FEDERAL MINISTRY OF ENVIRONMENT

GUIDELINES FOR BIOSAFETY ADMINISTRATION IN NIGERIA

September 2012

Contents

INTRODUCTION

1.1 Purpose of this guideline

The National Biosafety Management Agency National Biosafety Management Agency has a wide range of responsibilities. These include the general administration of biosafety processes in the country, development and implementation of the biosafety policy, staff training, outreach and training for stakeholders and the public, interaction with regional and international stakeholders, and keeping Nigerians informed about national biosafety issues.

The biosafety review process involves a large volume of documentation, movement of documents and tracking of input and responses from many stakeholders. This is in addition to the requirement for securing confidential business information and the legal nature of the decisions that are derived from the biosafety reviews. It becomes clear that the National Biosafety Management Agency needs to be well managed and functional in all aspects of its administration.

These guidelines have been developed to assist the National Biosafety Management Agency with the implementation of the National Biosafety Framework (NBF).

1.2. Using this guideline

The aim of this guidance document is to provide a practical biosafety administrative system for Nigeria. This includes handling of applications, decision-making on GMOs, monitoring, inspections and enforcement of biosafety decisions.

These guidelines cover the following aspects of an administrative system for biosafety:

- Quality management systems
- Handling applications
- Decision making
- Monitoring
- Inspection

The key terms used in this guideline are explained below:

- **Application** is used to cover all forms of notification or submission to the National Biosafety Management Agency for permission to carry out activities with genetically modified organisms (GMOs).
- **Applicant** is used to describe an individual or institution that will notify or apply to the National Biosafety Management Agency, when a particular GMO or an activity involving a GMO requires notification or prior authorisation under the national regulatory framework.
- **Confined use** describes the research and development of GMOs in short term restricted to demarcated field, animal house or clinical trials that are managed to minimise impact on or persistence in the environment.

- **Contained use** describes the research and use of GMOs inside a facility that is enclosed and designed to minimise the release of living organisms into the environment.
- **GM activities** are used to describe activities that could be carried out with GMOs in the course of their development, testing and use.
- **General release** describes the approved, general use of a GMO with regulation. Also termed 'unconfined release', and approvals may have some conditions.
- **Genetically Modified Organism** (**GMO)** describes a plant, animal or microbe derived through recombinant-DNA techniques.
- **GM product** is used to describe non-living products that are derived from GMOs.
- **Inspection** describes the check for compliance with regulatory conditions for activities with GMOs. This may include the review and investigation of facilities, materials, checklists, operational procedures and documents related to GMOs.
- **Monitoring** describes the scientific collection of biosafety data to support biosafety decisions and related pre- and post-approval obligations/requirements. It also describes the systematic measurement of the effects of GMOs over time.
- **National Biosafety Framework (NBF)** describes the national structures established by legislation to implement a biosafety regulatory process in Nigeria
- **Unconfined release** describes the approval for the general use of a GMO with regulation. This is also termed 'general release', and may have some conditions for use appended to the approval.

1.3. Administration and National Regulatory Policies

The components of an NBF are interdependent. The national policy on biosafety provides the rationale for the development of a regulatory system for modern biotechnology and guides how decisions will be made regarding the development, testing and use of GMOs. The regulatory system forms the basis for the administrative systems for handling applications and decision-making, systems for follow up and compliance, and mechanisms for public awareness, education, participation and access to information.

These guidelines set up the implementing administrative system that will enable the National Biosafety Management Agency to carry out the day-to-day biosafety activities required. In

2. QUALITY MANAGEMENT SYSTEMS

Quality management systems (QMS), which is a set of policies, processes and procedures required for planning and execution (production/development/service) in the core business area of an organization, have been adopted by the National Biosafety Management Agency to ensure timely, accurate and consistent implementation of day-to-day biosafety functions. This is to keep memory that the systems has been establish. The QMS are comprised of the following components that keep them current and useful where they are deployed:

- Guidance
- Documentation
- Training
- Inspection
- Auditing
- Review.

Establishing a QMS for biosafety administration will enable the National Biosafety Management Agency to keep functioning with minimal disruptions when key personnel move to new positions.

2.1. Guidance

This document determines the way activities are to be performed and should be made available to all personnel to facilitate consistent performance and institutional memory to cope with the movement of staff. This documentation helps to maintain quality control and can provide quality assurance processes for all of the important actions in the National Biosafety Management Agency. This helps to ensure compliance with existing Biosafety regulations and policies.

2.2. Documentation

Documentation of specific actions is important for maintaining adequate records of all activities in the National Biosafety Management Agency. This documentation is most often formatted as a set of forms that are completed as activities progress. These forms can be used to demonstrate that the national biosafety process is being managed in compliance with the regulations. The documentation can be examined by regulatory personnel and auditors to help investigate and understand problems should these arise. Importantly, to ensure that the documentation system remains viable and is implemented readily by biosafety personnel, it should be reviewed annually to see where improvements can be made.

In most cases documentation shall be handled manually and electronically. Thus, the basic electronic backup and disaster recovery systems are important, as is the security to ensure that the files and records are only accessed by authorised personnel.

2.3. Training

All personnel involved with biosafety administration shall be properly trained to ensure that they understand their responsibilities and are able to:

- Handle applications and administrative activities properly;
- Keep records that are accurate and correct; and
- Take appropriate actions in the event of problems arising.

2.4. QMS inspection and audit

Inspection and audit systems are valuable for regulatory compliance. Regular inspection is to be maintained for a high level of service and in keeping within appropriate timelines as established by the Biosafety Act 2015 and any other periodic guidelines to be issued to facilitate the implementation stages of a biosafety administrative process.

Auditing shall involve the appointment of an external or government expert to review the QMS to recommend where improvements are needed and where changes could facilitate the functionality of specific activities in the National Biosafety Management Agency or designated facility.

2.5. QMS review

Guidelines, forms and training curricula are to be reviewed annually by relevant scheduled staff and coordinated by the Director General/CEO of the National Biosafety Management Agency to ensure that they are updated and functional.

3. HANDLING APPLICATIONS

3.1. Setting up an administration system

Applicants are required to submit applications to the Director General/Chief Executive Officer of the National Biosafety Management Agency for permission to carry out certain activities with GMOs. The administrative process is designed to ensure efficient handling of the applications so that decision making is undertaken with due consideration and the necessary information. The administration process is distinct from the decision-making process.

The Biosafety administration process includes:

- Implementation of the institutional structures established by the NBF;
- Appointing and training staff for identified positions;
- Development of relevant guidance;
- Setting up internal procedures;
- Publicising the system; and
- Providing for pre-submission consultations, if required by applicants.

