



Plant Breeding: Harnessing Gene Editing Technologies for Crop Improvement and the Evolving Regulatory Framework

By

Agnes 'Yemisi Asagbra (Ph.D.)

**Director-General/CEO
National Biosafety Management Agency**

at

**The Maiden Annual Hybrid Conference of Plant Breeders Association of Nigeria
29th November to 1st December 2023**

Introduction to Plant Breeding

- The genetic improvement of plants by selective mating or hybridization
 - Allows the selection of progeny with enhanced agronomic performance/ improved combination of traits
- Contributes to improved crop yields for feeding the ever-increasing global population
 - Seeks to provide adapted crop varieties for tackling the growing environmental challenges such as diseases, pests, stresses
- Accelerated and targeted evolution
 - Critical in bio-fortification of crops



Historical Context to Plant Breeding

Primitive Selection (2.6 million years ago)

- Humans rely on plants as source of food and medicine
- Primitive selection for plants with beneficial traits for cultivation and reproduction

Domestication Breeding (12 thousand years ago)

- Humans purposefully selected and cultivated plants with beneficial traits to meet agricultural and economic needs
- Cultivation and propagation techniques were developed and applied (stem cuttings, grafting, plant transplants)
- Hybridization used to obtain desired traits from closely related species and incorporated into new cultivars
- Shift from primitive selection to domestication marked the beginning of an active human involvement in plant evolution

Molecular Plant Breeding

- Circumvents challenges of domestication breeding (species barrier, breeding efficiency, precision, time and resources limitations, etc.)
- Utilizes advanced techniques and global collaborative networks to enhance the sustainability and resilience of agricultural production

Differences between Classical Domestication Breeding and Molecular Plant Breeding

Domestication Breeding

- strategy places more emphasis on **phenotype**
- It takes a lengthy time (up to 2 decades) to release a new variety
- requires fewer technical skills and genetics related scientific understanding.

Molecular Plant Breeding

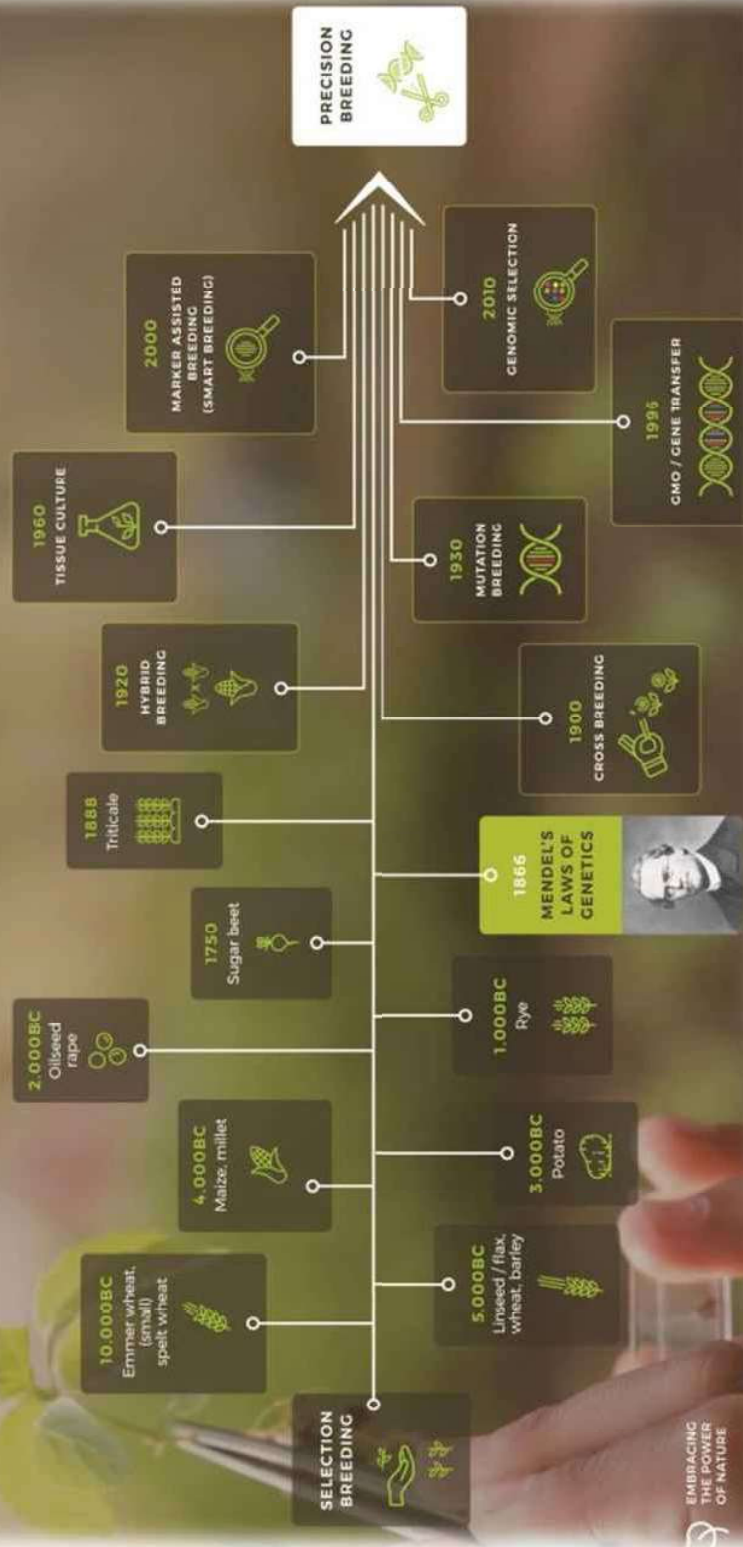
- **genotype-based** breeding strategy, making it easier to identify pure gene lines
- It takes less time to release a new variety
- requires a deeper understanding of genetics and greater technical abilities.



