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The rapid progress of modern biotechnology gave rise to new regulatory needs, in order to safeguard human health and the environment while at the same time taking advantage of the opportunities offered by biotechnology.

Genetic Engineering in particular have stirred up considerable public debate, leading to a higher demand in stringent regulations.

The application of modern biotechnology under a legal framework is therefore a valuable tool for addressing the several global and national concerns/challenges in the areas of human health, agriculture, environment and industry.
BIOSAFETY

The application of measures, laws, policies, knowledge, techniques, equipment and procedures for minimizing or elimination of potential risks that modern biotechnology and GMOs may pose on the conservation and sustainable use of biodiversity taking into account risks to human health.
A good regulation must be:

i. **Protective** – with clear goal  
ii. **Implementable** – with clear procedures  
iii. **Informed** – based on scientific evidence  
iv. **Enabling** – to allow access to technology  
v. **Enforceable** – for accountability
Functional Biosafety Regulatory System

- National policies and guidelines
- International Convention/Treaties requirements
- Information sharing and capacity strengthening
- Linkages with global and regional Institutions
NIGERIA AS A CASE STUDY
**EVOLUTION OF BIOSAFETY REGULATION IN NIGERIA**

- 1994: 1st National Biosafety Guidelines led by the Federal Ministry of Agriculture
- 1999: Establishment of the National Biosafety Unit, Fed. Min. of Environment
- 2001: 2nd National Biosafety Guidelines
- 2002-2006: Development of National Biosafety Framework-(NBF)
  - National Biosafety policy; and
  - Draft Biosafety Bill among others
- 2008/2013: Legislative process on Draft National Biosafety Bill by NASS,
- 2015: National Biosafety Management Agency Act
- 2015 Establishment of NBMA
  - Operationalization of NBMA Act
  - Commencement of draft Regulations, Guidelines and other Instruments
- 2016: Establishment and upgrading of the National GMO detection and analysis Laboratory
- 2017: Approved National Biosafety Regulations
  - Approved revised National Biosafety Policy
- National Biosafety Management Agency Amendment Act 2019
  (Synthetic Biology, Gene Drive, Genome Editing, Biosecurity)
To provide “regulatory framework, institutional and administrative mechanism for safety measures in the application of Modern Biotechnology in Nigeria with the view to preventing any adverse effect on human health, animals, plants, and environment”.
NBMA’S REGULATORY INSTRUMENTS

- BIOSAFETY ACT
- BIOSAFETY GUIDELINES
- NBMA’S REGULATORY INSTRUMENTS
- NATIONAL GM, DETECTION AND ANALYSIS LAB
- NBC AND NBTC
- NATIONAL BIOSAFETY MANUALS AND FORMS
Biosafety Regulations

✓ GMOs import, Export and transit,
✓ GMOs Packaging, identification and transport,
✓ GMOs Commercial release,
✓ Biosafety Liability and Redress,
✓ GMOs Contained Use and Confined Field trial
Biosafety Guidelines

✓ Biosafety Containment Facilities Guidelines
✓ Nigeria Biosafety Application Administration Guidelines,
✓ National Biosafety Application Processing Manual,
✓ National Biosafety Risk Analysis Framework,
✓ Decision document,
✓ National Biosafety Management Information Guide,
✓ National Biosafety Communication strategy,
✓ National Biosafety Emergency Response strategy,
✓ Cessation Order,
✓ Revocation Order,
✓ IBC Guidelines,
✓ Nigeria National Guidelines on Biosafety Socio-economic considerations in decision making process.
Biosafety Manuals and Forms

- Confined Field Trial Monitoring and Inspection Manual
- Biosafety application form;
- GMOs import/shipment form
- Accreditation of Institute application form;
- Certification of Biosafety containment Facility form
Risk assessment is a structured, reasoned approach to address uncertainty based on scientific/technical evidence.

There is no ‘zero risk’ in life, modern biotechnology and GMOs are not insulated from potential risks despite their numerous benefits.

The goal of each risk/safety assessment is to provide assurance, in the light of the best available scientific knowledge, that the GMO is not likely to cause harm when prepared or used according to its intended use.
ADMINISTRATIVE PRINCIPLES OF RISK ANALYSIS

- Protective
- Legal
- Current
- Defensible
- Transparent
- Consultative
- Robust
- Cautious
- Ethical
- Credible and Useful
- Accountable
- Timely
- Efficacious and Efficient
- Consistent and repeatable
## OVERALL PRINCIPLES OF RISK ASSESSMENT

### Science based
- Scientifically sound and Transparent

### Comparative
- Any identified potential adverse effect is considered in the context of the adverse effects posed by the use of non-modified recipient organisms

### Case by case
- Each LMO is considered relative to the environment in which the release is to occur and to the intended use of the LMO

### Concept of familiarity
- Reference to the history of safe use

### Concept of substantial equivalence
- Be compared with their counterparts
The current framework of safety assessment is based on:

1. **Analysis of the possible toxicity and allergenicity of the expressed substance(s) (proteins).**

2. **Assessment of both predicted and unpredicted effects of the transformation through the structured comparative basis enshrined in the concept of substantial equivalence.**

3. **Comparative nutritional studies in animals to assess the dietary sufficiency and equivalence to conventional varieties of the crop.**

4. **Possible additional studies as needed to further assess any unresolved toxicological, nutritional, or immunological issues arising from the results in 1, 2 and 3.**
Main issues in Biosafety

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

Food/feed safety/Human health
  . Nutrition
  . Allergy
  . Toxicity
  . Substantial equivalence

Agricultural sustainability
  . Weediness
  . pest resistance development
  . chemical inputs
  . Higher Costs
  . Others (Socio-Cultural, acceptability etc)
During the review of an application concerning any dealing with Genetically modified organisms, the following, are assessed:

**General Information:**
Name of Applicant;
Contact details;
Postal address;
Email/ Phone no.

**Background Information:**
Name of Event
Description of Event

**Identification of GMO:**
Description of traits (inserted gene);
Purpose of modification;
Safety of genetic elements;
Safety of expressed proteins.