The Administrative structure includes:

- N**ational Decision-Making Body**: The National Biosafety Management Agency reviews all applications/data on proposed GM activities and approves or rejects them on a case by case basis with technical advice from the National Biosafety Committee.
- **National Biosafety Management Agency:** The agency receives and processes applications for GM activities; carries out daily biosafety administration and coordinates public inputs, risk assessment and decision-making activities. It shall also be responsible for issuing biosafety communication (information about

biosafety) and coordinating consultations with stakeholders about biosafety processes.

- **National Biosafety Committee:** **A**ppointed by the National Biosafety Management Agency, reviews or audits risk assessments on GM activities and recommends what, if any, terms and conditions (risk management measures) needed to protect the environment and human health. This body may also advise on general biosafety issues. The body is ad-hoc.
- I**nspectorate**: National Biosafety Management Agency is responsible for inspections and enforcement to ensure compliance with the, terms of permits and regulations.
- M**echanism for public participation** in policy development and/or decision-making: When a biosafety policy is drafted or when an application is received for commercialization, the public will be notified through print media. Additionally, the document will be deposited at relevant location for public review and comment for a period of 21 days. Stakeholder meeting will be held to review draft policies and guidelines.

3.2. Administrative steps in processing GMO applications

When applications for GMO activities are received they would be processed in a manner that is efficient and meets the needs and expectations of applicants and the general public, as well as any obligations under National Legislation and International Agreements. The administrative processes may vary depending on the type of activity. These activities may include accreditation of institutions for genetic modification, certification of containment facilities, laboratory research, field development and confined field trials/testing, general (commercial) release and commodity imports and GMOs transit. To deal with this variability, the following basic steps follow the receipt of an application for GMO activity in many biosafety administrative systems:

- For each activity an application form has to be completed;
- Record receipt of the application:
    - Use a document tracking system;
- Assess whether approval for the proposed activity is required, and whether the application meets the requirements of the regulations:
    - Acknowledge receipt of the application or issue a letter requesting missing information needed to fulfil the requirements for review and decision making within 90 days;
    - Give the application a record number and enter its details into an administrative database linked to a document tracking system;
- Publicise the receipt of an application, if required;
- Call for public input, if required:
    - A public copy of the application that does not contain any confidential business information (CBI) is available for public review;

  - Receive and document public input before directing this to the National Biosafety Committee for review as may be required;

- Arrange for a risk assessment review:
  - Appoint National Biosafety Committee with expertise to carry out the risk assessment or review;
  - Where an application contains CBI ensure that confidentiality forms are signed and returned by the review committee before release of the application;
  - Ensure that the risk assessment addresses safety issues raised by the public consultation process;
- Ensure that the appropriate experts assess socio-economic issues:
  - Include review of socio-economic issues raised by the public consultation process;
- Where information is found to be missing or clarification is needed during the risk assessment process, or the socio-economic review process, request the information from the applicant. If information is requested from an applicant the decision-making period shall commence from the day response is received.
  - If necessary, a scheduled meeting between the applicant and National Biosafety Management Agency or the National Committee, or the socio-economic review body will be held;
- The safety recommendations or technical opinion/advice from the National Biosafety Committee(NBC) and socio-economic recommendations from the socio-economic experts would be received by the National Biosafety Management Agency and sent to the Director General/Chief Executive Officer for decision-making
- The Director General/Chief Executive Officer conveys the decision through a decision document and a cover letter to the applicant;
- The decision-making period is within 270 days from the period of receipt of the application;
- NBMA The BCH National Focal Point shall make decisions (risk assessments and decision documents) publicly available, on the National and International BCH within 15 days;
- The site of release is visited by the National Biosafety Management Agency(NBMA) officials prior to during the period of processing of application in company of some members of the NBC;
- NBMANBMA to schedule any necessary inspection(s) of release sites during and after the activity:
  - Review the inspection reports and follow up as needed;
- NBMA to ensure that activity reports are received:
  - Review the monitoring data to determine whether the terms and conditions need to be revised or the monitoring requirement can be removed;

- NBMA to manage any new information that is submitted on applications in the system;
- All appeals to be addressed to the Honourable Minister of Environment;
- NBMA to manage applications for appeals and the appeal process;
- NBMA to manage unintended releases and other non-compliance issues;
- NBMA to arrange for decisions to be reviewed in response to new information;
- BCH National Focal Point to monitor the Central Portal of BCH for GMO decisions that will impact on imports of food and feed, or may result in unintended trans-boundary movement:
    - NBMA BCH National Focal Point to alert the Director General/Chief Executive Officer of the National Biosafety Management Agency when decisions in other countries are likely to impact on national food and feed imports, or unintended transboundary movement of unapproved GMOs in to the country;

Before an application for an approval is formally submitted to a NBMA, there may be pre-submission consultations between the applicant and the NBMA to ensure that the application contains the required information and that the applicant clearly understands the processes for biosafety review and decision making. Applications and necessary dossiers should be submitted in hard and electronic formats.

3.2.1. Screening for completeness

A checklist shall be used internally to ensure completeness of submitted documents.

Screening an application for completeness shall require answering the following questions:

1. Is it clear who the applicant is and what the request is for, *i.e.* who wants to do what, why, when and where?
2. Do the proposed activities **require** an approval under our national biosafety law?
3. Does the application comply with the **information requirements** laid down in the national regulatory system for this type of activity?

Typically, information requirements will include the following:

- **Administrative data**, such as name and contact information of the applicant; whether the organism will be imported and what, if any, regulation has covered the development of the organism to date;
- **Biology Document**, that describes the growth, characteristics and uses of the plant, microbe or animal in the release environment;
- **Core Characterization**, which describes the GMO, the type of activity and the receiving environment. This information should be sufficient to **initiate** the risk assessment and be ***relevant to the planned activity*** (contained, confined, unconfined use, import, export, transit, etc),
- **Environmental Characterization**, which describes the interaction of the GMO with the receiving environment and can include sections on how the comparator was chosen for the safety assessment studies; the phenotype of the GMO; its

cultivation or use in the country; interactions with sexually compatible relatives; residual effects and impact on non-target organisms; and any other environmental interactions that may be relevant. The number of seasons of trials and number of trial environments will depend on the GMO and its biology and use in Nigeria.