Categories of Molecular Breeding

- Marker-assisted selection
 - Restriction Fragment Length Polymorphism (RFLP)
 - Random Amplified Polymorphic DNA (RAPD)
 - Simple Sequence Repeats (SSRs) or microsatellites
 - Single Nucleotide Polymorphism
- Genome Wide Association Mapping in Plants
- Forward and Reverse Genetics for Plant Breeding
- New Breeding Technologies (**Gene Editing**)

Milestones in Plant Breeding



EMBRACING
THE POWER
OF NATURE
EmbracingNature

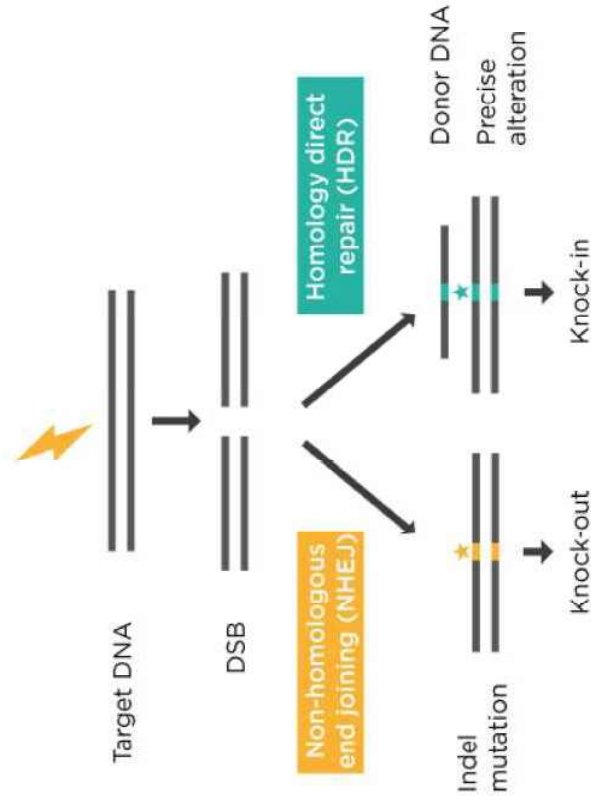
www.plantbreeding.eu

Gene Editing

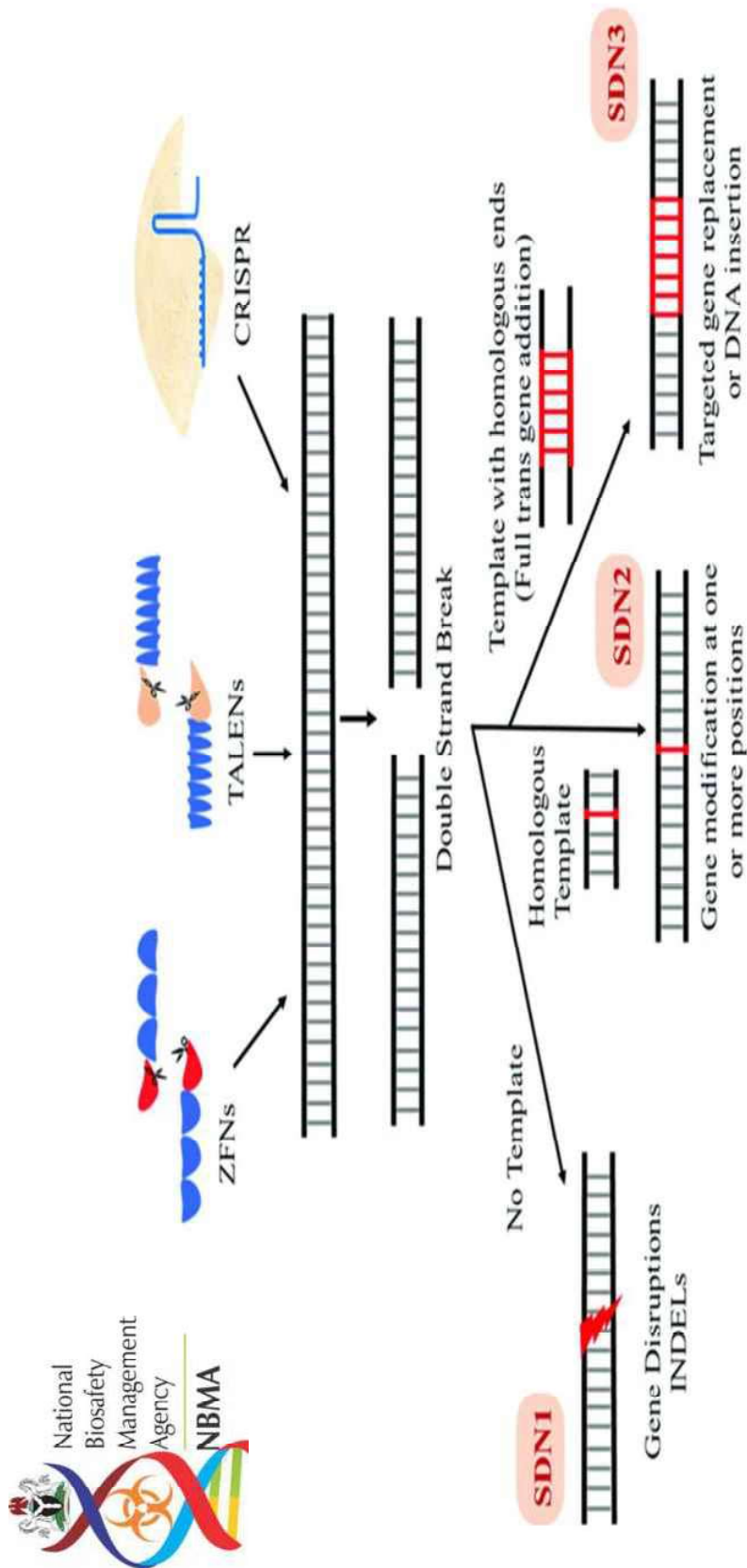
- Molecular techniques that allow targeted and precise alterations of the genome by inserting, deleting or replacing DNA
 - Enzyme-based (TALENs, ZFNs)
 - Nucleic-acid mediated (ODMs)
 - Combination of both (CRISPR-Cas9)
- Three types of genome editing, SDN1, SDN2 and SDN3 can be distinguished

