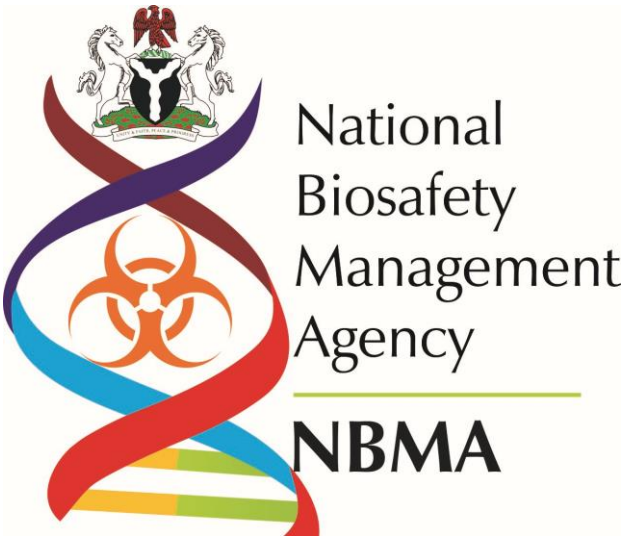

Federal Republic of Nigeria

National Biosafety Risk Analysis Framework

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Message from the DG/CEO, NBMA

I am delighted to approve the first edition of the Biosafety Risk *Analysis Framework* for the National Biosafety Management Agency.

In Nigeria, Modern Biotechnology is stringently regulated by laws that govern the research, development, trial, release and use of Genetically Modified Organisms (GMOs) to protect human health and safety and the Nigerian environment. The *Risk Analysis Framework* explains our approach to the Biosafety risk assessments, risk management and risk communication plans that are required in support of decisions on applications to use GMOs.

While many different models for risk analysis exist, there is no international consensus on the appropriate model to use for GMOs. We have, therefore, adopted our standard.

This edition of the framework, though dynamic and subject to periodic review, has benefited from the guidance of the relevant technical stakeholders and the funding of Global Environment Facility (GEF). Importantly, it is the culmination of many internal staff discussions about the evolving nature of the work of the NBMA. In particular, I thank the NBMA Staff who continue to be enthusiastic champions for the framework. I commend the 2017 Biosafety Risk *Analysis Framework* to you for guidance and compliance.

Dr. Rufus Ebegba,

Director General/ Chief Executive Officer,

National Biosafety Management Agency,

Nigeria.

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Abbreviations

AIA	Advanced Informed Agreement
DIR	Dealings involving Intentional Release
DNIR	Dealings Not involving Intentional Release
EDD	Emergency Dealing Determination
GEF	Global Environment Facility
GM	Genetically Modified
GMO	Genetically Modified Organism
IBC	Institutional Biosafety Committee
NBC	National Biosafety Committee
NBF	National Biosafety Framework
NBMA	National Biosafety Management Agency

OECD	Organization for Economic Co-operation and Development
PC	Physical Containment
RARMP	Risk Assessment and Risk Management Plan
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
WHO	World Health Organization

Executive summary

The National Biosafety Management Agency *Act 2015* (the Act) provides legislative context for the use of risk analysis in regulating activities with GMO in Nigeria. In particular, the Act mandates preparation of a risk assessment and risk management plan in consideration of application Permit.

Permits are required for proposed release of GMOs into the market, environment and activities of GMO in a contained facility. The decision on whether to issue a Permit is made by the DG/CEO of the NBMA.

The *Risk Analysis Framework* provides guidance on how the NBMA carries out risk analysis of GMOs in accordance with the Act.

The purpose of the *Risk Analysis Framework* is to:

- provide a guide to the rationale and approach to risk analysis used by the NBMA to enable a consistent and rigorous risk analysis approach to evaluating Permit applications;
- ensure that the use of risk analysis in the decision-making process is transparent to applicants and other stakeholders.

This *Risk Analysis Framework* incorporates recent advances in risk analysis methodology and increased scientific knowledge, as well as regulatory experience gained with GMOs both nationally and internationally.

The Risk Analysis Framework describes the principles of risk analysis used by the NBMA to protect human health and safety, and the environment, in accordance with the Act.

Risk analysis includes risk assessment, risk management and risk communication. Risk assessment identifies risks from plausible sets of circumstances that may result in harm to people or to the environment and estimating the level of risk on the basis of the seriousness and likelihood of harm. Risk management evaluates, selects and implements plans or actions to ensure that risks are appropriately managed. Risk communication is the

exchange of information, ideas and views between the NBMA and stakeholders. Risk communication also conveys the rationale for decisions made by the NBMA.

Risk Analysis integrates the assessment, management and communication of risks posed by, or as a result of modern biotechnology.

Establishing the risk context is the preparatory step that describes what will be done and how it will be done for the analysis of risk. In particular, the risk context defines the scope and boundaries, sets the broad terms of reference and criteria against which the significance of risk will be evaluated, as well as the structure and processes for the analysis.

All applications for Permit dealings with GMOs require case-by-case assessment by the Applicant and preparation of a risk assessment and risk management plan. Details of the GMO and the proposed activities, including any proposed controls, limits or containment measures form the specific context for the risk assessment and risk management plan. Details of the parent organism and the environment where activities with the GMO will occur form the comparative baselines for the risk assessment.

The Risk Context defines the parameters within which risk is assessed, managed and communicated.

The purpose of risk assessment is to identify and characterize risks to the health and safety of people or to the environment from dealings with GMOs, posed by or as the result of Modern Biotechnology. The risk assessment identifies risk by considering what could go wrong and how harm might occur. Risks are then characterized by considering how serious the harm could be and how likely it is that harm may occur.

Risks are identified by considering a broad range of circumstances whereby the proposed dealings with a GMO are postulated to have the potential to cause harm to people or to the environment through a plausible causal pathway between the GMO and an adverse outcome. Risks are then characterized in terms of the degree of seriousness and likelihood of potential harm, which are combined to estimate the level of risk as negligible, low, moderate or high.

There is a focus on scientific evidence in the risk assessment, involving extensive consultation with experts and other stakeholders, as well as consideration of knowledge gaps and other forms of uncertainty.

The risk assessment initially considers a wide range of possible risks, but puts great emphasis on more substantive risks, which receive more detailed characterization. Risks that are estimated to be greater than negligible are then considered by risk management for control or mitigation.

Risk Assessment identifies substantive risks and estimates the level of risk based on a combination of the likelihood and consequences of potential harm.

The purpose of risk management is to protect the health and safety of people and to protect the environment by controlling or mitigating risk. Risk management may be described as answering the questions:

i. Does anything need to be done about the risks?
ii. What can be done about it? and
iii. What should be done about it?

Risk management involves prudent judgments about which risks require management (risk evaluation), the choice and application of treatment measures, and ultimately, whether the dealings with GMOs should be permitted.

Risk management includes preparation of a risk management plan by evaluating and treating risk, applying general risk management measures, and proposing Permit conditions to give effect to management measures. In addition, risk management includes monitoring and reviewing to provide feedback on all steps in risk analysis and ensure the outcomes remain valid for future findings or changes in circumstances.

The risk assessment and risk management plan forms the basis upon which NBMA decides whether to issue a Permit. To issue a Permit, the NBMA must be satisfied that risks can be managed to protect human health and safety and the environment. If the NBMA considers that risks posed by proposed dealings with a GMO cannot be managed, a Permit would be refused.

Risk management evaluates risks that may warrant control measures and determines the appropriate Permit conditions to manage risk.

Risk communication is integral to the processes of risk assessment and risk management and involves development of an interactive dialogue between the NBMA and stakeholders.

The NBC undertakes extensive consultation with a diverse range of expert groups, authorities and key stakeholders, including the public, before deciding whether to recommend for Permit. In many instances differing perceptions of risk can influence the approach of stakeholders to particular issues. The NBMA can also seek advice on ethical and social issues raised by Modern Biotechnology from the NBC.

The NBMA endeavours to provide accessible information to interested parties on applications, Permits, dealings with GMOs, trial sites and the processes of risk assessment, risk management, monitoring and compliance undertaken by the NBMA. The Risk Analysis Framework is part of the NBMA commitment to clarity, transparency and accountability of decision-making processes.

Risk communication establishes an interactive dialogue between NBMA and stakeholders to provide open, transparent and consultative risk-based regulation of GMOs.

CHAPTER 1 INTRODUCTION

1.1 Preamble

The Federal Government of Nigeria has recognized the potential for Modern Biotechnology to positively contribute to society as well as the concerns in the community over development and deployment of the new technology. In response, a law was enacted to regulate activities with GMOs, namely, the National Biosafety Management Agency Act 2015.

The Act also established a statutory office – the National Biosafety Management Agency (NBMA) that is charged with the responsibility of making decisions about activities with GMOs in accordance with the legislation. The NBMA in support of its decision-making process, uses risk analysis.

The *Risk Analysis Framework* is a key document for informing applicants, stakeholders and the public about the NBMA's approach to applying risk analysis. It explains why and how the NBMA undertakes risk analysis by:

i. describing the National Biosafety Management Agency legislative context for risk analysis;
ii. describing the NBMA's approach to risk analysis, which is based on national and international standards and guidelines;
iii. outlining the methodology the NBMA uses when preparing a risk assessment and risk management plan in response to a GMO permit application ; and
iv. discussing the NBMA approach to risk communication.

The term **Risk Analysis** encompasses all components of risk; namely, risk assessment, risk management and risk communication.

Risk analysis = risk assessment + risk management + risk communication

i. **Risk assessment** identifies risks from plausible sets of circumstances that may result in harm to people or to the environment and estimating the level of risk on the basis of the seriousness and likelihood of harm.

ii. **Risk management** evaluates, selects and implements plans or actions to ensure risks are appropriately managed.

iii. **Risk communication** is the exchange of information, ideas and views between the NBMA (any of its agents and committees) and stakeholders. It also conveys the rationale for decisions made by the NBMA.

The Object of the Act is:

To protect the health and safety of people and the environment, by identifying risks posed by GMOs or as a result of modern biotechnology, and by managing those risks through regulating certain dealings with GMOs and their products.

1.1.1 Regulating Dealings with GMOs

The Act regulates dealings with GMOs to protect people and the environment. GMOs include organisms (biological entities that are viable, capable of reproduction or capable of transferring genetic material) that have been genetically modified or have inherited the genetic modification.

To '**deal with**' a GMO, is to conduct experiments with; make, develop, produce or manufacture, breed, propagate, use in the course of manufacture of a product that is not the GMO; grow, raise or culture, import, transport, dispose of the GMO, and includes the possession, supply or use of the GMO for the purposes of, or in the course of any of the above.

Regulation of dealings is achieved by prohibiting dealings with GMOs unless:

i. the person undertaking the dealing is authorised to do so by a GMO Permit
ii. the dealing is specified in an emergency dealing determination
iii. the dealing is a notifiable low risk dealing
iv. the dealing is an exempt dealing; or
v. the dealing is included in the GMO Register.

Two categories of GMO Permit include:

i. Dealings involving Intentional Release (DIR) of a GMO into the environment, DIR –including limited and controlled releases, such as field trials, and general/commercial releases,
ii. Dealings Not involving Intentional Release (DNIR) of a GMO into the environment, DNIR – for GMOs in contained facilities, such as laboratories, glasshouses, aquaria, insectaries or animal houses that are certified to a specified level of Physical Containment (PC).

Before issuing a Permit, the Applicant must prepare a risk assessment and a risk management plan in relation to the dealings proposed to be authorized by the Permit. Risk analysis may also be conducted for the other permitted classes of regulated dealings, as well as in relation to applications to vary an existing Permit. The risk analysis framework described here is primarily intended to inform consideration of applications for DIR and DNIR permits.

1.1.2 Identifying and Managing Risks

Risk is defined as 'the likelihood of harm from an activity'. In the context of the Act, harm refers to adverse impacts for the health and safety of people, or to the environment, while activity refers to 'dealing with' a GMO. The NBMA considers potential risks that can be attributed to the use of modern biotechnology. The National Biosafety Management Agency Act 2015 dealings with a GMO is therefore triggered by the process of genetic modification, rather than by a novel trait.

Other processes may also give rise to organisms with the same or similar novel trait. For instance, corn with improved water use efficiency (that is, increased drought tolerance) could be generated by chemical or radiation mutagenesis, wide crosses, genetic modification or by conventional breeding practices. Experience with organisms that have similar traits generated without use of modern biotechnology may provide useful information for considering potential risks from dealings with a GMO.

Risks are identified using a comparative risk assessment, whereby risk from a GMO is considered relative to the parent organism within the specific environment in which a

dealing with a GMO takes place (receiving environment). The focus of the assessment is whether modified properties of the GMO arising from modern biotechnology increase the level of risk, or give rise to additional risks. For instance, a parent organism may already have weedy or pathogenic characteristics; these characteristics form part of the baseline against which risk is identified.

1.1.3 Protection

The risk management goal, as directed by the Object of the Act, is to protect the health and safety of people and the environment. The Act emphasizes protection over approval of dealings. However, regulatory oversight also continues after approval is granted through mechanisms such as granting permits with specific obligations and restrictions; monitoring for compliance with permit conditions; adverse effects/events reporting; and, in the case of commercial/general releases, provisions for post release review (see Chapter 5).

Some of the protective measures applied to the regulation of modern biotechnology include:

A. Caution before authorization of a dealing:

i. dealings with GMOs are prohibited unless allowed according to provisions in the Act;
ii. provisions in the Act allow the NBMA to refuse a permit;
iii. consultation with the public, MDAs, stake holders and scientific experts;
iv. scientific and regulatory expertise within the NBMA;
v. emphasis of risk assessments on credible evidence;
vi. consideration of uncertainty in preparation of risk assessment and risk management plans;
vii. requirements for certification of facilities, accreditation of organizations and assurances of applicant suitability before granting a permit;
viii. maintaining awareness of new scientific findings and
ix. maintaining knowledge of assessments and decisions of overseas agencies that regulate GMOs.

B. Caution after authorization of a dealing:

i. specific permit conditions to manage risk ;
ii. permit conditions that limit and control the dealings;
iii. legislative requirements for compliance with permit conditions;
iv. provisions in the Act that allow the NBMA to suspend, vary or cancel a permit;
v. requirements for the applicant to provide sufficient information to identify the GMO and to provide locations of rooms/buildings used to contain GMOs, exact coordinates of limited and controlled releases, information on locations and volumes on general/commercial releases;
vi. monitoring of facilities and release sites;
vii. statutory Permit conditions such as reporting of additional information as to any risks to the health and safety of people, or to the environment, contravention of the Permit, or unintended effects;
viii. post release review for general/commercial releases of GMOs;
ix. maintaining awareness of new scientific findings and
x. contingency/ emergency plans.

The pathway for development of a GMO intended to be released into the environment would typically follow a staged approach namely:

i. initial laboratory-based research under physical containment;
ii. small-scale experimental releases (such as field trials) with conditions to limit and control the release in space and time;
iii. general/commercial release, with or without specific controls and
iv. inclusion on the GMO Register with or without specific conditions.

Regulatory approval for each stage is supported by the experience and scientific data gathered and evaluated from the previous stages. This enables a body of evidence to be assembled about potential risks, while ensuring that human health and safety and the environment are protected.

Although protective measures are intended to shield from harm, all activities and decisions involve some level of risk. Protective measures should, therefore, be commensurate with the potential level of risk.

1.1.4 Protection Goals – the Health and Safety of People and the Environment

The Object of the Act is to protect the health and safety of people and to protect the environment. Therefore, risks are identified in relation to the potential of harm for the health and safety of people, or to the environment.

Risk to the health and safety of people includes consideration of the occupational health and safety of workers dealing with the GMO, as well as the general public who may come in contact with a GMO. The risk will depend on the effects of the genetic modification and exposure of people to the GMO, or the introduced genetic material and/or its products. In particular, there is consideration of increased toxicity, allergenicity, disease or injury by the possible production of a toxin or allergen. Similarly, potential risk may arise from an increased production of an endogenous toxin or allergen.

Adverse impacts on the health of people may also occur through production of other types of compounds (for example, anti-nutrients that interfere directly with the absorption of vitamins, minerals and other nutrients); or reduced production of key nutrients or other compounds that promote good health (such as antioxidants).

The environment definition in this context includes:

i. ecosystems and their constituent parts,
ii. natural and physical resources and
iii. the qualities and characteristics of locations, places and areas.