- **Detection and identification** information provides a detection method capable of distinguishing the GMO from other organisms of the same species. This is not needed for contained or confined research but may be a requirement for confined commercial production or unconfined activities such as general release (commercial or public sector) to farmers or industry.
- **Food and feed use approval** information is often requested for general release and information will be required on biosafety components reviewed for this usage of the GMO.
- **Special management considerations**, which may be necessary for specific GMOs, such as insect resistance management plans, integrated weed management plans and stewardship plans to address market segregation, transboundary movement and/or prevention of trade disruption.
- **Post-release monitoring** plan, this is needed for assessing specific environmental uncertainties raised by the risk assessment for a general release application.
- **Payment** of the application fee:

Table 1: Fees for Various Biosafety Permits

S/No.	Activity/Application		Cost (₦)
1.	Accreditation of institution and certification of Biosafety facilities	Processing	400,000.00
		Permit	50,000.00
2.	Certification of new Biosafety facilities (Containment, Confined Fields and Stores)	Processing	300,000.00
		Permit	50,000.00
3.	Confined Field Trial	Processing	4,500,000.00
		Permit	100,000.00
4.	Renewal of trials	Processing	2,000,000.00
		Permit	50,000.00
5.	General/Commercial Release	Processing	5,500,000.00
		Permit	200,000.00

S/No.	Activity/Application		Cost (₦)
6.	Appeals	Processing	300,000.00
7.	Transit	Permit	150,000.00
		Processing	50,000.00
8.	Multi-locational Trials	Processing	10,000,000.00
		Permit	100,000.00
9	**Fast – Track Processing***		
i.	Accreditation of institution and certification of Biosafety facilities		500,000.00
ii.	Certification of new Biosafety facilities		400,000.00
iii.	Confined Field Trial		5,500,000.00
iv.	Renewal of trials		2,000,000.00
v.	General/Commercial Release		6,500,000.00
vi.	Appeals		400,000.00
vii.	Transit		250,000.00
viii	Multi-locational Trials		11,000,000.00

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

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Table 2. A checklist for assessing administrative completeness of applications.

Information category	Activity						
	Contained use	**Confined use**	**General release**	**Food & feed import**	**Export for research**	**Export for food & feed**	**Export for planting**
Applicant details and signature							
Description of activity and GMO					NN		
Molecular characterisation	NN	Vector; Method			NN		

Environmental risk assessment	NN	NN			NN	NN	
Food & feed risk assessment	NN	NN			NN		
Proposed risk management conditions					Packag-ing		
Site map and infrastructure details			NN	NN	NN	NN	NN
Stewardship plan	NN	NN			NN	NN	NN
Detection and identification method	NN	NN			NN		
Recipient details for shipping	NN	NN	NN				
Socio-economic assessment	NN	NN			NN	NN	NN
Advanced informed agreement	NN				NN		

NN = not needed

When an application does not fulfil the information requirements, additional information should be requested from the applicant. In such situation, the procedural 'time clock' may not start until the information is received or may be stopped until the information is received.

The conclusion that a certain application complies with the information requirements, does not mean that additional information may not be requested by the reviewers or decision makers through the national biosafety office. Requests for additional information can be made during the screening for completeness stage as well as during the risk assessment, socio-economic analysis and decision-making processes.

There can be an overlap in information requested during "screening for completeness" and technical information requested during the risk assessment review. Technical information requirements depend on the nature of the GMO and the development stage of the activity. An application for a new GMO will have less biosafety data than an application for a GMO already approved in other countries. Similarly, an application to place a GMO on the market usually contains more biosafety information than a request to move a newly developed GMO from a laboratory to a greenhouse for further testing.

3.2.2. Risk assessment

The types of activities with GMOs that require risk assessment include:

- Import and export of GMOs including for food, feed use/processing
- Transit
- Contained use (*e.g.,* for research and teaching, development, scale up or production and use)
- Confined use (*e.g.,* for field or clinical testing and development, or for production and use)
- General release (*e.g.,* for unconfined commercial or non-commercial production and use)

While the NBMA will still need to be notified that the activity is continuing, it may be comfortable with issuing a permit without repeating a full risk assessment. This permit would have the same terms and conditions for safety as were used with the earlier permits. This leads to what is called a 'fast track' process where the NBMA may decide to apply simplified procedures for familiar activities that have a low risk.

All appointed members of NBC must declare any conflict of interest if they are asked to review an application in which they have a personal, professional or economic interest. This is necessary to maintain the independence and credibility of the review process. Any member with conflict of interest would be dropped from the committee.

3.2.3. Confidential business information

Applicants are to mark information that they wish to keep confidential. If the confidential information is acceptable, the information would not be released to the public. All persons with access to confidential business information would be required to sign confidentiality agreements when they accept biosafety regulatory responsibilities.

If the NBMA does not accept that the identified information should be kept confidential, it would have a consultation with the applicant to review the request for confidentiality. If, after the consultation, the applicant wishes to withdraw the application rather than reveal confidential information, it would be given the option to do so.

In general, the following information is not kept confidential:

- The name and address of the applicant/notifier
- A general description of the LMO
- A summary of the risk assessment; and any risk management requirements.

When confidential business information is accepted in an application, it is marked as such in all documents distributed to reviewers and relevant personnel of NBMA.

3.2.4. Risk assessment

The procedures and minimum requirements for risk assessment and risk management are laid out in National Biosafety Risk Assessment Framework and application forms and should be followed by applicants.

When additional information is requested the NBMA would stop the procedure clock and give the applicant a reasonable amount of time to submit the information before resuming the review and restarting the clock, or considering the application as withdrawn.

The outcome of the risk assessment review will consist of recommendations or advice for the Director General/Chief Executive Officer of the National Biosafety Management Authority.

When the same GMO is being repeatedly assessed for the same use and released in the same location, the risk assessment procedures may be simplified, and attention can focus on the risks posed by any new traits or changes to the methodology of the activities. The decision to simplify risk assessment reviews for specific GMOs is usually taken on a case-by-case basis.

3.2.5. Decisions

The Director General/Chief Executive Officer of the National Biosafety Management Authority is the decision maker on biosafety applications. He takes the risk assessment review recommendations into consideration and may also consider socio economic impact and other issues allowed by regulations, such as national imperatives and benefits and alternative technologies that may address the same issue, or a comparison with existing practices.

The decision would include the risk management measures that are needed to carry out the activity and should contain the summary of the risk assessment.

Once the Director General/Chief Executive Officer of the National Biosafety Management Authority has made a decision about a specific application, t National Biosafety Management Agency, He/she has the responsibility to:

- compile a decision document;
- notify the applicant;
- issue a rejection letter, permit or other form of approval, with or without terms and conditions;
- make the decision public;
- make the decision available to the Biosafety Clearing House;
- confirm that distributed copies of the application have been returned, deleted or destroyed;
- schedule inspections;
- review inspection reports, and
- review activity reports.

3.2.6 Timeframes

The CPB stipulates timeframes for specific decisions and these have been adopted by Nigeria and provided below (Table 3). The timelines generally start at the receipt of an application.

Table 3. Procedural timeframes obligated by the Cartagena Protocol on Biosafety.

