

FEDERAL REPUBLIC OF NIGERIA

NIGERIA NATIONAL BIOSAFETY COMMUNICATION

STRATEGY

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NIGERIA NATIONAL BIOSAFETY COMMUNICATION STRATEGY

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Chapter 1 Preamble

Effective Biosafety communication is an integral component of Biosafety Risk analysis. Biosafety communication is the 'culture, processes and structures to communicate and consult with stakeholders about biosafety'. Such exchanges may not relate exclusively to risk but may also consist of expression of concerns, opinions or reactions to socioeconomic impact and risk messages or to legal or institutional arrangements for risk management.

The National Biosafety Management Agency is neither a proponent for nor opponent of modern biotechnology but an impartial regulatory Agency that is required to communicate to the Government and people on matters relating to the risk assessment and risk management of GMOs.

The National Biosafety Management Agency is committed to providing information to interested parties on applications, permits, dealings with GMOs, trial sites and the processes of risk assessment, risk management, monitoring, Inspection and compliance undertaken. The primary mechanism for providing information about the National Biosafety Management Agency to interested public is through the National Biosafety Management Agency website that would contain extensive information on the operations of the National Biosafety Management Agency, including various application forms, Regulations and Guidelines and GMOs Records, press briefing, news bulletin, risk assessment documents, decision documents, the annual report and direct response to e-mail and phone calls, seminars, workshops and direct interaction. Documents that provide essential background information for the National Biosafety Management Agency, such as the biology of plant species that have been modified by modern biotechnology, are also to be available on the website and at the office.

The Agency annual reports provide details on applications considered, monitoring activities undertaken, they also summarize other activities of the National Biosafety Management Agency in relation to reviews, research, freedom of information requests.

In addition, the National Biosafety Management Agency would provide regular workshops for Institutional Biosafety Committees (IBCs) on particular administrative matters and to help them and applicants recognize particular categories of dealings. The National Biosafety Management Agency would have regular contact with applicants on a range of matters, both scientific and administrative. The National Biosafety Management Agency would endeavor to foster a cooperative compliance culture, educating and informing applicants to minimize the likelihood of breaches of the legislation and subsequent application of penalties under the Act for noncompliance.

The Agency would provide information on the regulation of modern biotechnology. The aim of this biosafety communication strategy is to promote a clear understanding of all aspects of risk and the particular positions of interested parties. Specifically, it aims to provide information about risk to make decisions, to minimize conflicts, to improve understanding of perceptions and

positions, and to achieve equitable outcomes. It is to provide all parties with a better understanding of the issues; it is not to change basic values and beliefs.

This strategy focuses on risk perception and outlines consultative processes between stakeholders and the National Biosafety Management Agency. It demonstrates the National Biosafety Management Agency's commitment to effective communication with stakeholders.

Public perceptions of the risks associated with modern biotechnology range across a wide spectrum of positions and include ethical concerns such as 'meddling with nature' and social issues which require public education.

Chapter 2 Objective of the Strategy

The Objective is to keep stakeholders informed about national biosafety process, address concerns about modern biotechnology and products of modern biotechnology which are genetically modified organisms (GMOs) as relate to safety.

Chapter 3 Biosafety Communication strategy

It is to assist regulators to acknowledge and address concerns raised by stakeholders and the public. The ultimate focus is to clarify misconceptions and promote a clear understanding of biosafety and modern biotechnology processes and procedures from product development to preand post-market, commercialization.

There are two major areas of this biosafety communication strategy:

- Communication on the regulatory processes; and
- Communication on the safety of Modern biotechnology and its products.

Communication on the biosafety regulation includes providing information on the National biosafety policy, laws guidelines, how stakeholders are to participate in their development, how the applications are accessed and implementation. This is to increase the awareness on how assessment is done, how safety, benefits and risks are reviewed by the regulatory authority

The communication strategy would strengthen outline consultative processes that would improve the general understanding of the thoroughness of safety assessments for transgenic products, as well as the effectiveness of the national biosafety framework to ensure access to safe products and control of unsafe products. It is also to foster good communication of well-informed decisions built on confidence in the biosafety process and help to influence the public acceptance of approved products.

