NCRST
NATIONAL COMMISSION
ON RESEARCH SCIENCE & TECHNOLOGY

User Guide

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Title:	GUIDELINES FOR ENVIRONMENTAL RELEASE OF GENETICALLY MODIFIED ORGANISMS UNDER THE BIOSAFETY ACT, 2006 (ACT NO.7 OF 2006) **ENVIRONMENTAL RELEASE GUIDELINES**		
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Signature:			

DEFINITIONS/ ABBREVIATIONS/ ACRONYMS

Environment:	means the complex of natural and anthropogenic factors and elements that are mutually interrelated and affect the ecological equilibrium and the quality of life, and includes – (a) the natural environment being land, water, air, all organic and inorganic material and all living organisms; and (b) the human environment being the landscape and natural, cultural, historical, aesthetic, economic and social heritage and values.
Environmental Release:	an intentional introduction into the environment of a genetically modified organism in accordance with the Biosafety Regulations: Biosafety Act, 2016 and "release into the environment" or "released into the environment" has a corresponding meaning.
Gene flow:	means the transfer of alleles or genes from one population to another.
GMO:	means "Genetically Modified Organism".
Permit:	means a permit issued under section 25 of the Biosafety Act, 2006 to conduct any dealings with a genetically modified organism as authorized by the permit.
Risk assessment report:	means a risk assessment report as contemplated in section 23 of the Biosafety Act, 2006.
Risk management plan:	means the area where one or more field trials of genetically modified plant species may be grown.
Sexually compatible:	means the ability of a plant to cross-pollinate with other cultivated plants of the same species, or with wild plants of a related species, and form viable hybrids without human intervention.

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1. PURPOSE

The purpose of this document is to provide guidance to any applicant who intends to undertake an environmental release of Genetically Modified plants in Namibia These guidelines must be read together with the Biosafety Regulations (Government Notice No. 210) and Biosafety Act, 2006 (Act no 7 of 2006). The information presented in these guidelines do not preclude the applicant from any other requirements within the legislative frameworks of Namibia.

2. SCOPE

These guidelines shall apply to all environmental releases of genetically modified plants in Namibia. NORMATIVE AND INFORMATIVE

3. REFERENCES

3.1 Normative

Biosafety Act, 2006 (Act No. 7, 2006)

Biosafety Regulations: Biosafety Act, 2006 (Government Notice No. 210)

Environmental Management Act, 2007 (Act No. 7 of 2007)

3.2 Informative

FAO (Food and Agriculture Organization of the United Nations). 2011. *Biosafety Resource Book: Test and Post-Release Monitoring of Genetically Modified Organisms (GMOs)*, Geneva. Available at www.fao.org/docrep/014/i1905e/i1905e03.pdf.

EFSA (European Food Safety Authority). 2011. *Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants*, Parma, Italy.

Michigan State University. 2002. *Biosafety and Risk Assessment in Agricultural Biotechnology*, Michigan, USA.

4. GENERAL RULES

4.1 RISK ASSESSMENT AND RISK MANAGEMENT PLAN FOR AN ENVIRONMENTAL RELEASE

a) In order to evaluate risks posed to the health and safety of humans and animals and the environment, whether direct or indirect or whether immediate or delayed, and related

matters, by an environmental release, an applicant for an environmental release permit must, prior to submitting the application, undertake a risk assessment and draw up a risk assessment report and risk management plan in accordance with Annexure C of the Regulations: Biosafety Act, 2016.

b) In undertaking such risk assessment, the applicant must give particular attention to the risks to the health and safety of humans and animals and the environment posed by the environmental release of a GMO.

4.2 PURPOSE OF ENVIRONMENTAL RELEASE SAFETY ASSESSMENT

The specific purpose of safety assessment is to;

i. Avoid potential of the GMO to become a weed of agriculture or be invasive of natural habitats,

ii. Avoid potential for gene flow to sexually compatible plants whose hybrid offspring may become more weedy or more invasive,

iii. Avoid potential for the GMO to become a plant pest,

iv. Avoid potential impact of the GMO or its gene products on non-target species, including humans,

v. Avoid potential impact on biodiversity.

4.3 PLANTING

Environmental Release must not be carried out prior to the authorization date given in the official Terms and Conditions of a permit issued by the Biosafety Council. In terms of the Environmental Management Act, 2007 (Act No. 7 of 2007) an assessment report and environmental clearance certificate is required for the environmental release of a GMO into the environment.

