NCRST
NATIONAL COMMISSION
ON RESEARCH SCIENCE & TECHNOLOGY

User Guide

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Title:	GUIDELINES FOR CONDUCTING FIELD TRIALS UNDER THE BIOSAFETY ACT, 2006 (ACT NO.7 OF 2006) **FIELD TRIAL**		
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DEFINITIONS/ ABBREVIATIONS/ ACRONYMS

Event:	means a genotype produced from the transformation of a single plant species using a specific genetic construct.
Field Trial:	means any experimental field trial of a GMO - a) performed under terms, conditions and circumstances which mitigate the impacts, establishment and spread of the GMO on the surrounding environment; and b) which is conducted under conditions known to prevent – i. pollen- or seed-mediated dissemination of the GMO into and within the environment; ii. the persistence in the environment of the GMO or its progeny; and iii. the introduction of the GMO into the human food or animal feed.
GMO:	means "Genetically Modified Organism".
Permit:	means a permit issued under section 25 of the Biosafety Act to conduct any dealings with a GMO as authorized by the permit.
Prohibited plant:	means plants of any species that are sexually compatible with the regulated plant under field conditions, including volunteers that may arise in the isolation area during the conduct of field trials.
Trial Site:	means the area where one or more field trials of genetically modified plant species may be grown.

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1 PURPOSE

The purpose of this document is to provide guidance to any applicant who intends to conduct field trial 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 field trials of genetically modified plants in Namibia.

3 NORMATIVE AND INFORMATIVE REFERENCES

3.1 Normative

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

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

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.

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

4 GENERAL RULES

4.1 PURPOSE OF FIELD TRIALS

The specific purpose of field trial is to;

a) Evaluate and develop new varieties and techniques;
b) Prevent the escape from the trial site of novel genes in pollen, seed-mediated or other plant parts;
c) Prevent genetically modified plant material from entering human food or animal feed pathways;
d) Prevent genetically modified plants from escaping and establishing persistence of its progeny in the environment;

e) Ensure that experimental material remains confined in order to prevent adverse effects on the environment and human or animal health.

4.2 CHARACTERISTICS OF A FIELD TRIAL

A Field Trial of genetically modified plants has several key characteristics:

a) Field trial may be comprised of one or more events of a single plant species;
b) It is an experimental activity;
c) It is done in the open field, thus exposing the plants to the natural environment.
d) Shall not be more than 5 hectares;
e) Access to the field site shall be restricted and controlled;
f) The genetically modified plant material must be confined to the trial site and any volunteers arising from the field trial must be prevented from persisting in the environment.

4.3 PLANTING

Planting of genetically modified plants 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. Areas of non-genetically modified plants used for borders, buffers or border rows may be planted prior to the authorization date, when required.

4.4 FIELD TRIAL SITE PERSONNEL

The permit holder shall ensure that all personnel involved with handling the genetically modified plant materials from receipt of the shipment through the Field trial to devitalization 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 EQUIPMENT

All equipment used to plant genetically modified plants in a field trial shall be cleaned of any propagative genetically modified plant material before being moved from the trial site. Appropriate cleaning methods may include, brushing, compressed air, vacuuming or water.

All planting equipment shall be inspected after cleaning and verified to be free of propagative plant material by trial personnel. Disassembly may be required when necessary to verify that the equipment is free of propagative plant material.

4.6 DISPOSAL OF EXCESS GENETICALLY MODIFIED PLANT MATERIALS

Any excess planting material, and any propagative material recovered during the cleaning of equipment, shall be recorded and devitalized by heat, incineration, deep burial (2 meters), chemical treatment, grinding or crushing.

4.7 IDENTIFICATION OF THE TRIAL SITE AND PLOTS

During the growing season and for the period of post-harvest restriction, the trial site shall be identified with the following signage:

a) Description of plant undergoing research;

b) The entry authorization;

c) Border rows (buffer zone);

d) Genetically modified plants ***(Name of the plant under research) – for research purposes only not for food or feed (Board/Sign).***

Each individual genetically modified plant within the trial site shall have a label establishing the specific identity of that genetically modified plants including treatments. Requirements for trial site maps and an example of an appropriate map are found in Figure 1 below.

a) Detailed sign of a field trial (including authorization)

b) Security Personnel

c) Buffer zone

d) Dumping fill

e) Isolation distance

f) Description of a plant under research

g) Entrance for both cars and people with disinfectant baths.

