

APPLICATION FOR REGISTRATION OF A GMO CONTAINED USE FACILITY

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 3);
2. Map indicating the position of the facility as well as each unit within the facility;
3. Map indicating floor plan/ layout of the facility;
4. Risk assessment report and risk management plan for each activity within the facility;
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 Institution/Organization:	
Physical Address:	
Postal Address:	
Telephone Number:	
Email Address:	

2. DETAILS OF THE FACILITY:

Name of Institution/Organization:			
Department/Division/Unit:			
Physical Address:			
Postal Address:			
Contact Person:			
Contact Details:	Telephone Number:		Email Address:



3. DESCRIPTION OF FACILITY:

Please tick all relevant boxes

<input type="checkbox"/> Laboratory	<input type="checkbox"/> CL1	<input type="checkbox"/> CL2	<input type="checkbox"/> CL3	<input type="checkbox"/> CL4
<input type="checkbox"/> Greenhouse	<input type="checkbox"/> CL1	<input type="checkbox"/> CL2	<input type="checkbox"/> CL3	<input type="checkbox"/> CL4
<input type="checkbox"/> Growth room	<input type="checkbox"/> CL1	<input type="checkbox"/> CL2	<input type="checkbox"/> CL3	<input type="checkbox"/> CL4
<input type="checkbox"/> Pilot production plant	<input type="checkbox"/> CL1	<input type="checkbox"/> CL2	<input type="checkbox"/> CL3	<input type="checkbox"/> CL4
<input type="checkbox"/> Pilot production plant (please specify)			
	<input type="checkbox"/> CL1	<input type="checkbox"/> CL2	<input type="checkbox"/> CL3	<input type="checkbox"/> CL4

* CL = Containment levels 1 to 4 (see Annexure 1)

4. 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	

5. 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:		



6. 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	

7. 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	



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

CONTAINMENT REQUIREMENTS FOR LABORATORIES AND GREENHOUSES (Greenhouse requirements may be applied to growth rooms where appropriate)

LABORATORY CONTAINMENT LEVEL 1 CHECKLIST

	Meets requirements	Does not meet requirements
Facility		
Bench surfaces impervious to water and resistant to acids, alkalis, solvents and disinfectants		
Wash hand basin or sink in laboratory		
Autoclave on site		
Laboratory doors open outwards		
Adequate GMO storage available		
Disinfectants available for immediate use in the event of spillage		
Eye wash stations/bottles/equipment provided		
Proper signage for ultraviolet light and/or radioactive material		
Laboratory equipment properly labelled		
Radioactive/biohazardous material in refrigerator externally labelled		
Waste disposal procedures posted in laboratory		
Waste segregated in proper containers		
Chemical waste containers tagged, labelled, dated and kept closed		
Chemical waste containers used and disposed of properly		
Active and effective arthropod and rodent control programme		
Work procedures		
Doors closed while working		
Evidence of training provided to staff		
Written work procedures (SOPs) available		
Emergency procedures in place		
GMOs transported within the facility in closed, robust and leak-proof containers		
Work surfaces decontaminated daily and after a spillage		
Evidence of routine maintenance and checking of autoclaves		

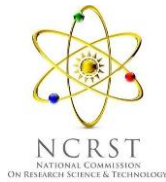


	Meets requirements	Does not meet requirements
Laboratory coats worn in laboratory and removed on leaving laboratory suite		
Personnel to wear closed shoes		
Regular identification and confirmation of purity of microbial strains		
Microwave oven clearly labelled: "No food preparation, laboratory use only"		
Food for human consumption stored outside the laboratory		
Smoking, eating, drinking and the application of cosmetics prohibited in workplace		