Risk to the environment includes consideration of effects on biotic and abiotic components of the environment. Adverse impacts on the environment may result from:

i. increased weediness or pestiness;
ii. impaired health of organisms due to toxicity or disease;
iii. reduced quality of biotic components (for example, reduced biodiversity);
iv. reduced quality of abiotic components such as soil, water, or air; and

v. disruption of ecosystem processes (such as increased salinity or altered fire regimes).

Different risks may be identified for different parts of the environment; for example, the potential for increased weediness of a GMO may differ between agricultural and undisturbed environments.

1.2 Regulatory Framework to achieve the Object of the Act

The regulatory framework to achieve the Object of the Act, includes to:

i. provide that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation;
ii. provide an efficient and effective system for the application of modern biotechnology;
iii. operate in conjunction with other national existing regulatory schemes relevant to GMOs and GM products.

Regulatory measures to prevent harm are often invoked to deal with uncertainty. Part of this uncertainty arises from a lack of experience with the products of a novel technology, particularly if its products may become persistent or widespread. Advocates of precautionary principles have argued for a gradual, step-by-step approach to managing new technologies until sufficient knowledge and experience is acquired to provide confidence in its safety. However, critics argue that precautionary strategies invoke less scientifically rigorous information and can lead to arbitrary regulatory decisions. Nevertheless, a plausible causal pathway would need to be established to indicate threats of serious or irreversible environmental damage from a GMO.

The framework also provides for an efficient and effective system of regulation for application of modern biotechnology and is supported by several components. These include:

i. classification of dealings such that the level of regulatory scrutiny is proportional to the potential level of risk;
ii. provision of a predictable process with specified statutory timeframes leading to reasonable, consistent and defensible decisions; and
iii. consultation with other MDAs to provide a coordinated and integrated approach to regulation of GMOs.

1.3 Purpose of the Risk Analysis Framework

Within the legislative context of the Act and other related Regulations, the purpose of this *Risk Analysis Framework* is to:

i. provide a guide to the rationale and approach to risk analysis used by the NBMA to enable a consistent and rigorous risk analysis approach to evaluating applications for DIR and DNIR Permit; and

ii. ensure that the use of risk analysis in the decision-making process is transparent to applicants and to other stakeholders.

A summary of considerations in the application of risk analysis for DIRs is provided in Appendix B.

CHAPTER 2 : RISK ANALYSIS MODEL

2.1 Preamble

This chapter describes the Risk Analysis Model used by the NBMA and international sources that informed development of the model. In addition, the role of uncertainty in risk analysis is discussed. Finally, guiding principles that the NBMA uses for risk analysis are provided.

2.2 Models of Risk Analysis

The Risk *Management* Standard has been developed to guide institutions/organisations that deal with risk. A number of international organisations and treaties (such as the World Organisation for Animal Health (OIE), the International Plant Protection Convention, and the *Codex Alimentarius* Commission) provide standards and guidance for risk analysis in the specific areas of human health and environmental risks.

Annex III of the Cartagena Protocol on Biosafety (Secretariat of the Convention on Biological Diversity 2000) also provides guidance for risk assessments of GMOs.

Risk is generally considered in the context of uncertain outcomes, which may be positive or negative. Therefore, some risk analysis approaches incorporate some form of cost–benefit calculation. However, the object of the Act aims to protect the health and safety of people and to protect the environment. Accordingly, the NBMA considers risks only in terms of adverse outcomes.

The risk analysis methodology the NBMA uses for GMO Permit applications may be depicted as a series of steps. However, this process is not necessarily linear as there is significant interaction of steps during preparation of a risk assessment and risk management plan (RARMP) for each Permit application.

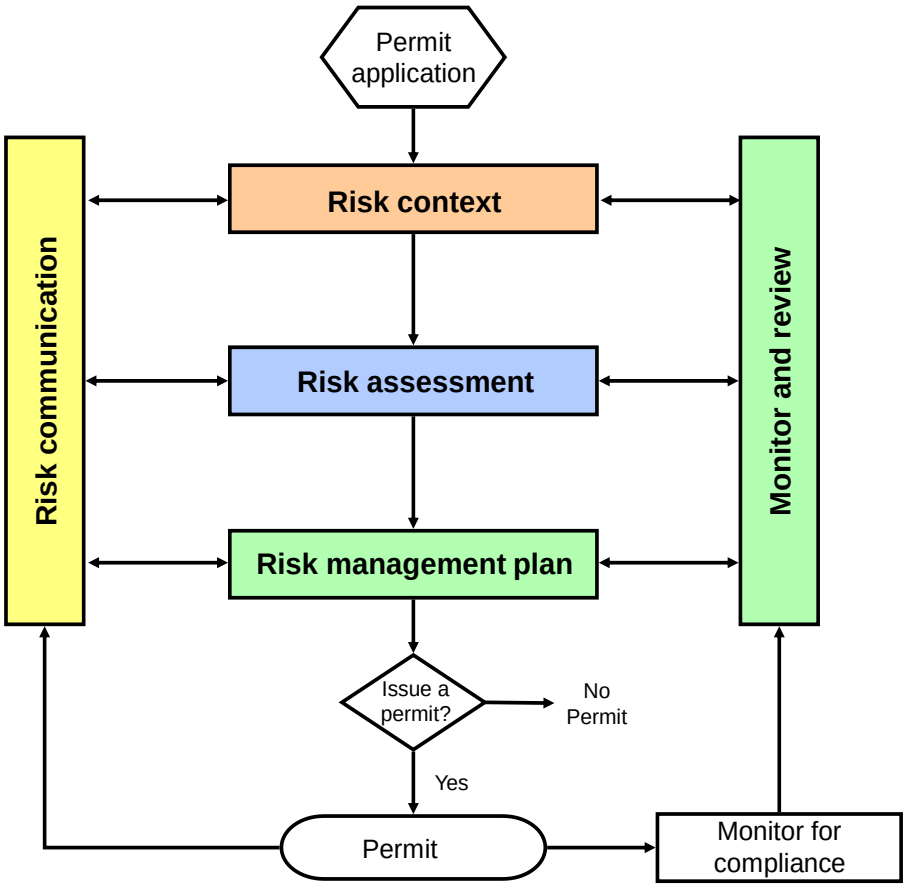

Figure 2.1: Risk Analysis Methodology for GMO permit Application

2.3 Components in risk analysis

2.3.1 *Risk Context*

Risk context is defined as the 'parameters within which risk is assessed, managed and communicated'. The risk context establishes the scope and boundaries, terms of reference against which the significance of risk will be evaluated, as well as the structure and processes for the analysis.

2.3.2 *Risk Assessment*

Risk assessment is defined as the 'overall process of risk identification and risk characterisation'. The risk assessment considers potential harm to the health and safety of people or to the environment from dealings with GMOs posed by or as the result of modern biotechnology.

Risk identification considers when, where, how and why a dealing with the GMO could lead to harm due to modern biotechnology, while risk characterisation examines the seriousness and likelihood of harm, and estimates the level of risk as negligible, low, moderate or high (see Chapter 4).

2.3.3 Risk Management

Risk management is defined as the 'mechanisms to control and mitigate risk'. It involves preparation of a risk management plan, which includes measures to reduce the level of certain risks identified in the risk assessment; and monitoring and reviewing, which considers the effectiveness of outcomes from each step in the analysis. It also provides for on-going improvements to accommodate future findings and changes in circumstances.

2.3.4 Risk Communication

Risk communication is defined as the 'culture, processes and structures to communicate and consult with stakeholders about risks'. Specifically, it is communication of the risks to human health and the environment posed by certain dealings with GMOs, and includes extensive consultation with experts and specified stakeholders during preparation of risk assessment and risk management plans for DIRs. In some cases the NBMA may also consult with experts on DNIR applications.

The risk assessment and risk management plan prepared for each Permit application forms the basis upon which the NBMA decides whether to issue a permit. Stakeholders are informed of permits issued, proposed locations of authorised releases, the decision-making processes followed, and information sources accessed.

2.3.5 Terminology

The literature on risk analysis, as well as national and international standards and guidance documents, use a variety of terms. The main risk analysis terms used in this framework are described in Table 2.1, which also provides alternative terms used in the literature to describe components with similar functions.

Table 2.1: Comparison of Terms used to describe Components of Risk Analysis

Terms described here	Related terms described in other risk frameworks
RISK ANALYSIS	**RISK MANAGEMENT**
Risk context	Planning
Risk assessment	
Risk identification	Problem formulation, risk hypothesis, hazard identification
Risk scenario	Conceptual model, hazard identification
Risk characterization	Risk analysis, risk profile, risk estimate
Consequence assessment	Dose response, hazard, effect assessment, stressor-response
Likelihood assessment	Exposure assessment, probability, likelihood, frequency
Risk estimate	Risk calculation, risk characterization
Risk evaluation	
Risk management	
Risk treatment	Risk control
Monitoring and review	
Risk communication	

a. Uncertainty

Uncertainty is an intrinsic property of risk and is present in all aspects of risk analysis, including risk assessment, risk management and risk communication. In addition, risk assessment is based on evidence, which is also subject to uncertainty. There are a number of different types of uncertainty. These include:

i. incertitude – uncertainty of knowledge, its acquisition and validation

ii. variability – uncertainty that expresses the inherent randomness or indeterminacy of a thing, quality or process

iii. descriptive – uncertainty of descriptions that may be in the form of words (linguistic uncertainty), models, figures, pictures or symbols

iv. cognitive – uncertainty of mental processes, including bias, perception and sensory uncertainty.

Examples of **incertitude** include incomplete knowledge or data gaps, limited sample size, measurement error (systematic or random), sampling error, ambiguous or contested data, unreliable data (such as mislabeled, misclassified, unrepresentative or uncertain data), use of surrogate data (such as extrapolation from animal models to humans), and ignorance that gives rise to unexpected findings or surprise.

Risk assessment of Permitted dealings for GMOs is evidence-based, primarily using information that is derived from scientific research. Consequently, incertitude is a major component of uncertainty in risk assessments. However, in principle, incertitude can be reduced by more effort through obtaining additional relevant data.

Variability arises from the observed or predicted variation of responses to an identical stimulus among the individual targets within a relevant population, such as humans, animals, plants, microorganisms, landscapes. Randomness can arise from spatial variation, temporal fluctuations, manufacturing variation, genetic heterozygosity or gene expression fluctuations. Indeterminacy results from a genuine stochastic relationship between cause and effect(s), apparently non-causal or non-cyclical random events, or badly understood non-linear and chaotic relationships.

A critical feature of variability is that it cannot be reduced by more effort, such as addition of more data or more accurate data. In risk management, safety factors and other protective measures are used to address this type of uncertainty.

The principal forms of **descriptive** uncertainty include vagueness, ambiguity, underspecificity, contextual uncertainty and undecidability. Qualitative risk assessments can be particularly susceptible to linguistic uncertainty. For example the word 'low' may be ambiguously applied to likelihood of harm, magnitude of a harmful outcome and to the overall estimate of risk. Furthermore, the word 'low' may be poorly defined both in meaning (vagueness) and coverage (underspecificity).

Cognitive uncertainty can take several forms, including bias, variability in risk perception, uncertainty due to limitations of our senses (contributing to measurement error) and as unreliability. Cognitive uncertainty can be viewed as guesswork, speculation, wishful thinking, arbitrariness, debate, or changeability. Bias is revealed as how people and organizations *do* respond to uncertainty rather than *should*.

Use of clearly specified terms can reduce cognitive uncertainty in some circumstances through dialogue to clarify meanings of terms, openness and transparency of the decision-making process, and exploration of underlying assumptions.

There is widespread recognition of the importance of uncertainty in risk analysis. In its narrowest use within risk assessments, uncertainty is defined as 'a state of knowledge under which the possible outcomes are well characterized' but there is insufficient information to confidently assign probabilities [likelihood] to these outcomes.

However, uncertainty can also be considered more broadly. It is recognized that both dimensions of risk (the potential adverse outcome or consequence and the likelihood), are always uncertain to some degree, including the language to describe risk. Within this context, uncertainty includes incertitude, variability and descriptive uncertainty. In addition, uncertainty extends throughout risk analysis, including:

I. Risk assessment;

    i. uncertain characteristics of the GMO, such as knowledge gaps in the biochemical and physiological outcomes of expression of the introduced genes, environment-specific performance of the GMO, its interaction with other biological entities and processes, or landscape changes over long time periods;

    ii. uncertainty of the calculations within the risk assessment process, including assessment of risk scenarios, likelihood and consequences;

    iii. uncertainty in the use of the risk estimate matrix to derive an estimate of the level of risk and

iv. uncertain descriptions used in qualitative risk assessments due to insufficient explanations of terminology, use of related terms that are not fully congruent, or use of the same term in different contexts.

2) Risk management;

i. adequacy, relevance and effectiveness of protective measures

ii. decision-making in the presence of incomplete knowledge and conflicting values.

3) Risk communication;

i. Uncertainty of communication effectiveness due to difference in knowledge, language, culture, traditions, morals, values and beliefs.

Consideration of different types of uncertainty is useful for a number of reasons, including:

i. applicability to qualitative risk assessments where the sources of uncertainty cover both knowledge and descriptions

ii. ensuring that information is not over- or under-emphasized during preparation of a risk assessment and risk management plan through identification of uncertainty

iii. highlighting areas where more effort is needed to improve estimates of risk and apply appropriate cautionary measures

iv. more honestly informing the decision-making process

v. helping produce a clearer distinction of the values and facts used in decision making

vi. developing trust between stakeholders through increased openness and transparency of the regulatory process

vii. increasing the opportunity for more effective communication about risk.

2.4 Guiding Principles of Risk Analysis

When undertaking risk assessments, risk management actions or risk communication, a number of principles are used to guide risk analysis to ensure the goals of Biosafety regulatory framework are achieved. These principles include:

i. Legal – all actions taken must satisfy the requirements of the Act;

ii. Protective – all actions associated with the risk analysis should support the risk management goal of protecting the health and safety of people and the environment;

iii. Transparent – risk analysis for GMOs should be coherent, open to public scrutiny, describe the risk assessment, risk management and risk communication processes and assumptions, and acknowledge and incorporate consideration of uncertainty;

iv. Consultative – communication and consultation with the community and relevant MDAs should take place to identify and address issues and concerns;

v. Robust – the risk analysis methodology should be generally applicable to all regulated dealings, no matter the species of GMO or the type of modified trait;

vi. Consistent and repeatable – risk assessment, risk management and risk communication documents should be in a common format but recognize the unique character of each case. The processes and considerations used to develop these documents should be clearly explained so that, in similar cases, different people can arrive at similar conclusions;

vii. Current – taking account of accrued international experience of modern biotechnology broadly, and similar GM traits and recipient species specifically;

viii. Defensible – wherever possible, the risk analysis should use relevant, nationally and internationally accepted criteria, standards or guidelines that have been endorsed by the Nigerian Government;

ix. Use of sound judgment – scientific judgments and policy-based decisions should be clearly identified so others may understand the role of judgment in interpreting evidence and managing risks;

x. Efficacious and efficient – only relevant information should be incorporated into the risk analysis. Information should also be appraised for its quality;

xi. Cautious – the risk assessment should be cautious to avoid failing to identify relevant risks and to provide thorough consideration of all substantive risks that are identified. The risk management process should display caution in determining management actions for risks, with the goal of protecting human health and the environment;

xii. Ethical – the risk analysis process should be consistent with the principles of modern biotechnology ethics;

xiii. Credible and useful – the results of the risk analysis process should be presented in a format that helps the NBMA make decisions, stakeholders interpret decisions, and the risk management actions be effectively performed;

xiv. Accountable –the evaluator(s) and inspector(s) should be accountable for the information, interpretation and conclusions provided to the NBMA;

xv. Continuous improvement – evaluation and management staff should receive continuous training to maintain scientific expertise and best practice in risk analysis. In addition, risk analysis methodologies should be evaluated and reviewed as appropriate to take account of progress in this area.

xvi. Timely – risk analyses should meet statutory timeframes.

