

PRECAUTION IN THE DESIGN OF NATIONAL AND INTERNATIONAL BIOSAFETY AND TECHNOLOGY REGULATIONS: THE NIGERIAN BIOSAFETY BILL CONTEXT

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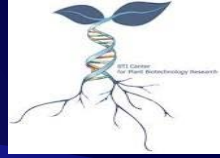
BIOSAFETY REGULATIONS AND THE NIGERIAN BIOSAFETY BILL

OUTLINE AND SCOPE OF DISCUSSION

- 1. General Introduction**
- 2. Why the need for biosafety regulation**
- 3. Components and characteristics of a functional and protective biosafety regulatory system**
- 4. The Nigerian Biosafety Bill and its elements**
- 5. Conclusion / Discussion**

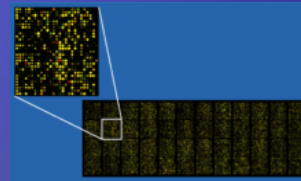


BIOSAFETY REGULATIONS AND THE NIGERIAN BIOSAFETY BILL



Agriculture is fundamental to the survival of any nation, especially in addressing the problems of....

POVERTY AND FOOD INSECURITY
UNBALANCED DIET and GOOD HEALTH



The World's exploding population has created two major problems (1) Many more mouths to feed and (2) Less land to farm

Biotechnology, properly applied, offers exceptional opportunities to meet the growing needs of food and feed security by enhancing productivity, profitability and environmental sustainability of farming systems.

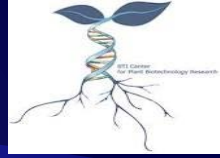
In medicine, modern biotechnology finds promising applications in such areas as: drug & vaccine production and pharmacogenomics



DNA microarray chip – some can do as many as a million blood tests at once



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❖ Gene therapy INTRODUCTION (cont'd)

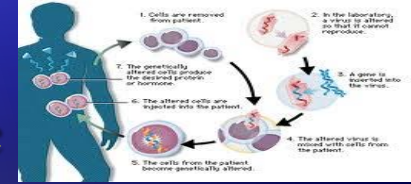
❖ Genetic screening: molecular techniques to detect genetic diseases, forensic/identity testing, etc

❖ Bioremediation and biodegradation: use of biotechnology to engineer and adapt organisms (especially microbes) in an effort to find sustainable ways of cleaning up contaminated environments

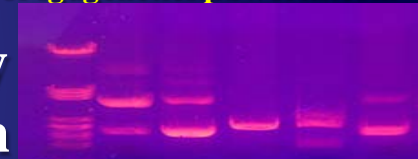
The potential contribution of biotechnology to life, especially sustainable agriculture, is indeed, truly great.

However, the introduction of new transgenic varieties, like any new variety, in an ecosystem deserves careful oversight and monitoring.

HENCE THE NEED FOR GOOD BIOSAFETY REGULATIONS



Courtesy of sgugenetics.pbworks.com





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BIOSAFETY – MEANING AND USAGES



Biosafety can be defined:

(1) the avoidance of risk to human health and safety, and the conservation of the environment as a result of the use of GM products (Ro, K. 2009).



The backbone of the practice of biosafety is “risk assessment”.

(2) Biosafety also refers to promoting safe laboratory practices, procedures proper use of containment equipment and facilities, risk assessment and risk management, evaluation of GMOs, etc





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THE NEED FOR BIOSAFETY REGULATION



Biosafety regulations are to facilitate and regulate the use of modern biotechnology work at different stages to achieve the objectives of biosafety, for example:

Transformation Biotechnology in Crop Improvement uses selection marker gene (s) to select transformation events

Selection Marker Genes are useful **ONLY WHEN USED AS GENE OF INTEREST** (e.g. selectable markers that provide herbicide tolerance).

Pose problems/legitimate Biosafety concerns which include:

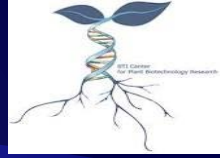
(a) Health

Concern that selectable marker genes (or product) might be toxic or allergenic when consumed.