Regulatory activity	Timeframe	Reference
Acknowledgement of receipt of notification and how to proceed with the first intentional transboundary movement of a LMO	90 days	Article 9(1)
Communicate a decision on an AIA import notification	270 days from date of acknowledgement	Article 10(3)
Take a decision on a GMO import for food, feed or processing (applicable to developing country Party or a Party with an economy in transition, in the absence of a domestic regulatory framework)	270 days	Article 11(6)
Inform the BCH of a decision to approve a LMO for domestic use as food, feed or processing, including placing on the market	15 days	Article 11(1)
Notify an applicant of a change in decision regarding a transboundary movement	30 days	Article 12(1)
Party response to changed decision on transboundary movement	90 days	Article 12(3)

Notification of unintentional transboundary movement likely to have significant adverse effect	Immediate	Article 17(1)

3.2.7 Other administrative duties

In addition to handling applications for activities with GMOs, the NBMA carries out a range of other biosafety administrative duties that are factored into the time allocations and staffing of the office. These include:

- Providing **secretarial services** to the Board, NBC and other committees;
- D**ealing with accidents, emergencies and unintentional releases**, which generally get priority over daily administration;
- Handling of new **information** that is submitted to the biosafety office about the safety of a previously approved GM activity;
- Administrating **appeals against decisions** made by the national authority;
- **Review** the regulations and guidelines with respect to how they are working and whether changes are recommended;
- **Modifications or additions to guidance documents** as new GMOs and related activities raise new biosafety issues that need to be addressed;
- Ongoing **liaison with stakeholders** such as parliament, ministers, ministries, applicants, the public and regional and international biosafety meetings and Protocols;
- Running the biosafety website and ensuring adequate communication, feeding and retrieving information from the Biosafety Clearing House(BCH);
- Ongoing **training of the human resources** involved in the biosafety review process and enforcement.

3.2.8 Resource requirements for national biosafety

Scientifically sound safety assessments and measures for safe handling of GMOs require human, financial, and information resources as well as an adequate infrastructure. The following resources are required in the NBMA:

3.2.8.1 Biosafety Enforcement Officers

Biosafety Enforcement Officers will need skills in:

- Priority setting;
- Resource acquisition and allocation;
- Coordination with multiple agencies;
- Meeting management;
- Communication across many sectors;
- Information access and management;
- Handling of confidential or proprietary information.

3.2.8.2 Scientists

The scope of scientific disciplines relevant to biosafety review is extensive. Expertise will be matched to each application taking into account the GMO, its use and the release environment. The NBMA assesses the required expertise for each application and pulls together a team that has the expertise (NBC) needed for the risk assessment or review. The relevant scientific expertise may be sourced by the NBMA within or from the scientific community.

To be effective, the biosafety reviewers will need skills in risk assessment and risk management procedures in addition to their biological expertise. They will also need a broad understanding of the principles of inspections and monitoring. Training programmes, organised regularly by the NBMA will help to provide biosafety skills for existing and new reviewers. The NBMA shall develop a Roster of Experts to capture the relevant expertise needed. The Roster shall be reviewed periodically and updated when needed.

3.2.8.3 Information access

Biosafety Enforcement officers of NBMA will be updated with significant amount of information and data on which to base their activities. Some of these information sources will include the Biosafety Clearing House (BCH).

Decision documents from other national biosafety committees are particularly rich source of information on identified risks and management options for particular GMOs and products. These will also form sources of information for Biosafety Enforcement Officers.

3.3.2 Feedback mechanisms

Feedback will be considered as essential component for GMO trials and general releases. Trials are carried out to collect data of commercial and biosafety importance. Feedback mechanisms would be used to ensure that findings and experiences from field trials are tabled for consideration by NBMA experts. This feedback will also provide NBMA with information to address concerns that may arise during or after the trials. The NBMA will request field trial reports that record compliance with the regulatory terms and conditions for the trial and summarise the data collected during the season and during post-harvest monitoring.

When the general release of a GMO is authorised, it is necessary for the applicant to collect *specific* data after the initiation of commercial production. The exact data and the reasons for collecting the data must be based on the scientific findings of the review body. Feeding this information back to NBMA enables on going monitoring of the impact of the crop on the environment. Collecting data after general release approval shall serve as a condition for the approval.

3.3.3 Financial support

The sustainability of the National Biosafety Management Agency will be determined by its funding as per the Financial Provisions of the Biosafety Act (2015) to maintain high safety standards and for effective compliance. The costs of establishing and operating the National Biosafety Management Agency will include:

- Education of policy makers and stakeholders;
- Development of regulations and guidance documents;
- Development and distribution of procedural information;
- Technical training for reviewers;
- Managing information and documentation;
- Administrative expenses of risk assessment and decision-making reviews and meetings;
- Salary and support for employees;
- Pre-release site visits (if required);
- Inspections of activities;
- Review of inspection reports for compliance;
- Training for inspectors;
- Review of processes and recording mechanisms; and
- Training customs and other sister Agencies personnel on cross border movement of regulated materials.

Applicants will be charged fees to cover some of these costs as indicated above. Differential fees may be charged between private sectors and public. Thus, in setting fees, regulators need to consider the constraints this will have on stakeholders and on access to new technology.

Compliance costs refer to expenses incurred by the applicant in meeting regulatory requirements may include:

- Generating data needed for the application;
- Financial losses resulting from delays in regulatory decision making;
- Implementation of risk management measures;
- Post-release monitoring prescribed as a condition of approval; and
- Reporting and documentation.

Food safety data from other countries may be used but additional environmental data may be collected locally to supplement existing environmental information on specific events. Additional food safety data to evaluate impact on communities where foods are used differently or in greater quantities, or where there may be a genetic disposition in local populations that requires additional risk assessment may be required. GMOs that have undergone prior review in another country may not require a complete replication of the data, particularly food safety data.

4. Decision making

There are two clear aims in decision making on GM activities and GMOs:

- Accountability, determined by compliance to the regulatory regime, and

- Transparency, provided through decision documents.

The types of decisions to be made by the NBMA will differ according to the activity that is regulated and the requirements of the guidelines and regulations. Contained research, confined field testing and clinical trials very rarely have an environmental risk assessment because the organisms are not released permanently and do not persist in the environment. Measures are established to deal with unintended release. The safety assessments for research therefore focus on the measures needed to contain and confine the organisms and on personnel safety. For low risk categories of GMO research and development and for facilities with high levels of containment, NBMA will introduce notification systems for specific activities with specific categories of GMOs to streamline their regulatory process. These systems will require facility registration that stipulates the need for an internal risk assessment and notification procedure for all new GMOs. This requires minimal regulatory action unless the internal risk assessment for a specific GMO triggers more extensive containment, confinement and/or regulation, at which point the NBMA needs to determine the terms and conditions for this higher risk research.