3.1 The Scope of the Biosafety Communication strategy

The scope shall include the following:

• Status of biosafety policy in the country and any proposed changes to policy

- Policy and all activities require for biosafety approval
- Biosafety laws, regulations and guidelines
- Application and review processes
- Risk assessment for food safety and environmental impact
- Risk management for specific products or activities
- Contingency plans for emergencies
- Compliance requirements and
- Public participation

3.2 Nigeria National Biosafety Communication Charter

Effective risk communication requires the active participation of all stakeholders, including government. This charter presents the principles of Biosafety communication that the National Biosafety Management Agency aims to uphold and demonstrates its commitment to active biosafety communication. It shall be the responsibility of the National Biosafety Management Agency National Biosafety Management Agency to provide transparent, factual and timely information to stakeholders so as to build trust and earn the confidence of the Nigerian public.

The National Biosafety Communication Strategy bases its Charter on:

- Objectivity/Neutrality
- Transparency
- Credibility and trust
- Consistency
- Proactive and systematic procedures
- Accuracy and relevance of information
- Accessibility
- Simplicity
- Balance
- Sensitivity to local views
- Brevity (Concise)
- Knowledge of audience
- Informative (not convincing)
- Timeliness (integrated into the process from the outset)
- Raising awareness of Nigeria's biosafety regulatory system for modern biotechnology nationally and internationally
- All stakeholder's inclusiveness in biosafety communications
- Information on scientifically-based risk assessment and risk management of dealings with GMOs in an open and transparent manner,
- Actively communicating the reasoning behind permit decisions in an open and objective manner in plain language
- Actively listening and responding, in a timely manner, to stakeholders' concerns

- Communicating consideration of social and ethical issues relating to modern biotechnology and action taken on such issues by the National Biosafety Management Agency
- Periodically reviewing the National Biosafety Management Agency communication strategies and practices to ensure effective, appropriately targeted and efficient communication with stakeholders

3.3 Risk Perception

Public perceptions of the risks associated with modern biotechnology range across a wide spectrum of positions and include ethical concerns such as 'meddling with nature' and social issues. One of the reasons that the biosafety regulatory framework was established was in response to public concerns about modern biotechnology and an associated desire for a nationally consistent, legally enforceable decision-making process. The Nigeria National Biosafety legislation is consistent with international trends for regulatory systems to incorporate high levels of transparency, accountability and strong enforcement capabilities.

Different organisations and individuals perceive risks in different ways and may have different attitudes to risk. Perception of risk can be influenced by:

- Material factors, such as gender, age, education, income, and personal circumstances
- Psychological considerations, such as early experiences, personal beliefs, attitudes to nature, religious beliefs
- Cultural matters, such as ethnic background

Across a spectrum of risk, attitudes can be broadly categorized as risk adverse, risk neutral or risk taking and will be dependent on the specific risk involved.

Generally, the perception of risk by individuals is dependent on a large number of factors including knowledge of the risk, its impact on that individual, the potential for long-term consequences, the potential for widespread effects, the extent to which the individual can influence the risk and possible benefits (if any) that might accrue to individuals, groups or society as a whole. If the risk arises as part of a familiar situation where factors increasing or decreasing the risk are well known and methods to control or reduce the risk are readily available, the risk will probably not be perceived as a threat. If the risk is unknown, there is potential for long-term impact over a wide area, and the individual feels powerless in the situation, the risk is likely to be perceived as high. The availability of information, the knowledge that concerns will be heard, and the opportunity for involvement in decisions are, therefore, all likely to increase the acceptance of risk. Table 1 summarises some of these elements.

Tolerable Risks	Threatening Risks	
Voluntary	Involuntary	
Controlled	Uncontrolled	
Familiar	Unfamiliar	
Immediate	Sometime in the future	
Short term	Long term	
Minor consequences	Severe consequences	
Reversible	Irreversible	
Personal involvement	No involvement	
Benefits	Costs	

Table 1: Factors in the perception of risks as either tolerable or threatening

Risk perception is fundamental to an individual's acceptance of risk. Therefore, an individual's perception and assessment of risk is a complex construction involving a number of factors that are weighed and balanced to achieve a final position.

Some factors that may contribute to disagreement in risk assessment and risk management are summarized in Table 2.

