



NATIONAL BIOSAFETY AUTHORITY
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Kenya's Approach to the Regulation of Genome Editing

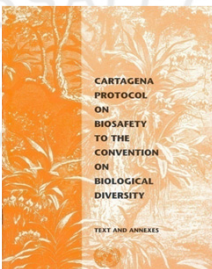
Dr. Roy B. Mugiira
Chief Executive Officer

4th Sustainable Bio-innovation Symposium: Enabling Genome Editing Based Innovation in South Africa
 28th September 2023

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The Cartagena Protocol on Biosafety

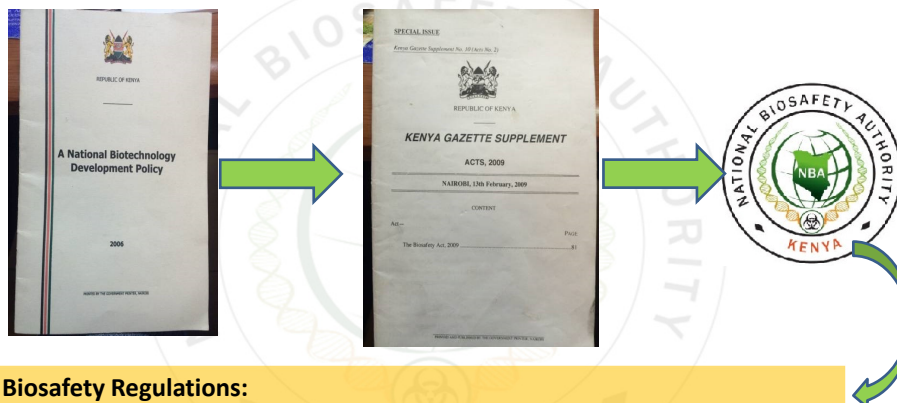

Convention on Biological Diversity

- Kenya signed/Ratified Cartagena Protocol on Biosafety - (2000 & 2003);
- Demonstration of Kenya's commitment to the global governance of modern biotechnology and biodiversity conservation;
- Aspiration to become a key participant in the global biotechnology enterprise (National Biotechnology Development Policy of 2006);

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Kenya National Biosafety Framework



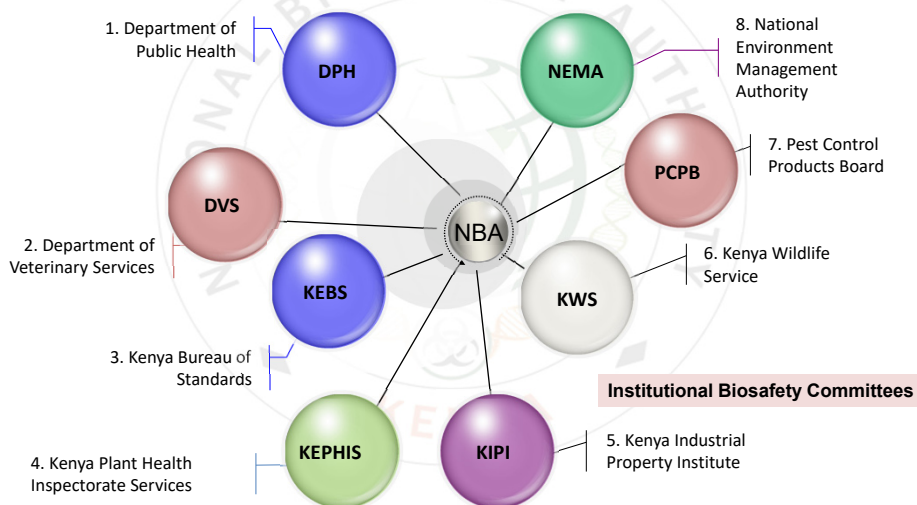
Biosafety Regulations:

1. The Biosafety (Contained Use) Regulations (2011)
2. The Biosafety (Export, Import and Transit) Regulation (2011)
3. The Biosafety (Environmental Release) Regulations (2011)
4. The Biosafety (Labeling) Regulations (2012)

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Consultation with other Regulatory Agencies



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Environmental Release Approvals

1) Bt cotton

- Monsanto/Bayer and KALRO;
- Commercialized in 2020;

2) Bt maize

- Approved for cultivation/placing on the market in October 2022;
- Awaiting variety release by KEPHIS;

