National Biosafety Management Agency

NBMA

FEDERAL REPUBLIC OF NIGERIA

NATIONAL BIOSAFETY ADMINISTRATIVE MANUAL

2017

1.0 Introduction

This manual serves as a step-by-step guide for Biosafety personnel with regard to handling applications for various biosafety services. It specifies the processes involved from the receipt of an application right through to when decision(s) is taken and communicated to the applicant. The manual shall be a working tool for personnel of the National Biosafety Management Agency (NBMA) as well as serve as a guide for prospective applicants.

2.0 Procedure for decision-making on Biosafety Applications

a) Receipt of application,

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

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

d) Confirmation of Payment of processing fee,

e) Review of application dossier for completeness,

f) Correspondence to applicant for incomplete dossier,

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

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

i) Constitution of National Biosafety Committee (NBC) and National Biosafety Technical Sub-Committee (NBTS) and referral of Application dossiers to the committees for review and recommendation.

   NOTE: Not all applications require referral to NBC and NBTS.

j) NBMA inspects site(s) of intended release prior to first NBC review meeting,

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

l) The Agency may, prior to the display, make announcement in at least two national and one local Newspapers or other news media.

m) The Agency may, in addition to the comments received, hold public hearings or consultations to obtain further comments and inputs that will assist in the review or processing of the application,

n) NBC second meeting holds for one or two days and reviews application within seven working days after the expiration of the period of the display of the application dossier, taking into account the recommendation of the NBTS,

o) NBC submits recommendation to 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 in the Biosafety Clearing House (BCH), NBMA website and other news media and

t) Inspection of site(s)/facility by NBMA for compliance to terms, conditions and safety measures based on the final decision on application.

In the case of GM foods, review of the food safety assessment and the determination that the food is safe for human consumption shall be certified by the National Agency for Food, Drug Administration and Control (NAFDAC).

3.0 Confidential Business Information

i. The Agency shall not disclose any confidential business information submitted by any Applicant.

ii. To determine if any information identified by an applicant qualifies as confidential business information that cannot be disclosed to the public, the Agency shall ascertain that:

a) the information has not previously been released to the public anywhere in the world;
b) the applicant has shown that steps have been taken to prevent the release of such information;
c) release of the information would be detrimental to the applicant.

iii. The following information shall not be considered confidential business information and can be disclosed to the public:

a) the name and address of the applicant;
b) a general description of the Genetically Modified Organism (GMO);
c) a summary of the risks assessment for the GMO;
d) any scientific data that specifically addresses potential environmental or food risk from GMOs and any method; and
e) plans for emergency response.

4.0 FEES FOR VARIOUS BIOSAFETY APPLICATIONS FOR PERMITS:

These fees cover expenses for servicing various Committees' meetings, Inspections and permit.

S/No.	Activity/Application		Charge (₦)	Charge ($)
1.	Accreditation of institution and certification of Biosafety facilities, Confined Fields(Green House/Laboratory)	Processing	500,000.00	
		Permit	50,000.00	
2.	Certification of new Biosafety facility (Green House/Laboratory)	Processing	300,000.00	
		Permit	30,000.00	
3.	Confined Field Trial (CFT)	Processing	2,500,000.00	
		Permit	100,000.00	
4.	Renewal of trials	Processing	1,000,000.00	
		Permit	50,000.00	
5.	General/Commercial Release	Processing	3,500,000.00	
		Permit	150,000.00	

S/No.	Activity/Application		Charge (₦)	Charge ($)
6.	Appeals	Processing	300,000.00	
7.	Transit	Processing	100,000.00	
		Permit	50,000.00	
8.	Multi-locational Trials	Processing	3,500,000.00	
		Permit	50,000.00	
9.	**Fast – Track Processing**[1]			
i.	Accreditation of institution and certification of Biosafety facility (Green House/Laboratory)		650,000.00	
ii.	Certification of new Biosafety facility (Green House/Laboratory)		400,000.00	
iii.	CFT		4,500,000.00	
iv.	Renewal of trials		1,500,000.00	
v.	General/Commercial Release		4,500,000.00	
vi.	Appeals		400,000.00	
vii.	Transit		150,000.00	
viii	Multi-locational Trials		4,500,000.00	

5.0 Application Reference Codes

Application	Code
GMO import for Food, feed and processing for commercialization	NBMA/CM/FFP/IM/00------
GMO export for food, feed and processing for	NBMA/CM/FFP/EX/00------

[1] For the fast-track, the charges indicated above are just for processing, fees for permits are same as for the applications under normal processing.