Sources of conflict	Possible explanations
Values	The parties have different underlying values, beliefs and views of the world.
Interests	The parties have different interests: commercial, environmental or social.
Language	The language that scientists or experts use may not be accessible to stakeholders.
Knowledge	There are differing views on what is known and not known.
Lack of transparency or openness	Stakeholders are not provided with relevant or sufficient information or included in the decision-making process.

Table 2: Sources of conflict in risk assessment and risk management

Historically, a number of approaches have been employed to gain community understanding and acceptance of certain risks that government or business believe are required for economic prosperity, contribute to society as a whole or are worthwhile in some way, even though some risk may be involved. Stakeholders' views should be treated with respect as they provide a valid and required input into risk assessment and risk management. The National Biosafety Management Agency recognises and accepts that the community holds many and varying views on gene technology and believes all stakeholders hold legitimate positions.

In terms of risk communication, the Act allows for public consultation during the assessment of permit applications for commercial/general release of Genetically Modified Organisms. The Act therefore provides a direct mechanism for two-way interaction between National Biosafety Management Agency and stakeholders by publishing in national dailies summary permit applications.

3.4 Biosafety Communication Key Messages

The Key messages are the information the National Biosafety Management Agency wishes the public to know about biosafety and modern biotechnology regulatory process and also the public wants to know about its activities and the regulatory process. Different messages which address questions from stakeholders would be distilled by the National Biosafety Management Agency to reflect the most important facts that should be known about biosafety (especially risk assessment) in the country.

The key messages in Nigeria's Biosafety communication strategy cover one or more of the following:

- i. The authority under which the National Biosafety Management Agency is established and operates
- ii. The regulatory processes;
- iii. The safety of biotechnology and its products;
- iv. Legal responsibilities;
- v. Awareness and visibility;
- vi. Information sharing;
- vii. Engagement
- viii. The relevance of biosafety to citizen and stakeholders.
- ix. The activities that trigger biosafety
- x. The importance of risk assessment and Risk Management
- xi. The way Biosafety decision are made, and
- xii. The opportunities for public participation,

a. Mission of Biosafety in Nigeria:

To promote the basic tenets of biosafety as enunciated in the Cartagena Protocol on Biosafety and enforce Nigeria National Biosafety Regulatory Regimes to ensure the safe application and use of products of biotechnology

b. Vision of Biosafety in Nigeria

To ensure that the practice, process and procedures of modern biotechnology are undertaken within the limits of a regulatory systems that guarantees its safe use, protection of Nigeria's biodiversity and with minimal risks to human health and environment.

c. The Goals of Biosafety

The Goals of Biosafety are to:

- Determine in advance when hazards to human health and natural systems will result if any particular GMO is released into the environment;
- Anticipate when a given GMO or its product(s) will be harmful if it becomes part of human food.
- Discern whether a GMO will actually yield the benefits it was designed to provide;
- Make sure that hazards do not arise when GMOs are transported (intentionally or otherwise) among different ecosystems and nations,
- Socio-economic and ethical concerns
- d. The main issues in biosafety:

i.Environmental safety

- gene flow (of GMOs will contaminate our indigenous crops)
- invasiveness (of GMOs might become predominant)
- non-target organisms
- other effects on ecology and dynamics

ii. Food/feed safety/Human health

- Nutrition
- Allergy
- Toxicity
- Substantial equivalence

iii. Agricultural sustainability

- Weediness
- pest resistance development
- chemical inputs
- Higher Costs
- Others (Socio-Cultural, acceptability etc)

- e. Approaches to addressing biosafety concerns:
 - <u>**Risk Assessment: Risk</u>** assessment is a major aspect of GMOs release. Itsthe scientific identification and evaluation of potential adverse effects of GMO on Environment and human health</u>
 - <u>**Risk management:**</u> management, control of any risks that may be identified by risk assessment, it entails monitoring, inspection
 - <u>Substantial equivalence:</u> Are the products the same as their conventional counterparts?
 - **<u>Precautionary principle/approach:</u>** conclusive proof of safety before approval,
 - **Benefit analysis:** is the impact on the environment greater than the benefit of the technology?
 - <u>Cost and impact of regulation:</u> will regulating GMOs increase food prices and affect food security?
 - <u>**Products labeling**</u>: for consumer choice and easy identification

