


NCRST
NATIONAL COMMISSION
ON RESEARCH SCIENCE & TECHNOLOGY

User Guide

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Title:	GUIDELINES FOR PLACING GENETICALLY MODIFIED FOOD OR FEED ON THE MARKET UNDER THE BIOSAFETY ACT, 2006 (ACT NO.7 OF 2016) PLACING ON THE MARKET GUIDELINES		
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DEFINITIONS/ ABBREVIATIONS/ ACRONYMS

Application:	means an application for a placing on the market permit or certificate as contemplated under regulation 6 of the Biosafety Regulations: Biosafety Act 2016 (Government Notice No. 210).
Act:	means to the Biosafety Act, 2006 (Act No. 7 of 2006).
Council:	means Biosafety Council as established under section 5 of the Biosafety Act.
Permit:	means a placing on the market permit issued under regulation 8 of the Biosafety Regulations: Biosafety Act 2016 (Government Notice No. 210).
Placing on the Market:	means the holding of food or feed for the purpose of sale, including offering for sale, or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer from one person to another and “place on the market” or “placed on the market” has a corresponding meaning.
GMO:	means “Genetically Modified Organism”.
GMO product:	means any article, material, substance or thing specified by the Minister under subsection (2) of the Biosafety Act to be a GMO product.
Feed:	means any substance or product, including but not limited to additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.
Food:	means any substance or product, whether processed, partially processed or unprocessed intended to be, or reasonably expected to be, ingested by humans and includes drink, chewing gum and any substance, including but not limited to water, intentionally incorporated into the food during its manufacture, preparation or treatment.
Genetically modified feed:	means feed containing, consisting of or produced from a GMO.
Genetically modified food:	means food containing, consisting of or produced from a GMO.
Registrar:	means Registrar of the Biosafety Council

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1 PURPOSE

The purpose of this document is to provide guidance to applicants who intend to place genetically modified food and feed products on the Namibian market. 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 genetically modified food and feed products that have been announced as such through gazetting by the Minister to be a GMO product under section (1) subsection (2) of the Biosafety Act, 2006 (Act no 7 of 2006).

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/WHO (Codex Alimentarius Commission). 2003.

Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003), Rome, Italy.

Available at: <http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/>

FAO/WHO (Codex Alimentarius Commission). 2003.

Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003), Rome, Italy.

Available at: <http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/>

4 GENERAL RULES

4.1 RISK ASSESSMENT

Unless exempted, food and feed to be placed on the market must undergo by a risk assessment that that complies with Annexure 3 of the Biosafety Regulations: Biosafety Act, 2016. Risk

assessments for food must be conducted in line with Principles and Guidelines of Codex Alimentarius Commission.

4.2 LABELLING REQUIREMENTS

As per the Biosafety Regulations (*Government Notice No 210*), all GMO products which exceed 0.9% GMO content and which the Minister has pronounced to be a GMO product, must be labelled during transportation and placing on the market.

4.2.1 During transportation, GMO products must be labelled as follows:

The transporter must ensure that the consignment as well as the outermost container in which genetically modified food or feed is being transported in is labelled with the words *“contains genetically modified organisms or genetically modified organism products”* or *“product or commodity created with a GMO”*.

4.2.2 GMO products placed on the market must be labelled as follows:

Type of Product	Label Text	Label Position
Separately or individually packaged raw agricultural commodity	“genetically modified” or “contains genetically modified ingredients”	On package
Raw agricultural commodity which is not separately or individually packaged	“genetically modified” or “produced through genetic modification”	Retail store shelf or container in which the commodity is displayed
Processed genetically modified food or feed	“partially produced through genetic modification”, “may have been produced through genetic modification” or “produced through genetic modification”	On package

5 PROCEDURE

5.1 APPLICATION PROCESS

An application for a placing on the market 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;

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 7 an applicant must advertise his/her intention to apply for a placing on the market 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 to Place on the Market Genetically Modified Food or Feed”.
- 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 genetically modified food or feed proposed to be placed on the market;
- c) The type of placing on the market activity or activities to which the application relates as contemplated in regulation 6, sub-regulation 1 of the Biosafety Regulations: Biosafety Act, 2016;
- d) 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;
- e) 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:

Registrar: Biosafety Council

National Commission on Research
Science and Technology

ERF 490, Platinum Street,

Prosperita

Windhoek

Postal Submission:

Registrar: Biosafety Council

National Commission on
Research Science and
Technology

Private Bag 13253

Windhoek

Electronically:

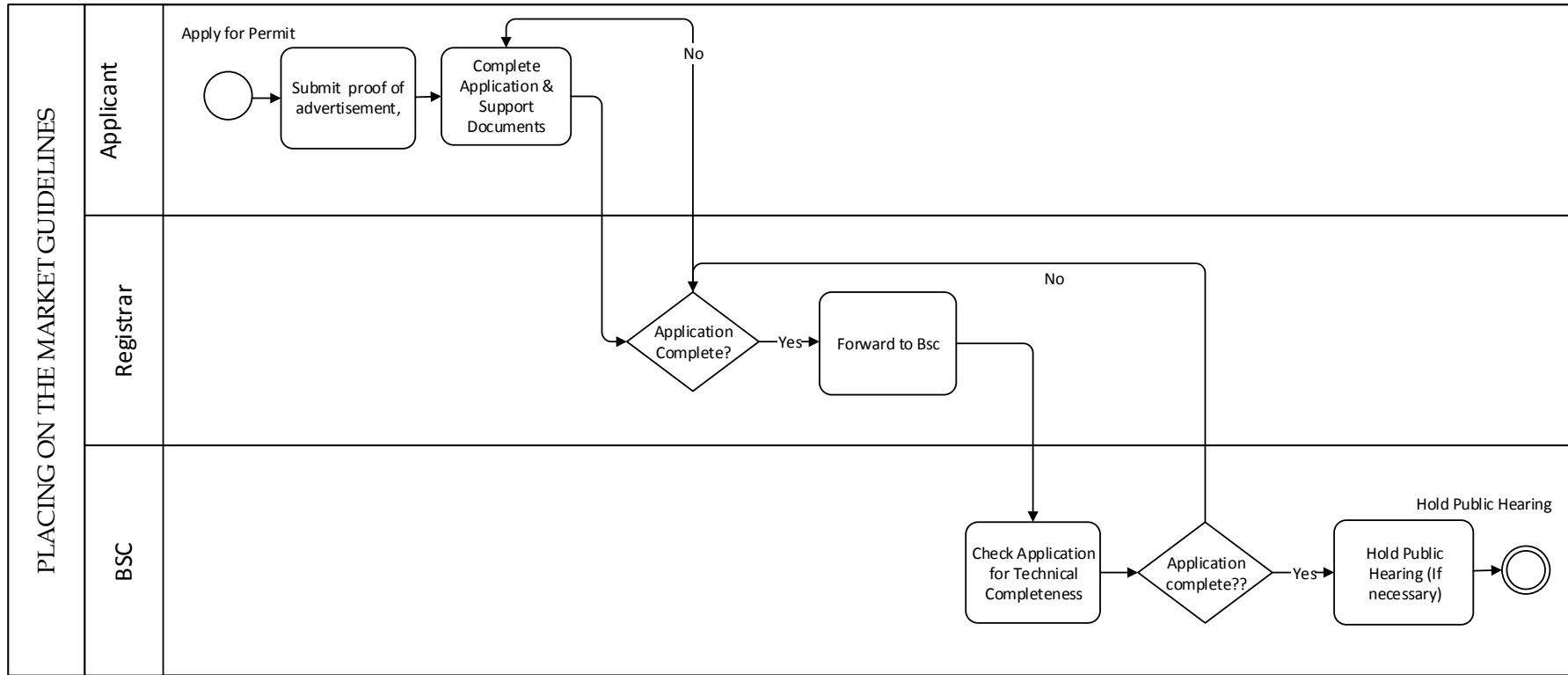
For attention of:

Registrar: Biosafety Council

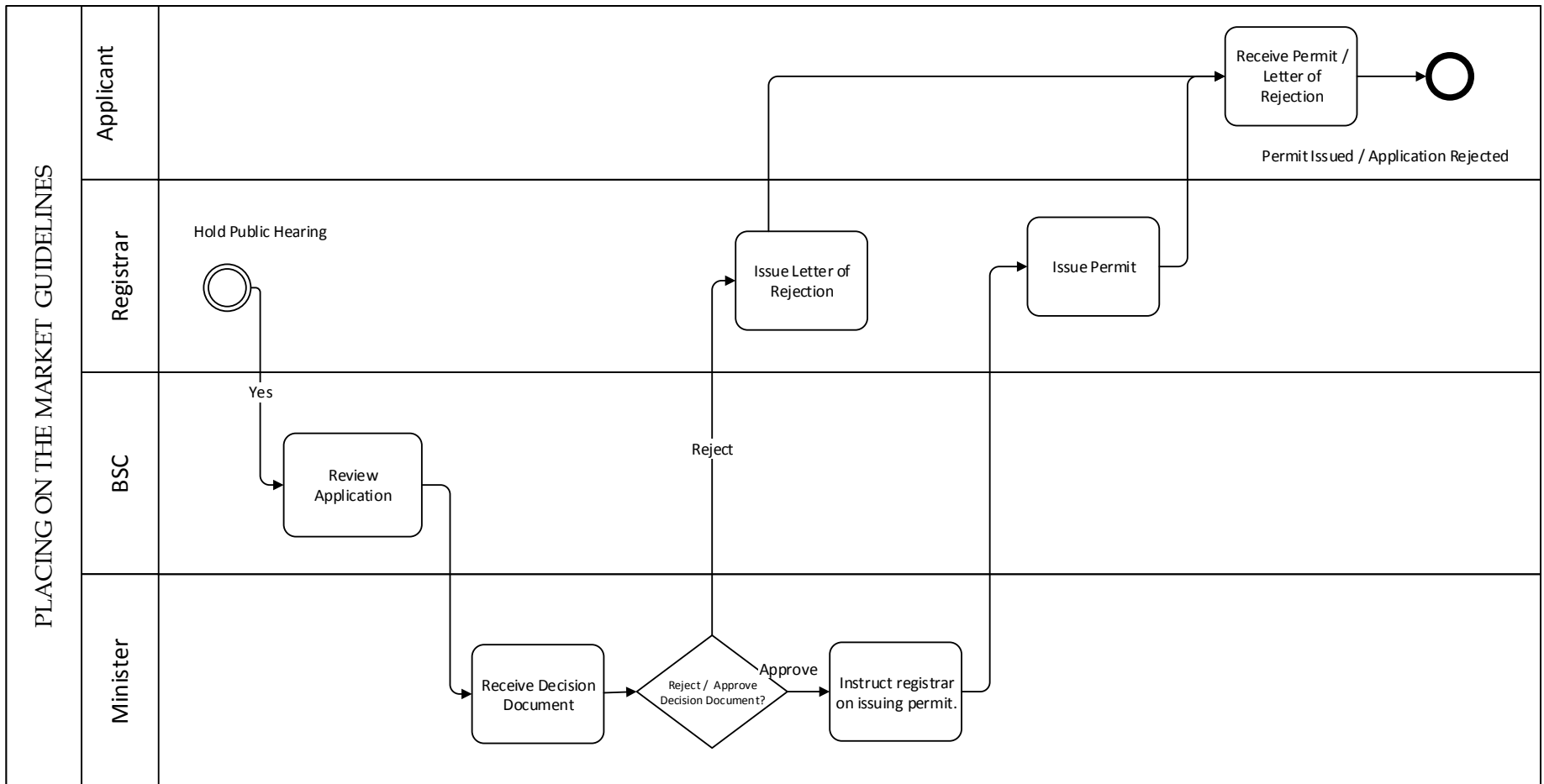
Email: registrarbiosafety@ncrst.na

Fax: + 264 61 216 531

5.4 Summary of Application Process



PLACING ON THE MARKET GUIDELINES



5.5 ISSUING AND DURATION OF A PLACING ON THE MARKET PERMIT

Once the application for a placing on the market permit is approved, the Council will issue the applicant with a permit.

Unless specifically granted for a shorter or longer period by the Minister and indicated as such on the placing on the market permit, a placing on the market permit is valid for a period of one year and may be renewed upon application.

An application for renewal of a permit may be made as set out in regulation 9, sub-regulation 4 of the Biosafety Regulations: Biosafety Act, 2016;

5.6 INSPECTION AND VERIFICATION

A placing on the market permit holder, or any other person importing genetically modified food or feed for purposes of placing such food or feed on the market, must report the arrival of consignments of genetically modified food or feed, destined for placing on the market in Namibia at the port of entry.

The Biosafety inspectorate, in conjunction with the Agro-Marketing and Trade Agency (AMTA) border inspectorate, or any other inspector appointed in terms of section 18 of the Biosafety Act will inspect and verify any consignment throughout the duration of the permit.

6 FORMS

BSC -F001 Application for registration of facility

BSC - F004 Application for placing on the market

7 REPLACEMENT AND WITHDRAWAL

None

8 REVISION/AMENDMENT HISTORY

Version number	Revision Date	Nature of Amendment