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THE NEED FOR BIOSAFETY REGULATION

➤ **Use of therapeutic antibiotics as selectable markers may compromise both clinical and veterinary application of antibiotics (increased resistance by bacterial flora of the human / animal gut). (No scientific evidence so far but banned in GM crops in EU since 2002)**

(b) Environmental

- **A marker encoding herbicide resistance may change the transgenic plant into a weedy pest**
- **Horizontal transmission of the marker into wild relatives may transform them into weedy pest**
- **Spread of the selectable marker to other organisms may upset balance of the ecosystem**



HENCE THE NEED FOR BIOSAFETY REGULATIONS



BIOSAFETY REGULATIONS AND THE NIGERIAN BIOSAFETY BILL

COMPONENTS AND CHARACTERISTICS OF A FUNCTIONAL AND PROTECTIVE BIOSAFETY REGULATORY SYSTEM

A protective biosafety regulatory system ensures that GMO present no significant risks to human/animal health or the environment.

Such a system must also be functional: it should be understandable, workable, equitable, fair, adaptive, and enforceable. (UNEP-GEF Biosafety Unit 2004).

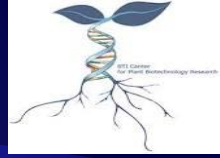
Today, existing biosafety regulatory systems from around the world reflect, among other things,

- a. the type of government and the politics in the country**
- b. the country's view on the relative safety of GE organisms, and the its regulation of food, agriculture, and environmental issues**

Require balancing numerous goals trading off of different interests.



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COMPONENTS AND CHARACTERISTICS OF A FUNCTIONAL AND PROTECTIVE BIOSAFETY REGULATORY SYSTEM

The following characteristics and components are generally important to a functional and protective biosafety regulatory system

1. MUST BE COMPREHENSIVE

- a. It needs to cover the different stages of development for a GE organism (UNEP-GEF Biosafety Unit 2004) e.g. release into the environment as confined and unconfined field trials; commercial products, and consumption (humans /animals)
- b. **Must analyze the range of potential safety issues associated with GE organisms: environmental & biodiversity issues, food safety issues and any other potential safety questions such as workers' safety (von Grebmer 2005).**
- c. Finally, the regulatory system's scope **MUST** include all plants & animals that could be engineered and the different products that they might produce.



BIOSAFETY REGULATIONS AND THE NIGERIAN BIOSAFETY BILL



COMPONENTS AND CHARACTERISTICS OF A FUNCTIONAL AND PROTECTIVE BIOSAFETY REGULATORY SYSTEM

2. MUST HAVE ADEQUATE LEGAL AUTHORITY

a. Biosafety regulatory system needs sufficient legal authority to subject each GM to a food-safety and environmental risk assessment and approval process before any unconfined release into the environment or is placed into market. (Jaffe 2004; Cohen et al. 2005).

b. **“Clear responsibility and legal authority is important not only for ensuring the protection of health and the environment, but also for providing the public and technology developers with a clear understanding of the regulatory pathway to market.”** (Pew Initiative 2004).

c. So, to ensure adequate legal authority for a biosafety regulatory system, countries **MUST** either use existing laws or pass new legislations



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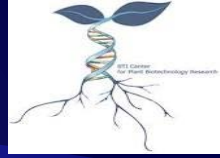
COMPONENTS AND CHARACTERISTICS OF A FUNCTIONAL AND PROTECTIVE BIOSAFETY REGULATORY SYSTEM

- 3. MUST HAVE CLEARLY STATED SAFETY STANDARDS**
 - a. Biosafety regulatory systems MUST establish safety standards which spell out protection level to be satisfied for application approval.**
 - b. And what factors the government will consider before making approval decisions, including the baseline for any risk analysis. (UNEP-GEF Biosafety Unit 2004; Jaffe 2004;2005).**
 - c. The safety standard and the legal authority the government needs to regulate GMO should be well defined and identifies the benefits from the GM or the opportunity costs of not introducing the GM (Delmer, 2005).**

In a functional and protective system, all interested parties must know and understand the safety standard beforehand and government decisions must apply such standard in a uniform and fair manner.