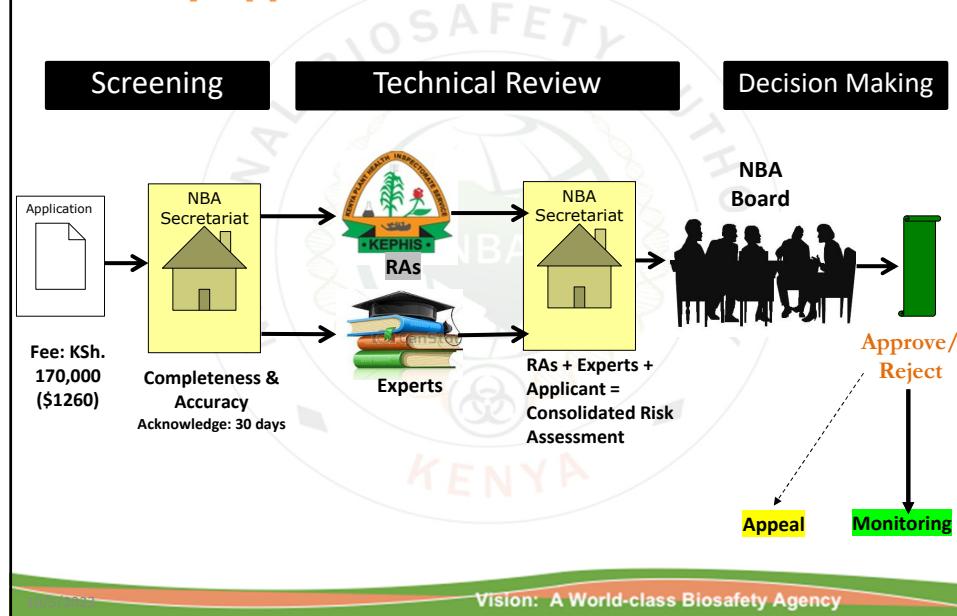
3) VIRCA Cassava

- Approved for NPTs in June 2021;
- NPTs on going;

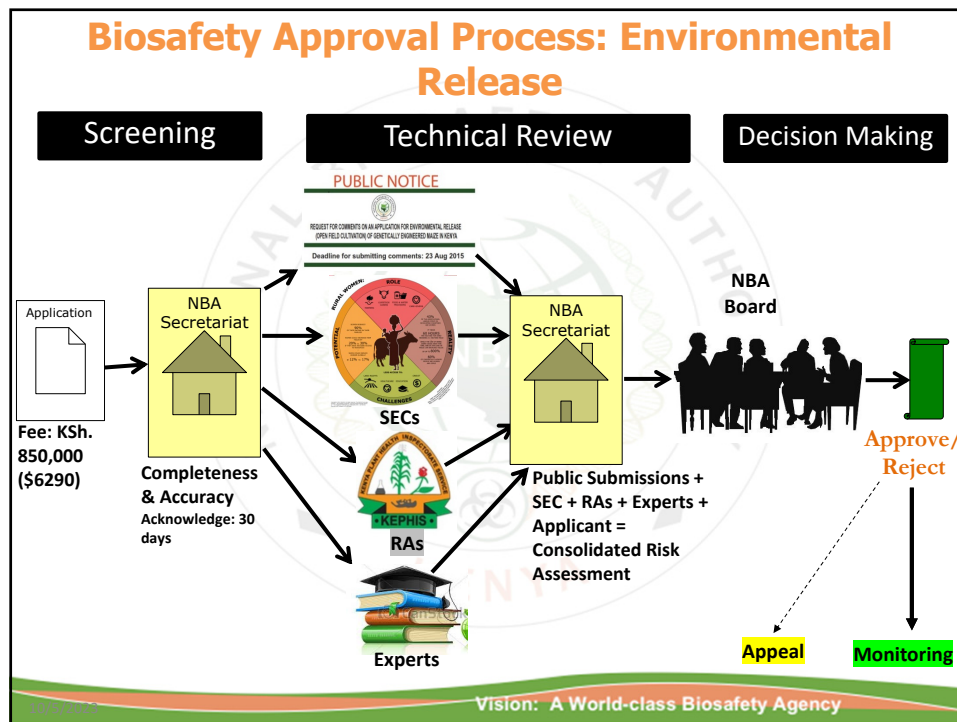
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Biosafety Approval Process: Confined Field Trials



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The Emergence of Genome Editing, New Breeding Technologies