f. Biosafety Land Marks in Nigeria

- Biosafety Unit established under the Federal Ministry of Environment,
- Biosafety Policy,
- Biosafety Bill passed by the NASS awaiting presidential assent
- Cartagena Protocol on Biosafety signed and ratified in 2000 and 2003 respectively,
- Nigeria has also signed the Nagoya-Kuala Lumpur supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety in 2012,
- Biosafety application form,
- Biosafety Containment Facilities Guidelines,
- Accreditation and certification forms,
- Decision document
- Any Institute that intends to practice modern biotechnology or deal on GMOs must seek accreditation of the Institute and certification of its Biosafety containment Facilities;
- Review of biosafety application by National Biosafety Committee,
- Guidelines for Confined Field Trials Monitoring and Inspection Manuals;
- GMOs import/shipment form;
- Confined field trials on going;
- <u>http://ng.biosafetyclearinghouse.net;</u>
- Nigeria National Biosafety Application Administration Guidelines;

• Nigeria National Biosafety Socio-economic Considerations Guidelines.

g. Reasons for Regulating GMOs

- To exercise the sovereign right over all her natural resources and authority to regulate access to such resources;
- To harness the potentials modern technology has to offer in the field of improved food production, medicine/health, Industrial growth and environmental protection in a safe manner;
- There are equally concerns on the environmental consequences of the release of GMOs into the environment, in particular the effects on biological diversity;
- To reaffirm Nigeria's commitment to the goals and objectives of the convention on Biological Diversity (CBD), and the Cartagena Protocol on Biosafety which Nigeria has signed and ratified and other related treaties;
- To prevent Nigeria serving as a dumping ground for unregulated Genetically Modified Organisms which may have adverse impact on our Environment and human health;
- To protect the populace from the socio-economic consequences of modern biotechnology products, especially among the small-scale farming systems that are prevalent in Nigeria;
- To guaranty the purity of grains/seeds;
- There is currently a lot of concern regarding the possible toxicity and allerginicity of food products derived from GMOs. There is, therefore, the need to minimize risks to human health;
- Availability of plants that can reduce Green House Gases thereby reducing effect of Climate Change;
- It will encourage green economy;
- Precise trait will be used.

h. Instruments of biosafety regulation in Nigeria:

- The Cartagena protocol on Biosafety and Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety;
- Biosafety Policy;
- Biosafety Act (2015)
- Biosafety Guidelines,
- Biosafety application forms;
- Biosafety Containment Facilities Guidelines;
- Accreditation of Institute application form;

- Certification of Biosafety containment Facility form;
- Confined Field Trial Monitoring and Inspection Manual;
- GMOs import/shipment forms;
- National Biosafety Risk Analysis Framework;
- Decision documents;
- Nigeria Biosafety Application Administration Guidelines;
- Institutional Biosafety Committee (IBC) Guidelines.

i. Current Biosafety Application review process in Nigeria:

- Accreditation of Institution / Organization;
- Certification of containment /Storage Facility;
- Completion of application form and submission;
- Acknowledgement of Application;
- National Biosafety Committee (NBC) meets to review application and constitutes National Biosafety Technical Sub-committee (NBTS);
- NBTS reviews application in details and submits recommendation to NBC;
- Public Participation: The public view may be required;
- NBC meets to take final position on application and advises the Director General/CEO;
- The Director General/CEO take decision on application; Decision document is prepared by the NBMA and sent to applicant within 270 days of receipt of application, after which the NBMA inspects the facility periodically;
- Decision posted into the NBMA website and the Biosafety Clearing House.

3.5 **Communication Pathways**

To be effective, risk communication requires an exchange of knowledge rather than a one-way transfer of information. It is most effective when it is two-way and when there is opportunity for input into decisions. Successful communication requires active involvement; however, in practice, time and resources can limit the extent of dialogue. The National Biosafety Management Agency will allocate greater resources to communication activities where there is a perception of greater risk such as those involving intentional release of GMOs into the environment, in particular, general/commercial releases.