LABORATORY CONTAINMENT LEVEL 2 CHECKLIST

	Meets requirements	Does not meet requirements
Facility		
Bench surfaces impervious to water and resistant to acids, alkalis, solvents and disinfectants		
Wash hand basin or sink in laboratory		
Autoclave in building		
Laboratory doors open outwards		
Adequate GMO storage available		
Disinfectants available for immediate use in the event of spillage		
Eye wash stations/bottles/equipment provided		
Proper signage for ultraviolet light and/or radioactive material		
Laboratory equipment properly labelled		
Radioactive/biohazardous material in refrigerator externally labelled		
Waste disposal procedures posted in laboratory		
Waste segregated in proper containers		
Chemical waste containers tagged, labelled, dated and kept closed		
Chemical waste containers used and disposed of properly		
Active and effective arthropod and rodent control programme		
Restricted access to the facility		
Biohazard sign on door		
Lack of floor drains in work area		
Biological safety cabinet available (laminar flow cabinet with HEPA class II filter)		
Work procedures		
Doors and windows closed while working		
Evidence of training provided to staff		
Written work procedures (SOPs) available		
Emergency procedures in place		
GMOs transported within the facility in closed, robust and leak-proof containers		
Work surfaces decontaminated daily and after a spillage		
Evidence of routine maintenance and checking of autoclaves and safety cabinets		



	Meets requirements	Does not meet requirements
Laboratory coats worn in laboratory and removed on leaving laboratory suite		
Personnel to wear closed shoes		
Regular identification and confirmation of purity of microbial strains		
All waste materials to be autoclaved or incinerated before disposal		
Microwave oven clearly labelled: "No food preparation, laboratory use only"		
Food for human consumption stored outside the laboratory		
Smoking, eating, drinking and the application of cosmetics prohibited in workplace		
All procedures likely to generate aerosols to be carried out in biological safety cabinet		
Personnel immunized/tested for agents handled		
Appropriate medical services contacted for medical evaluations, surveillance and treatment of occupational exposures		



LABORATORY CONTAINMENT LEVEL 3 CHECKLIST

	Meets requirements	Does not meet requirements
Facility		
Facility physically isolated		
Laboratory sealable for fumigation		
Ventilation system with continuous airflow into laboratory, extracted air to pass through a HEPA filter		
Ventilation system connected to an emergency power supply and alarmed to indicate system failure		
Switch for ventilation system accessible from outside laboratory in case of fumigation		
Safety lighting to facilitate exit in case of power failure		
Bench and floor surfaces impervious to water and resistant to acids, alkalis, solvents and disinfectants		
Wash hand basin or sink in laboratory, can be operated without being touched by hand		
Autoclave in laboratory suite		
All relevant equipment (centrifuges etc.) available in laboratory suite		
Laboratory doors open outwards		
Windows do not open		
Adequate GMO storage available		
Disinfectants available for immediate use in the event of spillage		
Eye wash stations/bottles/equipment provided		
Proper signage for ultraviolet light and/or radioactive material		
Laboratory equipment properly labelled		
Radioactive/biohazardous material in refrigerator externally labelled		
Waste disposal procedures posted in laboratory		
Waste segregated in proper containers		
Chemical waste containers tagged, labelled, dated and kept closed		
Chemical waste containers used and disposed of properly		
Active and effective arthropod and rodent control programme		
Restricted access to the facility		
Biohazard sign on door		
Lack of floor drains in work area		



	Meets requirements	Does not meet requirements
Biological safety cabinet available (laminar flow cabinet with HEPA class II filter)		
Observation window or alternative present so that occupants can be seen		
Intercom system to facilitate communication with persons outside the laboratory		
Work procedures		
Doors and windows closed while working		
Evidence of training provided to staff		
Written work procedures (SOPs) available		
Emergency procedures in place		
GMOs transported within the facility in closed, robust and leak-proof containers		
Work surfaces decontaminated daily and after a spillage		
Evidence of routine maintenance and checking of autoclaves		
Autoclave to provide a print-out showing temperature and time of sterilization		
Laboratory coats worn in laboratory and removed on leaving laboratory suite		
Personnel to wear closed shoes		
Gloves to be worn for all work with viable organisms		
Regular identification and confirmation of purity of microbial strains		
All waste materials to be autoclaved or incinerated before disposal		
All procedures likely to generate aerosols to be carried out in biological safety cabinet		
Personnel immunized/tested for agents handled		
Appropriate medical services contacted for medical evaluations, surveillance and treatment of occupational exposures		