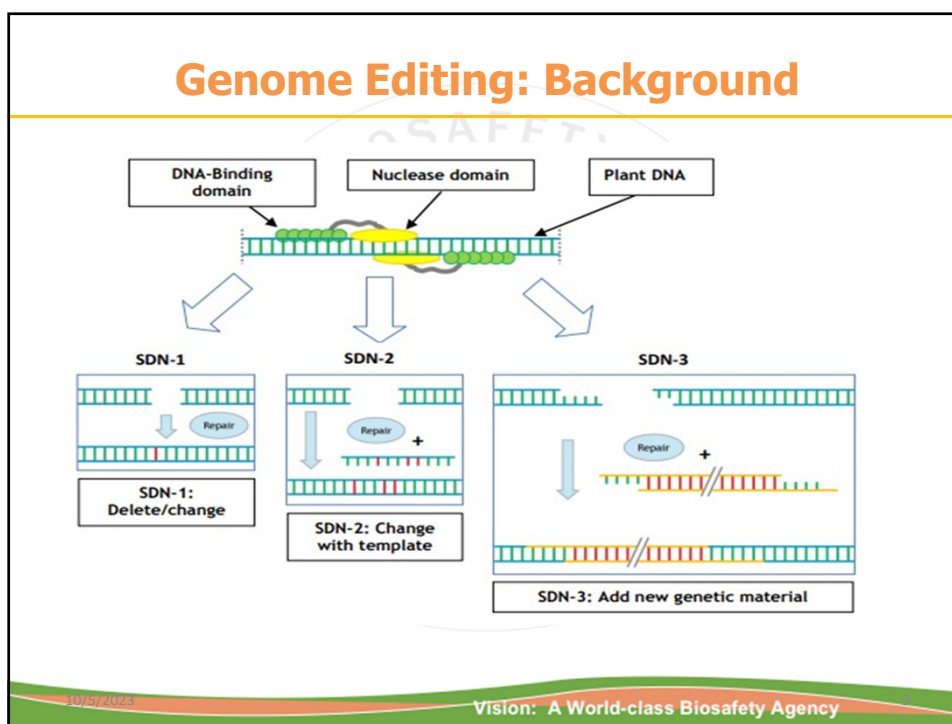
Emerging biotechnology tools such as genome editing and synthetic biology are presenting newer frontiers in the application of modern biotechnology for socio-economic development.



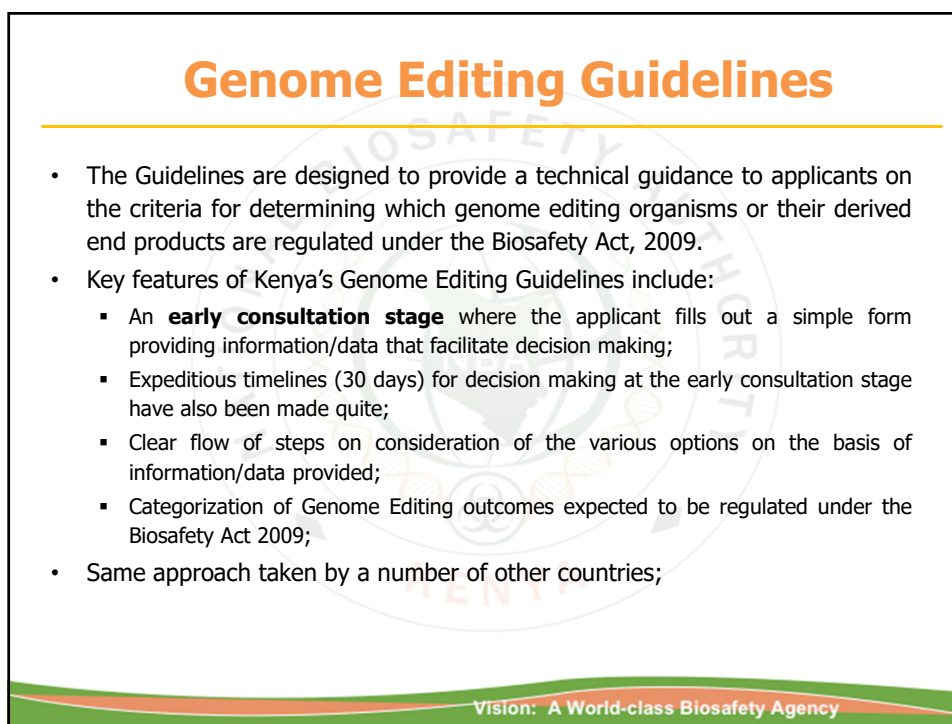
The Nobel Prize in Chemistry 2020 was awarded jointly to Emmanuelle Charpentier and Jennifer A. Doudna “for the development of a method for genome editing.”