In addition to these general principles, the following ethical principles should guide researchers and others involved in modern biotechnology:

xvii. Treat integrity as the guiding value in the search for, and application of, knowledge and benefits in regards to the obligations of and intentions underlying the national regulatory system and other relevant guidelines and regulations;

xviii. Take responsibility for ensuring that activities within their control do not cause damage to the Nigerian environment or to areas beyond the limits of the national jurisdiction; to achieve this, there must be a thorough assessment of the long-term side effects of applications of modern biotechnology;

xix. Minimize risks of harm or discomfort to humans and animals likely to be adversely affected by modern biotechnology;

xx. Assess and respect the environmental and health needs of present and future generations;

xxi. Conduct research in a manner that protects the environment, including protection of genetic diversity, organisms, species, natural ecosystems, and natural and physical resources ;

xxii. Act justly towards others, and demonstrate respect for human beings (as individuals and group members) in all activities associated with modern biotechnology, including obtaining proper consent;

xxiii. Promote equitable access to scientific developments and sharing knowledge, and recognize the value of benefit sharing ;

xxiv. Conduct research in a manner that promotes the benevolent and avoids the malevolent uses of modern biotechnology;

xxv. Conduct modern biotechnology research after appropriate consultation and ensuring transparency and public scrutiny of the processes.

CHAPTER 3 : RISK CONTEXT

3.1 Preamble

This Chapter describes the role of the risk context in risk analysis and how it is applied in preparation of a risk assessment and risk management plan for Permit applications.

Risk context defines the parameters within which risk is assessed, managed and communicated by defining what will be done in risk analysis and how it will be done. In particular, it defines the scope and boundaries, sets the broad terms of reference and criteria against which the significance of risk will be evaluated and describes the structure and processes for the analysis.

Defining the appropriate parameters is the key to identifying relevant risks, accurately assessing the level of risk, and implementing suitable measures to manage risk in an efficient, efficacious and transparent manner.

3.2 Scope and Boundaries

The Act provides the scope and boundaries for risk analysis of applications for DIR and DNIR Permit in relation to:

i. the subject of regulation – dealings with a GMO;
ii. the trigger for regulation – use of modern biotechnology;
iii. means for regulating dealings – such as Permits;
iv. protection goals – health and safety of people and the environment;
v. method to achieve protection goals – identifying and managing risks;
vi. matters to consider when preparing risk assessment and risk management plan;
vii. nature and extent of consultation;
viii. types and nature of permit conditions that can be imposed;
ix. functions and powers of the decision maker (DG/CEO of the National Biosafety Management Agency);
x. nature and extent of monitoring and enforcing compliance with Permit conditions;
xi. definition of key terms – such as, deal with environment, modern biotechnology, GMO *etc.*

Policy principles, policy guidelines and codes of practice may also determine the scope and boundaries for risk analysis.

Certain issues, such as impacts on trade, socio-cultural effects, as well as benefits that may be derived from modern biotechnology or food labeling, are outside the scope of the analysis.

3.3 Setting the Terms of Reference

The terms of reference against which the significance of risk is evaluated should be established before preparing the risk assessment and risk management plan. The legislative requirements, objectives and the scope and boundaries of the analysis form the basis for broad terms of reference.

The Act specifies matters that must be considered in preparing the risk assessment including consideration of both the short and long-term outcomes from the proposed dealings with a GMO. These matters include:

i. previous assessments;
ii. the potential of the GMO to be harmful to humans and other organisms;
iii. the potential of the GMO to adversely affect any ecosystems;
iv. transfer of genetic material to another organism;
v. the spread or persistence of the GMO in the environment;
vi. whether the GMO may have a selective advantage in the environment;
vii. whether the GMO is toxic, allergenic or pathogenic to other organisms;

Other factors that should also be clearly established as a part of the risk analysis include:

i. the nature and types of consequences that may occur and how they will be measured;
ii. how likelihood is defined in the likelihood assessment;
iii. how consequence is defined in the consequence assessment;
iv. how the level of risk is to be determined;
v. the timeframe of the likelihood and/or consequence;
vi. what level of risk may require treatment;

vii. if combinations of multiple risks should be taken into account;

viii. the types of uncertainties and how they will be considered.

The broad terms of reference can be elaborated upon to sequentially develop generic and then specific criteria against which risk can be evaluated during the risk assessment. Generic criteria for the nature and types of consequences provide a starting point for the consequence assessment and a basis for development of specific consequence assessment criteria. They are essential since Permit applications can relate to any type of organism and any type of genetic modification and it is not possible to define specific criteria for all potentially adverse outcomes to the health and safety of people or to the environment before the risk assessment.

The combinations of generic consequence criteria that are considered are developed with reference to elements of the risk assessment context such as the properties of the GMO and the types of dealings. For example, if a GMO for intentional release is not capable of producing pollen, there may be no reason to further consider consequence assessment criteria relating to transfer of genetic material to other organisms via pollen.

If, however, an initial assessment against the generic criteria identifies a need for further detailed investigation, more specific consequence criteria are then developed as a part of preparing a risk assessment and risk management plan. For instance, generic consequence criteria such as 'negative effects on organisms' and 'creating a new weed' would be relevant for preparing a risk assessment of a GM crop with an introduced *Bt* gene that confers resistance to attack by certain insect pests. During the risk assessment, potential risks might be identified, which are then assessed against more specific consequence criteria such as 'increased mortality of non-pest Lepidoptera' and 'reduced establishment of other plants'.

Examples of specific consequence criteria that might be developed during preparation of the risk assessment and risk management plan are provided in Table 3.1. The specific consequence criteria form the basis for identifying measurable properties that can be used to assess the occurrence of harm, whether to an individual, population, species, community, habitat or ecosystem. In developing specific consequence criteria it is

important to differentiate between effects that simply reflect the dynamic nature of biological systems from those effects that are considered harmful.

Table 3.1: Criteria for the nature and types of consequences and how they might be measured

Generic criteria for consequences	Examples of specific consequence criteria developed during consideration of a Permit application (assessment endpoints)	Examples of measurable properties for specific consequence criteria (measurement endpoints)
Negative effects on the health and safety of people	Increased production of endogenous glycoalkaloids Production of an allergen Production of an immunosuppressant compound	Biochemical, physiological, physical or developmental abnormalities; frequency and age of morbidity; frequency of infection; growth rate; mortality
Negative effects on valued organisms (including protected species and secondary impacts)	Reduced population size of valued lepidopteron Production of a chemical toxic to protected marsupials	Population morbidity; genotype frequency; presence and abundance; yield/production; biochemical, physiological, physical or developmental abnormalities
Negative effects on species diversity or genetic diversity within a species	Formation of monoculture in natural environments	Presence and abundance of species; genotype frequency; yield/production; biochemical, physiological, physical or developmental abnormalities
Creating a new or more vigorous	Reduced establishment of other organisms	Occurrence in new environment, new population or species of host; size/frequency of attack or

weed, pest or pathogen	Increased host range of pathogen	invasion; intensity of disease symptoms; yield/production; species richness of the community where the weed, pest or pathogen occurs
Disruptive effects on biotic communities and ecosystems	Production of an allelopathic chemical	Species richness; diversity indices; extent and area; production; indices of food web structure; carbon, nitrogen and phosphorous fluxes
Degradation of the abiotic environment	Reduced soil water table level Hotter, more frequent fire regimes	Frequency and intensity of floods, low flows and fire; pollutant concentrations; physical damage; soil structure

Note: The criteria listed in this table are illustrative and intended neither as a requirement for all risk assessments, nor as precluding the use of other criteria; they are a starting point for considering how to assess harm and describing the types of data that could be used as evidence for measuring potential adverse impacts.

3.4 Structures and Processes

Many structures and processes are relevant to establishing the risk context for DIRs and DNIRs including legislated processes for preparing a risk assessment and risk management plan; the choice of risk analysis methodologies; and development of the case-specific context for risk assessment, risk management and risk communication that is relevant to each Permit application.

3.4.1 Risk Analysis Methodology

The risk analysis methodology described in this *Risk Analysis Framework* form part of the risk context. In particular, the National Biosafety Management Agency identifies risks posed by or as a result of modern biotechnology by using comparative risk assessment

methodology. Therefore, risks posed by a particular GMO need to be considered in relation to the parent organism in the receiving environment. For example, non-GM crop species already present risks to the health of people (for example, gluten in wheat or allergens in soybeans or peanuts) or to the environment (for example, some pasture species have a degree of weediness). These risks associated with the parent organism form part of the baseline against which the GMO is assessed to determine whether modern biotechnology has increased the level of risks or poses additional risks. Similarly, where the parent microorganism is a pathogen (a common occurrence in DNIR applications) a consideration of the potential changes to pathogenicity of the GM microorganism relative to the parent organism is required.

3.4.2 Preparation of a Risk Assessment and Risk Management Plan

When preparing a risk assessment and risk management plan (RARMP) the applicant considers the risk assessment context, the risk management context and the risk communication context.

a. Risk Assessment Context

The Act requires a case-by-case assessment for applications for DIR and DNIR Permits. Establishing the risk assessment context includes consideration of certain information specific to each Permit application, namely:

i. GMO – details of the genetic modification and trait changes
ii. proposed dealings – proposed activities with the GMO, proposed controls and limits (for DIRs) or containment measures (for DNIRs);
iii. parent organism – details of the comparator (for example, origin and taxonomy, production and uses, biological characterization, ecology);
iv. receiving environment – baseline information (for example, environmental conditions, production or work practices, presence of sexually compatible relatives, presence of similar genes);
v. previous releases – previous risk assessment or experience gained with a particular GMO in the course of previous dealings in Nigeria or overseas.

Information on the GMO, including the nature of the genetic modification and any novel or altered phenotypic properties forms an essential part of the risk assessment context. This may include information on:

i. the genetic elements introduced into the parent organism, the source organism and any known adverse effects it may have on human health and safety or the environment, and changes to the genetic elements before introducing them into the parent organism;
ii. method of genetic modification;
iii. number of copies of the introduced genetic material present in the GMO and stability in subsequent generations;
iv. any conventional breeding of the GMO with sexually compatible relatives;
v. new or altered properties or traits of the GMO, the intended effect of the genetic modification and if they are observed;
vi. any observable unintended effects in the GMO.

The proposed dealings with the GMO provides the starting point for identifying risks. In addition, any proposed controls or containment measures to limit the spread and persistence of the GMO provide an important frame of reference to determine which people or environmental components are expected to come into contact with the GMO, introduced genetic material or GM product.

The parent organism and receiving environment form part of the baseline for a comparative risk assessment. Information on the parent species that is considered in relation to the GMO may include taxonomy, origin, means of production and uses, morphology, development, biochemistry, abiotic and biotic interactions with the environment, weediness, pestiness and/or pathogenicity, and the potential for gene transfer to sexually compatible relatives present in Nigeria. Relevant information from studies undertaken in Nigeria and overseas is included.

However, selecting the appropriate comparator is not always straightforward. Alternative comparators may include isogenic line (identical genotype except for the introduced genetic material), the same cultivar, subspecies, and/or strain, another widely available or

local cultivar, subspecies, and/or strain, any member of the same species, or even multiple species. A range of factors influence selection of the appropriate comparator, such as:

i. information on the parent organism may be lacking or it is not present in the Nigerian environment;
ii. the GMO proposed for release has undergone several generations of conventional breeding following genetic modification with genotypes distinct from the parent organism;
iii. the GMO is developed through hybridisation between different species.

For instance, insect-resistant GM pima cotton (*Gossypium barbadense*) was developed by crossing non-GM pima cotton with GM upland cotton (*G. hirsutum*). Following further breeding, the new GMO displayed many of the characteristics of pima cotton but still contained some of the upland cotton genes. In this case, both species were considered to be the parent organism and their characteristics were used in the comparative assessment.

The environment into which the GMO is released is also relevant for intentional releases. Information from an appropriate environment should be used for comparison. For example, the current growing and management practices applied to a GM crop plant, or the abundance of gene(s) already present naturally in the environment used in genetic modification will be considered in developing the baselines for the risk assessment.

Antibiotic resistance marker genes commonly used in the selection process for generating GM plants are derived from soil bacteria abundant in the environment. Therefore, exposure to an antibiotic resistance gene, or to the protein encoded by such a gene, derived from a GMO, may or may not be significant against the naturally occurring background.

However, receiving environments are not static and change over time due to factors such as the dynamic nature of ecosystems, climate change, or changes in agricultural practices. Reduced chemical application has also led to reports of changes in the abundance of non-pest insects in cotton growing areas. These changes form part of the baseline considerations when developing the risk context for analysis of a specific Permit application.

b. Risk Management Context

Establishing the risk management context for consideration of a permit application includes consideration of:

i. protection goals against which measures to manage risk, including proposed controls or containment measures, are evaluated;
ii. matters to consider when preparing a risk management plan about the ways to protect the health and safety of people, the environment and relevant advice ;
iii. decision-making processes to decide whether to issue a Permit;
iv. types and nature of Permit conditions that may be imposed, including adverse and unintended consequences ;

The Act also provides for a range of other structures and processes for developing the risk management context including:

i. certification of facilities to specified physical containment levels;
ii. the NBMA's powers for monitoring dealings with GMOs and to direct individuals or organizations to undertake actions necessary to protect the health and safety of people and the environment ;
iii. sanctions for non-compliance;
iv. technical and procedural guidelines.

The Act empowers the NBMA to issue technical and procedural guidelines in relation to GMOs.

c. Risk Communication Context

The risk communication context provides details of who is consulted, when, in what capacity, on what matters, and in what manner. In addition to consultation with the stakeholders, the NBMA can seek advice from any other person or Agency that it considers appropriate.

CHAPTER 4 : RISK ASSESSMENT

4.1 Preamble

This Chapter explains the risk assessment methodology the NBMA uses to consider applications for DIR and DNIR Permits. The purpose of the risk assessment is to identify and characterize risks to the health and safety of people or to the environment from dealings with GMOs, posed by or as the result of modern biotechnology.

Risk assessment can be usefully viewed as a narrative that answers a set of key questions namely:

a. What could go wrong? How could harm occur? (Risk identification). Initially a broad range of circumstances are considered, whereby the proposed dealings with a GMO are postulated to harm people or the environment (risk scenarios). Each risk scenario describes a plausible causal pathway between the GMO and an adverse outcome;
b. How serious could the harm be? (Risk characterization – consequence assessment). An identified risk undergoes an assessment of the seriousness of potential harm via the particular risk scenario;
c. How likely is the harm to occur? (Risk characterization – likelihood assessment). An identified risk is also assessed with regard to chance of the occurrence of a series of individual steps in a risk scenario that may lead to harm. The assessment will derive the chance of harm from the overall series of individual steps; and
d. What is the level of risk? (Risk characterization – risk estimation). The level of risk (negligible, low, moderate or high) of identified risk is estimated by a combination of both the seriousness and likelihood of harm.

Scientific and technical information to answer these questions, as well as consideration of uncertainty, in particular knowledge gaps, occurs throughout the risk assessment process.

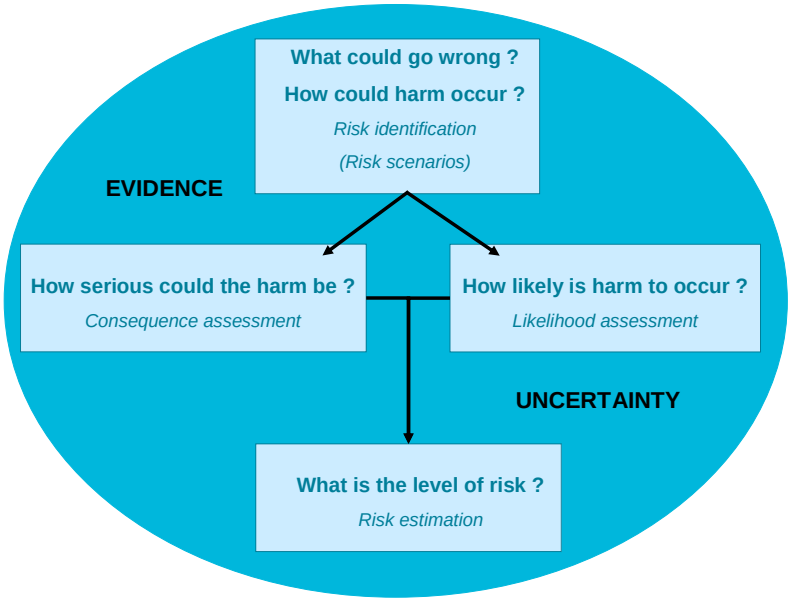

Figure 4.1: Consideration for Risk Assessment

In practice, the risk assessment process tends to be highly iterative and the steps depicted in Figure 4.1 can be viewed as part of a complete cycle. The risk assessment steps may be repeated as the result of:

a. ongoing accumulation of information (such as data requested from the applicant, expert advice, consultation, or literature searches);
b. development of more specific consequence criteria when more substantive risks are identified;
c. consideration of potential interactions between postulated risk scenarios, or
d. in response to the monitor and review process (see Chapter 5).

