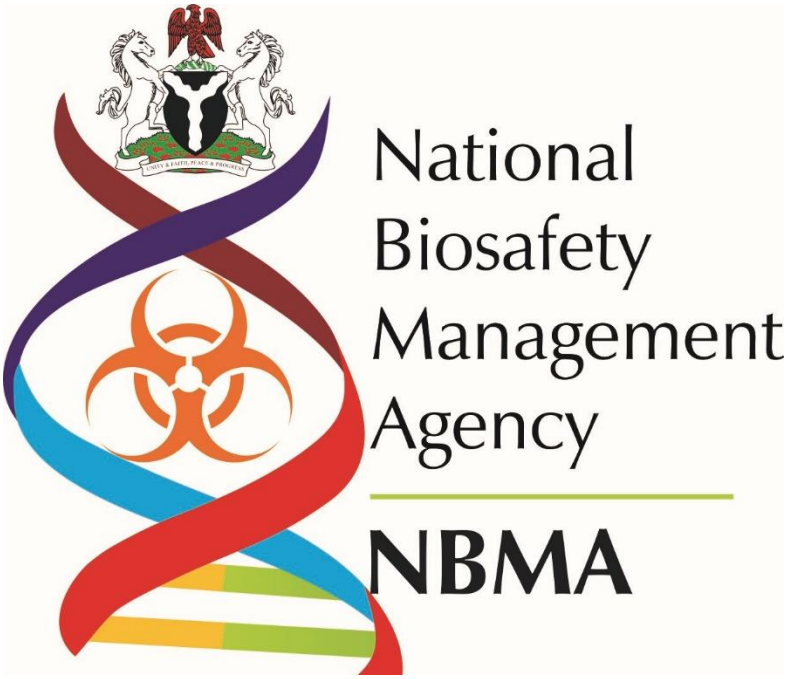


FEDERAL REPUBLIC OF NIGERIA

GUIDELINE FOR THE IMPORTATION OF GENETICALLY MODIFIED ORGANISMS FOR FOOD FEED AND/OR PROCESSING (FFP)

JANUARY, 2020

Chapter 1 Preamble

1.0 Introduction

These Guidelines serve as a step-by-step guide for importers of genetically modified organisms (GMOs) for food, feed and processing (FFP) on procedures to be followed to obtain Biosafety Permits. It also states the roles of all relevant border Regulatory Agencies as regards the importation of GMOs for FFP into Nigeria.

It specifies the first point of contact by Applicants who wish to import GMOs for FFP and the processes involved from the receipt of an application to when decision(s) is taken and communicated to the Applicant. This shall be a working tool for the National Biosafety Management Agency (NBMA) as well as serve as a guide for prospective GMOs for FFP Importers.

1.1 Objective of the Guidelines

The Objective of these Guidelines is to assist importers of GMOs for FFP on the process of obtaining Biosafety Permits in line with the Federal Government's Executive Order 1 on "ease of doing business". It also helps to keep stakeholders informed about what is required of them in the importation of GMOs. It is aimed at ensuring strict adherence to accountability and transparency in the conduct of international business by importers of GMOs for FFP as a first step towards ensuring that only safe GMOs are imported into the country. This objective is to be achieved by ensuring that the actual quality, events and quantity of all GMOs imports to the consignee tally with the claims on all accompanying documents.

2.0 Relevant Legislations and Policies on GMOs for FFP Importation

There are several pieces of legislations that are relevant to importation of GMOs for FFP in Nigeria. Some of the relevant National Policies, Laws and Regulations include:.

2.1 Laws

I. **National Biosafety Management Agency Act, 2015 (As Amended)**: This law provides regulatory framework, institutional and administrative mechanism for safety measures in the application of modern biotechnology in Nigeria with a view to preventing any potential adverse effect on human health, animal, plant and the environment.

II. **Plants Quarantine Act 2017**: This law regulates the importation and exportation of plant /plant products and establishes control on plant pests.

III. **Customs and Excise Management Act 2004** (As Amended): An Act to regulate the management and collection of duties of customs and excise and for purposes ancillary thereto.

3.0 PROCEDURE FOR GRANTING PERMIT FOR GMOs for FFP IMPORTATION

The mandate of the NBMA is to ensure that the application of modern biotechnology and use of its products (GMOs) are safe to the environment and human health. This entails detailed risk assessment and risk management of all GMOs before they are approved for importation. This is to ensure that only safe GMOs are permitted to be imported into Nigeria.

Commercial imports of GMOs for FFP coming from any exporting country (see http:/bch.cbd.int/databasmo-registry) must be accompanied by NBMA import permit**.** All shipments of imported GMOs for FFP will be inspected upon arrival at the port of entry.