4.4 ENVIRONMENTAL RELEASE SITE PERSONNEL

The permit holder shall ensure that all personnel involved with handling the genetically modified plant materials are trained on the nature of the material being handled and on other requirements of the permit condition.

Where seed or other propagative material is being harvested, a permit holder shall ensure that no such material unintentionally trapped in workers' clothing or bodies is removed from the site.

4.5 STORAGE FACILITIES

a) The regulated plant materials must be stored separately from conventional plant materials in Identifiable, fully enclosed, lockable space (e.g., boxes, almirahs, cabinets, closet etc.).

b) The storage area must be clearly labelled as containing regulated plant material and used exclusively for that purpose.

c) If multiple regulated articles are in storage, they must be within separate, sealed containers.

d) The storage area must be clean and free of any waste or debris.

4.6 IDENTIFICATION OF THE ENVIRONMENTAL RELEASE SITE AND PLOTS

During the growing season and for the period of post-harvest restrictions, the permit holder must make available to the National Commission on Research Science and Technology and keep on site either of the following;

(a) a map showing the location or locations where the applicant intends to release the GMO or GMOs into the environment;

(b) an accurate description in words of the area or;

(c) if necessary to clearly demarcate the area, the coordinates thereof in order to enable an interested person to clearly establish where such area is.

4.7 RECORD OF PLANTING

A Record of planting (i.e. dates of the environmental release and, if applicable, the duration thereof) including a final plot map shall be kept on site and a copy submitted to the Biosafety Council within two weeks after the completion of planting.

4.8 COEXISTENCE MEASURES

a) Management strategies to avoid the planting of transgenic crops in their centers of biodiversity or where wild relatives are present, or using buffer zones to isolate transgenic varieties from conventional varieties must be in place

b) Genetic engineering can be used to alter flowering periods to prevent cross-pollination or to ensure that the transgenes are not incorporated in pollen and developing sterile transgenic varieties

c) Woods and hedges can serve as barriers to air flow, having dual effects of depleting some pollen from the air flow by impaction and filtering. Dense stands of shrubs, herb covers and tree-sized vegetation with full foliage act as catchments for airborne particulates, including pollen.

4.9 MONITORING GENETICALLY MODIFIED PLANTS RELEASED INTO THE ENVIRONMENT

The holder of a permit must at all times have in place, implement and comply with a monitoring plan as part of the risk management plan in accordance with this Annexure C of the Biosafety Regulations

4.9.1 Monitoring of GMOs released into the environment

The objectives of an environmental post market monitoring plans are:

a) to confirm that any assumption regarding the occurrence and impact of potential adverse effects or benefits of the GMO or its use in the environmental risk assessment are correct; and

b) to identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated or intended in the environmental risk assessment.

4.9.2 Case specific monitoring

a) Case-specific monitoring is intended to assess whether GMO-related adverse effects on the environment occur.

b) It is based on specific risks that a particular GMO could present. Case specific monitoring can therefore be regarded as the continuation of the investigations performed during environmental risk assessment where defined hypotheses on possible anticipated effects are tested.

c) The hypotheses can be confirmed or rejected after a defined period of time, after which case specific monitoring can be terminated.

4.9.3 General surveillance monitoring

General surveillance, on the other hand, is intended to detect unanticipated adverse environmental effects that were not identified and considered during pre-market risk assessment.

4.9.4 Examples of parameters for monitoring

a) Changes in the population of target insects as a result of the toxin produced by the GMO

b) Changes in the population of non-target insects as a result of the toxin produced by the GMO -effects on

c) Organisms that normally feed on these non-target insects.

d) Impact on non-target organisms

e) Pollen transfer

f) Persistence

g) Dissemination

h) Insect resistance

i) Transfer of antibiotic resistance genes

j) Changes in bio-diversity

k) Cumulative environmental effects.

4.9.5 HANDLING OF NEW INFORMATION

a) Where there are any changes to a genetically modified organism or of a combination of genetically modified organisms as a result of the environmental release which could have adverse effects on human health and the environment after the Biosafety Council has given its written approval, the applicant shall immediately-

   i. take the measures necessary to protect human health and the environment;

   ii. inform the Biosafety Council in advance of any change or as soon as the unintended change is known or the new information is available; and

   iii. revise the measures specified in the application or approval.

b) Where there are any changes to a genetically modified organism or of a combination of genetically modified organisms as a result of the environmental release which could have

adverse effects on human health and the environment after the Biosafety Council has given its written approval, the Biosafety Council -

i. shall evaluate such information and may make it available to the public; and

ii. may require the applicant to, modify the conditions of, suspend or terminate the environmental release.