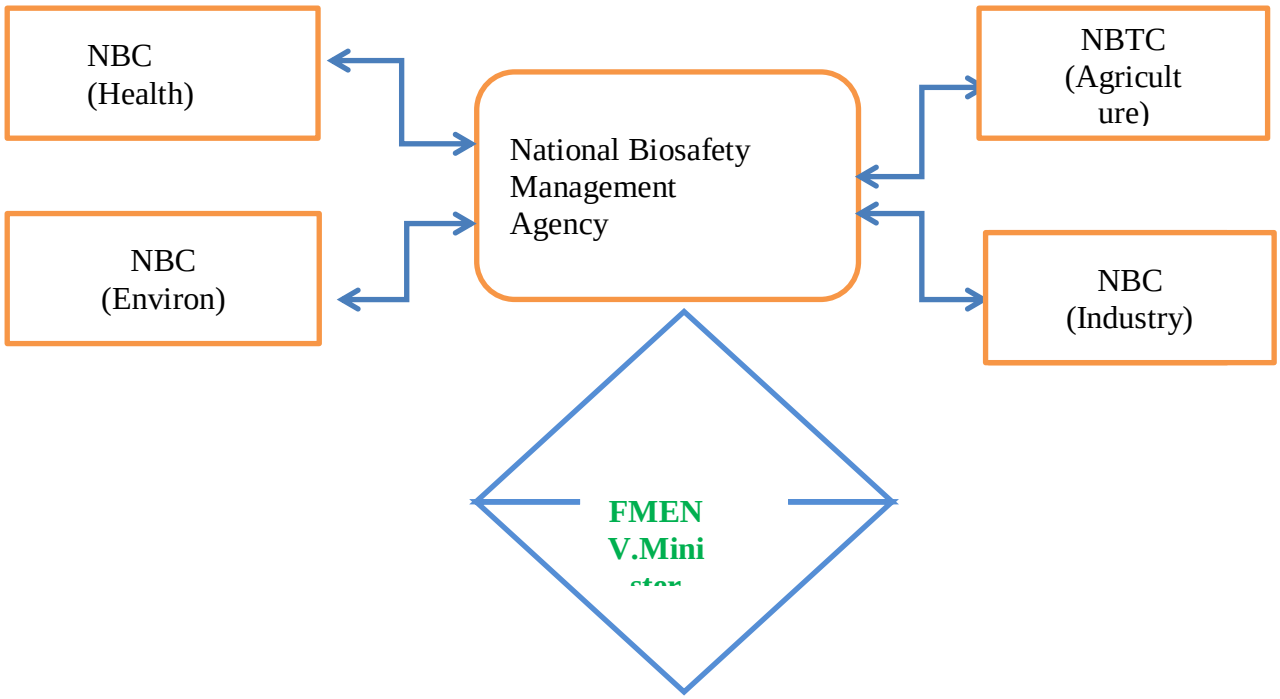
If initial development and testing of GMOs will require regulatory review up until the risks are better understood and the risk management conditions have proved effective and the applicant has a record of compliance with safety requirements. Once this level of experience has been established the regulatory input may diminish for familiar activities known to be of low risk but will be required again when the GMOs are moved out of containment for further evaluation and selection in field or clinical trials.

The level of regulation of field and clinical trials will also be determined relative to the risk of the activity. Once the risk assessment has clearly defined the potential risks and feasible risk management measures, the decision is given with terms and conditions under which the activity must be carried out.

Some level of regulation may continue after general use approval depending on the nature of the GMO and its use. Regulatory terms and conditions may sometimes be included in general use permits, *e.g.*, the implementation of insect resistance management systems applicable to some insect resistant GM crops. Other GMOs can be approved for commercial use without the need for any post-approval biosafety regulation.

4.1. Factors considered in national decisions

NBMA will make decisions about the development, import, or deployment of GMOs and their products.



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4.1.1. Applications for contained use

Activities carried out during the development of a new GMO are undertaken in contained facilities after the certification of the containment facilities by the NBMA. The Principal Investigator must notify the NBMA before any genetic manipulation can place in the containment facility.

Containment facilities will be inspected from time to time by the NBMA to ensure that the containment guidelines are being implemented.

4.1.2. Applications for confined field and clinical trials

The testing and selection phases of GMO development are used by the applicant to select the best GMOs for general release and to assess the environmental safety of the new GMOs and their food and feed safety. This testing entails releases into the environment in a confined space for a short period of time, after which the GMOs are completely removed from the release site.

The factors considered in decisions on field and clinical trials focus on the ability of the applicant to confine the GMO to the test site and to maintain control over the regulated material while it is transported, stored, used and removed from the site. The NBMA will also be interested in the post-use monitoring of the site to ensure that no viable GMOs remain after testing.

Field and clinical trials do not have a socio-economic impact on the release environment and so these issues may not be considered in decisions on applications for confined

testing. Similarly, the material from the trials does not enter the food and feed chain and so food and feed safety information is not needed for decisions on confined testing. Because of the transient nature of confined trials public comment for these applications will not be required. However, if the confinement measures extend to land adjacent to the trial sites, then the NBMA will mandate the applicant to discuss the consequences of this with neighbours who could be affected by the inspections and follow-up procedures in the case of an unintentional release.

Once applicants move toward general use and commercial release, they need to be confident that their products are safe for consumption and will not impact adversely on the environment, or on human health. These data are collected during confined testing to be presented in the application for general release approval.

4.1.3. Applications for general release

For general release applications the potential impact of the release on the environment, the safety of the food, feed, fibre and any other products derived from the GMO is included in the risk assessment and in decision making.

Other considerations by the NBMA may include national policies on technology, research and sustainable development; the potential benefits and role of the technology in meeting national goals and objectives in food production, food security, wealth creation, job creation, trade and related areas. NBMA may compare the product of the new technology to existing products and consider what impact deployment may have on indigenous knowledge, heritage and culture.

Table 3 summarises issues that have been factored into decision making on the general release and use of GMOs.

Table 3: Some decision-making considerations for general release of GMOs

Molecular characterisation	Human & animal safety	Environmental safety	Other issues
Insert effects Copy number Expression levels Stability, *etc*.	Food safety Toxicity Pathogenicity Allergenicity/Digestibility Nutrition Workers safety Unexpected products Gene stability Other	Impact on: **Living organisms** Biodiversity Outcrossing Weediness Invasiveness Non-target organisms **Gene flow** **Gene stability** **Air, soil, water** Other	**National imperatives** Food security Wealth creation Sustainable development **Economics** Access and cost Labour Trade, Product stewardship, *etc*. **Social** Ethics or religion, Indigenous knowledge Traditional technology Gender impacts Equity issues, *etc*., **Labelling**

Of necessity, decisions on GMOs would be made on a case-by-case basis, as each GMO may have a different level of risk and different impact on the release environment. GMOs may also differ in the benefits offered and the way in which they impact on local communities.

For general release applications the NBMA may consider the potential impact on trade, labelling, labour, food security, gender, small business development, sustainable

development and poverty alleviation. These are some socio-economic factors that may be important in the final decision as is highlighted in the Biosafety Act 2015 which may be periodically updated through operational guidance from the NBMA to assist in decision making

4.1.4. Applications for import of GM commodities

Applications for food and feed imports may require a full environmental risk, and safety assessment as they may get into the environment accidentally. They are to comply with GMOs import and export regulation.

4.1.5 Decision documents

Decision document with a covering letter shall be issued to the applicant on completion of the processing of any application. The decision document shall be made available in the BCH and the National Biosafety Website and the general media.