Application	Code
commercialization	
Locally commercialized GM for food, feed and processing	NBMA/CM/FFP/D/oo------
GMO import for general release for planting	NBMA/CM/P/IM /oo--------
Locally commercialized GMO for planting	NBMA/P/D/oo----------
GM imported for contained use	NBMA/CT/oo----------
GMO for single location confined field trial	NBMA/CFT/oo----------
GMO for multi-location confined field trial	NBMA/CFT/MLT/oo--------
GMOS for on Field Trial	NBMA/OFT/ oo--------
Accreditation of Institution	NBMA/AI/ oo--------
Certification of Containment Facility	NBMA/CCF/ oo--------

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**Representatives are expected from applicants to be at hand to answer questions that may arise during the course of consideration of the applications;*

Any institution that intends to apply for CFT shall seek accreditation of the Institutionand Certification of Containment Facility from NBMA

National Biosafety Management Agency
NBMA

Checklist for completeness of application dossier

Application Ref. Code----------

S/N	Information to look out for while checking for completeness of application dossier	Available (Yes)	Not available (No.)	Remarks
1.	Name of Applicant			
2.	Address, telephone, e-mail, fax, website of applicant			
A.	**Type of Application**			
3.	Name of the GMO. Purpose of release (i.e. contained use, CFT, General Release)			
4.	Scientific name, taxonomy and species of the GMO			
5.	Method of modification			
6.	Location/area of intended research			
7.	Biological and biochemical difference from related living species			

S/N	Information to look out for while checking for completeness of application dossier	Available (Yes)	Not available (No.)	Remarks
8.	Trait removed from the donor			
9.	Phenotypic and genetic markers of interest			
10	Degree of relatedness between donor and recipient or between parental organisms			
11	Description of the geographic distribution and of the natural habitat of the organisms including information on natural predators, preys, parasites and competitors, symbionts and hosts			
12	Description of genetic trait or phenotypic characteristics and, in particular, any new traits and characteristics which may be expressed or no longer expressed			
13	Nature and source of the vectors			
14	Purpose of modification and benefits			
15	Description of the proposed general/experimental release, including the purposes and foreseen products			
16	Foreseen date of the release and duration of release(s)			
17	Preparation of the site prior to the release			
18	Location and size of the site			
19	Quantity of GMO(s) to be released either in number or weight			
20	When and where the GMO has been approved previously and grown or consumed			

S/N	Information to look out for while checking for completeness of application dossier	Available (Yes)	Not available (No.)	Remarks
21	Method of land cultivation or other activities			
22	Worker protection measures to be taken during the release			
23	Post release treatment of the site of release			
24	Techniques for incineration or inactivation of the GMOs or products at the end of the experiment/release			
25	Likelihood of gene transfer to other organisms			
B.	**RISK MANAGEMENT/ POTENTIAL IMPACT**			
26	Is there a potential risk?			
27	Measures for mitigating adverse impacts			
28	Type of environment or the geographical areas of the country for which the product is suited			
29	Proposed packaging which must be appropriate so as to avoid unintended release of the Genetically Modified (GM) products			
30	Is the risk assessment report indicating the potential risk(s) available?			
31	Control of the Release (Methods and procedures to avoid or minimize the spread of the GMOs or GM products beyond their site of release or the designated area for use)			
32	Methods and procedures to protect the site from intrusion by unauthorized individuals			

S/N	Information to look out for while checking for completeness of application dossier	Available (Yes)	Not available (No.)	Remarks
33	Methods and procedures to prevent other organisms from entering the site			
34	Type of waste to be generated and expected amount of waste			
35	Description of waste treatment envisaged			
36	Methods and procedures for controlling the GMOs or GM products in case of unexpected spread			
37	Methods for the isolation of the area affected by the spread			
C.	**EMERGENCY PLAN**			
38	Plans for protecting human health, animals, plants and the environment in case of the occurrence of an undesirable effect			
39	Measures to take in case of unintended release of misused GM materials			
40	Methods for tracing the GMOs or GM products and for monitoring their effects			
41	Specificity (to identify the GMOs or GM products and to distinguish them from the donor, recipient or where appropriate, the parental organism), sensitivity and reliability of the monitoring techniques			
42	Methods for disposal or incineration of plants, animals, packaging materials, soil etc. that were exposed during or after the spread			

S/N	Information to look out for while checking for completeness of application dossier	Available (Yes)	Not available (No.)	Remarks
43	Techniques for detecting transfer of the donated genetic material to other organisms			
44	Methods to detect aberrant gene expression			
45	Specific instructions or recommendations for storage and handling			
46	Proposed isolation distance from related species and human habitation			
47	Proposed labelling			
D.	**INFORMATION ON PERSONNEL**			
48	Information on personnel and training which shall include qualifications and training of persons who shall be responsible for planning and carrying out the implementation of the project, including those responsible for supervision, monitoring and evaluation of the safety measures. (This applies to Trials and Containment Facilities)			

Conclusion/Recommendation

☐ Incomplete. ☐ Stop the clock and request for information on the

☐Complete ☐Proceed with application review

Following numbers above: ----------

Reviewed by:

Name: ----------

Signature: ---------- **Date:** ----------

Counter signed by:

Name: ----------

Signature: ---------- **Date:** ----------

Supplementary Completeness of Biosafety Application Checklist

Application Ref. Code----------

S/N	Information missing in the initial review of application dossier. This Check list would be used to assess further information provided by the Applicant after the first assessment.	Now available (Yes)	Not still available (No.)	Remarks
1.	Name of Applicant			
2	Address, telephone, e-mail, fax, website of applicant			
A.	**Type of Application**			
3.	Information on personnel and training which shall include qualifications and training of persons who shall be responsible for planning and carrying out the implementation of the project, including those responsible for supervision, monitoring and evaluation of the safety measures. (This applies to Trials and Containment Facilities)			
4.	Name of the Genetically Modified Organism (GMO)			
5.	Scientific name, taxonomy and species of the GMO			
6	Method of modification			
7	Location/area of intended release			

S/N	**Information missing in the initial review of application dossier. This Check list would be used to assess further information provided by the Applicant after the first assessment.**	**Now available (Yes)**	**Not still available (No.)**	**Remarks**
8	Biological and biochemical difference from related living species			
9	Trait removed from the donor			
10	Phenotypic and genetic markers of interest			
11	Degree of relatedness between donor and recipient or between parental organisms			
12	Description of the geographic distribution and of the natural habitat of the organisms including information on natural predators, preys, parasites and competitors, symbionts and hosts			
13	Description of genetic trait or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed			
14	Nature and source of the vectors			
15	Purpose of modification and benefits			
16	Description of the proposed deliberate release, including the purposes and foreseen products			
17	Foreseen date of the release and duration of release(s) applied for			
18	Preparation of the site prior to the release			
19	Location and Size of the site			

S/N	**Information missing in the initial review of application dossier. This Check list would be used to assess further information provided by the Applicant after the first assessment.**	**Now available (Yes)**	**Not still available (No.)**	**Remarks**
20	Purpose of release (i.e. contained use, Confined Field Trial, commercialization)			
21	Quantity of genetically modified organisms to be released either in number or weight			
21	When and where the GMO has been approved previously and grown or consumed			
22	Method of land cultivation or other activities			
23	Worker protection measures to be taken during the release			
24	Post release treatment of the site of release			
25	Techniques for incineration or inactivation of the genetically modified organisms or products at the end of the experiment/release			
26	Likelihood of gene transfer to other organisms			
27	Impacts on human and animal health and the environment.			
28	Measures for mitigating adverse impacts			
29	Type of environment or of the geographical areas of the country for which the product is suited			
30	Proposed packaging which must be appropriate so as to avoid unintended release of the genetically modified products			
31	Is the risk assessment report indicating the potential risk(s) available?			

S/N	**Information missing in the initial review of application dossier. This Check list would be used to assess further information provided by the Applicant after the first assessment.**	**Now available (Yes)**	**Not still available (No.)**	**Remarks**
32	Control of the Release (Methods and procedures to avoid or minimize the spread of the genetically modified organisms or products beyond their site of release or the designated area for use)			
33	Methods and procedures to protect the site from intrusion by unauthorized individuals			
34	Methods and procedures to prevent other organisms from entering the site			
35	Type of waste to be generated and expected amount of waste			
36	Description of waste treatment envisaged			
37	Methods and procedures for controlling the genetically modified organisms or products in case of unexpected spread			
38	Methods for the isolation of the area affected by the spread			
39	Plans for protecting human health, animals, plants and the environment in case of the occurrence of an undesirable effect			
40	Measures to take in case of unintended release of misused GM materials			
41	Methods for tracing the genetically modified organisms or products and of monitoring their effects			

S/N	Information missing in the initial review of application dossier. This Check list would be used to assess further information provided by the Applicant after the first assessment.	Now available (Yes)	Not still available (No.)	Remarks
42	Specificity (to identify the genetically modified organism or product and to distinguish them from the donor, recipient or where appropriate, the parental organism), sensitivity and reliability of the monitoring techniques			
43	Methods for disposal or incineration of plants, animals, packaging materials, soil etc. that were exposed during or after the spread.			
44	Techniques for detecting transfer of the donated genetic material to other organisms			
45	Methods to detect aberrant gene expression			
46	Specific instructions or recommendations for storage and handling			
47	Proposed isolation distance from related species and human habitation			
48	Proposed labelling			

Conclusion/Recommendation

☐ Information now complete ☐ Proceed with application review

☐ Still incomplete. ☐ Stop the clock and request for the information on the following numbers: ----------

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Reviewed by:

Name: ----------

Signature: ---------- **Date:** ----------

Counter signed by:

Name: ----------

Signature: ---------- **Date:** ----------