For instance, consultation with stakeholders on a risk assessment may identify additional risks, or provide further information relevant to risk characterisation or estimating the level of an identified risk.

The degree of consideration given to each cycle of the process should correlate with the degree of risk; greater consideration should be given to risks that are potentially more substantial.

The results obtained in the risk assessment process are used to prepare the risk management plan (see Chapter 5).

4.2 Risk Identification

Risk identification is the 'process of postulating risk scenarios and determining those that warrant detailed risk characterisation'. Risks are identified within the context established for the risk assessment (see Chapter 3), taking into account any proposed controls or limits for DIRs, or containment measures for DNIRs; relevant baseline information on the parent organism and/or other suitable comparator; and the receiving environment.

4.2.1 Postulating Risk Scenarios

Initially, risk identification considers a wide range of circumstances whereby the GMO or GM product, or the introduced genetic material, could come into contact with people or the environment. Consideration of these circumstances leads to postulating plausible causal or exposure pathways from dealings with a GMO to potential harm for people, or the environment (risk scenarios).

Therefore, a risk scenario can be viewed as a 'what if' statement that describes a possible set of circumstances that might give rise to harm in the future. For instance, a risk scenario might describe the chance of a particular disease occurring in people culturing a pathogenic GM microorganism in the event of accidental creation and inhalation of aerosols. The scenario would also consider how the genetic modification might increase the infectivity or severity of the disease compared to the parent organism. Many possible risk scenarios can be formulated but only those considered as potentially substantive are included in the risk assessment.

In addition, interactions between risk scenarios may give rise to synergistic, additive or antagonistic effects. For instance:

a. synergism arises when the combined effects are greater than the sum of the individual effects (for example, a GMO expressing two insecticidal genes with different modes of action may have greater potency than the addition of the effects from individual genes);
b. additive effects may occur where different scenarios lead to the same adverse outcome, which could increase the negative impact; and

c. antagonistic effects may occur where the GM trait alters the characteristics of the organism in opposing ways (for example, over-expression of a gene may lead to its silencing).

The postulation of risk scenarios may also include consideration of downstream effects. For example, growing a GMO may result in gene flow to other organisms by sexual or horizontal gene transfer. The recipient organism may then give rise to risks that are distinct from growing the GMO, but are contingent upon the occurrence of the proposed dealing. For instance, transfer of a stress tolerance gene from a GM plant to a sexually compatible species via pollen may increase the weediness of the recipient species.

The techniques available for developing a comprehensive set of risk scenarios range from checklists and brainstorming to targeted analysis. Techniques the NBMA uses may include previous agency experience, reported international experience, consultation, scenario analysis and inductive reasoning (fault and event tree analysis).

The type of information used to establish the risk assessment context includes the genotypic and phenotypic properties of the GMO, the proposed dealings, the parent organism, the receiving environment, and any relevant previous releases. Information on other factors might also be applicable to postulating risk scenarios, but not all will be relevant to all risk assessments or require the same degree of consideration. The factors include:

i. altered biochemistry;
ii. altered physiology;
iii. unintended change in gene expression;
iv. production of a substance toxic or allergenic to humans;
v. survival and persistence at the release site;
vi. survival and persistence outside the release site;
vii. gene flow by sexual gene transfer;
viii. gene flow by horizontal gene transfer;
ix. production of a substance that is toxic to, or causes ill-health or mortality in other organisms;

x. expression of an introduced gene that may alter the infectivity or pathogenicity, host range, pathogen load or vector specificity of a disease agent to other organisms;
xi. interaction of introduced pathogenic genes or products with other pathogens
xii. unintended effects on an existing non-GM weed, pest or pathogen;
xiii. secondary effects (such as development of herbicide resistance in related species as a result of gene flow);
xiv. production (such as farming practices);
xv. alteration to the physical environment including biogeochemical cycles; and
xvi. unauthorised activities.

Short and the long term should be considered when assessing risks. The NBMA does not fix durations, but takes account of the likelihood and impact of an adverse outcome over the foreseeable future, and does not disregard a risk on the basis that an adverse outcome might only occur in the longer term.

4.2.2 Identifying Risks that require further Characterisation

Risk identification should be comprehensive and rigorous; however, care should be taken to avoid over-emphasising insubstantial risk scenarios. Risks that warrant detailed consequence and likelihood assessments to determine the level of risk they pose to human health and safety or to the environment are generally identified by considering these questions:

a. Is the potential harm attributable to modern biotechnology/GMO? Any harm not posed by or resulting from the use of modern biotechnology cannot be considered;
b. Is there a plausible and observable pathway linking the proposed dealings to the potential harm? In cases where no plausible or observable pathways link the proposed dealings to the potential harm, the risk scenario should not advance in the risk assessment process; and
c. Is the risk substantive? That is, is the possible level of risk greater than negligible after an initial consideration of the chance and seriousness of harm?

Risk identification aims to include all risks that will require risk treatment. However, in the absence of extensive experience with impacts from a particular GMO, identifying all

substantive risks whose level of risk is greater than negligible is based on predicting the chance and seriousness of harmful scenarios that are yet to occur.

It is important to avoid underestimating or missing substantive risks. The approach the NBMA uses involves consulting a number of people with varying expertise in the risk assessment process and by extensive internal and external review of the risk assessment.

The NBMA, therefore, takes a cautious approach, which includes postulating and considering an extensive list of potential risk scenarios. As a result, some identified potential risks can subsequently be classified as negligible risks after more detailed consequence and likelihood assessments.

4.3 Risk Characterisation

Risk characterisation determines the level of risk by a combination of the chance (likelihood assessment) and seriousness (consequence assessment) of harm from dealings with a GMO. The likelihood and consequence assessments are based on inferences from the available scientific and technical information, and include consideration of uncertainty.

4.3.1 Quantitative and Qualitative Assessment

Likelihood and consequence assessments can be either quantitative (reporting risks numerically) or qualitative (reporting risks descriptively). For instance, likelihood can be expressed as a relative measure of either probability (from zero to one, where zero is an impossible outcome and one is a certain outcome) or frequency (the number of occurrences per unit of time). For qualitative assessments, likelihood is expressed in terms of highly likely, likely, unlikely and highly unlikely.

Quantitative risk assessment determines the conditional probabilities of risk and the associated statistical error (uncertainty). This type of analysis can be appropriate where there is a history of accumulated information, such as with chemical and industrial manufacturing. Quantitative risk assessments are most useful for addressing narrowly defined risks with relatively simple pathways leading to well specified adverse outcomes. However, some forms of structured decision making attempt to quantify probabilities in more complex situations.

Quantitative assessments use numerical values, which may be derived from:

i. experimental data,
ii. extrapolation from experimental studies on related systems,
iii. historical data, or
iv. inference from models used to describe the systems and its interactions.

By contrast, risk assessments of biological systems are often qualitative because the complex, dynamic and variable nature of such systems limits the degree of certainty that can be ascribed to our knowledge of them. There is often a degree of uncertainty about the mechanisms that may lead to an adverse outcome, making it impossible to quantify the probability of the adverse outcome occurring. Qualitative assessments can incorporate quantitative data where it is available. By using qualitative assessments, the maximum amount of information can be used in describing likelihood and consequence.

Qualitative assessments use relative descriptions of likelihood, consequence and risk estimate, and can combine data derived from various sources, including quantitative data.

Use of qualitative or quantitative approaches depends on the amount, type and quality of available data; the complexity of the risk under consideration; and the level of detail needed to make a decision. Some of the relative merits that distinguish the two approaches are listed in Table 4.1.

Table 4.1: Relative Merits of Qualitative and Quantitative Risk Analysis

	Type of assessment	
	Qualitative	**Quantitative**
Strengths	• Flexible – can be applied when there are data gaps, a lack of theory, properties of risk are unable to be analysed numerically, high complexity, limited resources, or ethical	• High objectivity. • Typically repeatable and testable. • Greater consistency between assessors. • Compatible with statistical interrogation.

	constraints in obtaining the experimental data. • Integrates a diverse range of analytical techniques. • Allows assessors to make judgments that aid decision-making despite data gaps and uncertainty. • Useful where there is a lack of experience in observing adverse effects. • Accessible to a wide range of stakeholders.	• Allows formal incorporation of some types of uncertainty.
Weaknesses	• Subject to greater ambiguity, vagueness and under-specificity (linguistic uncertainty). • Estimates are more subject to variation between assessors. • More prone to heuristics and biases of inputs such as expert opinion. • More difficult to incorporate uncertainty.	• Use of numbers can lead to overconfidence. • Not readily accessible to a range of stakeholders. • The accuracy is illusionary, if effects are serious but with little or indirect evidence. • Inability to apply to complex situations without many simplifying assumptions. • Difficult to use when there are insufficient or poor quality data.

For GMOs, qualitative risk assessments are, in most instances, the most appropriate form because:

i. there is a lack of long-term experience with particular organisms and/or introduced genes/traits
ii. potential adverse effects relating to human health and safety and the environment are highly varied
iii. environmental effects arise within highly complex systems that have many incompletely understood variables
iv. adverse effects may occur in the long term through indirect routes and are therefore difficult to quantify.

Qualitative risk assessment for GMOs provides the most feasible mechanism to assess risk for the majority of cases, as there is insufficient data to apply quantitative methods. Models can be used to inform the process but are unable to approach the complexity of the systems involved or contribute definitive answers. Qualitative assessments are also more accessible for risk communication.

The four weaknesses of qualitative assessments identified in Table 4.1 can be controlled and minimised in several ways and use of defined terminology for likelihood, consequences and risk can reduce ambiguity. Potential variations between assessors can be reduced through quality control measures including internal and external review and sourcing of expert advice. Differing viewpoints, perspectives and biases can be reduced through better descriptions of what the Act is trying to protect and through stakeholder input via effective consultation.

Nevertheless, there is a requirement for testable and repeatable scientific evidence to support qualitative estimates of likelihood and consequences, which are determined according to measurable, observable criteria of harm to human health and safety or to the environment. For example, when assessing risks to human health and safety, toxicological or epidemiological data may be used, where harm may arise from the presence of toxins, allergens or other chemicals that could have adverse effects on human health, such as enzyme inhibitors or anti-nutrients.

4.3.2 Likelihood Assessment

The likelihood assessment determines the degree of chance that harm will occur, and is expressed as highly likely, likely, unlikely and highly unlikely (see Table 4.2). If harm is not

expected to occur then risk is considered insubstantial and the impact needs no further analysis. However, care needs to be exercised when considering the remote possibility of risks that may have extreme adverse impacts.

Table 4.2: Scale for the Likelihood Assessment

Likelihood	Likelihood assessment definitions
Highly unlikely	May occur only in very rare circumstances
Unlikely	Could occur in some circumstances
Likely	Could occur in many circumstances
Highly likely	Is expected to occur in most circumstances

Factors that are important in considering the likelihood of harm occurring as a result of dealing with the GMO are related to circumstances whereby people or susceptible entities in the environment are exposed to the GMO, the introduced gene(s) or products of the introduced gene(s). Following exposure, there is consideration of the likelihood of adverse effects.

Assessing likelihood is more difficult for complex exposure pathways where many links between the individual steps of the risk scenario may exist. For instance, horizontal gene transfer from a GM plant or animal to a pathogenic microbe requires a large number of events to occur in sequence. However, occurrence of the gene transfer does not necessarily result in harm. Further steps are necessary, including the ability of the newly modified microbe to survive, replicate, display a selective advantage and give rise to some identifiable harm, such as increased virulence. In such cases, the combined likelihoods will be a substantially lower overall likelihood of an adverse outcome occurring than the likelihood of an individual step.

In contrast, scenarios that outline a simpler route to a potentially adverse outcome, such as a gene product that is toxic to non-target organisms, can usually provide more robust estimates of likelihood, particularly as there is often a direct correlation between the dose of toxin and the severity of the adverse outcome and the mechanism of action may have been experimentally verified.

Identifying all steps in a causal pathway leading to potential harm may be relevant for deriving an overall assessment of the chance that harm occurs. For instance, a causal pathway leading to increased weediness might be postulated, but involve many steps, including transfer of the introduced genetic material from the GMO into a sexually compatible relative, survival and increased fitness of the hybrid, followed by spread and persistence of the recipient species, which then results in harm (for example, reduced establishment of native plants in a protected area). If several steps have only a small chance of occurring, then the overall pathway has an extremely limited chance of occurring due to the combination of several low probability steps. Alternatively, one step may have almost no chance of occurring (for example, the co-occurence of a sexually compatible relative is not expected due to incompatible climate requirements between the GMO and its relative), which results in a low overall probability even if all other steps have a reasonable chance of occurring.

In the case of limited and controlled releases there is a fixed period for the intentional release but any potential for adverse effects beyond this period must also be considered. As with any predictive process, accuracy is often greater in the shorter rather than longer term.

4.3.3 Consequence Assessment

Consequence is an 'adverse outcome or impact of an activity' and is considered in respect of harm to people or to the environment. A consequence assessment determines the degree of seriousness of harm (see Table 4.3). The seriousness of harm is dependent on the scale at which impacts are considered. Harm to humans is usually considered at the level of an individual, whereas harm to the environment is usually considered at the level of populations, species or communities.

The potential existence of vulnerable individuals, populations, species, communities or ecosystems is also considered. For example, if a genetic modification resulted in production of a protein with allergenic properties, some people may have no reaction to that protein, others may react mildly, while others may be severely affected.

Assessing the seriousness of harm to people or to the environment may include consideration of the:

i. Magnitude of each potential adverse impact including the degree, extensiveness or scale of the harm: does it cause a large change over baseline conditions? Does it cause a rapid rate of change? Does it have long-term effects?
ii. Spatial extent of the potential adverse impact (for example, local, regional, national), including potential spread in the long term;
iii. Temporal occurrence of the impact: is it likely in the short or long term?
iv. Temporal extent of the adverse impact, that is the duration and frequency – the length of time (day, year, decade) for which an impact may be discernible, and the nature of that impact over time (is it intermittent and/or repetitive? if repetitive, then how often and how frequently)?
v. Reversibility – how long would it take to mitigate the adverse impact? Can the adverse impact be reversed and, if so, how long would it take?

Table 4.3 provides a descriptive scale for the seriousness of harm in relation to the health of people and in relation to the environment. The explanations are relatively simple in order to cover the range of possible Permit applications and potential risks. This variety of potential risks may be affected by different factors (magnitude, space, time, reversibility) that may contribute to the significance of adverse outcomes. Where appropriate and necessary, those descriptors may be defined in more detail for specific risks.

Table 4.3: Consequence Assessment Scale for the Health of People and the Environment

Consequences	Consequence assessment definitions relating to the health of people and the environment
Marginal	Minimal adverse health effects. Minimal or no damage to the environment or disruption to biological communities.
Minor	Adverse health effects that are reversible.

	Damage to the environment or disruption to biological communities that is reversible and limited in time and space or numbers affected.
Intermediate	Adverse health effects that are irreversible. Damage to the environment or disruption to biological communities that is widespread but reversible or of limited severity.
Major	Adverse health effects that are severe, widespread and irreversible. Extensive damage to the environment or extensive biological and physical disruption of whole ecosystems, communities or an entire species that persists over time or is not readily reversible.

4.3.4 Quality of Evidence

The NBMA will only consider applications containing sufficient information. The applicant must supply information as prescribed by the regulations (if any) and as specified in writing by the Agency (for example, in the application forms). In the absence of adequate information, the NBMA may not consider the application or may request further information from the applicant. If the Agency is unable to proceed with the assessment without the requested information, the time spent waiting for the information does not count towards the period within which the NBMA must make a decision on the application.

The NBMA also undertakes a thorough review of the relevant scientific literature in preparing the risk assessment and risk management plan. In addition to advice from NBC and other agencies, the NBMA may also consult other relevant experts for information or request further information from the applicant.