BIOSAFETY REGULATIONS AND THE NIGERIAN BIOSAFETY BILL



COMPONENTS AND CHARACTERISTICS OF A FUNCTIONAL AND PROTECTIVE BIOSAFETY REGULATORY SYSTEM

4. MUST HAVE PROPORTIONATE RISK-BASED REVIEWS

- a. Biosafety regulatory systems **MUST** look at each application individually and assess any potential risks to human health and the environment through a scientific risk-based analysis.
- b. The system **SHOULD** have the flexibility to treat products differently depending on the potential risks and concerns raised. (Delmer 2005).
- c. The key to establishing a proportionate risk-based review process is providing the regulatory system with the flexibility to address particular products differently depending on the nature of the product (the organism and the added gene), and the use of the product (IFPRI, 2006)



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COMPONENTS AND CHARACTERISTICS OF A FUNCTIONAL AND PROTECTIVE BIOSAFETY REGULATORY SYSTEM

5. MUST BE TRANSPARENT AND UNDERSTANDABLE

Biosafety regulatory systems that are transparent and understandable usually provide to the public information about:

- a. the regulatory process (a roadmap of the procedure and what is expected of the applicant) and how the agency will conduct its review, what criteria and standards it will use, and who will be the accountable public officials**
- b. where, when and how the public can be involved in the regulatory process and the decision on application, including the analysis and the reasoning behind the decision**
- c. The regulatory system must balance the competing interests of the applicant, who may want to keep some information confidential for business purposes while making information available to the public. (UNEP-GEF Biosafety Unit 2004**



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COMPONENTS AND CHARACTERISTICS OF A FUNCTIONAL AND PROTECTIVE BIOSAFETY REGULATORY SYSTEM

6. IT MUST BE PARTICIPATORY

In democratic societies, public participation is a necessary component in biosafety regulatory systems because:

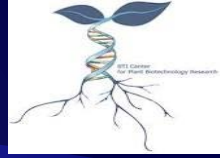
It gives public the opportunity to have inputs and give comments to regulators on regulations, guidance documents, and specific applications before a regulatory decision is made. This includes the opportunity to provide oral and/or written testimony at public hearings.

Thus the regulatory system responds to relevant public comments in its decision-making documents so as to improve its overall decision and assure the public that any and all relevant concerns were seriously considered.

While public participation helps to inform the decision-making process, the ultimate decisions remain with the regulatory agencies and designated leaders



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COMPONENTS AND CHARACTERISTICS OF A FUNCTIONAL AND PROTECTIVE BIOSAFETY REGULATORY SYSTEM

7. MUST PROVIDE POST APPROVAL OVERSIGHT

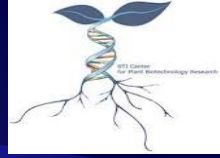
A biosafety regulatory system MUST NOT stop its oversight once a GM has been approved for a confined field trial or for a commercial release.

The system MUST continue to ensure adequate protection of humans and the environment after the product is released into the environment or enters the marketplace.

Post approval activities can include monitoring for adverse environmental or health effects and monitoring for compliance with any risk management conditions imposed on the GM



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COMPONENTS AND CHARACTERISTICS OF A FUNCTIONAL AND PROTECTIVE BIOSAFETY REGULATORY SYSTEM

8. MUST BE FLEXIBLE AND ADAPTABLE

Because Biotechnology is a rapidly changing discipline it is impossible to fully **ENVISAGE** the range of future applications.

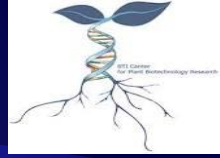
So in setting up a biosafety regulatory system to address currently unknown applications of genetic engineering, flexibility to adapt to new evidence on risks and benefits, and new types of products is crucially important.

There are several ways to build flexibility and adaptability into a biosafety regulatory system.

(a) **Laws, regulations, and guidance can be written broadly to accommodate not just the products being proposed today but products that might be developed ten or twenty years later.** (b) The regulatory system should also learn from its experiences of regulating products and adapt accordingly.



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COMPONENTS AND CHARACTERISTICS OF A FUNCTIONAL AND PROTECTIVE BIOSAFETY REGULATORY SYSTEM

9. MUST BE EFFICIENT, WORKABLE AND FAIR

Although the primary responsibility of a biosafety regulatory system is to ensure that GMO are safe for humans and the environment, it is also IMPORTANT that the system is efficient, workable and fair.

