FORM

BSC-F002-V1

APPLICATION FOR A GMO CONTAINED USE 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. Contained use facility registration certificate ;
3. Advertisement of permit application for contained use (see Biosafety Regulations, Regulation 27)
4. Risk assessment report and risk management plan;
5. Emergency response plan (see Annexure 1)
6. 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;
7. Please provide 10 hard copies and a digital 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 Institution/Organization:	
Physical Address:	
Postal Address:	
Telephone Number:	
Email Address:	

2. DETAILS OF THE FACILITY:

Name of Institution/Organization:					
Has the facility been registered for GMOs:	YES		NO		
If YES, provide registration number					
If NO, please complete NCRST-BSC-F001					

3. **DETAILS OF PROPOSED CONTAINED USE ACTIVITY:**

State the purpose of the genetic modification (brief description of proposed activities), including the expected results and the containment levels involved	
List the genetically modified organism(s) involved or intended to be involved	
Describe the recipient, donor and/or parental micro-organism(s) used and, where applicable, the host vector system(s) used	
List the source(s) and the intended function(s) of the genetic material(s) involved in the modification(s)	
State the culture volumes to be used, where applicable	

4. **DETAILS OF PERSON RESPONSIBLE FOR THE PROPOSED ACTIVITY:**

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

5. **WASTE MANAGEMENT INFORMATION:**

Provide details of waste treatment including types of waste, quantities, potential hazards and levels of live genetically modified micro-organisms in the waste	
Provide information on the waste management techniques used, including recovery of liquid or solid waste and inactivation techniques used	
Provide information on the ultimate form and destination of inactivated waste	

6. **ACCIDENT PREVENTION AND EMERGENCY RESPONSE:**

Provide information on the selection and training of laboratory staff and supervision of work	
Provide information on the source of hazards and conditions under which accidents might occur	
Provide information on the area/ room where the GMO will be stored, including how access to the storage area/room is controlled	

Provide information on the preventive measures applied such as safety equipment, alarm systems, containment methods and procedures and available resources	
Provide a summary of the emergency plan prepared prior to commencement of the activity	
Provide information on disinfection and disposal procedures of potentially infective material	
State the guidelines or measures put in place for ancillary and maintenance staff, contractors and visitors	
Provide information on the maintenance and test procedures of ventilation systems, high efficacy particulate air (HEPA) filters, microbiological safety cabinets and other safety equipment	
Provide information on health surveillance which should, where appropriate, include screening procedures including the immune status of the individual, sickness investigation, immunisation procedures, maintenance of baseline serum samples for staff	
State the name and designation of the health and safety officer	
Provide information on the duties of the health and safety officer	

7. **ADVERTISEMENT OF PERMIT APPLICATION FOR CONTAINED USE:**

Advertisement details	Newspaper 1:		Date:	
	Newspaper 2:		Date:	

8. **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) 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