Note: Importation of GMOs for FFP even for personal consumption without permit is absolutely prohibited the process of obtaining a biosafety import permit is as detailed below:

a) Obtaining, completion and submission of application forms

b) Receipt of completed application form by NBMA,

c) Documentation (Filing of Application and assigning appropriate Ref. Code),

d) Acknowledgement of application within 21 days (which includes communication of fees to be paid by Applicant),

e) Confirmation of Payment of processing fee (s),

f) Review of application dossier for completeness,

g) Correspondence to Applicant for incomplete dossier,

h) Stopping the clock if dossier is not complete until response is received from Applicant,

i) Summary of application and brief information on the place, duration and time for the display of application dossier,

j) Constitution of National Biosafety Committee (NBC) and/or National Biosafety Technical Sub-Committee (NBTS) and referral of Application dossiers to the Committees for review and recommendation.

NOTE: If the event has been initially approved by NBMA, there may be no referral to NBC and NBTS.

k) Display of copies of application and relevant information at strategic places to enable the general public, relevant government MDAs to study, make comments on the application and provide relevant information within 21 days to the Agency,

l) The Agency may , prior to display, make announcement in at least two national and one local newspaper or other news media indicating the location of the display of the dossier seeking public review and comments.

m) The Agency may, in addition to the comments received, hold public hearings or consultations to obtain further comments and inputs that may assist in decision making process on the application,

n) NBC meets to review application and make recommendation to NBMA, taking into account the recommendation of the NBTS,

o) NBC submits recommendation to the Director General/CEO of NBMA after meeting,

p) DG/CEO takes decision on application,

q) Decision document is prepared,

r) Decision document (permission/rejection) is communicated to Applicant,

s) Decision is made available on the Biosafety Clearing House (BCH) and NBMA website,

Inspection of facility by NBMA for compliance to terms, conditions and safety measures based on the final decision on application.

4.0 PROCEDURE FOR GMOs for FFP IMPORT IN NIGERIA

According to the NBMA Act, 2015 (As Amended), importation of GMOs without prior approval by NBMA contravenes the NBMA Act and is liable for seizure, and subject to prosecution. The procedures are laid out below:

A. Applicant shall contact NBMA or visit the NBMA website for proper guidance.

B. The Applicant shall request or obtain Biosafety application form from NBMA office or download it from the Agency's website (www.nbma.gov.ng) for completion

C. The Applicant shall submit the completed application form to NBMA directly or through the Agency's email (nbma@nbma.gov.ng) with evidence of non-refundable payment for application fee.

D. The completed Application form shall be accompanied with a dossier containing risk assessment and risk management of the GMO intended for importation.

E. The NBMA, after acknowledgement of the receipt of application shall, review application within 270 days provided the Agency is satisfied with the information supplied by Applicant

F. The Agency on receipt of application, shall checklist the application and request Applicant to proceed for processing fees or request for additional information where necessary

G. There shall be a display of public notice of application in at least two national dailies and one local newspaper, the national biosafety clearing house or such other news media as the Agency may from time to time determine, giving summary of the application and brief information on the place, duration and time for the display for public input in fulfillment of requirement for public participation.

H. The Agency may constitute a National Biosafety Committee (NBC) and the National Biosafety Technical Sub-committees for in-depth review of application.

I. The Committees may include representatives of relevant border regulatory agencies such as the Nigeria Customs Service (NCS), Nigeria Agricultural Quarantine Service (NAQS) and National Pest and Disease Control Department. Members may also be drawn from other relevant stakeholders such as MDAs, Research Institutes, Universities, experts on the subject, farmers, NGOs, CSO etc.

J. The NBMA may issue Permit or reject application based on the outcome of the risk assessment and other parameters

K. The Agency may send a copy of its decision to other border regulatory Agencies such as NCS and NAQS for notification.

L. Approval is made available on the Biosafety Clearing House (BCH) and the NBMA website: http/nbma.gov.ng

M. The Applicant shall present the Biosafety Permit to NCS, NAQS and NAFDAC.

N. In the absence of the attachment of Biosafety Permit by the Applicant, the concerned Agency may request a copy of the Permit from NBMA

O. NBMA shall carry out periodic Inspection of relevant facilities for Biosafety compliance.

OFFENCES AND PENALTIES

The importer should be aware that once Biosafety Permit has been issued for the importation of some GM events, any variation between the GMOs imported and those for which permit was granted will render the importer liable to penalties in accordance with the laws of the Federal Republic of Nigeria.