- a. Efficient regulatory systems minimize costs to applicants and the government agencies that implement it.**
- b. Functional systems make decisions promptly in a reasonable amount of time, understanding that if its decision-making process takes too long or is never completed, the non-decision is in effect a rejection.**
- c. Fair systems treat similar products in a similar manner and decisions on those similar products are consistent with one another and also equitable to developers, researchers and their products, the consumers and the public at large.**



THE NIGERIAN BIOSAFETY BILL

PREAMBLE



Nigeria is one of the largest countries in Africa



- **With a land area of about 923,768 km² and population of over 140 million**
- **the most populous black nation in the world**
- **To harness the benefits of modern biotechnology activities, Nigeria developed a National Biotechnology policy in 2001 to promote biotechnology activities in the country.**
- **This Biotechnology Policy gave birth to National Biotechnology Development Agency (NABDA) to further strengthen the promotion of biotechnology activities**



THE NIGERIAN BIOSAFETY BILL



PREAMBLE

➤ With the perceived GMO potential adverse impacts on the environment and human health, Nigeria joined the League of Nations that took precautionary safety measures by signing and ratifying the Cartagena Protocol on Biosafety

THE NIGERIAN BIOSAFETY BILL IS AN OFFSHOOT OF:

The signed and ratified Cartagena Protocol on Biosafety (a protocol of the Convention on Biological Diversity) in 2000 and 2003 respectively.

Prior to the passage by the SENATE, the Bill was subjected to rigorous various stakeholders review sessions (including PUBLIC DEBATES). The House of Representatives, had the 1st, 2nd and 3rd readings of the Bill on March 17, 2009, June 2, 2009 and December 7, 2010 respectively.

The Senate passed the reviewed Bill on the 1st of June 2011 and is now awaiting the assent of the President (overdue)



THE NIGERIAN BIOSAFETY BILL

PREAMBLE



- **With the Presidential assent, the Bill will serve as a safe guard against indiscriminate dumping of GMOs into the market (and environment) and also ensure that products of GMO are certified fit for human health and the environment.**
- **It will also open new avenues for our Research Institutes and the entire Biotech industry to break new grounds that will enhance the various sectors of the national economy: creating Wealth and Job opportunities**



NIGERIAN BIOSAFETY BILL

ELEMENTS OF THE BILL



1. INSTITUTIONAL ARRANGEMENTS

i. National Biodiversity Management Agency

- **Part 1 of the Bill establishes a discreet national governmental department called the ‘Biosafety Department’ to deal with GMOs in Nigeria, under the auspices of the National Biodiversity Management Agency. This Biosafety Department will serve both as the National Focal Point and Competent National Authority on Biosafety in Nigeria.**
- The Department is obliged to “ensure the safety of the Nigerian environment, its people, culture, health etc, from the risks posed by GMOs; holistic and case- by- case regulation and avoidance of risks by invoking the ‘precautionary principle’; and public participation, consensus building and so forth”.
- **Functions of the Dept. are set out in Part II section 3 of the Bill and are typical of a government department in charge of the administration of national legislation, where such department serves both as focal point and competent authority.**



THE NIGERIAN BIOSAFETY BILL

ELEMENTS OF THE BILL



1. INSTITUTIONAL ARRANGEMENTS (cont'd)

ii. National Biosafety Committee (NBC)

- Part III establishes a National Biosafety Committee (NBC) which comprised of government officials from several National Ministries /Agencies involved in some way in the regulation of GMOs, as well as three experts, a representative from the private sector, and a representative from NGO (who must be distinguished in biodiversity conservation).
- The NBC will play a critical role in reviewing and analyzing risk assessments, environmental impact assessments and socio-economic impacts of GMOs and assessing and recommending GMO applications for approval.
- However, the Committee is not a decision-making body and there will be no need for the recommendations of the Committee to represent the consensus of the group.
- However, it is important that regulators pay attention to the publication of dissenting views of the Committee, especially where there is disagreement with the majority view supportive of an approval.



THE NIGERIAN BIOSAFETY BILL



ELEMENTS OF THE BILL

1. INSTITUTIONAL ARRANGEMENTS (cont'd)

iii. National Biosafety Technical Sub-Committees

Part IV establishes 4 National Biosafety Technical Sub-Committees on

(a) Agriculture (b) Health (c) Industry and (d) the Environment. Each comprising of officials from relevant Ministries.