If the document is a rejection of an application, the reasons for rejection shall be clearly stated so that the applicant knows what these issues are. If the decision document is the approval notification it will list any terms and conditions deemed essential for the safe implementation of the activity. Decision documents would provide details of what is approved as the decision may not necessarily grant exactly what the applicant is requesting but may apply conditions such as time limits, geographical location limits, and other specific restrictions or requirements.

5. Monitoring

The term "***monitoring***" describes the collection of scientific biosafety data to support the scientific basis for biosafety decisions. It also describes the systematic measurement of the effects of GMOs over time. The aim of GMO monitoring is to identify direct, indirect, immediate, delayed, or unintended harmful effects that GMOs and their use might cause to the environment or human health. Because risk assessment is undertaken with an incomplete but sufficient understanding of the GMO, some potential risks may cause the NBMA to add monitoring requirements to an approval so that specific uncertainties can be studied and addressed with real data that is collected during the first years of the use of the GMO. These data obtained by monitoring would be used to impose new risk management conditions on approvals or to maintain, renew, or withdraw an approval for general release of a GMO.

Not all activities may require monitoring plans. If the NBMA requires monitoring as a condition of an approval, specific requirements for monitoring would be laid out clearly in the decision document for each approved application.

Monitoring may be carried out by the NBMA or by the applicant, who analyses the data and submits both the data and the analysis to the NBMA for review.

Monitoring activities require regular reporting and the NBMA will ensure that these reports are submitted on time and are reviewed.

6. Inspections and Enforcement

The term "***inspection***" describes the check for compliance with biosafety regulations, and with the terms and conditions of permits for activities with GMOs. Inspections will be carried out by the NBMA and will involve site visits. These may be to facilities, field trial sites, commercial release sites, clinical trial sites or storage areas. Inspectors may also visit ports and processing facilities. The NBMA will use checklist /inspection forms for all inspection of GMO activities. In the course of an inspection, the NBMA may review physical containment measures, confinement procedures, materials and documentation related to the movement, storage, planting and destruction of GMOs. Sites of unintended release may also be inspected. The NBMA shall schedule inspection activities and set priorities for inspections based on risk levels.

The NBMA shall enforce identified non-compliance to permit terms and condition in line with National Biosafety Regulations/Guidelines

The NBMA shall use its Enforcement officers to enforce non – compliance. It shall also provide and update guidance manuals for biosafety inspection and shall ensure that inspectors are well trained to carry out biosafety inspections.

The day-to-day activities of the NBMA will include inspection of facilities, imports, shipments, field trials, commercial field releases, as well as the follow up of reports of non-compliance and the ongoing review of planned GM activities in the country.

6.1. Applicant reporting requirements

To keep the documentation of the biosafety components by applicants, the following documents would be used as appropriate:

- Biosafety guidance documents,
- Regulatory containment and confinement requirements,
- Standard operating procedures; and
- Records of transport, storage, planting, reproductive isolation, harvest, post-harvest monitoring, monitoring and destruction.

These reports will be kept in files for facility registration, greenhouse, clinical trials and field trials and will be reviewed by inspectors during inspections.

6.2. Inspection reports

The inspection shall include a discussion with the NBMA both at the outset and at the end to clarify issues and address minor problems. Inspection report shall be submitted within 14 days after the inspection to both the Head of NBMA and the Facility Head. The report should clearly indicate actions that need to be taken at the facility and time frames within which these are to be done.

Reporting standard formats to ensure that all aspects are covered in the inspection, to minimise the time needed to prepare the inspection reports, and to provide a consistent inspection reporting format that is easy to analyse and that clearly identifies non-compliance and issues that need to be resolved would be adopted.

6.3. Training inspectors

NBMA Enforcement officers and Inspectors shall be trained on biosafety inspection and basic modern biotechnology to equip them for inspection of GM activities. The NBMA shall collaborate with other border control agencies like Nigeria Quarantine Service (NQS), Nigeria Customs Service and National Agency for Food and Drug Administration (NAFDAC). The designated control staff of these agencies will also be trained on inspection and identification of GMOs with the view of alerting the NBMA for appropriate action.

6.4. Skills required for biosafety inspection

Biosafety Inspectors/Enforcement Officers shall be equipped with four types of skills: legal, technical, organisational, and personal.

Legal skills will come through legal training and qualification as officers of the law. Technical skills will include a good understanding of basic biology ecology and molecular biotechnology. There should prove willingness to read scientific literature critically and a good understanding of what is needed to run a modern biotechnology laboratory and testing facilities.

Organisational skills will be impacted on NBMA Inspectors /Enforcement Officers for effective performance. The biosafety inspectors will be trained to understand processes and systems that enable them to cope with increasing numbers of approvals. In addition, inspectors/Enforcement Officers will be required to imbibe personal qualities that give them credibility to do their job. These qualities will include trustworthiness, high level of integrity high work ethics, disclosure of conflict of interest, and good interpersonal skills.

On-the-job training for biosafety inspectors/Enforcement Officers will also be encouraged.

6.5. Enforcement

The biosafety inspections would be carried out under several legal instruments, which are outlined in biosafety regulations/guidelines.

A biosafety enforcement officer may in company of Police enforce compliance to permit conditions once non-compliance is identified. The NBMA may take legal actions in line with the Biosafety Act (2015) once non-compliance has been identified.

6.5.1. Legal authority for enforcement

The legal authority for enforcement is derived from National Biosafety Act, Biosafety Regulations and Guidelines, the Cartagena Protocol and relevant extant laws.

6.5.2. Administrative tasks for enforcement

Biosafety Inspectors/Enforcement Officers will be required to take appropriate action immediately an infringement becomes evident. In some instances, this means contacting the NBMA to plan and approve corrective action. However, many infringements are unintended and easily corrected. The corrections will to be

implemented quickly to maintain safety levels and the credibility of the system. The corrective action should be recorded and kept in the applicant's documentation file.

Where an infringement cannot be quickly or easily corrected, the activity may need to be stopped until the corrections can be eeffected to the satisfaction of the NBMA. In extreme cases where the infringement may have resulted in harm, or the negligence is deemed unacceptable, the NBMA may take legal action.

6.5.3. Roles and responsibilities

The responsibility for enforcement falls primarily on the NBMA. The Biosafety Enforcement Officers/Inspectors concerned shall provide documents to support an infringement claim. These documents may include:

- the approval document with the conditions clearly stated;
- the inspection reports identifying the infringement;
- an assessment of the impact of the infringement with respect to safety; and
- any evidence seized or collected to support the claim, such as soil or plant analyses, photographs, signed statements, *etc.*

Enforcement officers/Inspectors may stand as witnesses during the prosecution proceedings.

7.0 Continuous improvement

The development of an administrative system for biosafety in Nigeria is a work in progress. Biotechnology is a rapidly evolving field in which new issues and activities are continuously emerging, and Nigeria has to be able to deal with changes in the national priorities and in public concerns. The Nigerian Administrative System is designed to evolve according to changing circumstances or demand.

