APPLICATION FOR A PERMIT TO CONDUCT A GMO FIELD TRIAL

INSTRUCTIONS:

Please answer all relevant sections of the form CLEARLY in accordance with the requirements of the Biosafety Act, 2006 and Biosafety Regulations published under Government Notice No. 210

Please return your completed application to the: ***The Registrar: Biosafety Council, National Commission on Research Science and Technology ERF 490, Platinum Street, Prosperita, Windhoek or Private Bag 13253 Windhoek***

Your application must consist of the following components –

1. Proof of payment of the correct fee (see Annexure 2);
2. Advertisement of Application for Permit for Field Trial relating to Genetically Modified Organism (see Biosafety Regulations, Regulation 36)
3. Risk assessment report and risk management plan;
4. Emergency response plan (see Annexure 1)
5. One original and 2 copies of the application with confidential information for use by the regulatory bodies appointed in terms of the Biosafety Act. This copy must be clearly marked: CONFIDENTIAL. Note that under Section 43 of the Biosafety Act, information may only be designated as commercially confidential if it is declared as such by the Council as a result of a written application;
6. Please provide 10 hard copies and a digital format of the application containing no confidential information. This copy must be clearly marked: NON-CONFIDENTIAL.

NEW		**AMMENDMENT**		**RENEWAL**		**CANCELLATION**	

1. GENERAL INFORMATION:

Name of Applicant:	
Name of Company/ Organization:	
Physical Address:	
Postal Address:	
Telephone Number:	
Email Address:	

2. DETAILS OF PROPOSED FIELD TRIAL:

Brief description of the GMO	
Intended function(s) of the genetic modification(s)	
GM traits of GMO	
Aim of proposed trial release	
Description of proposed trial release	

3. CHARACTERISTICS OF THE HOST OR UNMODIFIED RECIPIENT ORGANISM:

Specific and common names of the unmodified recipient or host organism																			
Natural habitat, geographic distribution, geographic origin, and centres for diversity																			
Does the unmodified recipient organism or host have any adverse effect on:	Humans	Y		Animals	Y		Plants	Y		Agricultural Production	Y		Environment	Y	
		N			N			N			N			N	
Provide information on any known toxins, anti-nutrients and allergens produced by the host or unmodified recipient organism																			
Provide information on how the host or unmodified recipient is usually utilised in agriculture, forestry, medicine, etc.																			
Reproduction																			
Provide detailed information on the mode(s) of reproduction																			
Provide detailed information on specific factors affecting reproduction																			
Provide detailed information on the generation time																			
Survivability in the environment																			
Provide details on structures produced by the host or unmodified recipient for survival or dormancy																			
Provide information on specific factors affecting survivability																			
Provide information on any tendency for weediness or evidence of allelopathy																			
Dissemination in the environment																			
Provide details on how the host or unmodified recipient may disseminate in the environment																			
Provide information on specific factors affecting dissemination																			

4. INSERTED OR DELETED NUCLEIC ACID SEQUENCES AND THE GMO:

Scientific and common names of the donor organism(s)	
Natural habitat, geographic distribution, geographic origin, and centres of diversity of the donor organism(s)	
Provide a description of the methods used to produce the GMO	
Describe the nature and source of any vector(s) used for production of the GMO. Provide information on the potential for mobilisation or transfer of the vector(s) to other organisms	

Provide detailed information on the recombinant vector construct(s), including the region of the vector intended for insertion, promoter(s) for expression of the inserted nucleic acid(s), reporter gene(s), and antibiotic resistance gene(s)	
Provide detailed protocols for the specific detection of the GMO in the application. Provide information on the sensitivity, reliability and specificity of the techniques for detection	
Provide information on the nucleic acid sequence(s) inserted or deleted in the GMO	
In the case of insertion(s), a description of the inserted nucleic acid sequence(s), size and function	
Describe the gene product(s) that are derived from the inserted gene(s)	
Describe the biological activity associated with the inserted sequences or their encoded products	
In the case of insertion(s), the copy number of all detectable inserts, both complete and partial	
In the case of deletion(s), a description of the deleted region(s), size and function	
Subcellular location(s) of insert(s) (e.g. nucleus, chloroplasts, mitochondria, or maintained in non-integrated form), and methods for determination of the location of the insert(s)	
The molecular characterisation of the inserted nucleic acid sequence(s) at the insertion site(s)	
Provide information on the expression of the inserted nucleic acid sequence(s) in the GMO:	
Provide information on the rate and/or level of expression of the inserted nucleic acid sequence(s) or inserted gene(s) and the sensitivity of the method of measurement of the rate and level	
State whether expression is constitutive or inducible	
Provide information on the part(s) and/or organ(s) of the GMO, or organ(s) of a host organism to which the GMO is administered, where the inserted sequence(s) or inserted gene(s) are expressed or expression product(s) are targeted	