These Sub-Committees are responsible for the review of GM applications and provide technical advice to the National Biosafety Committee.

iv. Institutional Biosafety Committee

➤ Section 12 of Part IV obliges any institution or body in Nigeria wishing to undertake any activity relating to GMOs, to first establish an 'Institutional Biosafety Committee'.

➤ **It also prescribes how this committee is to be constituted, the nature of the expertise, etc. while Section 14 deals with the functions of such an Institutional biosafety committee**



THE NIGERIAN BIOSAFETY BILL



ELEMENTS OF THE BILL

1. INSTITUTIONAL ARRANGEMENTS (cont'd)

These provisions make it POSSIBLE for the government to hold clearly identified and identifiable persons responsible for GMO activities in public and private institutions and bodies involved in GMO related activities. It also ensures that such institutions are regulated and also regulate themselves.

v. Biosafety Officer

- Section 15 obliges any person, institution or body who may wish to make use of GMOs in import, export, transit, contained use, a confined field trial, or commercial release to appoint a Biosafety Officer.
- The Biosafety Officer is to make a day-to-day check on compliance with biosafety issues in the Institution or body, ensure safety is not compromised, keep records, liaise with the Institutional Biosafety Committee, etc.
- In section 16, the Institution or body is obliged, to designate a principal investigator who is to be the person responsible for conducting the GMO research.



THE NIGERIAN BIOSAFETY BILL

ELEMENTS OF THE BILL



1. INSTITUTIONAL ARRANGEMENTS (cont'd)

v. Biosafety Officer (cont'd)

➤ This person **MUST** ensure that experiments are conducted in accordance with the provisions of the Act; that safety procedures and best practices are adhered to; and

➤ **must also notify the Committee promptly of any research related accident that results or could result in injury to the health of humans, animals or plants or the escape of organisms into the environment.**

vi. Approval of permits

➤ Part V deals with approvals of permits and section 17 creates a standard requirement from the Agency before any person, institution or body **imports, exports, transits, carries out contained use, contained field trials or commercial releases of GMOs. The requirements are detailed here.**



THE NIGERIAN BIOSAFETY BILL

ELEMENTS OF THE BILL



1. INSTITUTIONAL ARRANGEMENTS (cont'd)

Section 18(3) mandates the Agency to set requirements for each activity with GMOs and to determine the level of potential risk posed by such activity

vii. GMOs and products imported for food, feed etc

Section 19, deals specifically with GMOs for food. Requires that a permit be acquired before any person imports, transits or commercializes any GMO or product of a GMO intended for direct use as food, feed or processing.

It is clear that GMOs and products of GMOs imported for direct use as food, feed and industrial processing have been singled out for special consideration, because it is anticipated that this area will see the most activity in Country- NIGERIA IS A MAJOR IMPORTER OF FOOD



THE NIGERIAN BIOSAFETY BILL

ELEMENTS OF THE BILL



2. ACCESS TO INFORMATION

The Bill contains a number of clear provisions relating to access to information and confidential business information which could be emulated by other African Countries.

i. Public display of application on GMOs

Section 20(1) obliges the Agency, upon receipt of the application and accompanying information as required by the Act, to display copies of such application and relevant information at “such places” for “such periods” as the Agency may, from time to time determine, to enable the general public and relevant government ministries and agencies to study and make comments on the application and relevant information (All applications)

➤ “Such places” gives the Agency a broad discretion to make the application and information available in accessible places to interested and affected parties, because it is required to “ensure that such access will enable the general public to study and make comments.”



THE NIGERIAN BIOSAFETY BILL

ELEMENTS OF THE BILL



2. ACCESS TO INFORMATION

i. Public display of application on GMOs (cont'd)

Additionally, section 20(2) requires the Authority, prior to the display, to make announcement in at least two national and one local newspaper, the National Biosafety Clearing House or such other news media as the Agency may from time to time determine.

Such announcement must provide a summary of the application, and brief information on the place, duration and time for the display.

ii. Public hearing and consultations

Section 21 gives the Agency the discretion to hold public hearings or consultations to obtain further comments and inputs that will assist in the review or processing of the application but strangely / curiously silent on the conditions necessary for this decision.

iii. Access to information /confidential business information

The Agency is prohibited from disclosing any confidential business information (CBI) submitted to the Agency.