LABORATORY CONTAINMENT LEVEL 4 CHECKLIST

	Meets requirements	Does not meet requirements
Facility		
Facility physically isolated		
Laboratory sealable for fumigation		
Ventilation system with continuous airflow into laboratory, input and extract air to pass through a HEPA filter		
Ventilation system connected to an emergency power supply and alarmed to indicate system failure		
Negative pressure to be maintained relative to pressure of immediate surroundings		
Switch for ventilation system accessible from outside laboratory in case of fumigation		
Entry to lab via an airlock with two interlocking doors		
Safety lighting to facilitate exit in case of power failure		
Bench, floor, wall and ceiling surfaces impervious to water and resistant to acids, alkalis, solvents and disinfectants		
Shower in laboratory		
Wash hand basin or sink in laboratory, can be operated without being touched by hand		
Double-ended autoclave in laboratory		
All relevant equipment (centrifuges etc.) available in laboratory suite		
Laboratory doors open outwards		
Windows do not open		
Adequate GMO storage available		
Disinfectants available for immediate use in the event of spillage		
Eye wash stations/bottles/equipment provided		
Restricted access to the facility		
Proper signage for ultraviolet light and/or radioactive material		
Laboratory equipment properly labelled		
Radioactive/biohazardous material in refrigerator externally labelled		
Waste disposal procedures posted in laboratory		
Waste segregated in proper containers		
Chemical waste containers tagged, labelled, dated and kept closed		
Chemical waste containers used and disposed of properly		



	Meets requirements	Does not meet requirements
Active and effective arthropod and rodent control programme		
Biohazard sign on door		
Lack of floor drains in work area		
Biological safety cabinet Class III available		
Observation window or alternative present so that occupants can be seen		
Intercom system to facilitate communication with persons outside the laboratory		
Work procedures		
Doors and windows closed while working		
Evidence of training provided to staff		
Written work procedures (SOPs) available		
Emergency procedures in place		
GMOs transported within the facility in closed, robust and leak-proof containers		
Work surfaces decontaminated daily and after a spillage		
Inactivation of GMOs in effluent from the hand washing sinks or drains and showers and similar effluents		
Evidence of routine maintenance and checking of autoclaves		
Autoclave to provide a print-out showing temperature and time of sterilization		
Laboratory coats worn in laboratory and removed on leaving laboratory suite		
Personnel to wear closed shoes		
Gloves to be worn for all work with viable organisms		
Regular identification and confirmation of purity of microbial strains		
All waste materials to be autoclaved or incinerated before disposal		
All procedures likely to generate aerosols to be carried out in biological safety cabinet Class III level		



GREENHOUSE CONTAINMENT LEVEL 1 CHECKLIST

	Meets requirements	Does not meet requirements
Facility		
Frame may be aluminium, steel, wood or pipe		
Glazing may be standard greenhouse glass or plastic material		
Ventilation may use roof/side vents, fans, cooling pads, fog system		
Floors may be gravel, soil or concrete with impervious walkways		
Drains discharge into groundwater or sanitary/storm sewer		
Hinged or sliding entrance doors		
Benches may have solid or porous bottoms		
Appropriate caging and precautions in place to prevent escape of motile organisms		
Work procedures		
Experimental organisms to be biologically inactivated at the end of the experiment		
Pest control programme in place		
Written work procedures available		
Records available of experiments undertaken		

GREENHOUSE CONTAINMENT LEVEL 2 CHECKLIST

	Meets requirements	Does not meet requirements
Facility		
Frame may be aluminium, steel, wood or pipe		
Glazing may be standard greenhouse glass or plastic material		
Ventilation may use roof/side vents, fans, cooling pads, fog system		
Floors should be made of an impervious material. Collection of runoff water may be required depending on organism used		
Drains discharge into groundwater or sanitary/storm sewer		
Hinged or sliding entrance doors with locks at entry		
Screening with standard 30 mesh or higher fly screen		
Benches may have solid or porous bottoms		
Appropriate caging and precautions in place to prevent escape of motile organisms		
Autoclave must be available		