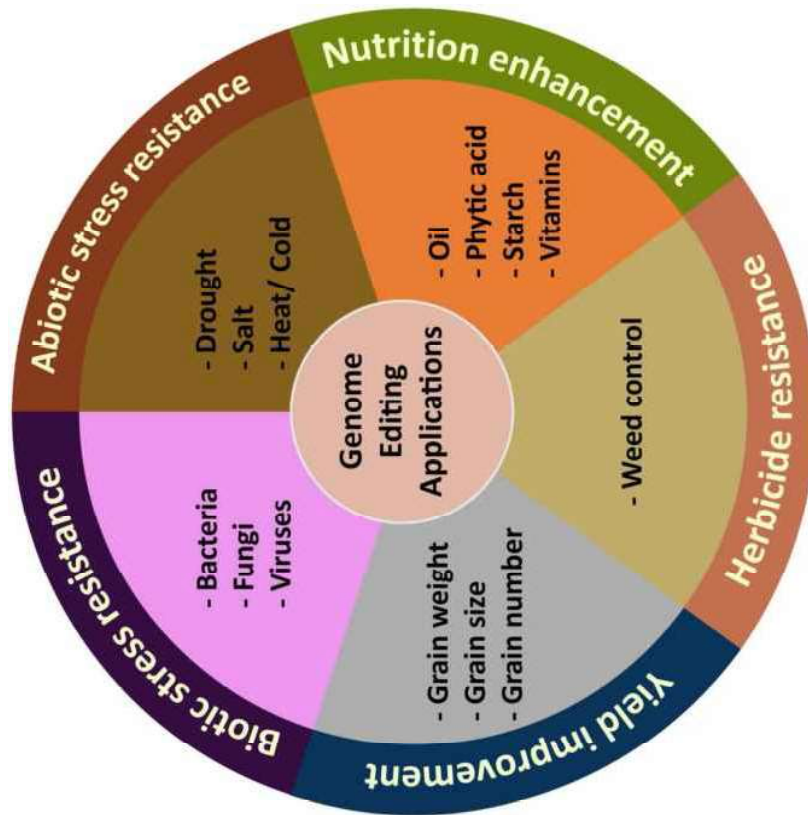


Mechanism of Editing

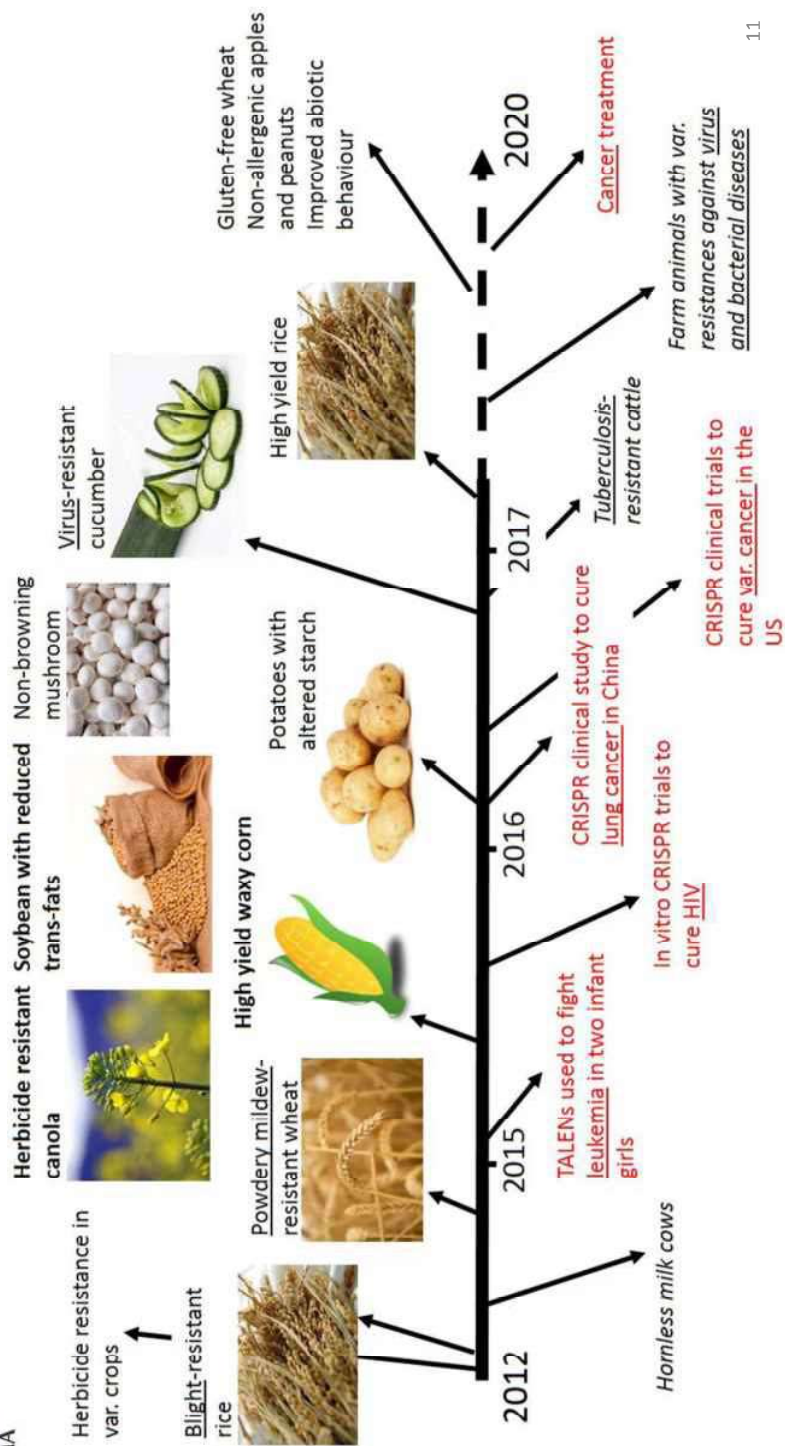


The double stranded break triggers the DNA repair mechanism of the cell resulting in different genome editing outcomes (basis for most regulations).





Applications of Gene Editing so far...