Provide information on how the GMO differs, or is expected to differ, from the host or unmodified recipient organism in regard to:	
General traits	
Natural habitat and geographic distribution	
Reproduction	
Dissemination/dispersion, including persistence and invasiveness	
Survivability, especially in the spectrum of conditions which are likely to be found in the proposed release area(s) and surrounding environments(s)	
The ability of the GMO to transfer genetic material to other organisms, including bacteria and plants	
Provide information on how the GM plant differs from the recipient organism in general agronomic traits and/or in any other characteristics	
If the foreign genes give rise to crops tolerant to agrochemicals, provide information on the registration of the agrochemicals to be used on the crop	
Effects on humans	
Effects on animals	
Effects on plants	
Effects on agricultural production	
Effects on the environment	
Other effects	

5. PREVIOUS AUTHORISATIONS:

List of previously authorised field trials undertaken by the applicant with the GMO in Namibia (Provide documentation from the body controlling the release)	
List of previously authorised field trials undertaken by the applicant with the GMO in other countries (Provide documentation from the body controlling the release)	
Provide a scientific summary of the field performance of the GMO, including a scientific explanation of the efficacy of the introduced trait(s) for each of the previously authorised field trials. Discuss any factors that might suggest a greater, or a lesser, risk of adverse consequences for the now-	

proposed trial release? (Provide references or reports to support your statements)	

6. FIELD TRIAL GENERAL INFORMATION:

Trial site location	
What quantity of the GMO is to be released, and what are the arrangements for producing the GMO in the quantities required for the field trial?	
What are the arrangements for transporting the GMO to the release site?	
What is the desired duration of the field or clinical trial and the reason for the desired duration?	
Provide details of the data that you intend to gather from the field trial or clinical trial	
Provide details of the experimental design for the field trial or clinical trial	

7. ENVIRONMENTAL IMPACT AND PROTECTION:

Will the GMO or its products enter the human or animal food chains as part of the field or clinical trial experiments? If no, what measures will be taken to prevent human or animal ingestion of the GMO (if relevant)? If yes	
Provide information on the toxicity to humans and animals of the newly expressed protein(s) (including any marker proteins) or new constituents other than proteins	
Provide information on the allergenicity to humans and animals of the newly expressed protein(s) (including any marker proteins)	
Provide information on whether the genetic modification might result in any alteration in expression of the common/major toxicants, anti-nutrients and allergens	
What are the implications of the proposed trial release 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 indicate the proposed health and safety measures that would be applied	

8. MONITORING AND RISK MANAGEMENT PLAN:

Please specify a supervision / monitoring and risk management plan (approach, strategy, method and analysis) that would be implemented for the trial release. The plan should include information on arrangements for storing the GMO in preparation for the trial release, for handling the GMO during the trial release, and for the monitoring of potential hazardous or deleterious effects that may result from the trial release of the GMO	
Indicate any contingency plans and emergency procedures that will be applied in the event of an accident or to deal with extreme conditions such as storms, floods, and fires during the course of the trial release	
Please specify the provisions to remove 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	

9. REPRODUCTION AND SEXUALLY COMPATIBLE SPECIES:

For pollen spread, identify pollinating agents and the distances to which pollen is known to spread from the GM plant	
Provide details (including their distribution and proximity to trial release areas) on cultivated species that may become cross-pollinated with the GM pollen	
Give details (including their distribution and proximity to trial release areas) of wild or indigenous species that may become cross-pollinated with the GM pollen	
In the case of vegetative reproduction, describe methods to be used to limit vegetative spread of the GM plant into the environment	
How do seeds of the GM plant interact in the environment and what long-term effects will the seed likely have on the environment?	