THE NIGERIAN BIOSAFETY BILL

ELEMENTS OF THE BILL



2. ACCESS TO INFORMATION (cont'd)

iii. Access to information /confidential business information

Implicit in section 21(3)(a), is the notion that the applicant is entitled to identify the information it deems to be CBI.

- The applicant **MUST** show that it has taken steps to prevent the release of the information and that the release of the information would be detrimental to the applicant.
- **Certain information is also guaranteed to the public and this includes the name and address of the applicant, the general description of the GMO, a summary of the risk assessment for the GMO, and any scientific data that specifically addresses potential environmental or food risk from GMOs and any methods, plans and emergency response.**

Clearly balancing the public's right to access information and the bona fide confidential business interest of the applicant is given attention.



THE NIGERIAN BIOSAFETY BILL

ELEMENTS OF THE BILL



3. APPROVALS AND DECISION-MAKING

The Agency may approve applications where it has been so recommended to do so by the National Biosafety Committee and if the followings have been satisfied:

- i. that the application meets with the criteria set out in the Act; the GMO would not be harmful;
- ii. in the case of agricultural crops, livestock, fish and other GMOs that the GMO in question does not pose new substantial risk different from the non-GM counterparts; a
- iii. the Agency is satisfied that measures have been taken or would be taken for remediation for any adverse effects on human health, animals , plants or the environment.
- iv. Section 24 obliges the Agency to take the inputs and comments received from the public into account.
- v. In decision making, the Agency may specify steps to be taken in implementation of the risk management plan where there are potential risks to human health, animals, plants and the environment.



THE NIGERIAN BIOSAFETY BILL

ELEMENTS OF THE BILL



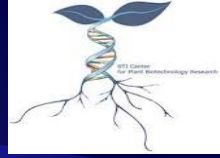
4. REVOCATION AND REVIEW OF DECISION

- Section 25 makes it possible for the Agency to revoke or suspend an approval if there is (are) new information to the effect that the GMO or its product is capable of having adverse effects on human health, animals, plants or the environment.
- **The Agency also has the right to review a refusal of an application if there is “new and relevant information.”**
 - ii. **RIGHT OF APPEAL**
- Only an aggrieved applicant is given the right to appeal against a decision of the Agency.
- **No comparable right is given to interested and affected parties who may be adversely affected by a decision.**



THE NIGERIAN BIOSAFETY BILL

ELEMENTS OF THE BILL



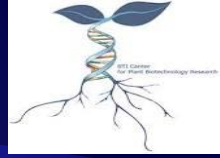
5. RISK ASSESSMENT AND RISK MANAGEMENT

- Section 27 makes it obligatory for every applicant who seeks approval for any GMO, to conduct a risk assessment of the potential risk the GMO poses to human health, animals, plants or the environment in Nigeria.
- Section 29 makes it obligatory for every person, institution or body that carries out any activity relating to GMOs to develop and maintain a risk management plan and strategy in accordance with the provisions of the “Fourth Schedule”.
- The Fourth Schedule sets out a monitoring regime for imported and locally produced GMOs , for various purposes.
- Section 30(a) gives the Agency the discretion to direct that any GMOs undergo a period of observation commensurate with the life cycle or generation time, at the cost of the applicant before or after the GMO is certified for usage.



THE NIGERIAN BIOSAFETY BILL

ELEMENTS OF THE BILL



6. PROHIBITION OF GMOs

- Section 30(b) gives the Agency a discretion to prohibit the import, transit, contained use, release or placing on the market of any GMO if it contains characteristics or specific traits which pose significant risks to human health, animals, plants and the environment. This is an extremely important provision.
- **Sub section (c) deals with the imposition of measures on the part of the Agency to prevent or limit any harm to human health, animals, plants and the environment.**
- However, the Agency will only be in a position to impose such measures if monitoring of the approved activities takes place by the Agency since the bulk of the monitoring functions will be done by the applicant itself, once approval is granted.
- **Subsection (d) requires that the applicant submit periodic reports of the monitoring and evaluation of risk carried out after the approval.**



THE NIGERIAN BIOSAFETY BILL



ELEMENTS OF THE BILL

7. SECONDARY LEGISLATION, GUIDELINES

- Sub-sections (e) and (f) deal with the measures the Agency itself may take to avert risk or danger to human health etc, where the person responsible for such action fails to act and the person so responsible is to bear the costs of any measures.
- On the recommendation of the National Biosafety Committee or the Agency, the Act contemplates that the Minister would make regulations, for the bringing into effect of any provision of the Act.
- **The Agency is also empowered to provide safety standards, guidelines and rules on public participation processes and procedures, risk management and risk assessment, handling, transport, identification or labeling of GMOs.**



THE NIGERIAN BIOSAFETY BILL

ELEMENTS OF THE BILL



SO, WHAT'S MISSING?

