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Safety Standards for GMOs & Regulations

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By

Mrs. Jane Omojokun,

MD/Lead Consultant, Nugata Consults Ltd, Lagos

website: www.nugataconsults.com



Introduction

- Efforts to improve plant traits dates back to several thousands of years with plant breeders using traditional breeding and selection techniques.
- Plants and animals with **desirable characteristics** which appeared through **naturally occurring variations in their genetic make-up** were reserved for replanting or breeding the next generation of food and feed (e.g. plants with increased yield and resistance to disease).
- Plant breeders, over time, began to develop increasingly sophisticated techniques to attain specific traits.



Introduction

- The latest technique called genetic modification also known as genetic engineering is used to produce Genetically Modified Organisms.
- GMOs are produced by artificially modifying the genetic make-up of living cells and organisms using modern biotechnology known as gene technology to give it a new property (e.g. resistance to a plant disease, insect pests, drought, tolerance to a herbicide, improving a food's quality or nutritional value, increased yield).
- This process was first developed in the 1970s and used to make the first commercial GM product, human insulin, in the early 1980s.

Examples of GM Foods

Top 10 genetically modified foods



Corn



Soy



Cottonseed



Papaya



Rice



**Rapeseed
(Canola)**



Potatoes



Tomatoes



Dairy products



Peas



Regulation of the Release of GMOs

Regulations regarding the release of GMOs outside the laboratory varies widely by country.

- Countries such as the United States, Canada, Lebanon and Egypt use the **substantial equivalence** as the starting point when assessing safety
- Countries such as those in the European Union, Brazil and China authorize GMO cultivation on a **case-by-case basis**



Regulation of the Release of GMOs

- Many countries allow the import of **GM food with authorization**, but either do not allow its cultivation (Russia, Norway, Israel) or have provisions for cultivation, but no GM products are yet produced (Japan, South Korea).
- Most countries that do not allow for GMO cultivation do permit research.



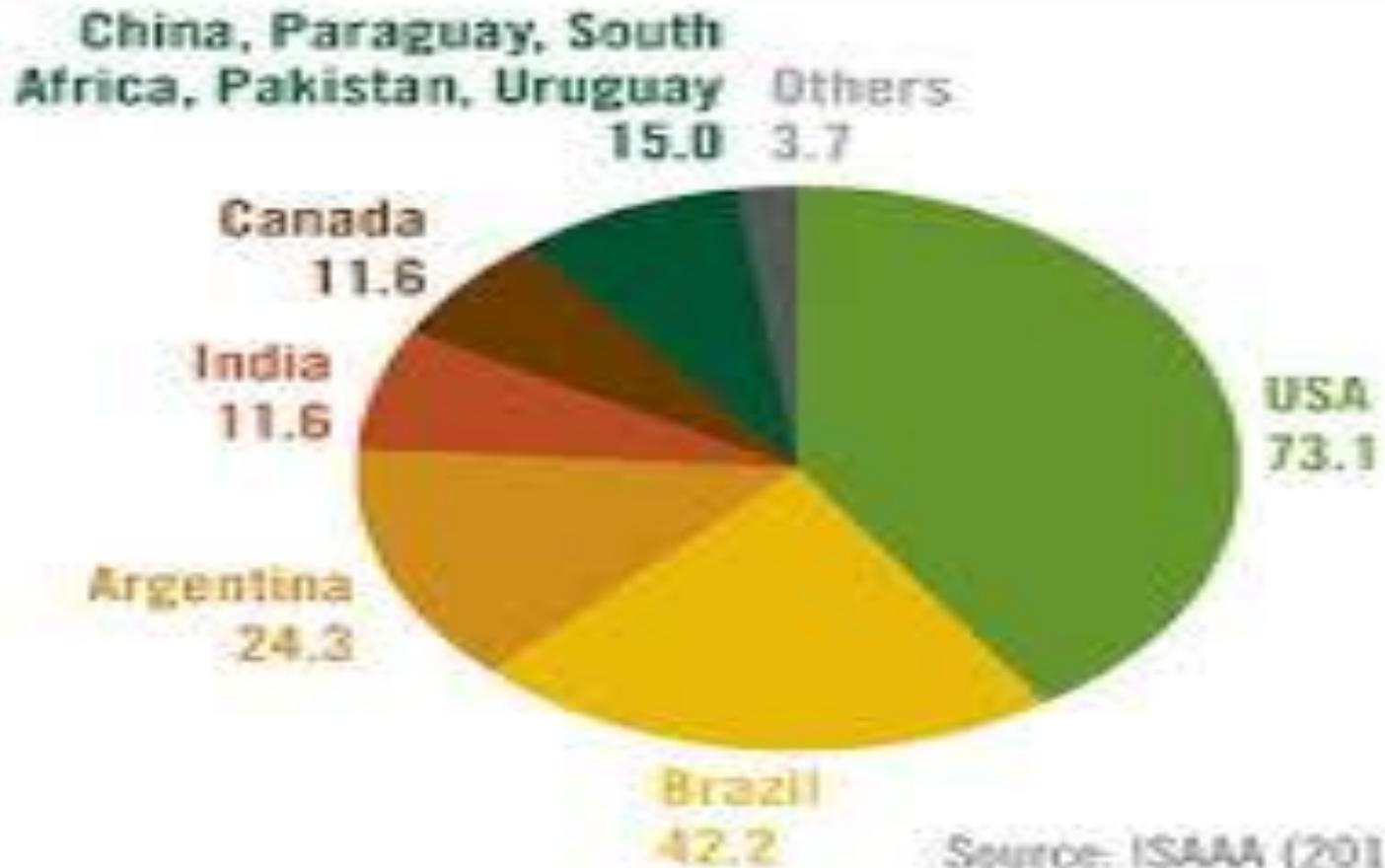
Regulation of the Release of GMOs

- National Bodies
 - ✓ The National Biosafety Management Agency (NBMA)
 - ✓ The National Biotechnology Development Agency
- International Protocol, Standards & Regulation
 - ✓ The Cartagena Protocol on Biosafety
 - ✓ Codex Guidelines
- EU Regulations



Global Areas of GM Crops

Global area of genetically modified crops





Relevant National Bodies: NBMA & NABDA

Safety standards for GMOs and Regulations is within the purview of the National Biosafety Management Agency and National Biotechnology Development Agency.