The development of Nigeria's administrative system is an on-going, iterative exercise. Consequently, feedback during the implementation of the NBF gives the NBMA an opportunity to ensure that the Nigeria Biosafety Framework is able to respond to changing needs, priorities and circumstances.

The answers to the following questions will determine further review of this document in future:

- **Clarity**
    - Is it clear what processes and procedures apply to GMOs, GM derived products and activities involving GMOs?
    - Will users of the system –government, the public, or applicants – understand how the administrative system works?
    - Is a clear message or consistent instructions being communicated through the country's policy, laws, websites, employees, messages to the media, *etc.?*
- **Transparency**
    - Is the system transparent?

  - Can applicants and other stakeholders find out and understand how the administrative system works?
  - Is it possible to follow the decision-making process from the initial filing of an application through to the final decision?

- **Consistency**
  - Are terms and definitions used throughout the administrative system in a consistent manner?
- **Practicality**
  - Is the process workable?
  - Can the process work in practice as well as on paper?
  - Are the resources available to implement this process?
  - Do the stakeholders understand the process?
  - Are they willing to comply with it or will it create enforcement problems?
- **Authority**
  - What sort of authority are required to implement the administrative system procedures? For example, the authority to inspect private property or the authority to request test data from an applicant.
  - Does the NBMA that is charged with implementing this process actually have the authority to implement it?
- **Participation**
  - Is the system participatory?
  - Are there mechanisms for all interested stakeholders to participate in the decision process?
  - Is public participation allowed at various stages in the decision-making process?
- **Effectiveness**
  - Does the administrative system achieve its objective?
- **Predictability**
  - How predictable is the administrative system?
  - Has it been designed in such a way that applicants and other stakeholders can expect the administrative system to work in a predictable manner?
  - Is it clear to applicants and other stakeholders whose responsibility it is to take decisions and on what basis?
  - Are the time frames, for example, clear and definite?
- **Enforceability**

- Do the resources exist to carry out this enforcement?
- Is enforcement likely to be a problem or will there be willing compliance?
- Can there be non-governmental enforcement through the help of industry and/or the public?
- What sort of training will be needed in the future for enforcement?

- **Adaptability**
  - How adaptable does the system need to be?
  - How adaptable is it?
  - Will changes be difficult, costly, or confusing?
  - Are the elements that will most likely need changing relatively easy to change?

The review of the Nigeria biosafety administrative processes, guidelines, regulations will be carried out as when necessary.

APPENDIX 1

GUIDANCE FOR DOCUMENT TRACKING CODES

Document tracking codes will be used for the administration of biosafety submissions by NBMA to support the review and processing applications for biosafety work as follows:

Date received,

Date acknowledged,

Type of activity
Applicant
Number of application from that submitter in that year,

Decision on activity
Activity code

Activity code

The Activity code is arbitrary and is used to quickly identify applications for specific types of activities. A common code is:

A= facility registration
B = contain use (lab research; greenhouse work; microorganism production)
C = confined trials (field trials and clinical trials)
D= unconfined release (growing, using)
E = food and feed import
F = others

APPENDIX 2

Sample SOP for Handling Applications

STANDARD OPERATING PROCEDURE (SOP) FOR THE HANDLING OF BIOSAFETY APPLICATIONS WITHIN COUNTRY

Note: This Standard Operating Procedure (SOP) is to be used by Regulatory Offices that are handling applications for approval of activities with genetically modified organisms (GMOs).

A. DESCRIPTION OF THE ACTIVITY

A.1. To ensure compliance with requirements for handling biosafety applications in Nigeria

B. SCOPE

B.1. This SOP applies to the handling of applications for approval of activities with GMOs in Nigeria and covers applications for import, export, transit, contained use, confined use, food and feed commodity imports and commercial/general release.

C. **DEFINITIONS**

C.1. **Administration office**: An office within a national biosafety framework that is responsible for receiving biosafety applications for approval of GM activities.
C.2. **Applicant**: A permanent resident of Nigeria or designated agent to whom all correspondence with respect to the application including the notification of authorisation shall be addressed.
C.3. **Confidential Business Information (CBI):** Information in applications that will be kept confidential.
C.4. **Confined use:** The research and development of GMOs in short term clinical or field trials that are managed to minimise impact on or persistence in the environment.
C.5. **Contained use**: The research and use of GMOs within a facility that is designed to minimise GMO release into the environment.
C.6. **Event:** Each individual GMO produced during the modification of a single plant species using a specific genetic construct.
C.7. **General release**: The approved general use of a GMO with no or minimal regulation. Also termed 'unconfined release' and may have some conditions appended to the approval for use.
C.8. **Genetically Modified Organism (GMO):** A plant, animal or microbe derived through recombinant-DNA techniques.
C.9. **Genetically Modified Product:** A non-living product that is derived from a GMO.
C.10. **Inspection**: A check for compliance with regulatory conditions for activities with GMOs. This may include the review and investigation of facilities, materials and documents related to approved activities with a GMO.
C.11. **Monitoring:** The scientific collection of biosafety data to support biosafety decisions, including the systematic measurement of the effects of GMOs over time.
C.12. **National biosafety framework (NBF):** The national structures established by legislation to implement a biosafety regulatory process in a country.

C.13. **Unconfined release:** The approved use of a GMO with no or minimal regulation. This is also termed 'general release' and may have some conditions for use appended to the approval.

D. GENERAL REQUIREMENTS FOR THE HANDLING OF BIOSAFETY APPLICATIONS

D.1. The biosafety administration officers shall comply with this SOP.

D.2. All biosafety applications shall be handled in an efficient manner, honouring timeframes and communication requirements.

D.3. All biosafety applications shall be securely transported between the NBMA and individuals/Institutions.

D.4. All biosafety applications shall be clearly documented and labelled.

D.5. The confidential information in biosafety applications shall be accessed only by persons who have signed confidentiality agreements with the NBMA.

D.6. Only public information shall be released in public communication from the biosafety NBMA.

E. SPECIFIC REQUIREMENTS FOR THE HANDLING OF BIOSAFETY APPLICATIONS

E.1. The biosafety application shall be given a processing number and a tracking sheet shall be opened on the day it is received at the NBMA

E.2. The administrative completeness of the application shall be assessed within 90 days of receipt.

E.2.1. Receipt of the application shall be acknowledged in written communication with the applicant within 90 days of determination of administrative completeness or administrative deficiency.

E.3. Confidential business information shall be identified and secured.

E.4. Applications that do not require risk assessment or public comment shall be processed within 90 days.

E.5. An appropriate NBTS to review risk assessment shall be established within 90 days for applications that require risk assessment prior to decision making and are deemed to be administratively complete.

E.5.1. Applications shall be forwarded for risk assessment review within 90 days of acknowledgement for administrative completeness.