It is important to consider the quality of the evidence including how much and what type of data are needed. Determining the quality of the evidence includes consideration of:

i. appropriateness – the degree to which the data are relevant and applicable to the risk assessment question;
ii. reliability – the accuracy and integrity of experimental design, methodology, and statistical analysis used to report data and conclusions;

iii. transparency – the clarity and completeness with which all key data, methods and processes, as well as the underlying assumptions and limitations, are documented and available;
iv. expertise – the standing of the author(s) or expert(s) presenting the data;
v. strength – how much data there is to support the conclusion in the scientific literature; whether there is conflicting data and the strength of the conflicting data;
vi. robustness – if data from disparate sources, experiments or researchers support similar conclusions.

Each piece of information may be ranked differently against these criteria and, where contradictory information exists, the NBMA must judge the relative strength of each piece. Some information may be redundant or not of high enough value to be used as evidence.

Factors that may influence the relevance and value of the information include whether the:

i. subject of the experiment is identical, similar or different to the GMO being assessed;
ii. experiment is addressing a question relevant to the risk assessment;
iii. experiment was performed in Nigeria or overseas.

Scientific papers published in peer-reviewed journals generally provide some assurance of quality; however, even such papers can vary in quality. It is important to check that the conclusions of the authors or experts presenting particular evidence are supported by associated data and by other data reported by different authors. A judgment may also be made about the expertise of the authors or experts presenting the data.

Peer-reviewed papers are often regarded as high value evidence, but they are not automatically accepted and used in the risk assessment without further evaluation. Their appropriateness, transparency and robustness are all factors in determining how much reliance is placed on each piece of evidence.

Figure 4.2 illustrates how the NBMA may view the value of some different types of information. Information may be ranked low in one criterion but high in others. The overall value of the data for the risk assessment is open to the judgment of the NBMA.

	Reliability	Appropriateness
Increasing value	Validated studies conducted according to international protocols meeting defined standards. Peer reviewed literature – strongly supported reports, models, theories. Peer reviewed literature – single report, model, theory. General biological principles. Opinion of an expert familiar with the GMO, parent organism, modified traits, ecology. Other technical reports, specialist literature, government reports, etc. No information to indicate a problem. Unsubstantiated statements.	Experimental data on the GMO and/or parent organism in the Australian environment. Experimental data on the GMO and/or parent organism overseas. Experimental data on modified traits in other organisms. Experimental data on related, surrogate systems.

Figure 4.2: Some Types of Information and their Relative Values as Evidence

The combined weight of evidence may also influence the risk assessment, a single strong piece of information (as judged by the above criteria) may stand on its own or a number of weaker pieces of evidence may support each other in order for the NBMA to have sufficient confidence in the information. In addition, judgment is needed to determine the sufficiency of the data to achieve a reliable and robust estimate of risk following a consideration of uncertainty. Collection and assessment of unnecessary or excessive data is an inefficient use of resources for applicants and the NBMA.

Where a regulatory agency of another country has made an assessment of the same or a similar GMO, their findings may also be considered during risk assessment by NBMA .The NBMA has established links with relevant agencies that can facilitate exchange of information. It is important to consider not only the available information, but also uncertainty associated with the evidence. For example, if data regarding a proposed dealing with the GMO are unavailable, inconsistent or incomplete, the significance of that absence, inconsistency or incompleteness will be considered in the risk assessment process.

4.4 Risk Estimation

An estimate of the level of risk (see Table 4.4) is derived from a combination of the chance and seriousness of harm to human health and safety or to the environment from dealings with a GMO.

Table 4.4: Scale for the Level of Risk

Risk estimate	Risk estimate definitions
Negligible	Risk is insubstantial and there is no present need to invoke actions for mitigation.
Low	Risk is minimal, but may invoke actions for mitigation beyond normal practices.
Moderate	Risk is of marked concern that will necessitate actions for mitigation that need to be demonstrated as effective.
High	Risk is unacceptable unless actions for mitigation are highly feasible and effective.

		RISK ESTIMATE			
LIKELIHOOD ASSESSMENT	Highly likely	Low	Moderate	High	High
	Likely	Low	Low	Moderate	High
	Unlikely	Negligible	Low	Moderate	Moderate
	Highly unlikely	Negligible	Negligible	Low	Moderate
		Marginal	Minor	Intermediate	Major
		CONSEQUENCE ASSESSMENT			

Figure 4.3: Risk Matrix to Estimate the level of Risk from a combination of Outcomes of Likelihood and Consequence Assessment

Risk matrices should generally keep the number of risk categories within the matrix to a minimum and the inherent sources of uncertainty associated with formulation of a risk matrix should be reduced.

The NBMA applies a set of distinct descriptors to the likelihood assessment (Table 4.2), consequence assessment (Table 4.3) and risk estimate (see Table 4.5) to reduce ambiguity of terminology used in qualitative risk assessments. Application of these descriptors to identified risks must be considered in the context of the proposed dealings, including the introduced trait, the parent organism and the receiving environment. Comparisons between Permit applications are only possible in the broadest sense, even for related scenarios. It is important to note that uncertainty about likelihood and/or consequences will affect the risk estimate.

4.5 Significant Risk

After preparing the risk assessment for DIRs, the NBMA considers whether one or more dealings proposed to be authorised by the Permit may pose a significant risk to the health and safety of people or to the environment. If NBMA determines there is a significant risk, there is a longer period of consultation.

Although determination of significant risk is made on a case-by-case basis, it is expected that in most cases risk would be considered significant if the risk requires control or mitigation measures. These risks correspond to a level of risk that the NBMA has estimated as either moderate or high. In some cases, risks estimated to be low, but evaluated as requiring risk treatment, may also be determined as significant. In contrast, risks considered not to need mitigation (that is, negligible risks) would not be expected to be considered significant.

4.6 Summary

Typically, the methodology used for preparing a risk assessment in relation to DIR and DNIR Permits is an iterative process that places increasing focus on risks that are more substantive and usually require more information, more detailed characterisation, and a closer examination of uncertainty (Figure 4.4). The numbers of risks that involve more

detailed assessment and warrant consideration of risk treatment are, therefore, fewer than in earlier phases.

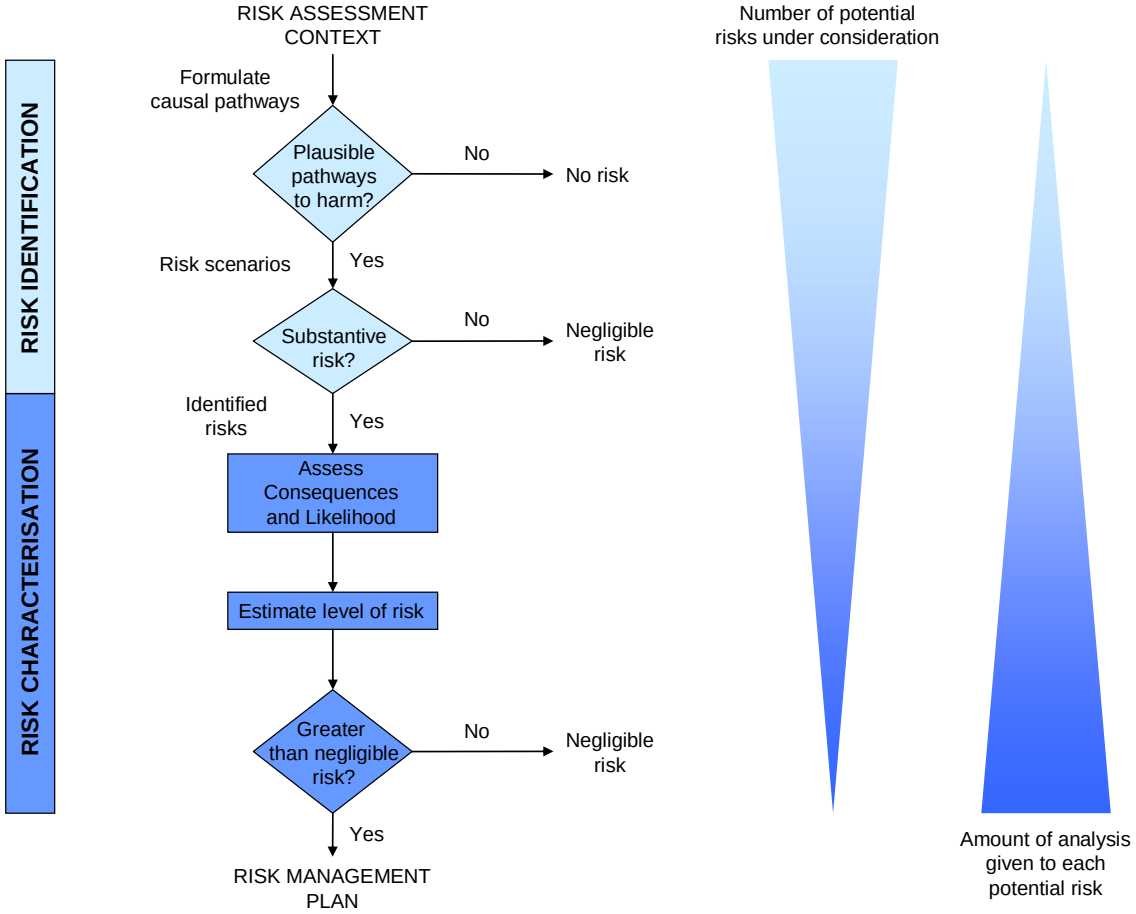

Figure 4.4: Summary of Methodology used for preparing a Risk Assessment for DIRs and DNIRs

CHAPTER 5 RISK MANAGEMENT

5.1 Preamble

This Chapter explains the risk management approach the NBMA uses to inform decisions on applications for DIR and DNIR Permit. The purpose of risk management is to protect the health and safety of people and to protect the environment by controlling or mitigating risk.

Risk management encompasses:

i. preparing a risk management plan – includes evaluating and treating risk, general risk management measures, and proposed Permit conditions
ii. monitoring and reviewing – measures to assess the effectiveness of all steps in risk analysis, including post release review of general/commercial releases of GMOs.

The risk assessment (Chapter 4) and risk management plans form the basis upon which the NBMA decides whether to issue a Permit.

5.2 Risk Management Plan

The risk management plan provides an answer to the question: 'Can the risks posed by a proposed dealing be managed in such a way as to protect the health and safety of people and the environment?'

Preparation of a risk management plan may be informed by considering a number of general questions, including:

i. Which risks need managing?
ii. What measures are available for managing risk?
iii. How effective are the measures?
iv. How feasible, practical or compatible are the measures?
v. Which treatment measure(s) provide the optimum and/or desired level of management for the proposed dealing?
vi. Do the measures themselves introduce new risks or exacerbate existing ones?

When preparing the risk management plan, the NBMA also takes into account relevant advice from stakeholders. Consistent with the overarching objective of protection, the NBMA prioritises preventative risk treatment measures over ameliorative or curative ones; that is, the risk treatment measures will be focused on preventing the risk being realised, rather than on measures to reduce or repair the harm that would result.

The risk assessment includes consideration of the causal pathway(s) necessary for any given risk to be realised. This understanding of how dealings with the GMO might result in harm and the nature of the harm provides valuable information for identifying risk treatment options. For example, knowledge of the causal pathway enables identification of 'weak links' in the chain where treatment may be most easily and/or effectively applied.

While the focus of risk management will be on treatment measures to prevent risks occurring, attention will also be paid to the important questions of 'what could be done if a particular risk occurred?' and 'what actions would need to be undertaken to reduce, reverse or repair damage or harm?'. Where possible management conditions for dealings that involve moderate or high risk estimates were being considered, it would be important to establish whether harm or damage that might result could be reversed, and that not only preventative measures but also curative or ameliorative actions be identified. For example, if a GMO produced a protein toxic to humans, it would be important to establish if a medical treatment exists to treat the toxicity. Such remedial measures should be included in contingency or emergency plans.

Redundancy in risk treatment options, for example, by establishing measures that 'break' more than one point in a causal pathway, would increase the effectiveness of risk management. It is important to note that in such cases failure of a single risk treatment measure would not necessarily result in realisation of an adverse outcome. For example, a standard preventative condition in transporting GM seeds is double containment, often related to managing a risk of potential weediness. However, even if the double containment was breached and seed spilled, it is unlikely that the weediness risk should be realised, because clean up measures would be invoked.

5.2.1 Risk Evaluation

The purpose of risk evaluation is to determine, based on risk assessment outcomes, which risks need treatment. Risk is evaluated against the objective of protecting the health and safety of people and the environment. Risk evaluation may also aid consideration of whether the proposed dealings should proceed, need further assessment or require collection of additional information during the release.

Factors used to determine which risks need treatment may include:

i. risk criteria;
ii. estimate of the level of risk;
iii. uncertainty associated with the risk estimate;
iv. interactions between potential risks.

Risk evaluation compares the estimate of risk against the likelihood and consequence criteria, which are continually reviewed during preparation of the risk assessment. In the process of more detailed characterisation of identified risks, the generic criteria for the nature and types of consequences described in Table 3.1 become more clearly specified.

Three categories of risk, which may relate to the risk estimate, can be elucidated for the purposes of risk evaluation, namely:

i. risks generally considered intolerable save in extraordinary circumstances (expected if risk is estimated as moderate or high);
ii. risks generally considered as tolerable, but may require reduction if practicable (expected if risk is estimated as low);
iii. risks generally considered as broadly acceptable (expected if risk is estimated as negligible).

Risk estimated as low may or may not require treatment, depending on the specific circumstances, such as the nature of the risk, degree of uncertainty, advice during consultation, or the nature of the risk treatment measures.

Uncertainty associated with either the consequence or likelihood assessments affects the accuracy of the risk estimate. For instance, if a large degree of uncertainty exists, risk estimated as low may require further studies or specific risk reduction measures.

The NBMA may, where appropriate, consider interactions between potential risks due to synergistic, additive, antagonistic, cumulative or aggregate effects. In most cases, the combination of effects is not expected to be significant when the associated risks are estimated to be negligible.

5.2.2 Risk Treatment

When risk requires treatment, options to reduce, mitigate or avoid the risk are identified and assessed, and selected management measures are implemented through Permit conditions. Options to reduce exposure to the GMO or its products and limit opportunities for the spread and persistence of the GMO, its progeny or the introduced genes must be considered.

For DIRs, the scale of the release is an important consideration in selecting risk treatment options because this influences the level of exposure to potential adverse consequences. Other measures could include specifying physical controls (such as fences), isolation distances, monitoring zones, pollen traps, post release clean-up and specific monitoring requirements (such as removal of sexually compatible species from the release site). Again, it is important to note that such measures will be applied to all limited and controlled releases in order to restrict the release to the size, duration and location(s) as requested by the applicant, and is crucial to establishing the risk context for assessing risk.

For DNIRs, risk treatment measures could include the level of physical containment of the facility in which the dealings may be undertaken (that is, PC1, PC2, etc.), and specific work practices that reduce exposure (such as using face masks).

The range of suitable controls and limits will depend on the nature of the:

i. proposed dealings;
ii. control and limits proposed by the applicant;
iii. nature and properties of the organism (such as seed longevity);

iv. trait (the characteristics of the GMO conferred by NBMA);
v. introduced genes (including ability to identify/detect the GMO and introduced genes);
vi. environmental conditions at the site of releases;
vii. normal production and management practices.

Once measures have been identified they must be evaluated to ensure they will be effective and sufficient over time and space. Specifically, they must:

i. be feasible to implement and able to operate in practice;
ii. meet currently accepted requirements for best practice (for example, good agricultural practice, good laboratory practice, good manufacturing practice);
iii. manage the risks to the level required for the requested duration of the dealings and period of the Permit;
iv. be able to be monitored.

Selection of risk management measures is made according to their efficacy and efficiency, commensurate with the level of risk. If risk treatment measures are selected for an identified risk, then risk should be reduced sufficiently such that any residual risk does not compromise protection of the health and safety of people and the environment.

The most appropriate options available to manage the risk are selected. It is possible to envisage a number of options that may provide different levels of management of a specific risk. Equally, one management strategy may control a number of risks. The NBMA must be satisfied that the risks would be managed by the proposed options before a Permit can be issued. This may include options that manage the risks most comprehensively and/or ones that are judged to provide a sufficient level of management.

