APPLICATION FOR A GMO ENVIRONMENTAL RELEASE PERMIT

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 Environmental Release of Genetically Modified Organism (see Biosafety Regulations, Regulation 46)
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 ORGANISM FOR ENVIRONMENTAL RELEASE:

Brief description of the GMO	
Intended function(s) of the genetic modification(s)	
GM traits of GMO	

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 plant 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																
Provide information on the generation time																
For pollen spread, identify pollinating agents and the distances to which pollen is known to spread. What is the range and distribution of the pollinating agents in Namibia?																
Sexually compatible species																
Provide information on cultivated species, their distribution, and proximity to general release areas																
Provide details of wild species and their distribution and proximity to general release areas																
Provide details of members of the family of plants that are known to be weeds in any environment																
Identify any plants in the area of general release that may become cross-pollinated with the host plant																
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																
Provide information on pollen viability																
Dissemination in the environment																
Provide details on how the plant may disseminate in the environment																
Provide information on specific factors affecting dissemination																

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

Provide a description of the methods used for genetic modification	
Describe the nature and source of the vector used. Provide information on the potential for mobilisation or transfer of the vector to other organisms.	
Provide detailed information on the vector construct and the region intended for insertion, including the source of donor DNA and the size and intended function of each constituent fragment of the region intended for insertion	
Provide information on the sequences actually inserted or deleted in the GM plant:	
The copy number of all detectable inserts, both complete and partial	
In the case of deletion(s), the size and function of the deleted region(s)	
Chromosomal location(s) of insert(s) (nucleus, chloroplasts, mitochondria, or maintained in non-integrated form), and methods for its determination	
The organisation of the inserted genetic material at the insertion site	
Describe the trait(s) and characteristics which have been introduced or modified :	
Identify all inserted sequences and genes in the GM plant	
Describe the gene products that are derived from the inserted genes	
Describe the biological activity associated with the inserted sequences or inserted gene products	
Provide information on how the GMO differs, or is expected to differ, from the host or unmodified recipient organism in regard to:	
General agronomic 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	
Other	
Inserted Sequences	
Provide information on the rate and	

level of expression of the inserted sequences or inserted genes and the sensitivity of the measurement of the rate and level	
State whether expression is constitutive or inducible	
Provide information on the parts of the plant where the inserted sequences or inserted genes are expressed	
Provide protocols for the detection of the inserted sequences or inserted genes in other plants in the environment including sensitivity, reliability and specificity of the techniques	
Provide information on the genetic stability of the inserted sequences	
Provide information on the phenotypic stability of the GM plant	
Provide information on any change in the ability of the GM plant to transfer genetic material to bacteria, plants, or other organisms	

5. RESISTANCE DEVELOPMENT:

Detail whether any component of the environment can develop resistance to any of the foreign gene products in the GM plant	
For a GM plant that will have resistance to a chemical agent (e.g. a herbicide) or biological agent (e.g. a fungal disease) give details of any environmental risks related specifically to that resistance	
Highlight the occurrence of resistance in previous field trials / general releases or in the literature for plants containing the same or similar genes	
Detail what methods are available to minimise the risk of resistance developing in the environment	

6. SUMMARY OF FIELD TRIALS UNDERTAKEN:

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 SADC countries (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 GM plant, including a scientific explanation of the efficacy of the introduced trait for each of the previously authorised activities (Provide references or reports to support your statements)	

