENT (HUMAN AND ENVIRONMENT) CONTAINING THE FOLLOWING INFORMATION

- Hazard identification
- Assessment of the exposure to the hazard and the consequences of that exposure
- Assessment of the level of risk (by consideration of the magnitude of the harmful consequences and likelihood of their being realised)
- Selection and assignment of appropriate control measures (risk management)

6. CHARACTERISTICS OF THE DONOR, RECIPIENT OR (WHERE APPLICABLE) PARENTAL ORGANISM (Kindly take note that not all the information is applicable to the donor, recipient and parental organism)

- Give the name, species, subspecies and strain of the organism
- What is the degree of relatedness between the donor/recipient organism in relation to which the assessment is being carried out?
- What is the source of the organism?
- Describe the reproductive cycle of the organism?
- What is the history of prior genetic modifications to the organism?
- What is the stability of the genetic traits of the organism?
- Give the nature of the pathogenicity, virulence, infectivity, toxicity and vectors of disease transmission of the organism.
- Give the base sequence, frequency of mobilisation and specificity of the organism's indigenous vectors?
- Give information on the presence of genes in the organism, which confers resistance.
- Give the host range of an organism that is a parasite or pathogen.
- Give the organism's other potentially significant physiological traits, and the stability of those traits.
- What is the organism's natural habitat and geographical distribution?
- What are the climatic characteristics of the organism's natural habitat?
- Describe the significant involvement of the organism in environmental processes, including nitrogen fixation and pH regulation.
- Describe the interaction of the organism with other organisms in the environment and its effect on those organisms, including its likely competitive or symbiotic properties.
- What is the ability of the organism to form survival structures, including seeds, spores or sclerotia?

7. CHARACTERISTICS OF THE MODIFIED ORGANISM

- Supply an identification name for the GMO
- Give a description of the modification, including the technique used or proposed to be used to introduce a vector or insert into the organism.
- What is the nature and source of the vector introduced into the organism?
- Give the function of the genetic modification and/or of the new nucleic acid?
- Give the structure and amount of any vector or donor nucleic acid remaining in the final construction of the modified organism.
- Give the frequency of mobilisation of the inserted vector or the genetic transfer capability.
- What is the rate and level of expression of the new genetic material in the organism, and the method and sensitivity of measurement of that rate and level?
- Give the activity of the expressed protein.

8. HUMAN HEALTH CONSIDERATIONS

- Give the toxic or allergenic effects of viable and non-viable organisms and/or their metabolic products (if any)?
- Provide product hazards.
- Give a comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity.
- What is the capacity for colonisation of humans?

- If the organism is pathogenic to humans, what characteristics are necessary to be immuno competent?
- Describe the diseases caused, and mechanism or pathogenicity including invasiveness and virulence.
- What is the communicability?
- Give the infective dose.
- What is the host range and possibility of alteration?
- What is the possibility of survival outside of human host?
- Give the presence of vectors or means of dissemination?
- What is the biological stability?
- Identify any antibiotic resistance patterns.
- Give the availability of appropriate therapies.
- 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.

9. ENVIRONMENTAL CONSIDERATIONS

- Give the factors affecting survival, multiplication and dissemination of the modified organism in the environment.
- Identify available techniques for detection, identification and monitoring of the modified organism in the environment.
- Identify available techniques for detecting transfer of the new genetic material to other organisms.
- What are the known and predicted habitats of the modified organism?
- Determine the ecosystems to which the modified organism could be disseminated as a result of an escape.
- Determine the anticipated mechanism and result of interaction between the modified organism and the organisms that might be exposed in case of the escape of the organism?
- Describe the known or predicted effects of the organism on plants and animals, including pathogenicity , infectivity, toxicity, virulence, vector or pathogen allergenicity, colonisation, predation, parasitism, symbiosis and competition.
- What is the known or predicted involvement of the organism in biogeochemical process, including nitrogen fixation and pH regulation?
- Determine the availability of methods for decontamination of the area, in case of release to the environment.

10. MONITORING AND ACCIDENTS

10.1 Indicate the methods and plans for monitoring of the GMO

10.2 Indicate any emergency procedures that will be applied in the event of an accident

11. PATHOGENIC AND ECOLOGICAL IMPACTS

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

12. 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 to be submitted to the Registrar's office)

- Activities with GMO's for research and academic purposes, conducted at containment levels 1 and 2 (determined through a risk assessment conducted by the officer in charge) within a laboratory or growth room in an academic or research facility, are exempted from the requirement of a contained use permit in terms of Regulation 2(2). A contained use permit is required once the research is scaled up from basic research to product development, or when conducting the activities in a greenhouse or when the containment level is 3 and above.
- Please provide 1original 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).
- Please provide an additional hard copy of the application containing no confidential information. The latter application will be made available for public scrutiny.
- 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 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:

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>

C. 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