	Meets requirements	Does not meet requirements
Signage stating restricted experiment in process, mention plant names, persons responsible and special requirements		
Material moved in/out of greenhouse must be contained.		
Work procedures		
Access limited to individuals directly involved with experiments		
Experimental organisms to be biologically inactivated at the end of the experiment		
Decontaminate gravel periodically		
Pest control programme in place		
Written manual and work procedures available, should include contingency plans		
Records available of experiments undertaken as well as movement in/out of the greenhouse		

GREENHOUSE CONTAINMENT LEVEL 3 CHECKLIST

	Meets requirements	Does not meet requirements
Facility		
Rigid greenhouse structure with a wind resistant frame.		
Internal walls, ceilings and floors should be resistant to liquids and chemicals		
Glazing must be laminated, strengthened and sealed		
No screening permitted		
Ventilation should have a separate negative pressure system, air supply fans with back-flow damper, and exhaust air should be HEPA filtered		
Floors should be made of an impervious material. Collection and decontamination of runoff water may be required depending on organism used		
Drains should have provision for collection and decontamination of run-off		
Double set of self-closing, locking doors		
Benches should be seamless with bench tops resistant to water and chemicals		
Appropriate caging and precautions in place to prevent escape of motile organisms		
Autoclave must be within the facility; filtered vacuum lines; disinfectant traps for liquid lines		
Hand washing facility with hands free on/off		
Signage stating restricted experiment in process, mention plant names, persons responsible and special requirements. Biohazard symbol if there is a risk to humans.		



	Meets requirements	Does not meet requirements
Material moved in/out of greenhouse or externally decontaminated must be contained.		
Work procedures		
Access restricted to required personnel only		
Experimental organisms to be biologically inactivated at the end of the experiment (including water run-off), equipment and supplies decontaminated		
Pest control programme in place		
Written manual and work procedures available, should include contingency plans		
Records available of experiments undertaken as well as movement in/out of the greenhouse		
Evidence of routine maintenance and checking of autoclave		
Autoclave to provide a print-out showing temperature and time of sterilization		
Protective clothing to be worn to minimize dissemination, and wash hands before leaving facility		
Procedures in place to minimize aerosol creation to reduce contamination		

GREENHOUSE CONTAINMENT LEVEL 4 CHECKLIST

	Meets requirements	Does not meet requirements
Facility		
Reinforced and rigid greenhouse structure with a wind resistant frame.		
Walls, floors and ceiling should form a sealed internal shell that is resistant to liquids and chemicals		
Glazing must be double paned, laminated, strengthened and sealed		
No screening permitted		
Ventilation should be air conditioned and HEPA filtered; closely monitored negative pressure, no roof or side vent allowed		
Floors should be sealed as part of the internal shell, provision for run-off collection and decontamination		
Drains should have provision for collection of run-off, and sewer vents should be filtered		
Double set of self-closing, locking doors with air-lock. Only means of entry/exit is via a shower room through airlock		
Benches should be seamless with bench tops resistant to water and chemicals		
Appropriate caging and precautions in place to prevent escape of motile organisms		