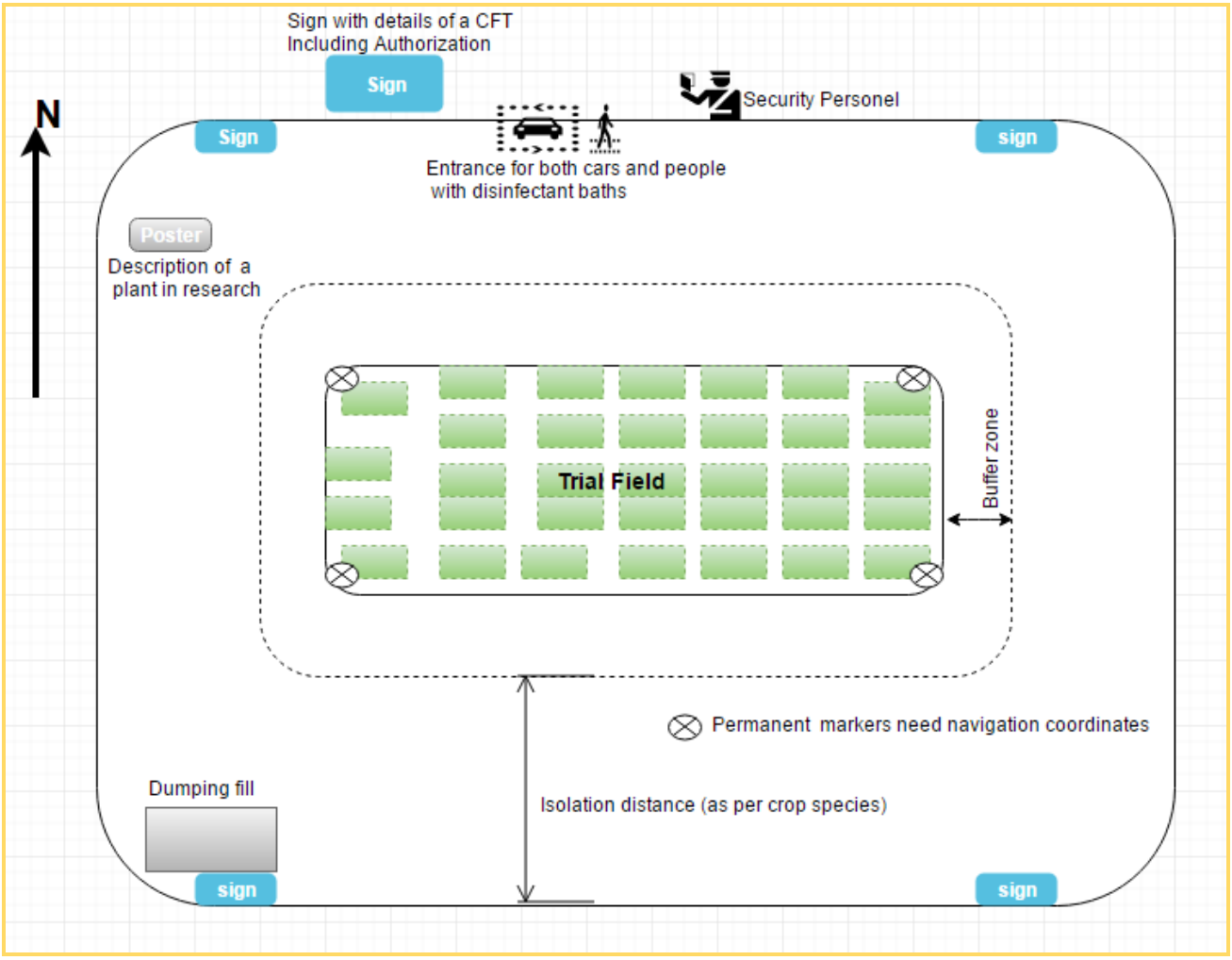


Figure 1. Field trial site Map

4.8 RECORD OF PLANTING

A Record of planting (i.e. description of plants, planting date, number of plants etc.) 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.

4.9 REPRODUCTIVE AND SPATIAL ISOLATION

To prevent the escape of genes in pollen (pollen-mediated gene flow) from the trial site, genetically modified plants shall be isolated from sexually compatible plant species in approved proximity to the trial site. The techniques used vary with the particular crop species. Spatial isolation distance shall be monitored at a given interval as indicated for some species, on Table.1.