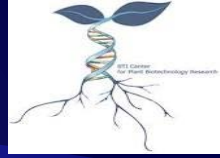
- **Labeling rules are not put in place - thus GMO and its products and many of the provisions pertaining to it will be of no force and effect.**
- **Liability and Redress regime SHOULD have special attention crafted to the Bill.**
- **Special monitoring and reporting functions of the Agency SHOULD be clearly and well defined.**
- **Attention should be given to implementing the provisions of the Biosafety Protocol dealing with cross border contamination, illegal trans-boundary movements, product recall, the taking of emergency measures.**

Happily, any of these can be addressed through secondary legislation (s)



THE NIGERIAN BIOSAFETY BILL

CONCLUSION



- The Nigeria's Biosafety Bill is unique and embodies a great deal of originality and authenticity, sorely missing in other African Biosafety laws.
- **It appears to have travelled a truly Nigerian journey and does not exhibit the traits of influence found in other Biosafety Bills**
- The law cleverly ensures that government is able to hold clearly identified and identifiable persons responsible for GMO activities in public and private institutions and bodies involved in GMO related activities.
- **Sadly, it also ensures that such institutions regulate themselves as very little, if any, real monitoring takes place by the government agencies!**



THE NIGERIAN BIOSAFETY BILL



CONCLUSION

- The Bill exhibits a distinct policy position on GMOs: that GMOs can be made safe if properly and holistically regulated.
- **This position is enshrined in the embrace of the PRINCIPLE OF SUBSTANTIAL EQUIVALENCE**
- **The Bill meets ALL National and International standards**
- GMOs and products of GMOs imported for direct use as food, feed and industrial processing have been singled out for special consideration, because we are essentially an “importing country”
- **The Bill contains a number of interesting and clear provisions relating to access to information and confidential business information.**
- These provisions should be shared with other African countries that are in the process of developing or reviewing their biosafety laws.



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Biosafety Bill, Underway - Minister



■ **Prof. Ita Okon Bassey Ewa**, Hon. Minister of Science & Technology



■ **Prof. Bamidele Ogbesolomon**, DG/CEO, National Biotechnology Development Agency (NABDA) represented the Hon. Minister of Science & Technology

The Honourable Minister of Science and Technology, Professor Ita Okon Bassey Ewa disclosed that the long awaited Biosafety Bill is soon to be signed into law by President Goodluck Jonathan.

The Minister was represented by the Director-General/CEO, National Biotechnology Development Agency (NABDA), Professor Bamidele Solomon stated that the presidency recently sent a letter to the Ministry of Justice, to proceed on actualizing the Biosafety Bill.

"In few months, Mr. President will give his assent to the Biosafety Bill after all necessary adjustments have been made. The progress made on the passage of the Bill is highly commendable and launching the ISAAA report today is very appropriate as it marks a very special period in our journey towards the preparation for the assent of the Bill," he stated.

DG NABDA further conveyed the excitement of the Honourable Minister on the progress of Agricultural Biotechnology in the nation, as it coincides with the great effort towards the enactment of the Biosafety Law, which will ensure a regulated practice of this technology, thereby protecting the environment and ensuring human safety.

In his words "I know that there are many stakeholders present with us today, who had contributed immensely to the process of passing the Biosafety Bill. The Minister is extremely excited about the opportunities embedded in modern biotechnology and hopes for the deployment of this technology in the agricultural sector of the economy in order to address food security issues in the country, as well as matters concerning health, the environment and climate change. ■



THE NIGERIAN BIOSAFETY BILL

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- The Ministry of Environment (Biosafety Desk) for the opportunity to be part of the drafting committee and a member of the Biosafety Technical- Sub committee.



BIOSAFETY REGULATIONS AND THE NIGERIAN BIOSAFETY BILL



THANK YOU VERY MUCH FOR YOUR ATTENTION