	Meets requirements	Does not meet requirements
Double-door autoclave must be within the facility; self-contained vacuum system, in line filters and back-flow protection for all liquid gas services		
Hand washing facility with hands free on/off		
Signage stating restricted experiment in process, mention plant names, persons responsible and special requirements. Biohazard symbol if there is a risk to humans.		
Material moved in/out of greenhouse or externally decontaminated must be specially packaged. Airlock or decontamination is required for removal		
Supplies and materials must enter through a special chamber		
Work procedures		
Access restricted to required personnel only, and record kept of all entries/exits		
Experimental organisms to be biologically inactivated at the end of the experiment (including water run-off), equipment and supplies decontaminated		
Chemical control programme for pests and pathogens must be in place		
Written manual formally prepared and adopted, personnel required to follow contingency plans		
Procedures in place to report and record all accidents		
Records available of experiments undertaken as well as movement in/out of the greenhouse		
Evidence of routine maintenance and checking of autoclave		
Autoclave to provide a print-out showing temperature and time of sterilization		
Street clothing to be removed, complete change into lab clothing which is autoclaved before laundering		
Procedures in place to minimize aerosol creation		
Standard microbial procedures to decontaminate equipment and containers must be in place		
Laboratory coats worn in laboratory and removed on leaving laboratory suite		
Personnel to wear closed shoes		
Gloves to be worn for all work with viable organisms		
Regular identification and confirmation of purity of microbial strains		
All waste materials to be autoclaved or incinerated before disposal		



ANNEXURE 2

CONTAINMENT REQUIREMENTS FOR PILOT SCALE/LARGE SCALE PRODUCTION OF GENETICALLY MODIFIED MICROORGANISMS

CONTAINMENT MEASURES	CONTAINMENT LEVELS			
	1	2	3	4
GENERAL				
Viable microorganisms should be contained in a system which separates the process from the workplace and wider environment	Required where and to the extent the risk assessment shows it is required	Required	Required	Required
Closed systems located within a controlled area	Not required	Required where and to the extent the risk assessment shows it is required	Required	Required and required to be purpose built
Control of exhaust gases from the closed system	Not required	Required so as to minimise release	Required so as to prevent release	Required so as to prevent release
Control of aerosols during sample collection addition of material to a closed system or transfer of material to another closed system	Required where and to the extent the risk assessment shows it is required	Required so as to minimise release	Required so as to prevent release	Required so as to prevent release
Seals should be designed so as to minimise or prevent release	Not required	Required where and to the extent the risk assessment shows it is required	Required	Required
The controlled area designed to contain spillage of the entire contents of the closed system	Required where and to the extent the risk assessment shows it is required	Required	Required	Required
The controlled area sealable to permit fumigation	Not required	Required where and to the extent the risk assessment shows it is required	Required where and to the extent the risk assessment shows it is required	Required
Biohazard signs posted	Required where and to the extent the risk assessment shows it is required	Required	Required	Required



CONTAINMENT MEASURES	CONTAINMENT LEVELS			
	1	2	3	4
EQUIPMENT				
Entry via airlock	Not required	Not required	Required where and to the extent the risk assessment shows it is required	Required
Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required for any bench	Required for any bench	Required for floor and any bench	Required for bench, floor, ceiling and walls
Specific measures to adequately ventilate the controlled areas in order to minimise air contamination	Required where and to the extent the risk assessment shows it is required	Required where and to the extent the risk assessment shows it is required	Required where and to the extent the risk assessment shows it is required	Required
The controlled area maintained at an air pressure negative to the immediate surroundings	Not required	Not required	Required where and to the extent the risk assessment shows it is required	Required
Extract and input air from the controlled area should be HEPA filtered	Not required	Not required	Required for extract air, optional for input air	Required for input and extract air
SYSTEM OF WORK				
Access restricted to nominated personnel only	Not required	Required	Required	Required
Decontamination and washing facilities provided for personnel	Required	Required	Required	Required
Personnel should shower before leaving the controlled area	Not required	Not required	Required where and to the extent the risk assessment shows it is required	Required
Written procedures and records of staff training	Not required	Not required	Required	Required
WASTE				
Inactivation of GMOs in effluent from hand washing sinks and showers or similar effluents	Not required	Not required	Required where and to the extent the risk assessment shows it is required	Required



CONTAINMENT MEASURES	CONTAINMENT LEVELS			
	1	2	3	4
Inactivation of GMOs in contaminated material and waste including those in process effluent before final discharge	Required by validated means	Required by validated means	Required by validated means	Required by validated means



ANNEXURE 3

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