Any identified uncertainty in aspects of the risk assessment or risk treatment measures must be addressed in determining the appropriate risk management. Uncertainty in risk estimates may be due to insufficient or conflicting data about the likelihood or severity of potential adverse outcomes. Uncertainty can also arise from a lack of experience with the GMO itself. For example, plants (including GM plants) perform differently when grown under controlled growth conditions (such as in green house) compared to performance in the open environment as evidenced by ‘field trials’. Risk treatment measures would be

devised to take account of such uncertainty. For instance, the size of a reproductive isolation distance for a GM plant would be based on the overall distribution of pollen, and not just on the median distance pollen might travel.

In the case of DIRs, the NBMA endeavours to assist GMO developers by identifying data that may be needed to assess applications for future proposed releases that are larger in scale and/or have fewer restrictions, as in the case of general/commercial releases. In addition, the NBMA is to impose Permit conditions to require collection of data or conduct of research. The findings of such research may result in changes to Permit conditions to better manage risk and will inform future evaluations of the same or similar GMOs.

The risk management plan may also evaluate certain measures to manage risk, including:

i. proposed controls and limits for DIRs;
ii. proposed containment measures for DNIRs;
iii. risk treatment measures;
iv. any new or increased risk from measures to manage risk.

Applications for DIR Permit may include means proposed to control the spread and persistence of the GMO and its genetic material in the environment, and limit the release to the size, location and duration. Similarly, applications for DNIR Permit include means proposed to contain the GMO and its genetic material, including physical containment to a specified level (that is, PC1, PC2, PC3 or PC4). These proposed measures to manage potential risks are evaluated against criteria established to protect the health and safety of people and the environment. In some cases, additional or modified measures to manage risk may be required. However, in some cases, the proposed measures may be evaluated as excessive or not required for protecting the health and safety of people or to the environment.

In addition, a measure to manage one risk may introduce a new risk or increase the level of risk; for example, applying a tourniquet to a snakebite victim's limb can reduce the amount of snake venom that enters the bloodstream, but it can also lead to limb damage through reduced blood flow.

5.3 General Risk Management Measures

Other statutory requirements contribute to the overall management of risk, including:

i. suitability of the applicant;
ii. identification of the persons or classes of persons covered by the Permit;
iii. existence of contingency plans;
iv. existence of reporting structures, including a requirement to inform the NBMA if the applicant becomes aware of any additional information about risks to the health and safety of people or to the environment.

Before issuing a Permit, the NBMA must be satisfied that the applicant is a suitable person (whether a natural person or a body corporate) to hold a Permit. The NBMA must have regard to any relevant convictions of persons or body corporate or any revocation or suspension of a Permit relating to laws about the health and safety of people or the environment, and to the capacity of the person to meet the conditions of the Permit.

Applicants are required to have contingency plans in place in case of emergency. The nature of such plans will vary depending on the Permit and nature of the dealings. For instance, many large-scale facilities are required to have a physical barrier in place capable of containing volumes greater than the maximum volume of the fermentation tank(s) that will contain any spills and also specific emergency procedures. All Permits include a requirement that the NBMA be informed if there is an unintentional release of the GMO.

All Permits also contain reporting provisions in case of unexpected events occurring or new information becoming available relating to the GMO and the dealings. The permit holder is required to provide regular reports to the NBMA and to report any changes in circumstances and any unintended effects, new risks or contravention of conditions.

If the risks associated with the authorised dealings are identified, the NBMA may vary Permit conditions, or if necessary, suspend or cancel the Permit.

In cases of non-compliance with Permit conditions arising from monitoring/inspection, the NBMA may initiate an investigation to determine the nature and extent of non-compliance. If proven, a range of remedies is available that include provision for criminal sanctions of

large fines and/or imprisonment for failing to abide by the National Biosafety Management Agency Act 2015, conditions of the Permit or directions from the NBMA, especially where significant damage to health and safety of people or to the environment could result.

5.3.1 Permit Conditions

The NBMA imposes Permit conditions for a range of issues including, for example, the scope of the dealings and actions to be taken in the case of release of a GMO from a contained environment. These Permit conditions are imposed as a means of implementing the risk management plan and other statutory requirements. The Permit Holder is legally required to comply with these conditions. Formulation of clear and unambiguous Permit conditions is therefore critical to ensure:

i. treatment measures or controls are applied as intended and to manage risk effectively;
ii. Permit Holders understand the specific requirement so compliance with the conditions can be demonstrated;
iii. the NBMA can enforce compliance with the conditions and identify non-compliance, and where necessary or appropriate, undertake remedial and/or punitive actions.

The ability to identify the GMO and the introduced genes is an important consideration for risk management so preventative and/or ameliorative treatment measures can be applied with confidence. The requirement to provide the NBMA with a reliable method to detect the GMO and its modified genes is included in all risk management plans.

5.3.2 Monitor and Review

The purpose of monitoring and reviewing all steps in risk analysis is to ensure the right things are done, each step is done correctly, and that the outcomes remain valid in the light of future findings or changes in circumstances. A number of both internal and external feedback mechanisms can be used to maintain the effectiveness and efficiency of risk assessment and risk management, and which consider the concerns of all interested and affected stakeholders.

Internal processes of monitor and review include:

i. standard operating procedures for specific administrative processes;
ii. internal peer review of DIR and DNIR risk assessment and risk management plans;
iii. merit based selection processes for the NBMA staff;
iv. conflict of interest declarations and procedures for the NBMA staff and expert committee members.

External processes of monitor and review include:

i. expert scrutiny by NBC of permit applications and risk assessment and risk management plans;
ii. external scrutiny and review through the extensive consultation processes with Government agencies, interested parties and the public on all DIR risk assessment and risk management plans;
iii. oversight by the NBMA Board;
iv. production of annual report.

A critical aspect of overall quality assurance is that the NBMA maintains the expertise and capacity to undertake the risk analysis of GMOs. This is achieved through the qualifications and skills of staff, remaining up-to-date on developments in modern biotechnology, biosafety and relevant scientific disciplines by reference to the scientific literature, attending conferences, and monitoring the determinations, experience and policy developments of agencies regulating GMOs in other countries.

Monitoring and reviewing contributes to identifying situations where treatment measures are not adequately managing the risks, either as a result of non-compliance or because of changed circumstances and/or unexpected or unintended effects; and facilitates an ongoing review of the conclusions of risk assessment and of the risk treatment options. Identifying changed circumstances enables a reassessment of the risks posed by the dealings and the treatment measures in the light of experience, and for risk management to be modified where necessary. Such review activities may also provide important information for the risk assessment of subsequent Permit applications for the same or related GMOs.

5.3.3 Oversight Provisions

Some general/commercial release DIR Permits, particularly those requesting unrestricted release, may incorporate a requirement for oversight in the risk management plans which may be achieved through identified post release review activities.

Accordingly, the NBMA may impose Permit conditions that require the Permit Holder to supply, or enable the NBMA to collect, specific information on the progress of the release. This provides a mechanism for 'closing the loop(s)' in the risk analysis process, or for verifying findings of the risk assessment and risk management plan, by monitoring specific indicator(s) of harm that would usually have been identified in the risk assessment. Potential 'triggers' for this component of post release review may include where the risk estimate is greater than negligible, or there is uncertainty (for example, lack of consensus among expert advisers).

A second component of post release review is establishment and maintenance of an adverse experience/effects reporting page on the NBMA website to collect information about possible adverse effect(s) of released GMOs on human health and the environment. This could result in reports over the short and long term about any DIR Permit. Credible information would form the basis of further investigation.

A third component of post release review is the review of risk assessment and risk management plans any time after the Permit is issued. Such reviews would take into account any relevant new information or may be triggered by findings from either of the other components of post release review. The purpose of the review would be to ensure that the findings of the risk assessment and risk management plan remain current. If the review findings justify either an increase or decrease in the initial risk estimate(s), or identify new risks to people or to the environment that need managing, this could lead to review of the risk management plan and changes to the Permit conditions.

5.4 Decision Making

Preparation of the risk assessment and the risk management plan are essential components of decision making in relation to DIR and DNIR Permit applications.

The NBMA Chief Executive is charged with making decisions on whether to issue a Permit to authorise dealings with GMOs, which includes imposition of Permit conditions. The Chief Executive also decides on suspending, cancelling, transferring or varying a Permit. Each of these decisions is based on whether the Chief Executive is satisfied that any risks posed by the dealings can be managed in such a way as to protect the health and safety of people and the environment.

There are no one-size-fits-all solutions for the risk assessment and risk management of GMOs; the Chief Executive adopts a case-by-case approach, weighing the available evidence against any uncertainty of likelihood or consequence, and the availability of management measures, to arrive at a prudent judgement.

To support the decision-making process for DIR applications the Chief Executive must seek advice from NBC, staff of the NBMA and anyone else the Chief Executive thinks appropriate.

The key factors in making the decision include:

i. setting the terms of reference for the risk assessment;
ii. establishing the risks to the health and safety of people or to the environment that require management;
iii. determining Permit conditions that define the scope and boundaries of the proposed dealings and manage the risks.

Another important factor the Chief Executive must consider before issuing a Permit is whether the applicant would be able to effectively implement all the conditions considered necessary to manage the risks associated with the proposed dealing.

After a Permit is issued it can be varied, suspended or cancelled according to provisions under the National Biosafety Management Agency Act 2015 and regulations. This enables the Chief Executive to respond to new information or changed circumstances that affect the level of risk.

5.4.1 Monitoring for Compliance

Where risks requiring management have been identified and treatment measures imposed through Permit conditions, or in guidelines, monitoring is necessary in order to verify that those treatment measures or obligations are being applied and that risks are being appropriately managed.

Specific monitoring activities to support compliance include:

i. routine monitoring of limited and controlled environmental releases and certified facilities;
ii. unscheduled monitoring of limited and controlled environmental releases and certified facilities (spot checks);
iii. profiling of dealings to aid strategic planning of monitoring activities (such as conducting inspections of GM plants during the flowering period);
iv. conducting education and awareness activities to enhance compliance and risk management planning of Permit Holders and organizations;
v. conducting audits and practice reviews in response to findings of routine monitoring;
vi. incident reviews in response to 'self-reported' non-compliance;
vii. investigations in response to allegations of non-compliance with conditions or breach of the legislation.

The Act stipulates, as a condition of every Permit, that a person who is authorised by the Permit to deal with a GMO, and who is required to comply with a condition of the Permit, must allow inspectors and other persons authorised by the NBMA to enter premises where a dealing is being undertaken for the purpose of monitoring or auditing the dealing. Unannounced spot checks and audits can apply at any time irrespective of non-compliance.

In the case of controlled and limited DIRs, post-harvest monitoring continues until the NBMA is satisfied that all the GMOs resulting from the authorised dealings have been removed from the release sites.

CHAPTER 6 RISK COMMUNICATION

6.1 Preamble

Effective communication is an integral component of risk analysis. Risk communication is defined as the 'culture, processes and structures to communicate and consult with stakeholders about risks'. Such exchanges may not relate exclusively to risk but may also consist of expression of concerns, opinions or reactions to risk messages or to legal or institutional arrangements for risk management (National Research Council 1989).

The aim of risk communication 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 help people make decisions, to minimise 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 Chapter discusses the way risk is perceived, outlines consultative processes, describes the present communication processes between stakeholders and the NBMA and sets out a risk communication charter to demonstrate the commitment of the NBMA to effective communication with stakeholders.

6.2 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, such as claims that multinational corporations might seek to achieve market dominance by controlling access to the technology. In many instances, the debate over modern biotechnology has raised heated arguments both for and against its use. One of the reasons that the biosafety regulatory framework was established was in response to community 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 risk in different ways and may have different attitudes to risk. Perception of risk can be influenced by:

i. material factors, such as gender, age, education, income, and personal circumstances;
ii. psychological considerations, such as early experiences, personal beliefs, attitudes to nature, religious beliefs;
iii. cultural matters, such as ethnic background.

Across a spectrum of risk, attitudes can be broadly categorised as risk averse, 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 6.1 summarises some of these elements.

Table 6.1: Factors in the perception of risks as either tolerable or threatening

Risks may be seen as tolerable if they are:	Risks may be seen as threatening if they are:
• 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

Social scientists have conducted considerable research into the way different members of the community estimate and perceive risk. Often, technical experts and scientists have very different perceptions and estimations of risks to other people. Although it is accepted that experts may arrive at a better quantitative assessment of risks where they have specialist knowledge, the way they estimate risks outside their area of expertise is no different to that of other members of the community and can be influenced by subjective values.

Risk perception is fundamental to an individual's acceptance of risk. For instance, despite the level of risk associated with car travel, it continues to be an accepted form of daily transport. And, while commercial air travel is also an accepted form of transport, many people may perceive it as more risky than car travel, although the probability of death is actually higher with car travel in relation to the distance travelled. These perceptions exist due to people's greater familiarity with cars, greater control in operating a car, and a greater chance that a car accident is less likely to be fatal than an airline accident. It can be seen, therefore, that 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 summarised in Table 6.2.

Table 6.2: Sources of conflict in risk assessment and risk management

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.

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. All these things are important and lead to the conclusion that stakeholders' views should be treated with respect as they provide a valid and required input into risk assessment and risk management. The NBMA recognises and accepts that the community holds many and varying views on modern biotechnology 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 DIRs. The Act therefore provides a direct mechanism for two-way interaction between NBMA and stakeholders by publishing in national dailies notification and display of Permit applications for public input.

6.3 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 NBMA allocates 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.

6.3.1 Stakeholders

Release of GMOs into the Nigerian environment is of significant interest to a wide spectrum of the community, including Government, Non-Governmental Organisations (NGOs), Community-Based Organizations (CBOs), 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 6.6.

Table6.3: Stakeholders with interests in modern biotechnology

Group	Stakeholders
Research	Pro/Vice Chancellors R&D of universities, CEOs/Directors of research institutes, Institutional Biosafety Committees, research and development corporations, other research groups
Industry	Retailers, food industry, proponents of the technology
Primary producers	National and state farmers' federations, peak 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
Government	State and local governments, Federal Ministries(of Environment,Agriculture and Rural Development, 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).
Public	Consumers and interested parties

Table6.4: Forms of communication with stakeholders and potential constraints on that communication

Stakeholders	Form of communication	Constraints on effective communication
Applicant	Application form Informal/formal 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 Limited resources
Experts	Meetings, informal discussions Letters requesting advice	
Prescribed agencies	Memoranda of understanding Informal/formal discussions Letters requesting advice or notification	
Local councils	Letters requesting advice	
Government	Memoranda of understanding Informal/formal discussions Letters requesting advice	
Public	telephone number Advertisements Website Email Client register	

6.3.2 Consultation on Applications

The requirement for consultation on DNIRs is more limited in scope than for DIRs. The NBMA provides information to stakeholders through the print media, GMO Record on the dealings, including the aims, a description of the project, and the date of issue and expiry of the Permit.

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

When an application for a DIR Permit is received, the NBMA makes a determination about whether it qualifies as a limited and controlled release application, notification is published in National and local newspapers, the application dossier is also placed in the Local Government Headquarters where the release will take place for public review and comments.

Each submission the NBMA receives on a particular application is analysed to identify matters relating to risks to human health and safety or to the environment that require detailed consideration. As part of the response to stakeholders and to ensure all relevant concerns have been considered, summaries are prepared that identify the issues raised and where they are addressed in the RARMP; these are included as appendices to the RARMP. Resolution of specific concerns and issues relating to risks to human health and safety and to the environment may involve intensive discussions between the stakeholders and NBMA staff which may lead the Chief Executive to seek further information from the applicant. Before releasing the RARMP for consultation, the NBMA must 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 30 days if the NBMA is satisfied that the dealings do not pose significant risk(s). If the NBMA considers that the proposed dealings may pose significant risk(s), additional period will be allocated.

The consultation version of the RARMP is then finalised, taking into account 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 RARMP would be reworked to address them.

The NBMA endeavours to address such concerns through documents such as this *Risk Analysis Framework*, by providing a detailed outline of the rationale behind the process of risk assessment and risk management undertaken by the NBMA and by making the documents underpinning the decisions of the NBMA readily available.

6.3.3 Social and Ethical Issues

As a relatively new area, modern biotechnology generates significant public interest and has the potential to raise ethical issues important to society as a whole. Consequently, the NBMA staff should have expertise in community consultation, risk communication, the impact of modern biotechnology on the community, issues relevant to businesses that are using modern biotechnology, modern biotechnology research, local governance, issues of consumers' concerns, law, religious practices, human health, animal health and welfare, primary production and ethics to address environmental, social and ethical concerns.