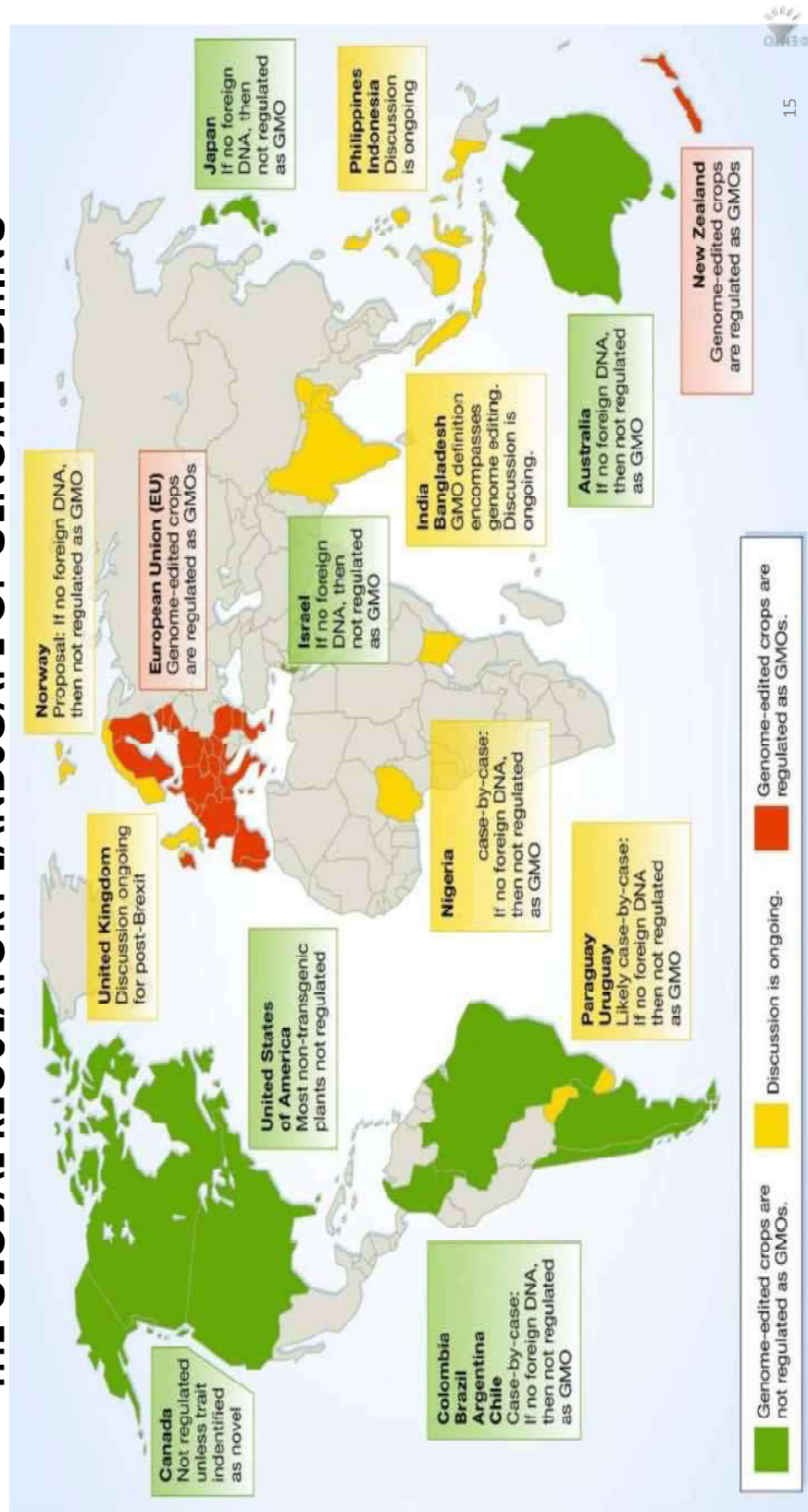
Biosafety Regulations of GM Crops

- The Cartagena Protocol on Biosafety defines a GM crop as one that:
 - (1) contains a novel combination of genetic material,
 - (2) which was introduced by using modern biotechnologywhere “**modern biotechnology**” is defined as an application of either *in vitro* nucleic acid techniques (which includes recombinant DNA and direct injection of nucleic acid into cells or organelles) or the fusion of cells beyond the taxonomic family
- National regulations are product-oriented (1) and/or process-oriented (2)
- Product-oriented regulations emphasize the novel characteristics of the product compared to those produced by conventional breeding.
- Process-oriented regulations consider GM technologies as novel, compared to conventional methods of breeding

Points to Consider in Regulating Gene Editing

- Is modern biotechnology used in the process?
 - Yes!!!
- Is there a novel combination of genetic material in the product?
 - SDN1 (point mutations, single base insertions or deletions)
 - SDN2 (insertions of oligonucleotides of up to 25bp)
 - SDN3 (insertions of complete coding genes)
- Most regulations on Gene Editing is based on what is considered as a **“novel combination of genetic material”**

THE GLOBAL REGULATORY LANDSCAPE OF GENOME EDITING





REGULATORY REGIME FOR GENE EDITING IN AFRICAN COUNTRIES

- Nigeria was the first African country to develop national biosafety guidelines for regulating gene-edited products