7. ENVIRONMENTAL RELEASE 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	

8. HUMAN AND ANIMAL HEALTH:

State whether the GM plant or its products will enter human or animal food chains	
Provide information on the anticipated intake or the extent of exposure to the GM plant	
Provide information on the comparative assessment of the GM plant regarding the choice of comparator and the production of material for the comparative assessment, including locations, replicates and growing seasons	
What evidence is there concerning the potential effects of food processing, including home preparation on food or feed derived from the GMO? Is there any evidence of changes in the heat stability of an endogenous toxicant or the bioavailability of an important nutrient after processing	
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 indicate the proposed health and safety measures that would be applied	
Toxicology	
Detail the results of experiments undertaken to determine the toxicity to humans and animals of the newly expressed proteins (including antibiotic markers) or new constituents other than proteins	
Detail the results of experiments undertaken to determine the toxicity of whole GM food or GM feed	
Provide information on any changes in natural food and feed constituents, especially toxins and anti-nutrients	
Where the GM plant is tolerant to particular agrochemicals as a result of the introduced genes, provide data on possible toxic effects arising from the use of the agrochemical on the crop	
Allergenicity	
What are the common/major allergens present in the recipient organism before modification?	
Detail the results of experiments undertaken to determine the allergenicity of the newly expressed gene products (including antibiotic markers) to humans and animals	
Detail the results of experiments undertaken to determine the allergenicity of whole GM food or GM feed	
What evidence is there that the genetic modification described in this application did not result in over-expression of the possible allergens indicated in 8.5.1, i.e. is the expression of the possible allergens in the non-GM counterpart substantially equivalent to that in the GM organism?	
If the newly expressed 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	
Nutritional assessment	

Detail the results of the experiments done in the nutritional assessment of the GM food or feed. Include information on the baseline used for consideration of natural variations	
Provide information on any changes in natural food and feed constituents	

9. ENVIRONMENTAL IMPACT AND PROTECTION :

Identify any plants in the area of general release that may become cross-pollinated with the GM pollen	
How do seeds of the GM plant interact in the environment and what long term effects will the seed be likely to have on the environment?	
If cross pollination between the GM plants and other plants were to occur, provide details of the likely resulting plants and an assessment of whether they would survive and compete well with other plants	
In the case of vegetative reproduction, describe methods to be used to limit vegetative spread of the GM plant into the environment	
Detail any effects, especially long-term, that the general release of the GM plant is likely to have on the biotic and abiotic components of the environment. Information on the impact on non-target organisms should be provided	
Provide data and information on ecosystems that could be affected by use of the plant or its products	
Specify what effect the general release of the GM plant will have on biodiversity	
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	
Provide an assessment of the likely environmental impact of increased use of the agrochemicals in question, as a result of the introduction of the GM plant	
Please submit an evaluation of the foreseeable impacts, in particular any pathogenic and ecologically disruptive impacts	

10. MONITORING AND RISK MANAGEMENT PLAN :

Please indicate any risk management measures that users of this trait will have to adhere to with regard to commercial planting and use	
Please specify an environmental monitoring plan (approach, strategy, method and analysis) which encompasses but is not limited to the following	
Spread, including vegetative spread, of GM plants	
Environmental impact and protection (focusing on issues such as weed and insect resistance management; direct and indirect impacts on non-target organisms)	
Pathogenic and ecological impacts	
Effects on human and animal health	
Impacts of the cultivation, management and harvesting techniques specific to the GMO	

11. SOCIO-ECONOMIC IMPACTS :

Specify what, if any, positive or negative socio-economic impacts the GM plant is likely to 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	
Income, competitiveness or economic markets	
Food security	
Rural labour	
Access to genetics and other natural resources previously available	
Cultural traditions, knowledge and practices	
The continued existence and range of diversity of the biological resources	

12. GENERAL INFORMATION ABOUT ENVIRONMENTAL RELEASE :

When will environmental release be implemented?	
Location of environmental release	
Detail the type of environment and the geographical areas for which the plant is suited	
Estimate the quantity/volume of production of the GM plant within Namibia per annum, and/or the amount of viable plant product to be imported into Namibia per annum	

Give a description of the intended use of the GMO and/or derived product. Indicate if the derived products are for food/feed or industrial use.	
Identify the parts of the plant to be used for the product, the type of product, and the use of the product as well as the market sector in which the product may be marketed	
Provide information on the proposed labelling of the product for marketing	
State whether the benefits of the product are available in any other non-GM form. If so, state why the GM form should be approved for environmental release when other, non-modified products are available	
State any other countries where the this environmental release has been approved	

13. DETAILS OF PERSON RESPONSIBLE FOR THE ENVIRONMENTAL RELEASE:

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

14. 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