Any false or fraudulent misrepresentation of facts will result in rejection of permit and subject to prosecution

A. PRE-IMPORT PROCEDURES FOR BIOSAFETY PERMIT OF NEW **GMOs for FFP**					
STEP	**AGENCIES INVOLVED**	**PROCEDURE**	**REQUIREMENTS/ PRE-REQUISITES**	**TIMELINE**	**COST**
1.	NBMA	• Applicant Contact NBMA or visit the NBMA website (www.nbma.gov.ng) for proper guidance. • Applicant requests/obtains Biosafety application form from NBMA office or download it from the Agency's website for completion.	Nil	At least 30 days before importation	Nil
2.		• Applicant submits the completed application form and dossier to NBMA directly online/ the Agency's email address (nbma@nbma.gov.ng) with evidence of payment of application fee	• Completed Application Form • Risk assessment, dossier of the GMO intended for importation. • Evidence of payment of non-refundable Application fee	At least 30 days before importation	Application Fee
3.		• NBMA Acknowledges the receipt of application		Within 90 days of the receipt of the application	
4.		NBMA Carries out check-listing of the application and reviews the application; • If the Agency is satisfied with the information supplied by the Applicant, requests the Applicant to proceed for payment of non-refundable Processing fees or		Within 90 days of receipt of application	Processing fee

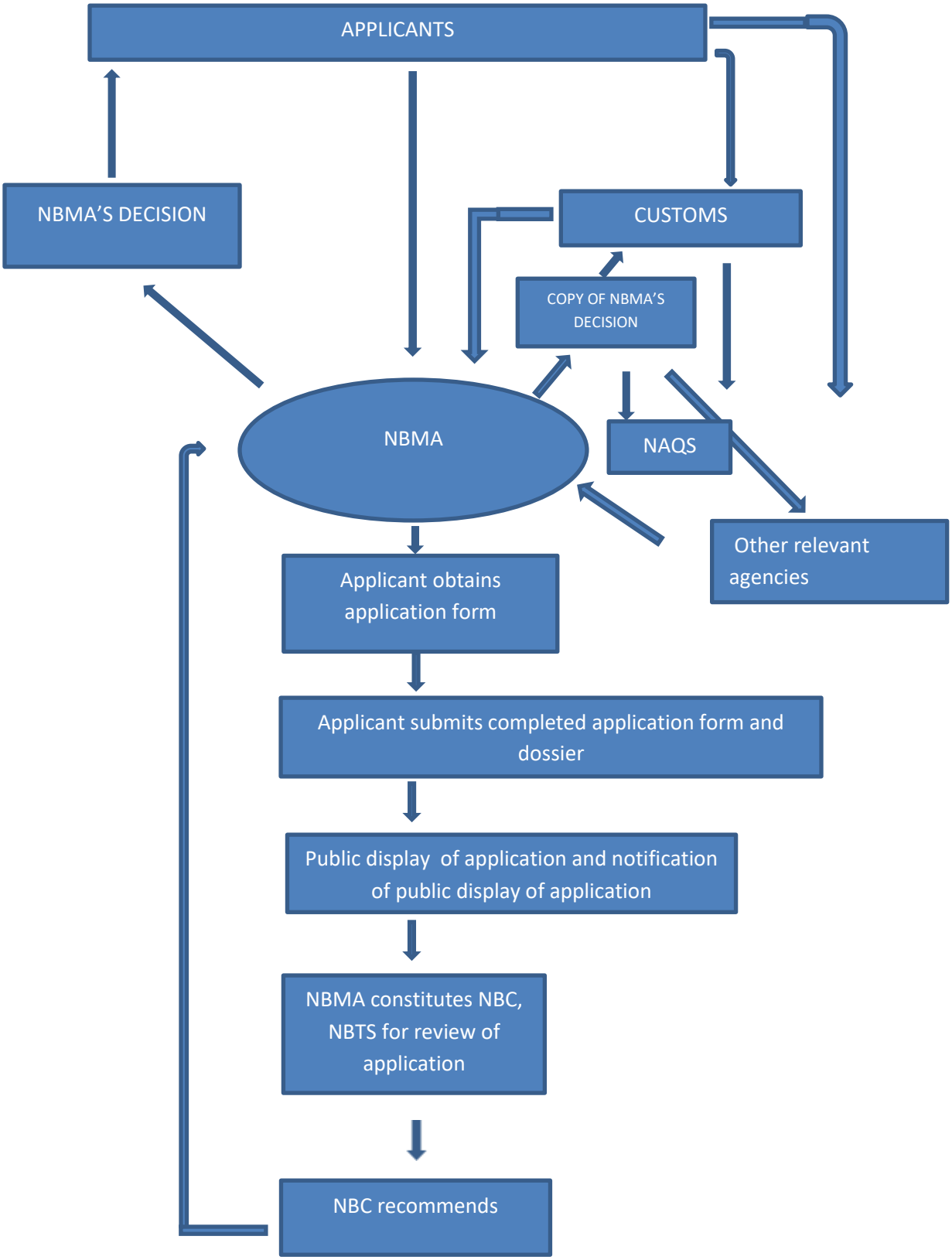
		• If not, requests additional information while the clock is stopped			
5.		If additional information is requested, the process is stopped until Applicant submits the additional information	Additional information		
6.		NBMA displays public notice of application in at least two national and one local dailies as well as NBMA website for public inputs in fulfillment of requirement for public participation.	If the GMO has not been previously approved in Nigeria	21 days	
7.		• NBMA may constitute a National Biosafety Committee (NBC) and a National Biosafety Technical Sub-Committee (NBTS) once application is confirmed complete, for in-depth review of application, if it's a new GMO. • The Committee reviews the application and makes recommendations to NBMA on whether to grant Permit, reject application or request for further information	Completed application dossier and public input		Nil
8.		The DG/CEO may issue a Permit or reject the application on the basis of NBC recommendation and the decision of NBMA <u>Approved Application</u> The Permit certificate is generated and is issued to the Applicant via their e-	Decision Document	Upon approval Biosafety Permit is issued.. If not approved, Applicant is also notified immediately.	Nil