4.10 TRANSPORTATION OF GENETICALLY MODIFIED MATERIALS

a) As a condition of a permit, a permit holder must, before the commencement of a placing on the market, contained use, field trial or environmental release activity, draw up and put in place such measures or plans which may mitigate any adverse effects that may arise from an accident or accidental or unintentional release caused by the activity, subject thereto that such measures or plan may form part of the emergency response plan.

b) In the event of an accident or accidental or unintentional release, the relevant permit holder must forthwith inform the Registrar of the accident or accidental or unintentional release as anticipated in section 41 of the Biosafety Act, 2006 by means a report as set out in regulation 51, sub-regulation (3) of the Biosafety Regulations: Biosafety Act, 2016.

c) The report on the accident or accidental or unintentional release must include as much of the following information as is known or ought reasonably to have been known at the time of the accident or accidental or unintentional release of the relevant GMO or GMO product:

d) The permit holder must, if necessary, ensure that the relevant emergency services and persons likely to be affected thereby are informed of the accident or accidental or unintentional release and activate other relevant provisions of the permit holder's emergency response plan.

e) Where the Registrar is notified of an accident, the Registrar must -

i. collect, where possible, the information necessary for a full analysis of the accident or accidental or unintentional release and, where appropriate, make recommendations to avoid a similar accident or accidental or unintentional release in the future and to limit the effects of any such future accident or accidental or unintentional release, and

ii. ensure that all appropriate measures necessary are taken by the permit holder.

f) As anticipated in section 41(3) of the Biosafety Act, 2006, in the event of an accident or accidental or unintentional release, the Council may require the permit holder to defray or

contribute towards any or all reasonable costs incurred, whether by the Council, the Government or any other institution or body, arising from such accident.

5. PROCEDURE

5.1 APPLICATION PROCESS

An application for an environmental release permit must be submitted to the Registrar on the relevant form.

The application form must be accompanied by the following:

a) Application fee of N$ 1000.00;

b) An emergency response plan as set out in regulation 50 of the Biosafety Regulations: Biosafety Act, 2016;

c) The risk assessment report and risk management plan prepared in accordance with and containing the information set out in Annexure 3 of the Biosafety Regulations: Biosafety Act, 2016;

d) A monitoring plan contained in the risk management plan in accordance with Annexure 3 of the Biosafety Regulations: Biosafety Act, 2016;

e) The assessment report and environmental clearance certificate as anticipated under the Environmental Management Act, 2007 (Act No. 7 of 2007);

f) A monitoring plan contained in the risk management plan in accordance with Annexure 3 of the Biosafety regulations which must include a proposal for a time period for the monitoring plan, which may vary from the anticipated duration period of the permit.

5.2 Submission of applications

Completed applications with all relevant technical documentation must be hand delivered in hard copies (at least 10 copies) and electronic format to the Office of the Registrar at:

Registrar: Biosafety Council
National Commission on Research Science and Technology
ERF 490, Platinum Street, Prosperita
Windhoek

5.3 Advertisement of Application

According to regulation 46 an applicant must advertise his/her intention to apply for an environmental release permit as contemplated in section 22(4) of the Biosafety Act. A copy of the advertisement together with written confirmation that it has been advertised must be submitted to the office of the Registrar no later than 7 days after submission of the application.

5.3.1 *Purpose of the Advertisement*

The purpose of the advertisement is to inform the public that the applicant is applying for permission to conduct a certain activity, and to request the public to submit comments or objections to the application made.

5.3.2 *Publishing of the Advertisement*

(a) The advertisement must be under a clearly marked heading stating "Advertisement of Application for Permit for Environmental Release of a Genetically Modified Organism".

(b) The application must be advertised once a week for two consecutive weeks in at least two newspapers circulated widely in Namibia.