Table 1. Spatial Isolation of some crop common species.

Plant	**Minimum Spatial Isolation Distance (m)**
Maize (*Zea mays*)	200 m from other Maize spp.
Cassava (*Manihot esculeta)*	100 m from other Cassava spp.
Cotton (*Gossypium spp.*)	200 m from other Cotton spp.
Millet (*Pennisetum spp.)*	200 m from other Millet spp.
Wheat (*Triticum spp.)*	50 m from other Wheat spp.
Potato (Solanum *spp.)*	400 m from other Potato spp.
Rice (*Oryza spp.*)	3 m from other Rice spp.
Sorghum (*Sorghum spp.)*	200 m from other Sorghum spp.
Tomato (*Solanum spp.)*	200 m from other Tomato spp.
Soya Bean (*Glycine spp.)*	10 m from other Soya Bean spp.
Water Melon (*Citrillus spp.*)	400 m from other Water Melon spp.

Adapted from: Biosafety Resource Book: Test and Post-Release Monitoring of Genetically Modified Organisms (GMOs)

4.10 DISPOSAL OF MATERIAL FROM FIELD TRIALS.

No harvested material or any other product from a Field trial may be used for human or animal consumption.

Seed or other plant material harvested from field trials (including border rows) must be disposed i.e. by, dry heat, steam heat, incineration, deep burial (2 meters), chemical treatment, or crushing or burying on the trial site.

Composting of harvested materials as a method for the disposal of plant materials is prohibited.

The field trial site must be cleaned within 14 days after harvesting.

4.11 POST-HARVEST RESTRICTIONS, LAND USE AND MONITORING

Post-harvest monitoring period for various plant species shall be done as per the Table 2 below, case-by-case basis should also apply when necessary.

Table 2. Land use **restriction and monitoring intervals of some crop species.**

Plant	**Post-harvesting regular Monitoring Intervals**	**Post-harvesting Monitoring Intervals during rainy season**	**Period of Post-Harvest Land Use restriction**
Maize (*Zea mays*)	Every month	Every 2 weeks	2 years
Cassava (*Manihot esculeta)*	Every 3 months	Every month	2 years
Cotton (*Gossypium spp*.)	Every 2 months	Every month	2 years
Millet (*Pennisetum spp.)*	Every month	Every 2 weeks	2 years
Wheat (*Triticum spp.)*	Every month	Every 2 weeks	2 years
Potato (Solanum *spp.)*	Every month	Every month	2 years
Rice (*Oryza spp*.)	Every 2 months	Every month	2 years
Sorghum (*Sorghum spp.)*	Every month	Every 2 weeks	2 years
Tomato (*Solanum spp.)*	Every month	Every 2 weeks	2 years
Soya Bean (*Glycine spp.)*	Every 3 months	Every 2 weeks	2 years
Water Melon (*Citrillus spp*.)	Every month	Every 2 weeks	2 years

Adapted from: Biosafety Resource Book: Test and Post-Release Monitoring of Genetically Modified Organisms (GMOs)

The following measures shall be implemented during this Post-harvesting period:

a) The area under restriction must be monitored during the post-harvest period to ensure that any prohibited plants (volunteers or sexually compatible species) are destroyed prior to flowering.
b) No plant species may be planted in the restricted area during the post-harvest period.
c) The restricted area is limited to the area of the trial site and does not include the surrounding isolation area.
d) In situations where a breach of reproductive isolation occurred during the performance of the Field trial, the restricted area will then include the trial site and the surrounding isolation area.

4.12 TRANSPORTATION OF GENETICALLY MODIFIED MATERIALS

a) A permit holder must notify the Biosafety Council in writing of any intention to transport genetically modified materials;
b) All genetically modified material transportations must be accompanied by a representative from the Biosafety Council;
c) The Permit holder shall ensure that genetically modified plant material for planting is transported in clearly identified, secure containers and kept separate from non-genetically modified plant material;
d) In the case of accidental release or spillage of genetically modified plant material during transport, recoverable seeds or seedlings shall be collected and rendered non-viable and disposed;
e) The site shall be marked and monitored, and a notification shall be immediately provided to the Biosafety Council. Any plants arising from unrecoverable seed or seedlings must be rendered non-viable and disposed of before flowering.