As a continuous background communication process, the National Biosafety Management Agency will provide information that will raise public awareness and proffer answers to concerns. For this aspect of the communication three key elements that will be used to capture the public's attention:

Information on biosafety would be:

- Easily available;
- Easily understood and;
- Interesting (but not embellished)'

The delivery of information will include the following tools:

- Television;
- Radio;
- Print, fliers especially newspapers and magazines;
- CDs/ DVDs;
- Internet;
- Public workshops and seminars, including field visits.

The National Biosafety Management Agency will consider the most appropriate language or languages to use, as well as the literacy rates in the targeted stakeholder groups.

3.6 Stakeholders

Release of GMOs into the Nigerian environment is of significant interest to a wide spectrum of the public, including government, non-government organisations, community-based organizations, businesses, companies and individuals. The form of communication with specific stakeholders and potential constraints on effective communication that need to be addressed for different groups is shown in Table 3.

Group	Stakeholders	
Research	Pro/Vice Chancellors R&D of universities, CEOs/Directors of research institutes, research and development corporations, other research groups,	
Industry	Retailers, food and feed industry, proponents of the technology, breweries	
Primary producers	Research Institutions, National and state farmers' federations, farming organisations (often include industry representation)	
Interest groups	Environmental groups (Environmental Right Action, Friends of the Earth,), consumer groups, health professionals, lobbyists, consultants, regulatory affairs advisors	
Press /Medial Houses	Television stations, Print media, Journalists	

Government	State and local governments, Federal Ministries of Environment, Agriculture and Rural Development (NAQS), Foreign Affairs, Trade and Investment, Health(National Agency for Food and Drug Administration and Control), Science and Technology(National Biotechnology Development Agency), Consumer Protection Council), Nigeria Customs Service, Nigeria Airports Authority, Maritime Authority	
Public	Consumers and interested parties	

Table 4: Forms of communication	with stakeholders an	d potential con	nstraints on that
communication			

Stakeholders	Form of communication	Constraints on effective communication	
Applicant	 Application form Informal/formal discussions, Regulations, Guidelines, website, Telephone, email, courier Formal and informal discussions, Commercially Confidential Information application RARMP – consultation and final permit 	Different language styles Different knowledge base Different interests, values, beliefs Unclear requirements or explanations Lack of understanding Lack of context Uncertainty	
Experts	Meetings, informal discussions Letters requesting advice, research information		
Prescribed agencies	Informal/formal discussions Letters requesting advice or notification		
Local councils	Letters requesting advice,	-	
Press/Medial Ho	uses Press release, phone calls, Annual re Website	ports, emails, Advertisements	
Public	telephone number Advertisements Website Email Client register		

3.7 Stakeholders Information Needs

The National Biosafety Management Agency would collaborate with other Government Ministries and agencies and stakeholders in biosafety information sharing. To ensure the effectiveness of the National Biosafety Communication Strategy, the following bodies information needs have been identified and grouped as follows:

Group one.

- i. The General public;
- ii. Policy makers;
- iii. Non-Governmental Organization.

Information needs

- a. Approved GMOs that have been subjected to rigorous risk assessment and are found to be safe to the environment and human health,
- b. Approved GMOs will be monitored using both national and international protocol
- c. Risk assessment was carried out in strict compliance with local and international standard

Group two.

- i. Nigeria Custom Service;
- ii. National Agency for Food, Drug Administration Control;
- iii. Plant quarantine services;
- iv. Ministry of justice;
- v. Ministry of Trade and Investment;
- vi. Consumer Protection Council.

Information needs

- a. The Biosafety Law does not apply to GMO Pharmaceuticals for humans but they are addressed by other relevant Laws;
- b. List of approved GMOs for import and Export;
- c. List of banned GMOs for import and export;
- d. Biosafety laws, regulations and guidelines;
- e. All GMOs to be released/commercialised or imported must be approved by the NBMA,
- f. Approved GMO/ GM foods;
- g. All risk assessments are carried out in scientifically sound manner.

Group three.

- i. Federal Ministry of Agriculture;
- ii. National Biotechnology Development Agency(NABDA);
- iii. Institutional Biosafety Committees.