		mail, courier or picked up from the NBMA office. <u>Declined Application</u> A Remark stating reason for the decline is made available to Applicant via their e-mail address or may obtain it from NBMA office To download User Guide e-Biosafety application visit www.nbma.gov.ng			
9.		The Agency sends a copy each of its decision to relevant border regulatory agencies.	**Decision Document**	Nil	Nil
NCS AND NAQS PROCEDURE FOR GMOs for FFP IMPORTATION					
10.	Nigeria Customs Services (NCS-Enforcement), Nigerian Agricultural Quarantine Service (NAQS)	NCS Enforcement, NAQS & other relevant agencies receive copy of Biosafety Permit and Decision Document from NBMA.	Biosafety Permit and Decision Document	Within 72 hours of the Decision	
11.		The Applicant presents the Biosafety Permit to NCS, NAQS.	Biosafety Permit	During Declaration	Nil
12.		NCS & NAQS Officers request NBMA Biosafety Permit from importer **If authentic,** NCS proceeds with relevant procedures and other extant laws <u>If not authentic,</u> NCS halts process and informs NBMA ➢		If not submitted, NCS and NAQS request for the decision document fromNBMA. <u>If not authentic,</u> NCS halts	

				process and informs NBMA for necessary action.	
B. RENEWAL /SUBSEQUENT IMPORTATION OF GMOs for FFP AFTER PERMIT BUT WITHIN THE PERMIT PERIOD BY INITIAL APPLICANT					
13	NBMA	Applicant Informs NBMA	Letter of Information	Before Importation	Nil
14		**NBMA notifies NCS, NAQS and other relevant agencies.**	**Letter of information**	**Before importation**	
C. POST IMPORT PROCEDURE FOR ILLEGAL IMPORTATION OF GMO-SUSPECT (WITHOUT PERMIT) IF COMING FROM COUNTRY THAT HAVE COMMERCIALIZED THE GMO BEING IMPORTED					
AGENCIES INVOLVED		**PROCEDURE**	**REQUIREMENTS/ PRE-REQUISITES**	**TIMELINE**	**COST**
15	NCS, NAQS & other relevant agencies	<u>SAMPLE COLLECTION AND EXAMINATION</u> ✓ Halt process, ✓ collect sample, ✓ inform NBMA and ✓ conduct rapid diagnostic test GMO Events are subject to physical examination, sample collection and rapid test for presence of GM in the NBMA GMO detection\analysis laboratory	Copy of Biosafety Import Permit List of commercialized GMOs for FFP and countries of commercialization List of approved GMOs for FFP in Nigeria and List of companies granted the permit Rapid test kit	At the border/port.	
16	NBMA	✓ NBMA Collects Sample, ✓ Analyzes the sample in the NBMA National GM Detection and Analysis			

		laboratory. NBMA may subject the samples to independent laboratory analysis ✓ **If it is GMO but the Event is different from the Permit given** **Halt process** and Penalize offender in accordance with the NBMA Act 2015 (as amended). ✓ **If GMO and no approval has been given** **Halt process** and Penalize offender in line with NBMA Act 2015 (as amended)			
MONITORING OF IMPORTED GMOs for FFP/ VERIFICATION OF COMPLIANCE TO TERMS OF BIOSAFETY PERMIT					
17	NBMA	Unannounced visit to GMO facilities for compliance, if found wanting penalize the offender which may include withdrawal of permit, sealing of premises, prosecution, conviction (fine and\or imprisonment).		Periodically and continuous from the time of importation	

ILLUSTRATIVE PROCESS-MAP FOR GMO for FFP IMPORTATION IN NIGERIA
FIG 1



ILLUSTRATIVE PROCESS MAP FOR GMOs for FFP IMPORTATION IN NIGERIA FIG 2