5 PROCEDURE

5.1 APPLICATION PROCESS

An application for a field trial 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 detailed description of the geographic landscape of the field trial site and adjacent areas as set out in regulation 35, sub-regulation 2(b) of the Biosafety Regulations: Biosafety Act, 2016;

e) Information and test data relevant to identifying the phytosanitary risk including, wild populations of the recipient organism and closely related species;

f) A map of the site where the field trial is to be conducted indicating the information shown in figure 1;

g) A description of the confinement measures as set out in regulation 35, sub-regulation 2 (e) of the Biosafety Regulations: Biosafety Act, 2016;

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

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 36 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 Field Trial relating to 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.

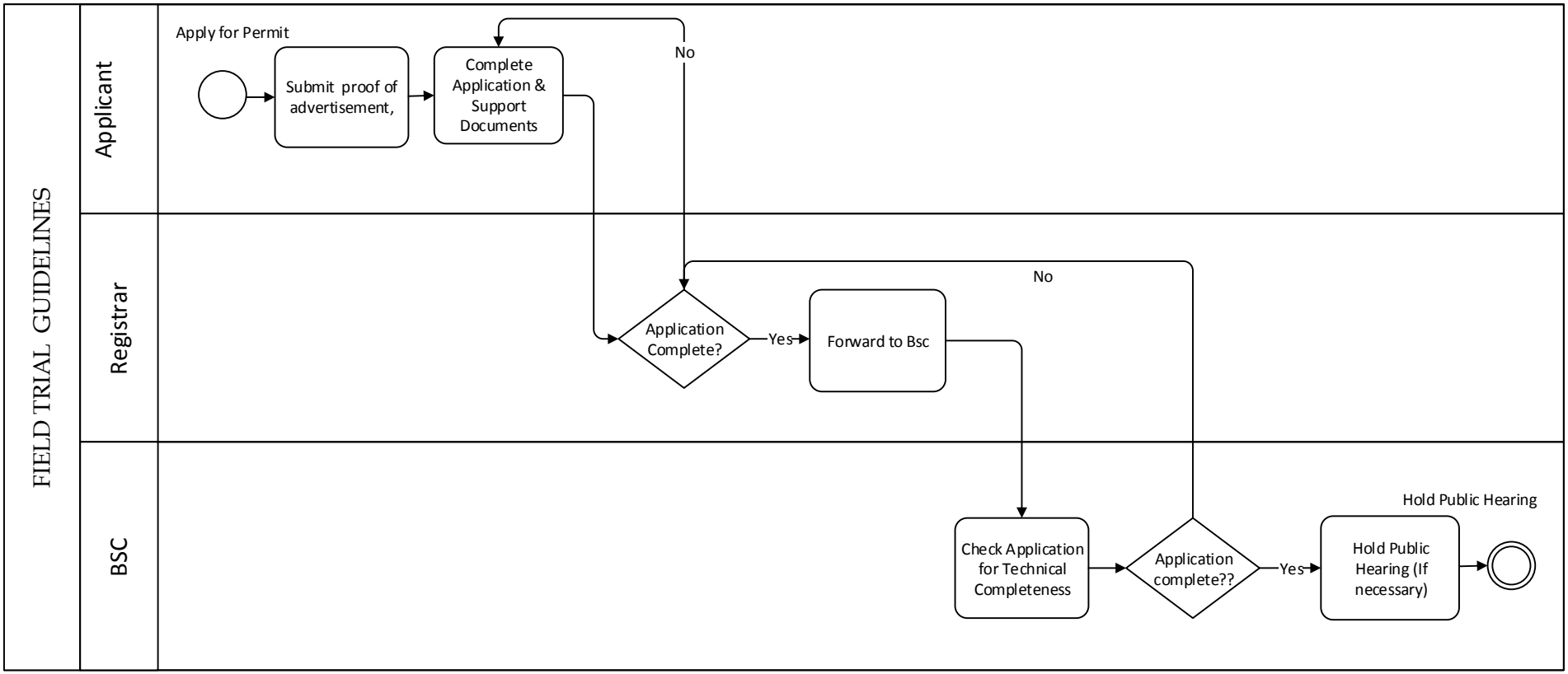
5.3.3 Content of the Advertisement

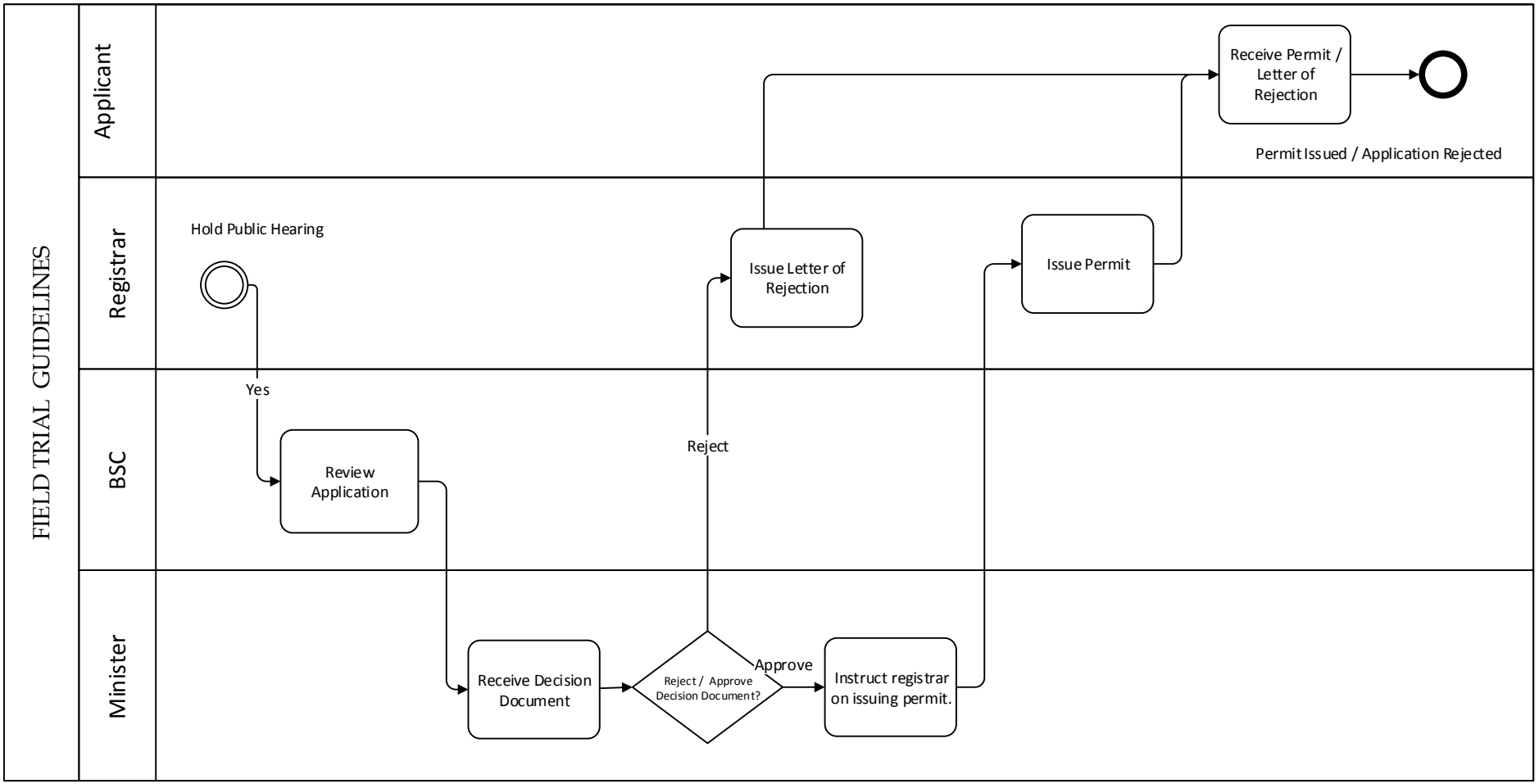
The advertisement must contain the following particulars:

a) Full name, identification, nationality, address and contact details of the applicant;
b) Description of the GMO to which the field trial relates;
c) Purpose of the proposed field trial;
d) A map showing the proposed location or locations where the applicant intends to conduct the field trial;
e) The period of time in which the field trial will be conducted and the anticipated commencement date;
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 – F003 Application for field trail

7 REPLACEMENT AND WITHDRAWAL

None

8 REVISION/AMENDMENT HISTORY

Version number	Revision Date	Nature of Amendment