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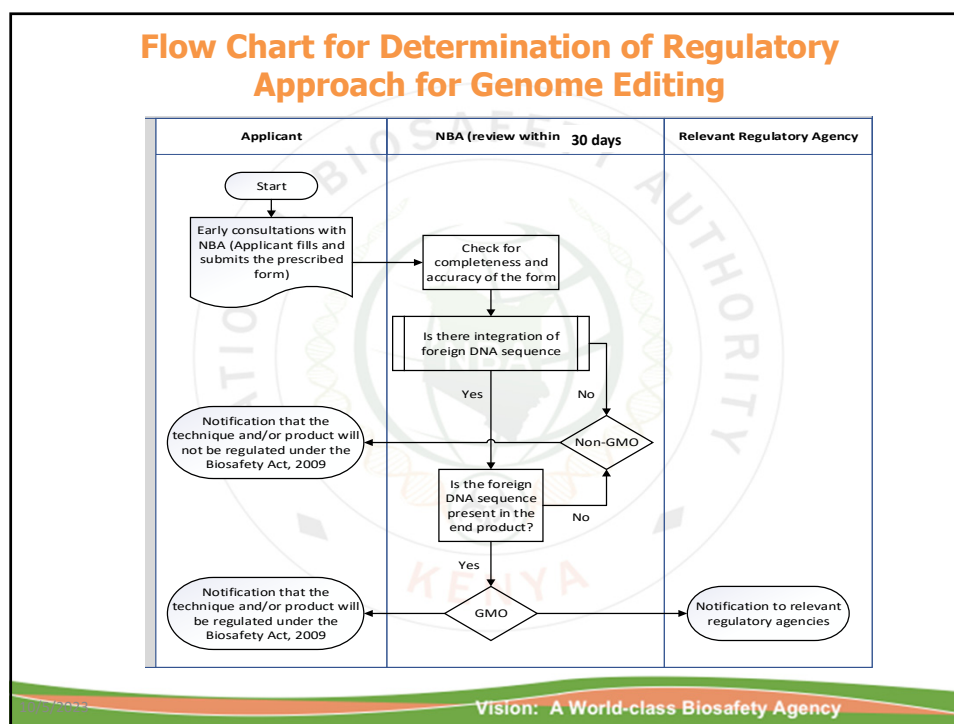
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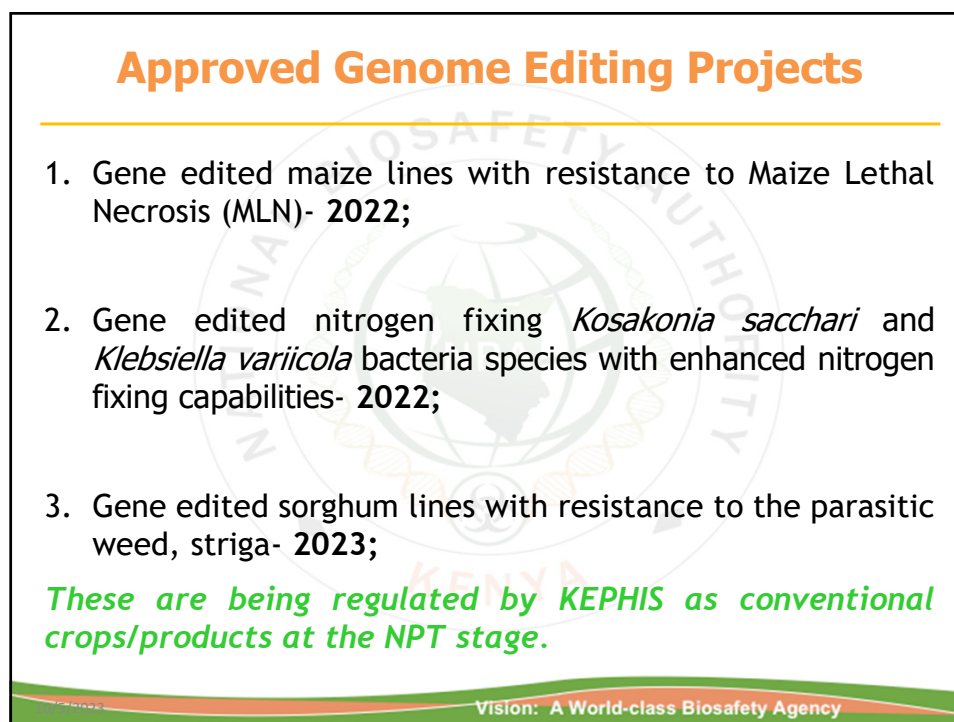
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Divergence and Convergence of Genome Editing Regulatory Approaches

Link: <..\..\Pictures\CONVERGENCE OF GE REGULATION.pdf>

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The Desired Regulatory Framework

1. Consistent and risk-proportionate;
2. Science-based;
3. Globally harmonized;
4. Case-by-case basis;

“Plant varieties developed through the latest plant breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier plant breeding methods”

<https://www.worldseed.org/wp-content/uploads/2018/06/Plant-breeding-criteria-for-the-scope-of-regulatory-oversight.pdf>

 International Seed Federation
Seed is Life

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What does South Africa Have?



1. Long experience with Genetic Modification of crops;
 - Personal experience with seeing is believing visits;
2. Great technical human resource capacity;
3. Great science and technology infrastructure;
 - Personal experience with Square Kilometer Array project;
4. Tried and tested regulatory framework;

Rallying call: *to harness these resources and make them work for the people of South Africa.*

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Thank You

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