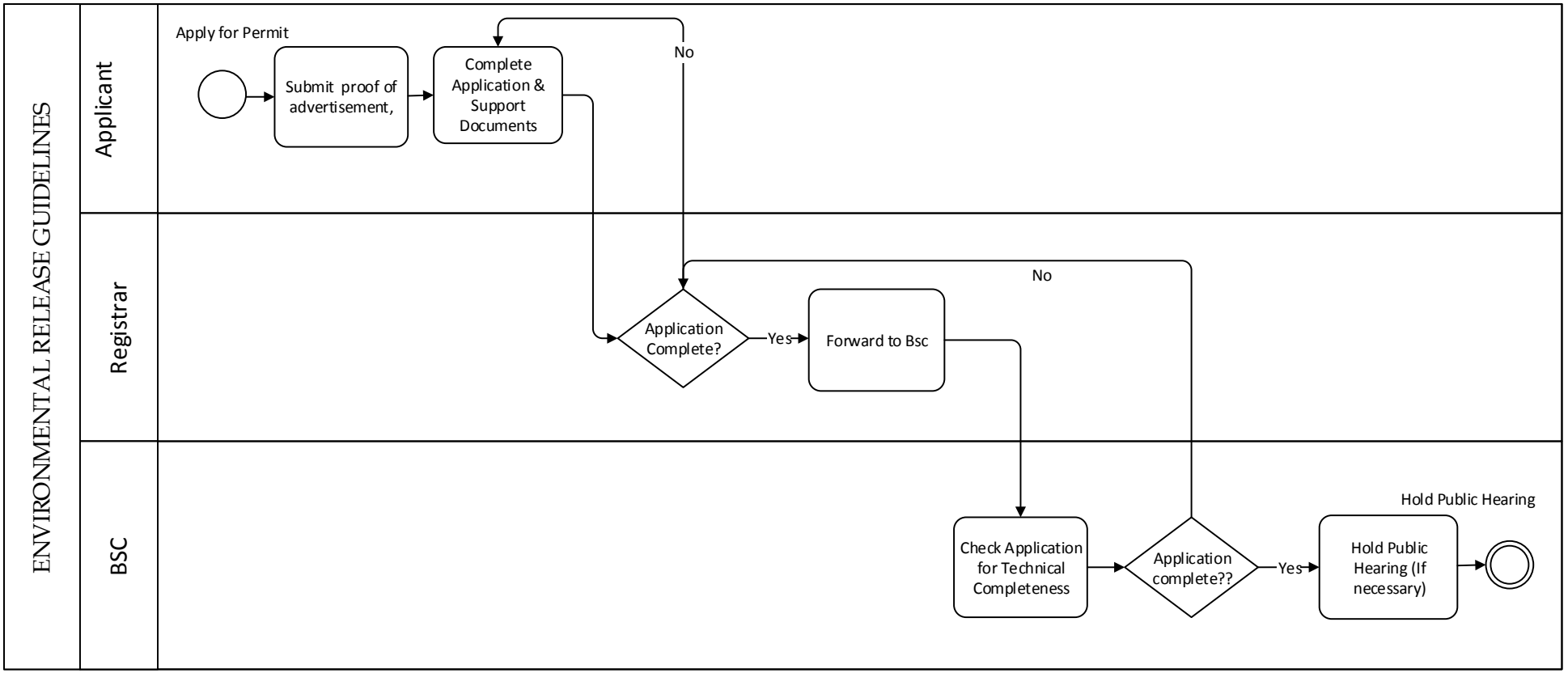
5.3.3 *Content of the Advertisement*

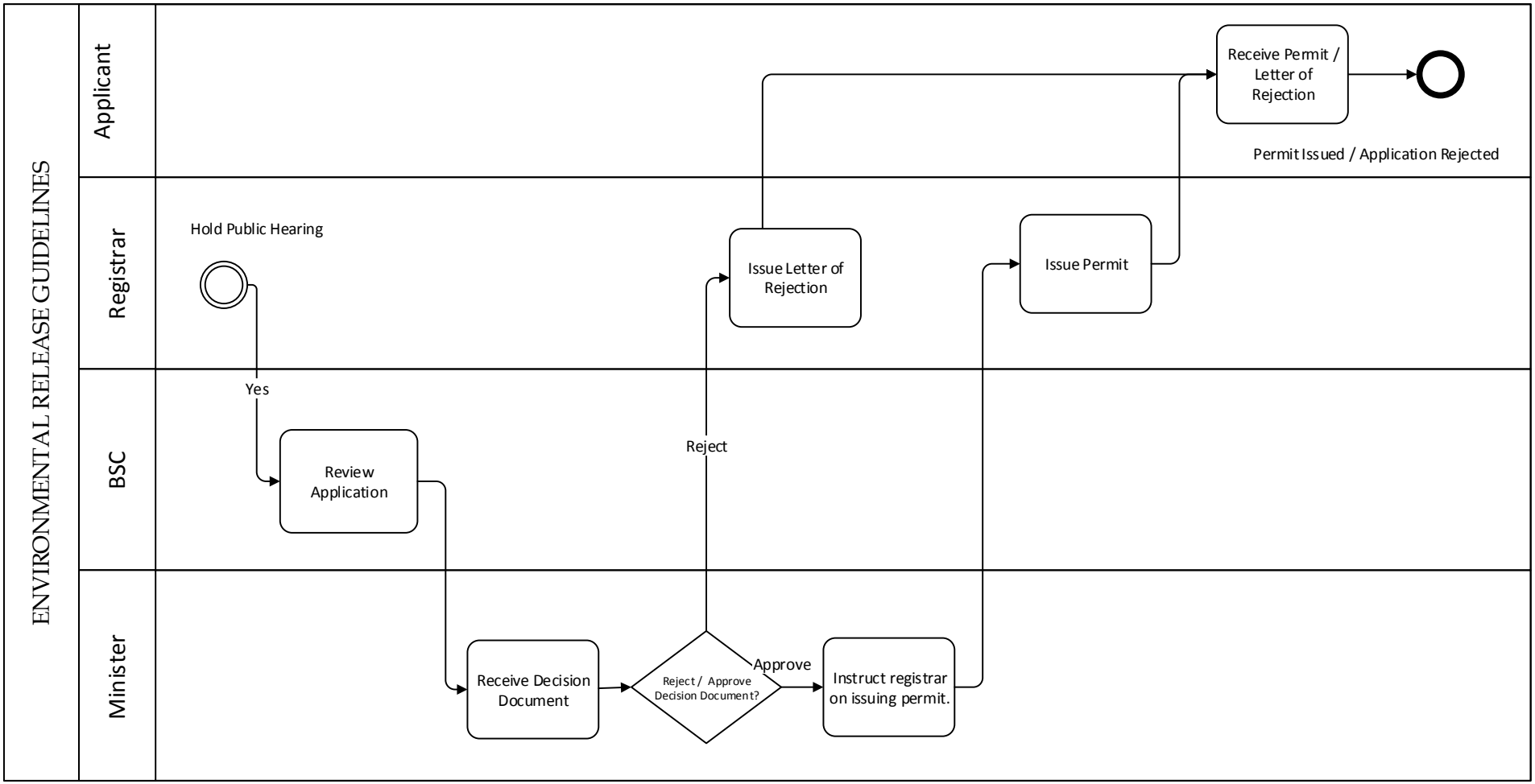
The advertisement must contain the following particulars:

(a) Full name, identification, nationality, address and contact details of the applicant;
(b) Description of the GMO proposed to be released into the environment;
(c) Purpose of the proposed release into the environment;
(d) A map showing the proposed location or locations where the applicant intends to release the GMO or GMOs into the environment;
(e) The anticipated commencement date or dates of the environmental release;
(f) Date on which the application was submitted, together with a list of all information submitted with the application to the Registrar and the physical address and business hours of the Registrar;
(g) An invitation for interested parties to submit comments or objections, in connection with the application, to the Registrar at the address below, within 30 days after the date of the last advertisement:

Hand Delivery:	*Postal Submission:*	*Electronically:*
Registrar: Biosafety Council	Registrar: Biosafety Council	For attention of:
National Commission on Research	National Commission on	Registrar: Biosafety Council
Science and Technology	Research Science and	Email:
ERF 490, Platinum Street, Prosperita	Technology	registrarbiosafety@ncrst.na
Windhoek	Private Bag 13253,	Fax: + 264 61 216 531
	Windhoek	

5.4 Summary of Application Process





6. FORMS

BSC -F001 Application for registration of facility

BSC – F004 Application for GMO Environmental Release

7. REPLACEMENT AND WITHDRAWAL

None

8. REVISION/AMENDMENT HISTORY

Version number	Revision Date	Nature of Amendment