10. FIELD TRIAL LOCATION:

GPS coordinates	
Size of Trial	
Type of soil	
Groundwater level	
Topography	
Provide details on flora and fauna, with special consideration of threatened or endangered species	
Climate, especially prevailing winds	
Former use and history of the site	
Intended use of the site after completion of the field trial	
Distance from the nearest human settlements, along with the size of such settlements	
Distance from surface waters	
Distance from listed ecosystems, critical biodiversity areas, and protected areas	
Provide a description of the environment immediately surrounding the trial release site. In addition, provide a map indicating the trial site and the location of, and distance to, nearby (within 3 km) structures (e.g. fences, roads, and buildings), landmarks, and crops	
Describe the barriers planned (physical and/or biological) in order to segregate the experiments comprising the trial release from the surrounding environment	
Provide one or more recent maps (aerial photo or orthophoto) at the appropriate scale with the trial site(s) marked	

11. DETAILS OF PERSON RESPONSIBLE FOR THE FIELD TRIAL SITE:

Title:		Surname:		Full name(s):	
Position:					
Qualification (s)					
Other relevant training					
Contact Details:	Telephone Number:		Email Address:		

12. DECLARATION:

I declare that the particulars given in this application and accompanying supporting documentation are complete and accurate to the best of my knowledge and that I have not withheld any required information.

Name: .....

Signature: .....

Date: .....

ANNEXURE 1

Details to be included in emergency response plan:

(a) The name and postal and physical address of the applicant;

(b) The telephone number, including the area code and, if applicable, the electronic mailing address and facsimile number of the applicant;

(c) The type and size and means of containment use with regard to the GMO or GMO product to which the emergency response plan relates;

(d) The geographical area covered by the emergency response plan;

(e) The contact number, including the area code, to call to have the emergency response plan activated immediately;

(f) A description of the emergency response capabilities available to the person in possession of the GMO or GMO product including the contact number of persons qualified to telephonically give technical advice about the GMO or GMO product involved;

(g) The contact number of the person or persons qualified and available to give advice and assistance at the site of an emergency;

(h) A list of the equipment which can be transported to and used at the site of an emergency;

(i) A general description of the response actions capable of being taken at the site of an emergency;

(j) A description of the transportation arrangements to bring specialised emergency response personnel and equipment to the site of an emergency;

(k) A description of the communication systems which can be made available at the site of an emergency;

(l) A potential accident assessment, including -

i. a general analysis of how an unintentional or accidental release could occur;

ii. a general description of the potential consequences of an unintentional or accidental release; and

iii. a description of the action expected to be taken in the event of an unintentional or accidental release;

(m) A copy of any formal agreement with a third party for the provision of assistance, where applicable; and

(n) Such additional information as the Council may require.

ANNEXURE 2

Fees

Regulation	Nature of Fee	Fee
6(4)	Application fee for a permit to place on the market genetically modified food or feed	N$ 1000.00
26(4)	Application fee for a contained use permit	N$ 1000.00
21(2)	Application fee for registration of facility	N$ 1000.00
44(2)	Application fee for an environmental release permit	N$ 1000.00
35(2)	Application fee for field trial permit	N$ 1000.00
8(1)	Issue fee for placing on the market permit	N$ 5000.00
28(1)	Issue fee for contained use permit	N$ 5000.00
23(2)	Issue fee for registration of facility certificate	N$ 10,000.00
47(1)	Issue fee for environmental release or field trial permit	N$ 5000.00
37(1)	Issue fee for field trial permit	N$ 5000.00
9(2)	Annual renewal fee for placing on the market permit	N$ 1000.00
29(2)	Annual renewal fee for contained use permit	N$ 500.00
24(2)	Annual renewal fee for certificate	N$ 500.00
48(2)	Annual renewal fee for environmental release permit	N$ 500.00
38(2)	Annual renewal fee for field trial permit	N$ 500.00
14(2)	Fee for inspection of genetically modified food or feed arriving in Namibia	N$ 5000.00