6.3.4 Other Forms of Communication

The mandate of the NBMA under the Act is to implement the regulatory system for biosafety. There are both explicit requirements for communication prescribed by the legislation and implicit requirements deriving from obligations of public duty as an office of government. The NBMA 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 NBMA 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 and compliance undertaken. The primary mechanisms for providing information about the NBMA to the public are the NBMA website, press briefing, news bulletin, the annual Report and direct response to e-mail and phone calls. Documents that provide essential background information for the NBMA, such as the biology of plant

species that have been modified by modern biotechnology, are also available on the website.

The website provides extensive information on the operation of the NBMA, including various application forms, Certification Guidelines, the GMO Record, etc.

The NBMA annual reports provide details on applications considered, monitoring activities undertaken, they also summarise other activities of the NBMA in relation to reviews, research, freedom of information requests, etc.

In addition, the NBMA:

i. provides regular workshops for IBCs on particular administrative matters and to help them and applicants recognise particular categories of dealings;
ii. maintains regular contact with applicants on a range of matters, both scientific and administrative;
iii. fosters a cooperative compliance culture, educating and informing applicants to minimise the likelihood of breaches of the legislation and subsequent application of strict penalties under the Act for non-compliance;
iv. provides information on the regulation of modern biotechnology, etc.

6.4 Risk Communication Charter

Effective risk communication requires the active participation of all stakeholders, including government. This charter presents the principles of risk communication that the NBMA aims to uphold and demonstrates its commitment to active risk communication.

The NBMA aims to:

i. raise awareness of Nigeria's biosafety regulatory system for modern biotechnology nationally and internationally;
ii. undertake rigorous, scientifically-based risk assessment and risk management of dealings with GMOs in an open and transparent manner,

iii. actively communicate the reasoning behind Permit decisions in an open and objective manner and in plain language;

iv. actively listen and respond, in a timely manner, to stakeholders' concerns;

v. communicate consideration of social and ethical issues relating to modern biotechnology and action taken on such issues;

vi. periodically review the NBMA communication strategies and practices to ensure effective, appropriately targeted and efficient communication with stakeholders.

Appendix A

Table A- 1: Classes of GMO dealings

Category	Permit required	Containment
Exempt	No	No intentional release to the environment
NLRD	No, dealings must be assessed by IBC; notified in annual report	Yes PC1 or PC2 (usually)
DNIR	Yes, applications must be assessed by IBC; RARMP prepared and Permit decision by the NBMA	Yes ≥PC2 (usually)
DIR (except for limited and controlled releases)	Yes, applications must be reviewed by IBC; consultation on application, RARMP prepared, consultation on RARMP and Permit decision by the NBMA	Containment measures may be required, determined on a case-by-case basis and other Permit conditions will apply
DIR (limited and controlled)	Yes, applications must be reviewed by IBC; RARMP prepared, consultation on RARMP and Permit decision by the NBMA	Containment measures will be required based on size/scope of release sought by applicant; and other Permit conditions will apply
Inadvertent dealing	Yes, Permit decision by the NBMA, only for the purposes of disposal of the GMO	Containment and/or disposal measures will apply
GMO Register	No, but must be previously permitted Review of related RARMPs	Containment measures may be required

EDD	No, determination by the DG/CEO, subject to advice of threat and utility of GMO from competent authorities and risk assessment advice from the Regulator	Containment and/or disposal measures may be included in EDD conditions

Notes: DIR = dealings involving intentional release; DNIR = dealings not involving intentional release; EDD = emergency dealing determination; GMO = genetically modified organism; IBC = Institutional Biosafety Committee; NLRD = notifiable low risk dealing; PC = physical containment; RARMP = risk assessment and risk management plan.

The Permit System is based on a rigorous process of risk assessment using science-based evidence. For those dealings that involve an intentional release of a GMO into the environment (DIR), the legislation requires extensive consultation with experts, agencies and authorities, and the public. More data must be submitted for assessment and a more rigorous assessment process is set out than is required for dealings not involving intentional release of a GMO into the environment (DNIR).

The NBMA may adapt the risk assessment methodology described in Chapter 4 that are prepared in relation to inadvertent dealings, proposed EDD inclusion of dealings on the GMO Register or variations to existing permits, as well as to review of NLRDs and exempt dealings.

Timeframes

Under the Act, the NBMA will issue or refuse to issue a Permit within the time limit prescribed. Similarly, prescribe timeframes for consideration of applications to vary Permits, to accredit organisations/Institutions and to certify facilities. These statutory timeframes are shown in Table A2. They do not include weekends or public holidays or periods where the NBMA has requested more information from the applicant, including resolving a CBI claim, and cannot continue assessment until that information has been provided.

Table A- 2: Time Frames

Category	Timeframe
DNIR	90 working days
DIR - (except for limited and controlled releases)	270 working days
DIR – (limited and controlled, no significant risk)	270 working days
DIR – (limited and controlled, significant risk)	270 working days
Permit variation	90 working days
Accreditation	90 working days
Certification	90 working days

Notes: DIR = dealings involving intentional release; DNIR = dealings not involving intentional release.

Dealings involving minimal Risks

The GMO Register is a mechanism provided for authorisation of dealings with GMOs that have a history of safe use. The NBMA may make a determination to include dealings with a GMO on the GMO Register only if the dealings have previously been authorised by a GMO Permit, and the NBMA must be satisfied that risks posed by the specific dealings are minimal and that it is not necessary for anyone conducting the dealings to be covered by a Permit in order to protect the health and safety of people or to the environment. The principles of risk analysis set out in this framework are applicable to determine whether a GMO should be included in the GMO Register. After inclusion in the Register, the dealings no longer require authorisation by another Permit but may still have conditions attached to their registration.

Exempt dealings are dealings with GMOs that have been assessed over time as posing negligible risks to people or to the environment and are therefore exempt from further Permit after the initial Permit and do not require a case-by-case risk assessment. These

dealings comprise basic genetic engineering techniques and activities that have been conducted extensively in laboratories worldwide. Exempt dealings do not require a specified level of containment but must not involve intentional release of a GMO into the environment. Examples of exempt dealings include dealings with:

i. an animal into which GM somatic cells have been introduced, where the introduced somatic cells do not produce infectious agents;

ii. small volumes (<10L) of an approved host/vector system into which low risk genetic material has been introduced (for example, the gene must not be uncharacterised, it must not be derived from a pathogenic organism, nor code for a toxin).

Notifiable low risk dealings (NLRDs) are dealings with GMOs that have been assessed over time as posing negligible risks provided certain management conditions are met. Before a type of dealing is listed, the NBMA must have considered whether the GMOs involved are biologically contained, whether the dealings involve minimal risks to people and the environment, and whether no or minimal conditions would be needed to manage any such risks. NLRDs must not involve intentional release of a GMO into the environment.

NLRDs may only be undertaken in a facility meeting appropriate technical guidelines issued by the NBMA (usually PC1 or PC2 certified facilities). Before being conducted, the dealings must be assessed by an IBC as meeting the NLRD classification. Details of all new NLRDs that have been assessed by an IBC must be reported to the NBMA annually. NLRDs are included on the Record of GMO and GM Product Dealings but do not require case-by-case risk assessment.

An example of NLRD which may be conducted in PC1 facilities include dealings with:

GM mice/rats

Examples of NLRDs that may be conducted in PC2 facilities include dealings with:

i. a genetically modified animal (other than a mouse or rat) including invertebrates

ii. a genetically modified plant, provided the dealing occurs in a facility designed to prevent release of its pollen and seed

iii. an approved host/vector system into which a gene that may pose a higher level of risk has been introduced (for example, the gene may encode a pathogenic determinant or uncharacterised gene from a pathogen).

Permit Dealings

Any dealing not exempt, an NLRD, on the GMO Register, or specified in an EDD must not be conducted unless permitted.

The NBMA considers Permit applications on a case-by-case basis, based on whether the risks posed by the dealing can be managed to protect human health and safety and the environment. The NBMA shall decide whether to issue a Permit for that dealing, and the management conditions to be imposed to manage any risks (if a Permit is issued).

The application forms detail the information the applicant must provide.

The application forms issued by the NBMA for both DIRs and DNIRs require the applicant to identify risks that the dealings may pose to human health and safety, the environment and any measures proposed to manage those risks. Both also require the IBC to support the application.

Preparing a RARMP

The NBMA shall take into account the risks posed by the proposed dealings, including any risks to the health and safety of people or risks to the environment. Preparation of a risk assessment must have regard to:

i. the properties of the organism to which dealings proposed to be authorised by a Permit relate before it became, or will become, a GMO;

ii. the effect or the expected effect, of the genetic modification, that has occurred, or will occur, on the properties of the organism;

iii. provisions for limiting dissemination or persistence of the GMO or its genetic material in the environment;

iv. the potential for spread or persistence of the GMO or its genetic material in the environment;

v. the extent or scale of the proposed dealings;

vi. any likely impacts of the proposed dealings on the health and safety of people;

vii. any previous assessment by a regulatory authority, in Nigeria or internationally in relation to allowing or approving dealings with the GMO and the potential of the GMO concerned to:

a. be harmful to other organisms;

b. adversely affect any ecosystems;

c. transfer genetic material to another organism;

d. spread, or persist in the environment;

e. be toxic, allergenic or pathogenic to other organisms.

In taking into account any risk or potential capacity mentioned above, the NBMA must consider both the short term and the long term.

Consulting on the RARMP

The NBMA may consult, on any aspect of a DNIR application, with relevant Government Agencies, Research Institutions, NBC, IBC and other stake holders. In addition, the public may be consulted.

Considering whether to issue a Permit

Applicant suitability is an important aspect in the NBMA's consideration whether or not to issue a Permit. In addition, certification of facilities and accreditation of organisations, will form part of the risk context. In addition, the NBMA may prescribe or impose additional conditions on the Permit to manage risk to a tolerable level.

Deciding whether to issue a Permit and notifying the decision

The NBMA shall not issue a Permit unless satisfied that any risks posed by the dealings proposed to be authorised by the Permit are able to be managed in such a way as to protect the health and safety of people and the environment. When the NBMA has made a decision whether to issue it must notify the applicant.

After a Permit has been issued

Once a Permit is issued, the Permit Holder must comply with the conditions of the Permit. Part of the Act concerns the topics 'enforcement' and 'powers of inspection'. The Act also specifies that the NBMA may suspend, cancel or vary an existing Permit.

In addition, the Act provides for substantive penalties for undertaking unlawful dealings with GMOs. The risk assessment takes account of any risks to human health and safety and the environment posed by the dealing and the risk management plan outlines how these risks can be managed.

The NMBA may impose conditions on all Permits. Measures will be imposed to restrict the persistence and spread of the GMO and its genetic material in the environment for all DIRs determined to be limited and controlled releases. Non-compliance with conditions placed on Permits issued under the Act is a criminal offence.

For both DNIR and DIR applications, the applicant must provide information specified in the application forms as to their suitability to hold a Permit. This information includes any relevant convictions, revocations or suspensions of Permits under laws relating to human health and safety or to the environment and an assessment of the applicant's capacity to manage any risks posed by the proposed dealings.

Dealings not involving intentional releases

DNIRs usually take place under specified physical containment conditions in certified facilities, which minimise risks to the environment. The preparation of RARMP for DNIR by applicants for applications is required. The application form specifies the information the NBMA requires.

The NBMA considers the RARMP in deciding whether to issue a Permit and in determining the Permit conditions that should be imposed (if a Permit were to be issued). Typical Permit conditions require the applicant to conduct the dealings in certified facilities, to follow particular handling requirements (such as using biosafety cabinets), to train and supervise staff, to transport and dispose of the GMO appropriately, to have contingency plans and implement them if necessary.

As a guide to the legislative requirements, the process required in respect of DNIR applications is described in Figure A2.

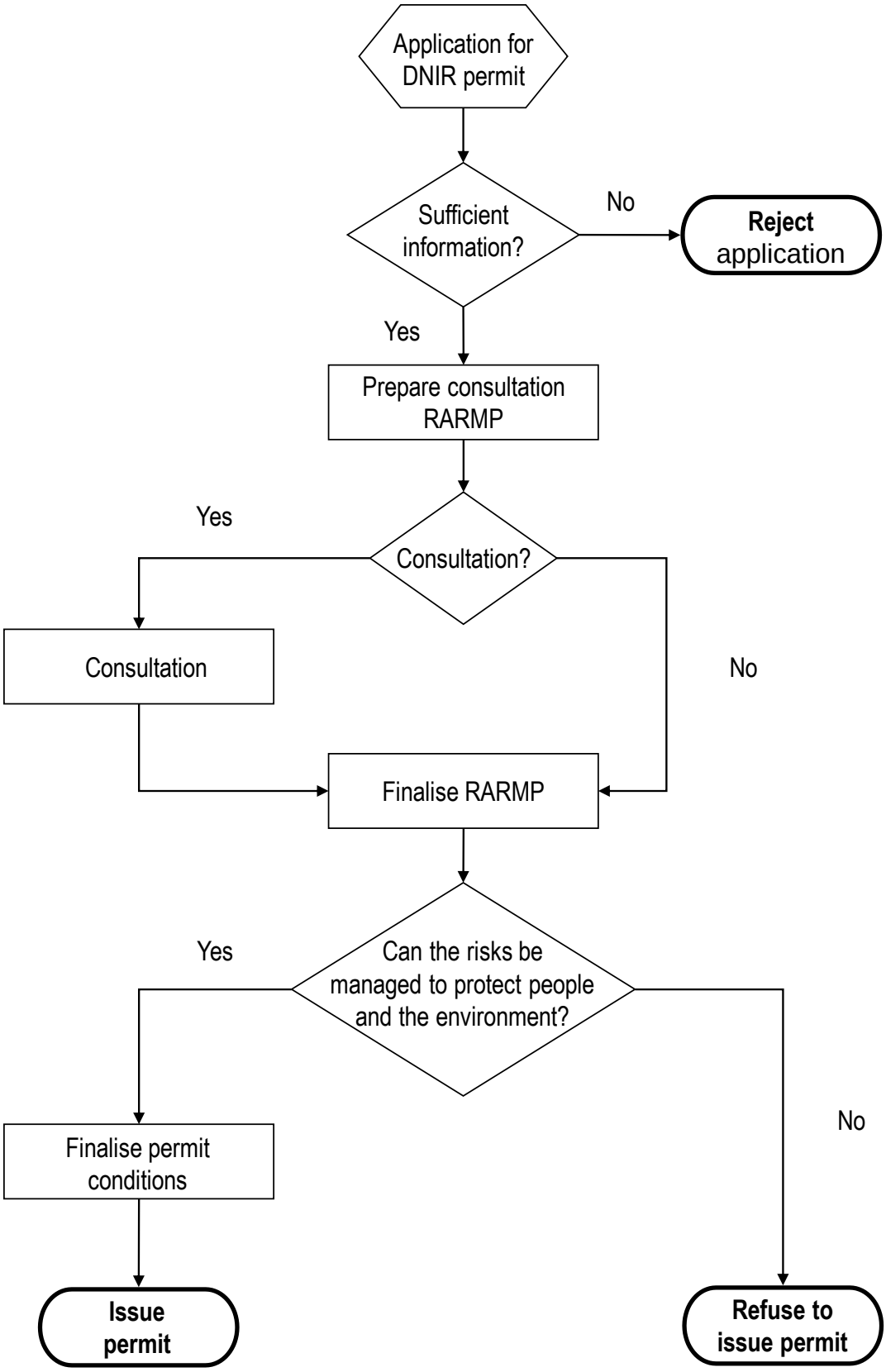

Figure A - 1: DNIR Assessment Process

Dealings involving intentional release

The application form is the same for all DIRs (including limited and controlled releases) and the NBMA will use information submitted by the applicant (as specified in the application form) to determine which consultation process will apply, terms and conditions of Permit and the timeframe allowed for processing the application, on a case-by-case basis.

This *Risk Analysis Framework* outlines the approach taken to risk analysis and to preparation of RARMPs. As a guide to the legislative and administrative requirements, the stage process adopted in respect of DIR applications is ascribed below.