- NBMA regulates modern biotechnology activities and the release into the environment, handling and use of genetically modified organisms which are products of modern biotechnology to prevent adverse impact on the environment and human health.
- NABDA promotes modern biotechnology activities and GMOs.



Functions of NBMA

- Formulates overall **policy guidance on issues of Biosafety in Nigeria;**
- Implements the provisions of the Conventions and the Protocols on matters relating to GMOs
- Develops measures and requirements for **Biosafety risk assessment;**
- Develops **risk management plan and strategy for protecting human health, biological diversity and the environment from potential risks associated with genetically modified organisms;**



Functions of NBMA

- **Accepts and verifies GMO applications** and keeps records of all approvals and unapproved application
- Conducts **laboratory analysis of crops, products or materials** for purposes of determining if they contain genetically modified organisms and ensure compliance with the Act;
- Inspects facilities, conducts research activities with GMOs covered by the Act, collects and analyzes samples of materials, **monitors human health and the environment to determine the effects of GMOs.**



Functions of NBMA

- Liaises with the secretariat of the convention and the Biosafety clearing house with respect to the administrative functions required under the Protocol;
- Carries out and maintains inventory of laboratories with physical and human capacities to conduct research in modern biotechnology;
- Monitors the activities of institutional committees and Biosafety officers.



Functions of NABDA

Promotes, coordinates and deploys cutting-edge biotechnology research & development, processes and products for the socio-economic well-being of the nation.



The Cartagena Protocol on Biosafety

- The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international agreement on biosafety as a supplement to the Convention on Biological Diversity
- It entered into force on 11 September 2003. As of March 2015, the Protocol had 170 parties, which includes 167 United Nations member states, the State of Palestine and the European Union
- The Biosafety Protocol seeks to **protect biological diversity from the potential risks posed by GMOs resulting from modern biotechnology.**



The Cartagena Protocol on Biosafety

The provisions of the Biosafety Protocol include:

- i. Rules and procedures for the **safe transfer, handling, and use of Living Modified Organisms** (LMOs), with specific focus on trans boundary movements of LMOs (GMOs).
- ii. Procedure for LMOs that are to be intentionally introduced into the environment called **the advanced informed agreement** procedure, and
- iii. Procedure for LMOs that are intended to be used directly as food or feed or for processing.



The Cartagena Protocol on Biosafety

- Exporters to provide **appropriate documentation** specifying, among other things, identity of LMOs and contact point for further information.
- Allowing **developing nations to balance public health against economic benefits**. It will for example let countries ban imports of LMOs if they feel there is not enough scientific evidence that the product is safe
- Parties to the Protocol must ensure that LMOs are **handled, packaged & transported under conditions of safety**.



Codex Guidelines & Principles

- Member governments can use Codex text as a basis to build a regulatory mechanism to address the food safety of GM foods namely:
 - ✓ Principles For The Risk Analysis of Foods Derived From Modern Biotechnology
 - ✓ Guideline For The Conduct of Food Safety Assessment of Foods Derived From Recombinant-DNA Plants
 - ✓ Guideline For The Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms
- Each government is free to adopt its own policy as to the use of GM organisms in the agriculture and other sectors.



EU Regulations on GMOs

The EU Regulations on GMOs are as follows:

- Directive 2001/18/EC on the deliberate release of GMOs into the environment
- Regulation (EC) 1829/2003 on genetically modified food and feed
- Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory
- Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms
- Directive 2009/41/EC on contained use of genetically modified micro-organisms. Regulation (EC) 1946/2003 on trans boundary movements of GMOs



The Biotechnology Debate

The current food biotechnology debate is between two groups:

1. Agri-biotech investors and their affiliated scientists who say it is a solution to:
 - ✓ food shortage,
 - ✓ the scarcity of environmental resources and
 - ✓ weeds and pests infestations.

The proponents claim that bio-engineering of food is absolutely safe and it is similar to what has been happening through traditional agriculture for thousands of years. They say in selective breeding when two parental plants are crossed to obtain a desirable trait, it is likely that other unpleasant characteristics are transferred as well.



The Biotechnology Debate

2. Independent scientists, environmentalists, farmers and consumers warn that genetically modified food introduces new risks to:
 - ✓ food security,
 - ✓ the environment and
 - ✓ human health such as loss of biodiversity; the emergence of superweeds and superpests; the increase of antibiotic resistance, food allergies and other unintended effects.



The Biotechnology Debate

Whatever side of the debate, Countries that produce genetically engineered food need to be continuously vigilant and must strictly adhere to the international scientific bio-safety testing guidelines containing reliable pre-release experiments and post-release track of transgenic plants to protect public health and avoid future environmental harm.



Conclusion

This round table with the theme “Food Security and Biotechnology in Nigeria” is very apt at this period in time of increased government support of the diversification of the economy through agriculture and other non-oil exports.

In as much as GMOs can ameliorate food shortage, improve food security, produce plants that have better yield and are resistant to pests it is important to emphasize that their use must be closely monitored and controlled to avoid negative effects or impacts on humans and the environment.

Government bodies and stakeholders with regulatory or legislative roles in food safety and regulation need to work together to optimize the benefits derived from biotechnology and genetic engineering.



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