E.5.2. Applicants shall be notified within 90 days if additional information is required for the risk assessment review process.

E.6. An appropriate socio-economic review team shall be established for applications that require socio-economic review prior to decision making.

E.6.1. Applications will be forwarded for socio-economic review within 90 days of acknowledgement for administrative completeness

E.6.2. Applicants shall be notified within 90 days if additional information is required for the socio-economic review process.

E.7. Public comment shall be invited for applications that require public comment prior to decision making.

E.8. Applications for which risk assessment recommendations, and/or socio-economic assessment recommendations, and/or public comments have been received shall be forwarded to the NBMA/HMEnv 7 days of completion of reviews and comments by the NBTS/ Socio-economic review team.

E.8.1 Applicants shall be notified within 90 days if additional information is required for decision making.
E.10. Decisions shall be forwarded to the applicant within 270 days from the start of the decision-making process.
E.11. A decision document shall be made public within 15 days of notification to the applicant of the decision.
E.12. Appropriate inspections shall be scheduled within 15 days following notification to an applicant of a decision to approve an application.
E.13. Reporting requirements for applications shall be monitored and documented within the timeframes stipulated in the decision document.

F. ASSESSING ADMINISTRATIVE COMPLETENESS
F.1. The application shall be assessed to confirm that it contains all the components required in the national regulations for an application of that type.
F.2. Applicants shall be notified in writing within 90 days when the application meets the administrative requirements for submission and the application shall enter the review process immediately.
F.3. The applicant shall be notified in writing within 90 days if information sections or other components are missing from the application.
F.2.1. The review clock shall be stopped until the missing information is received.
F.2.2. The applications shall be considered withdrawn if the information is not received within the allotted timeframe of 90 days unless the applicant has applied for extended time to meet the submission requirements for the application.
F.4. The NBMA shall notify the applicant in writing when the application meets the administrative requirements within 90 days of receiving the additional information requested for completeness and the application shall enter the review process immediately.

G. CONFIDENTIAL BUSINESS INFORMATION (CBI)
G.1. The NBMA shall review information that is marked as confidential and determine whether this meets the national regulatory requirements for CBI.
G.1.2 The applicant shall be consulted if changes are needed to the information that can be considered CBI.
G.2.1. The applicant shall have the opportunity to withdraw the application if agreement on CIB is not reached.
G.3. Copies of the application that contain CBI shall be secured within the NBMA and only distributed to authorised persons who have signed confidentiality agreements.
G.4. Only a copy of the application that has had the CBI deleted shall be made available for public access.
G.5. All persons who have access to applications that contain CBI shall have signed confidentiality agreements prior to receiving applications with CBI.
G.6. The confidentiality agreement that allows access to CBI shall contain measures to ensure that all distributed applications containing CBI, with the exception of the official copy held at the NBMA, shall be deleted and/or destroyed after the decision on the application has been made.
G.7. Confidential business information will remain confidential in applications that have been withdrawn.

H. RISK ASSESSMENT REVIEW

H.1. The NBMA shall establish a scientific review NBTS for an application that requires risk assessment review.
H.2. The risk assessment review NBTS shall be established within 90 days of acknowledging in writing to the applicant that the application fulfils administrative requirements.
H.3. The risk assessment review NBTS shall have the expertise needed to evaluate the safety of the specific GMO activity.
H.4. All members of the risk assessment review NBTS shall sign and return confidentiality agreements prior to receiving applications that contain confidential business information.
H.5. The administration officer shall stipulate a return date for the risk assessment recommendations.
H.6 The applicant shall be notified in writing within 90 days if the risk assessment team require additional information.
H.6.1. The review clock shall be stopped until the additional information is received.
H.6.2. Applications shall be considered withdrawn if the information is not received within the allotted timeframe of 90 days unless the applicant has applied for extended time to submit the additional information.
H.6.1. The NBTS shall be reminded of the deadline one week prior to its date.
H.6.2. The risk assessment recommendations shall be drafted and dated by the NBTS. The recommendations shall state clearly the risks that were assessed, the risk management measures that are recommended for the activity, any specific inspections or monitoring that is recommended, and shall be signed by all the Members of the NBTS.
H.6.3 Any member of the NBTS who disagrees with the final recommendations shall send a written explanation of his/her objections and findings to the Head of the NBMA. These objections shall be submitted to the NBMA by the deadline set for the risk assessment.

I. PUBLIC COMMENT

I.1. The NBMA shall enable public comments on the applications that require this input under the National Biosafety regulations.
I.2. The public comment period shall occur within 21 days from when comments are required
I.3. The public shall be notified of the comment period and the deadline in the manner stipulated in the regulations.
I.4. Public comments shall be received by the NBMA
I.5. The public comments shall be assessed and summarised within 90 days of the deadline, by the NBMA.
I.6. Public comments requiring response by the applicant or the scientific or socio-economic advisory bodies shall be forwarded to these bodies within 90 day of the deadline for written response.
I.6.1. The applicant shall submit his/her response in writing to the administration office within 90 days of receiving the public comments.
I.7. The summary of the public comments may be made public.

J. DECISION MAKING

J.1. The NBMA shall forward the NBTS recommendation to the Honourable Minister of Environment for decision within 7 days of compiling the required documentation.

J.1.1.The Honourable Minister may request additional information, if required, from the applicant or NBTS within 15 days of receiving the recommendation.
J.2.1. The applicant /NBTS shall submit the information within 15 days of receiving the request.
J.3. The NBMA shall inform the applicant of the decision with decision document within 270 days of receiving of application.
J.4. The decision document shall contain the risk management terms and conditions for the activity, when/if application is approved.

K. CORRECTIVE ACTION
K.1. If biosafety application does not comply with the regulatory requirements, NBMA shall notify the applicant within 90 days of confirmation that the regulatory requirements have not been complied with.
K.2. In the event of an application or documentation relating to an application, being released to an unauthorised person all attempts shall be made to recover the documents as quickly as possible by the NBMA.
K.2.1. The NBMA shall notify the applicant within 48 hours of confirmation that documentation has been misdirected to an unauthorised source.

L. RECORD KEEPING
L.1. Copies of the Record of Application Receipt and Handling, including the record of timeframes for review, shall be retained by the NBMA for 15 years from the decision on the application.
L.2. All records associated with the handling of the application shall be available for inspection by the Auditor General upon request.

M. **REVIEW AND DISTRIBUTION**
M.1. This SOP shall be reviewed by the NBMA annually.
M.2. Revised SOPs shall be distributed to all personnel involved with the handling of applications, who shall then destroy their older copy.
M.3. Archival copies of this SOP shall be maintained by the NBMA.

General comments

I suggest the different application procedures be put in

i. Simplified small booklets in the future for applications as some may only be requiring guidance on contained use, registration of facilities etc
ii. Develop schematic diagrams or posters of the different application/administrative procedures to assist the applicant