**History of Safe use** including countries where events have been grown/used;
Purpose of use.

**Criteria for the environmental assessment**
(weedy/invasiveness potentials; gene flow; impact on non-target organisms; resistance).
Food and Feed Safety evaluation
(Toxicity, formation of new or increased allergens etc);
Toxicity of whole food/feed; Nutritional Assessment;
Substantial equivalence.

Ethical and Sociocultural issues

Availability of new information

Recommendation
Completion and submission of application form (from www.nbma.gov.ng) along with dossier and a covering letter by applicant

Acknowledgement of application within 90 days

Check listing of Application/Internal review

Public view and display of application in 3 national dailies

NBMA collates public responses

National Biosafety Committee (NBC) is constituted and meets to review application
National Biosafety Technical Sub-committee (NBTS) is established and meets to review application in details and submits recommendation.

NBC meets to review NBTS recommendation.

NBC advises NBMA on decision.

Final decision is taken by NBMA within 270 days.

Decision document (DD) is prepared and communicated to Applicant.

Permit issued.

Accreditation of the following Institutes for modern biotechnology activities:

- National Root Crops Research Institute, (NRCRI) Umudike;
- Institute for Agricultural Research, (IAR) Zaria;
- Federal University of Technology, (FUTA) Akure;
- National Cereals Research Institute, (NCRI) Badeggi;
- National Biotechnology Development Agency (NABDA)
Approved Confined Field Trials in Nigeria:

- Bio-fortified cassava enhanced with pro-vitamin A at National Root Crops Research Institute, Umudike
- Bio-fortified cassava enhanced with Iron, at National Root Crops Research Institute, Umudike
- Cowpea modified for resistance to *Maruca* insect pest at IAR
- Africa Biofortified Sorghum: bioavailability of iron, zinc, protein and pro-Vitamin A at IAR
- GM rice modified for Nitrogen use efficiency, water use efficiency and salt tolerance at National Cereals Research Institute, Badeggi
- GM Cassava resistant to cassava mosaic virus and brown streak virus at National Root Crops Research Institute, Umudike.
NBMA DECISIONS MADE SO FAR cont’d

Permit for Commercial Release and Importation of GM Crops for Feed and Food Processing:

- Bt. Cotton to Monsanto Agriculture Nigeria Ltd. (Commercial Release)
- Biosafety Permit to WACOT Nig. Ltd to use the following nine (9) events of GM Maize: lines Bt11, GA21, MON810, NK603, DAS1507, MIR162, MIR604, MON 89034, MON88017 for Feed Processing.
- Biosafety Permit to Agboola Farms Ltd. for the importation GM Soybean for feed processing
- Biosafety Permit to CHI Farms Ltd. for the importation GM Soybean for feed processing
- Biosafety Permit to CHI Farms Ltd. for the importation GM Maize for feed processing
• Bt. Cotton to Monsanto Agriculture Nigeria Ltd. (Commercial Release)
• Biosafety Permit to WACOT Nig. Ltd to use the following nine (9) events of GM Maize: lines Bt11, GA21, MON810, NK603, DAS1507, MIR162, MIR604, MON 89034, MON88017 for Feed Processing.
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• Biosafety Permit to CHI Farms Ltd. for the importation GM Maize for feed processing
A CROSS SECTION OF THE REVIEW OF AN APPLICATION BY NBC/NBTS
Compliance and trust from the people have greatly increased after these victories.

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<thead>
<tr>
<th>EXPERIENCE</th>
<th>OUTCOME</th>
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<tr>
<td>• The importation of a large quantity of maize consignment without GM grain import Permit from NBMA</td>
<td>• Importation was averted as ship was repatriated</td>
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<td>• Suit filed against the NBMA by HOMEF</td>
<td>• Court ruled in favor of the Agency</td>
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<td>• Detractors feeding stakeholders misleading information</td>
<td>• Increased direct sensitization of stakeholders by NBMA</td>
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<td>• More media engagement</td>
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**Compliance and trust from the people have greatly increased after these victories.**
REGULATORY CHALLENGES

- Inadequate funding
- Capacity strengthening cost
- Misinformation of the public by Activists
CONCLUSION

There is need for government, national and international non-governmental organizations as well as private enterprises (national and international) to strictly comply with the regulations of modern biotechnology application and its products.

The goal of risk/safety assessment is to provide assurance, in the light of the best available scientific knowledge, that the food is not likely to cause harm when prepared, used or eaten according to its intended use.
The scope of risk/safety assessments and strict regulations ensure that the environment, as well as humans and animals are safeguarded against any perceived effect that may arise through the use of modern biotechnology.
THANK YOU

www.nbma.gov.ng