- In 2022, Kenya's National Biosafety Authority published their science-based guidelines. Both gene-editing research and gene-edited products will be reviewed on a case-by-case basis.
- Both Nigeria and Kenya will review genome edited products on a case-by-case basis.
- Malawi and Ethiopia have developed guidelines for Gene Edited crops
- Talks are underway for guidelines to be developed in Ghana, Burkina Faso





NIGERIA'S REGULATORY APPROACH FOR GENE EDITING





THE NBMA ACT (2015)

The enactment of the NBMA Act 2015 birthed the National Biosafety Management Agency (NBMA).



The NBMA is charged with the responsibility of providing **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 the environment.





AMENDMENT OF THE NBMA ACT

In August 2019, the National Biosafety Management Agency (NBMA) Act, 2015 was amended to include the regulation of emerging aspects of modern biotechnology which are gene drive, gene editing and synthetic biology, and to ensure biosecurity, as well as related matters. Thus, the amendment comprises the insertion of section 25(A), which states:

"A person, institution or body shall not carryout gene drive, gene editing and synthetic biology except with the approval of the Agency".

The NBMA, in implementing its mandate of providing a safety regulatory framework, harnesses the potential of modern and emerging biotechnology and its derivatives, for the benefit of Nigerians and the economy



19



NIGERIA'S GUIDELINE ON GENE EDITING

Nigeria unveiled her National Biosafety Guidelines on Gene Editing in 2020.