Stage 1 – The applicant must prepare comprehensive information about the proposed dealings with the GMO, possible hazards and consequent risks posed by the dealings and proposed ways that each risk would be managed. The NBMA's information requirements are set out in detail on the application form. The applicant must ensure all responses are supported by appropriate data and literature citations. Wherever possible, quantitative data should be provided. It is expected that the applicants will collect relevant data during contained work and early trials to support applications for dealings involving intentional releases of GMOs.

Stage 2 – The IBC reviews the application and appends an evaluation report setting out its advice as to the completeness of the application form. The IBC's role is to ensure the quality of applications submitted to the NBMA.

Stage 3 – The NBMA is to determine whether the application is for a limited and controlled release, which would follow a shorter process.

The limited and controlled release applications apply, if the NBMA is satisfied that:

i. the principal purpose of the application is to enable the Permit Holder and persons covered by the Permit to conduct experiments;

ii. the application proposed is in relation to any GMO in respect of which dealings are to be authorised:

    a. controls to restrict dissemination or persistence of the GMO and its genetic material in the environment;

b. limits on the proposed release of the GMO.

iii. that the controls and limits are of such a kind that is appropriate. The controls include:

a. methods to restrict the dissemination or persistence of the GMO or its genetic material into the environment;
b. methods for disposal of the GMO or its genetic material;
c. data collection, including studies to be conducted about the GMO or its genetic material;
d. the geographic area in which the proposed dealings with the GMO or its genetic material may occur;
e. compliance, in relation to dealings with the GMO

The term 'limits' includes:

i. the scope of the dealings with the GMO
ii. the scale of the dealings with the GMO
iii. the locations of the dealings with the GMO
iv. the duration of the dealings with the GMO
v. the persons who are permitted to conduct the dealings with the GMO.

Stage 4 – Publication of application and summary of the application dossier in relevant media and placed on the NBMA's website for comment, aimed to increase participation in the consultation process.

Stage 5 – The NBMA shall seek advice on the application regarding matters relevant to preparation of the RARMP, from NBC/NBTS. If the application is for a limited and controlled release, this consultation step is not required.

The actual risk assessment process is, to some extent, shaped by the data requirements set out in the DIR application form; however, the NBMA can require submission of any data required to comprehensively identify hazards and evaluate risks posed by the dealing. The NBMA is specifically permitted by the legislation to seek and take into account any other relevant information such as independent research, independent literature searches, and the advice of any person or group. The NBMA may also request more information from the applicant or hold a public hearing.

Preparation of the risk assessment involves developing risk scenarios that describe how risks that may be posed by the dealings with the GMO could result in harm, identifying risks that require more detailed characterisation and estimating the level of risk based on the likelihood of the event occurring and the likely consequences of that occurrence. Risks are then evaluated to determine which require treatment in order to protect people and the environment.

The risk management plan considers how risks to human health and safety or to the environment posed by the dealing with the GMO that require management may be able to be managed. This then provides the basis for conditions that may be applied to the Permit and conditions are included in the consultation version of the RARMP.

Stage 6 – Once the consultation version of the RARMP is prepared for a DIR application, the NBMA must determine if any of the proposed dealings poses a significant risk to the health and safety of people or to the environment. The minimum consultation period specified is 90 days if NBMA is satisfied that the dealings may pose a significant risk to the health and safety of people or to the environment. If the NBMA considers that the proposed dealings do not pose significant risks, a minimum 90-day consultation period is specified. The statutory timeframe allowed for consideration of a DIR application, except for a limited and controlled release application, is 270 days. The NBMA is required to seek public comment on the consultation RARMP via advertisements in a national newspaper, and place notices on the NBMA's website. In practice, the NBMA advertises more broadly, including National and local newspapers.

Stage 7 – The NBMA then finalises the RARMP, taking into account the advice provided in relation to the consultation version of the RARMP. The NBMA then makes the decision on issuing the Permit and any conditions to be imposed, based upon the finalised RARMP. The NBMA shall notify the applicant in writing that a Permit decision has been made. The NBMA also publishes the finalised RARMP on its website and the BCH.

GMO Record

The NBMA is required to maintain records of approved GMOs and GM product dealings (the GMO Record). Details of Permits issued (DNIR, DIR), information about NLRDs, GMO dealings included in the GMO Register and information about GM products approved by the NBMA are included in the GMO Record.

The GMO Record is divided into separate sections for recording:

i. GM products – those used in food processing, therapeutics, pesticides and veterinary medicines;

ii. notifiable low risk dealings – NLRDs;

iii. contained dealings – DNIR Permits;

iv. intentional releases – DIR Permits;

v. GMO Register;

vi. emergency dealing determinations.

National Biosafety Committee (NBC)

NBC shall advice the NBMA on matters relating to the safe practice of modern biotechnology and the handling, transfer and use of products of modern biotechnology.

The NBC shall be constituted as an ad-hoc committee by the Director General/Chief Executive Officer (DG/CEO) of NBMA on case by case of each application and other roles as may be directed by the Agency. The NBMA shall provide the Secretariat of the NBC.

NBC shall carry out the following functions and advise the NBMA on biosafety matters:

i. Reviewing risk assessment and proposing risk management measures for individual applications;

ii. Providing advice and review, as necessary, on regulations, guidelines and policies relating to all matters regarding modern biotechnology, including but not limited to physical and biological containment and/or control procedures appropriate to the level of assessed risk involved in relevant research, development and application activities as appropriate.

iii. Advising, where appropriate, on the training of personnel with regard to safety procedures;

National Biosafety Sub-committees may be established by the NBC for sectoral interests such as agriculture, health, industry and environment to carry out detail review of applications and advise the NBC.

Accreditation and Certification

Accreditation of organisations and certification of individual physical containment facilities helps manage risk that may be associated with dealings with GMOs by providing an administrative system in which to monitor and oversee their development and use.

An organisation undertaking certain dealings with GMOs will be required to be accredited by the NBMA. The process of accreditation enables the NBMA to assess if the organisation has the resources and the internal processes in place to enable it to effectively oversee work with GMOs. Before an organisation can be accredited, it should have established, or have access to, an appropriately constituted IBC.

IBCs provide on-site scrutiny of contained dealings internally within the organization or institution. IBCs are required to comprise a range of suitable experts and independent persons and they provide a quality assurance mechanism that reviews the information applicants submit to the NBMA. The NBMA is also to carry out certification of laboratory or production facilities to ensure that they meet appropriate standards for containment of GMOs and that trained and competent staff carry out those procedures and practices. Guidelines for certification of physical containment facilities have been developed by the NBMA and should be complied with before a facility can be certified. All certified facilities should be inspected before certification by the IBC and NBMA. The NBMA inspects all facilities before certification and re-certification.

Appendix B

Table B - 1: Risk analysis for a release of a GMO into the Nigerian environment

Legislation	
What is the primary legislation that covers the release of GMOs into the environment?	*National Biosafety Management Agency Act 2015*
What is the purpose/object of the legislation with respect to GMOs?	To protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of modern biotechnology, and by managing those risks through regulating certain dealings with GMOs.
Is GMO defined?	Yes,
Which agency is responsible for the primary legislation?	National Biosafety Management Agency
Who is the decision-maker?	National Biosafety Management Agency
What processes does the Agency follow to support the decision maker(s)?	NBMA staff prepare a Risk Assessment and Risk Management Plan (RARMP) for the Agency on each application. The NBC provides expert advice to the NBMA on the application and RARMP.
What is the trigger for regulation?	Process based, use of Modern biotechnology and GMOs
What are the types of approvals granted? (for example, notification, Permit)	Permit for DIRs, DNIRs (dealings involving intentional release of a GMO into the environment) and GMO Register
What are the timeframes for the assessment process and do the approvals have a lifespan?	90 working days for limited and controlled releases and 270 working days for general/commercial releases, Yes.

Are all organisms covered? (for example, plants, animals, microbes, viruses, humans)	Yes, except humans
Does the system distinguish between different types of environmental release? (such as confined field trials and commercial releases)	Yes. Environmental releases are divided into two classes, namely: • 'limited and controlled' (Confinement, typically field trials) • all others (typically commercial or general releases)
Are GM products covered?	GM products are covered
Is the applicant required to pay fees for the regulatory process?	Yes
What other agencies are required to be collaborated with in the regulation of GMOs?	National Agency for Food, Drug Administration and Control (NAFDAC), Nigeria Agriculture Quarantine Service (NAQS), Nigeria Customs Service (NCS), National Seed Council (NSC), Consumer Protection Council (CPC), National Committee of Registration of Crop Variety, Livestock and Fisheries (NCRCVLF)
Methodology	
Is there a guidance document publicly available on the risk analysis methodology and terminology?	Yes, Nigeria Biosafety *Risk Analysis Framework*,
What type of assessment methodology is used? (such as risk, safety, impact or effect assessments)	Case-specific, science-based risk assessment is required before approval.

What is the subject of the assessment?	Dealings with GMOs, which include: conduct experiments of; make, develop, produce or manufacture; breed; propagate; use in the course of manufacture of a thing that is not the GMO; grow, raise or culture; import; transport; dispose; and includes the possession, supply or use of the GMO for the purpose of any of the above activities.
Who does the assessment?	The applicant does the initial risk assessment which the National Biosafety Management Agency (NBMA) reviews based on information supplied by the applicant, literature searches and expert advice. The risk assessment may be carried out by the NBMA
What are the scope and boundaries of the assessment?	Health and safety of people and the environment (within the Nigerian territory) which may give consideration for social, cultural or ethical values, or economic impacts.

Is a cost–benefit analysis performed?	It may be considered for National interest
Are qualitative or quantitative assessments used?	Qualitative, but using quantitative data where available.
Are data requirements and assessment endpoints specified?	Yes
Are baseline comparisons used in the assessment?	Yes, comparison of GMO to non-GM parent and other baselines such as receiving environment
Is hazard identification performed as part of the assessment?	Yes, in the form of risk scenarios that postulate plausible causal or exposure pathways from dealings with a GMO to potential harm for people or a desirable environmental entity

Is there a risk calculation?	Yes, based on a combination of likelihood and consequences assessments.
Does the assessment include consideration of uncertainty?	Yes, uncertainty and its effect on the estimate of the level of risk and possible control measures are discussed.
Is there monitoring/inspection of compliance with conditions of the release?	Yes.
Are there provisions for regulatory oversight of the environmental release after the approval is granted?	Yes, including case-specific surveillance of an identified risk of commercial releases, verification of the assessment, reporting adverse experience/effects, and reviews.
Communication/consultation	
Are decisions publicly available?	Yes, available in the GMO record at the BCH and NBMA website
Are applications publicly available?	Yes, upon specific request
Are assessments publicly available?	Yes, available as part of the GMO record at the NBMA website and at the Agency's Office.
Is there consultation before approval of the release?	Yes, consultation with the public, NBC and other stakeholders.
Are advisory committees or groups consulted?	Yes, NBC, IBC
Are external experts consulted?	Yes, if required.
Are other government agencies consulted?	Yes, if required.

Is there an ability to hold a public forum on applications?	Yes, but not mandatory
Are there any provisions for Confidential Business Information (CBI)?	Yes
Are the locations of field trial sites publicly available? (including environmental releases that are experimental, limited or contained)?	Yes

Notes: Risk Management, except that risk is considered only in respect of adverse outcomes.

Glossary

Consequence Adverse outcome or impact of an activity.

NOTE 1: Consequences are considered in relation to harm to the health and safety of people and the environment.

NOTE 2: A consequence assessment determines the degree of seriousness of harm ranging from marginal to major.

Deal with	In relation to a GMO, means: i. conduct experiments with the GMO ii. make, develop, produce or manufacture the GMO iii. breed the GMO iv. propagate the GMO v. use the GMO in the course of manufacture of a thing that is not the GMO vi. grow, raise or culture the GMO vii. import the GMO viii. transport the GMO ix. dispose of the GMO and includes possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of numbers (i) to (ix).
Environment	Includes: i. ecosystems and their constituent parts ii. natural and physical resources iii. the qualities and characteristics of locations, places and areas.
Genetically modified organism	i. an organism that has been modified by modern biotechnology ii. an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of modern biotechnology, or iii. anything declared by Nigeria Biosafety regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms, but does not include:

	iv. a human being; v. an organism or class of organisms declared by Nigeria Biosafety regulations not to be a genetically modified organism
Harm	Adverse outcome or impact. *NOTE: Harm refers to an adverse outcome or impact for the health and safety of people or to the environment.*
Likelihood	Chance. *NOTE 1: Likelihood is a general description of the probability, frequency or possibility of something happening.* *NOTE 2: A likelihood assessment determines the degree of chance that harm occurs ranging from highly unlikely to highly likely.*
Modern Biotechnology	Any technology which uses in-vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (r-DNA) and direct injection of nucleic acid into cells or organelles. It entails the fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection, but does not include: i. sexual reproduction ii. homologous recombination, or iii. any other technique specified in the regulations for the purposes of this paragraph.
Post release review	Ongoing oversight of general/commercial releases, focused on informing the findings of the RARMP and providing feedback into risk analysis.
Risk	Chance of harm from an activity. *NOTE: An activity is 'dealing with a GMO' and risk is the potential for adverse outcomes to human health and safety and the environment from those dealings.*

Risk analysis	Overall process of risk assessment, risk management and risk communication.
Risk analysis framework	Guidance on the systematic application of legislation, policies, procedures and practices to risk analysis.
Risk assessment	Overall process of risk identification and risk characterisation. *NOTE 1: Risk assessment is a specific requirement of the National Biosafety Management Agency Act. 2015,* *NOTE 2: The purpose of the risk assessment is to consider risks to the health and safety of people and the environment from dealings with GMOs, posed by, or as a result of, Modern Biotechnology.*
Risk characterisation	Overall process of consequence and likelihood assessments for an identified risk, and risk estimation.
Risk communication	Culture, processes and structures to communicate and consult with stakeholders regarding risks.
Risk context	Parameters within which risk is assessed, managed and communicated. *NOTE: The risk context defines the scope and boundaries, criteria against which risk will be evaluated, as well as the structure and processes for the analysis.*
Risk criteria	Terms of reference against which the significance of risk is evaluated.
Risk estimate	Level of risk determined by a combination of consequence and likelihood assessments.
Risk evaluation	Process of determining if risk requires risk treatment.
Risk identification	Process of postulating risk scenarios and determining those that warrant detailed risk characterisation.
Risk management	Mechanisms to control and mitigate risk. *NOTE 1: The purpose of risk management is to protect the health and safety of people, and to protect the environment.*

	NOTE 2: Components of risk management include preparation of a risk management plan and ongoing oversight through monitoring and reviewing.
Risk management plan	Scheme for managing risk posed by dealings with a GMO. *NOTE 1: The risk management plan refers to a specific requirement of the National Biosafety Management Agency Act. 2015* *NOTE 2: The risk management plan is implemented through Permit conditions.*
Risk scenario	Occurrence of a particular set of circumstances that may result in harm from an activity. *NOTE 1: A risk scenario describes a plausible causal pathway through which dealings with a GMO could lead to harm.* *NOTE 2: A risk scenario includes points of human and environmental exposure to a changed attribute of the GMO or of its products, or to the introduced genetic material.*
Risk treatment	Process of selection and implementation of measures to reduce risk.
Stakeholders	People and organisations that may affect, be affected by, or perceive themselves to be affected by a decision, activity or risk.
States	Includes all state governments and the Federal Capital Territory of Nigeria
Uncertainty	*Imperfect ability to assign a character state to an entity or activity; a form or source of doubt.* *NOTE 1: 'Imperfect' refers to qualities such as incomplete, inaccurate, imprecise, inexact, insufficient, error, vague, ambiguous, under-specified, changeable, contradictory or inconsistent; 'ability' refers to capacities such as knowledge, description or understanding; 'assign' refers to attributes such as truthfulness or correctness; 'character state' refers to properties such as time, number, occurrences, dimensions, scale, location,*

	magnitude, quality, nature, or causality; 'entity' refers to things such person, object, property or system; 'activity' refers to actions and processes such as assessment, calculation, estimation, evaluation, judgment, or decision; 'a form or source of doubt' is an informal definition of uncertainty. *NOTE 2: Different types of uncertainties are relevant to risk analysis, including incertitude (uncertainty regarding knowledge), variability, descriptive and cognitive.*