Information needs

- a. All risk assessment are carried out in scientifically sound manner;
- b Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of risk posed by a GMOs to human health, animal and environment shall not prevent the country from taking appropriate decisions on the said GMOs
- a. List of approved GMOs for import and Export;
- b. List of banned GMOs for import and export;
- c. Biosafety laws, regulations and guidelines;
- d. Monitoring for compliance,
- e. compliance with terms and Conditions of approvals;
- f. All GMOS to be released/commercialised, imported must be approved by the NBMA.
- g. NBMA may at any time in light of new scientific information on potential adverse effect on the conservation and sustainable use of biodiversity and risk to human health review and change a decision regarding an international trans-boundary movement or domestic use of GMOs.

Group four

Police

Information Needs

- i. Police to accompany Biosafety Regulators to enter facilities during enforcement
- ii. Emergency situations
- iii. Police to arrest defaulters of biosafety laws, regulations and guidelines,
- iv. Police to assist the NBMA in enforcement
- v. Biosafety laws, regulations and guidelines

Group five

- i. News Agency of Nigeria
- ii. National Orientation Agency
- iii. Media Houses
- iv. NGOs

Information Need:

- i. List of approved GMOs for import and Export,
- ii. List of banned GMOs for import and export,
- iii. Approved GMOs that have been subjected to rigorous risk assessment and are found to be safe to the environment and human health
- iv. Emergency situations,
- v. Biosafety laws, regulations and guidelines,
- vi. All risk assessments are carried out in scientifically sound manner.

3.8 Consultation on Applications

The National Biosafety Management Agency shall provide information to stakeholders, Applicants and other members of the public through any of the above channels on GMOs on dealings, including the aims of genetic modifications, a description of the project, and the date of issue and expiry of the permits.

The process of consultation on permit applications provides an opportunity for stakeholders to have direct input into the decision-making process.

When an application for a commercial permit is received, the National Biosafety Management Agency will notify the public in National and local newspapers, the application dossier will also be placed in the Local Government Headquarters where the release will take place for public review and comments within 21 working days.

As part of the response to stakeholders and to ensure all relevant concerns have been considered, summaries of view would be prepared that identify the issues raised and where they are addressed. Resolution of specific concerns and issues relating to risks to human health and safety and to the environment may involve intensive discussions between the stakeholder and National Biosafety Management Agency. This might require the Agency to seek further information or clarification from the applicant. Before releasing any information on general release for consultation, the National Biosafety Management Agency will determine whether the proposed dealings may pose a significant risk to the health and safety of people or to the environment. The minimum consultation period specified is 21 working days if the National Biosafety Management Agency is satisfied that the dealings do not pose a significant risk. If the National Biosafety Management Agency considers that the proposed dealings may pose significant risk(s), additional period will be allocated.

The consultation then finalized, considering the feedback received in a similar way to feedback on the application to ensure relevant issues of concern are addressed in as much detail as possible and practical. If deficiencies, such as new risks, inaccurate assessments, or better risk management strategies, were identified through the consultation process, the Risk Assessment and Risk Management plan (RARMP) would be updated to address them.

The National Biosafety Management Agency would endeavor to address such concerns through documents such as its *Risk Analysis Framework*, by providing a detailed outline of the rationale behind the process of risk assessment and risk management undertaken by the National Biosafety

Management Agency and by making the documents underpinning the National Biosafety Management Agency's decisions readily available.

3.9 Biosafety Communication Officer:

A Biosafety Communication Unit headed by an Officer shall coordinate the various activities under the Biosafety Communication Strategy. The Coordinator shall work with other Officers in the National Biosafety Management Agency and other stakeholders.

The Coordinator's Information details shall be made available in the press and to Collaborative Agencies:

- i. Office Address:
- ii. E-Mail Address:
- iii. GSM No.

General Comments:

- a. The document should be a living document to be periodically reviewed. Please consult the new framework for a Communication Strategy agreed in COP 13 as you could pick some elements
- b. Please create a section on Social Media and Social Networks and indicate how you would use to reach out or communicate. you have already started e.g. Your facebook page, the website etc. but it is not highlighted
- c. Wherever feasible reduce text and use imagery through schematic diagrams and flow charts. E.g you could create such for the various stakeholder groups. The end users might not read much