Some highlights of the guidelines are:

- a. A clear reference and alignment with the provisions of the Cartagena Protocol on Biosafety**
- b. establishes an internal review process to determine the regulatory pathway of any application**
- c. It includes clear administrative and contextual guidance in the form of a standard application form.**



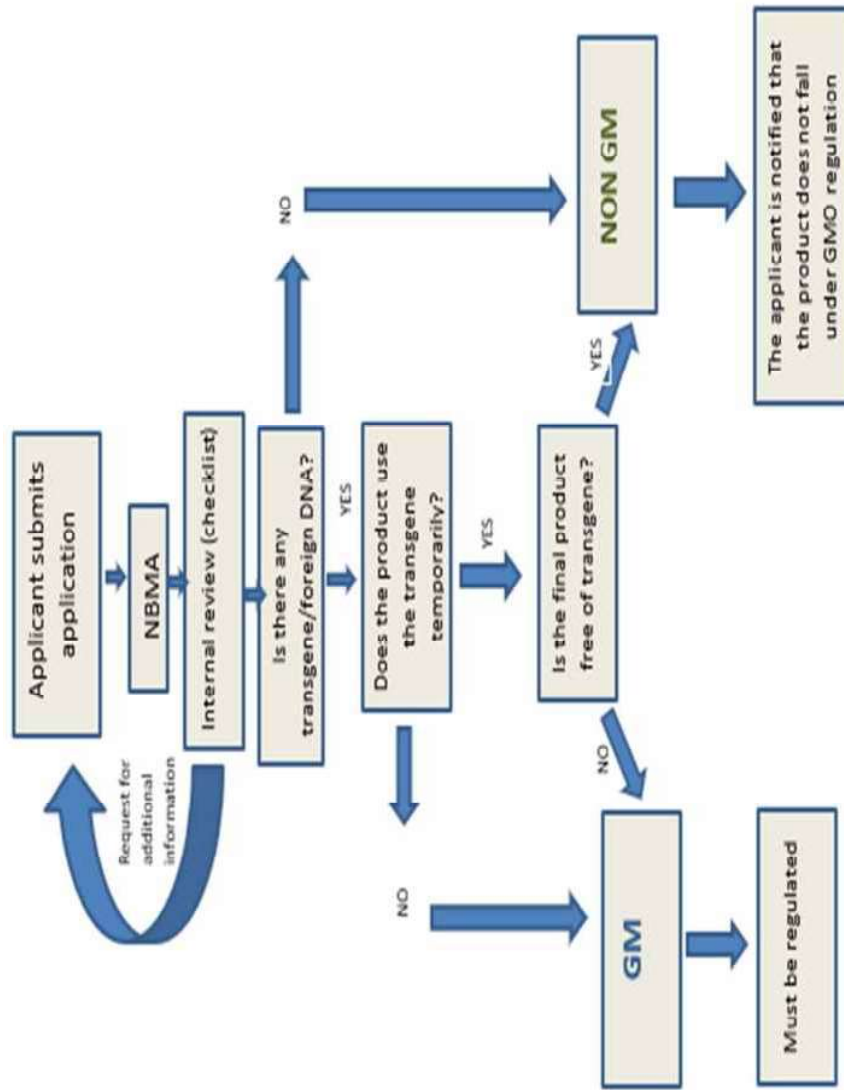
In Nigeria, if the gene editing process or the gene-edited product **does not lead to or have a new combination of genetic material** (e.g. does not use a transgene or /uses a transgene which is removed in the final product), **a non-GM regulatory classification is applied**: in this case, basic information on the overall breeding process, genetic changes, traits, bred-out of helper transgenes, etc will be required from the applicant.

If on the other hand, the gene editing process requires the use of recombinant DNA sequences or the gene-edited product has a new combination of genetic material (e.g. uses a transgene which remains in the final product), the regulatory classification stipulates that the final product falls under GM regulation

Nigeria uses both
Process and
Product trigger
Gene Editing
regulatory
approach.



NIGERIA'S PROCESS MAP TOWARDS DECISION MAKING ON GENOME EDITED PRODUCTS



Conclusion

- Gene editing has a prominent role to play in improving agriculture globally and its potential is currently being exploited in developing crop varieties for a better and more sustainable food system.
- The NBMA is positioned to effectively manage and ensure the safety of humans, animals, and the environment in the application of this technology while harnessing its benefits.
- The Agency would continue to strengthen the regulatory framework for gene editing in Nigeria bearing in mind the rapid evolution of the technology.





For more information about the National Biosafety Management Agency:

- ❖ Please visit our Website@ www.nbma.gov.ng
- ❖ Do send an E-mail to nbma@nbma.gov.ng
- ❖ Do place a call to **+234 818 080 5451**
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