

# Global Regulatory Fates of Gene Edited Crops: *A Case Study of the SWEET SNP BLB Resistant Rice*

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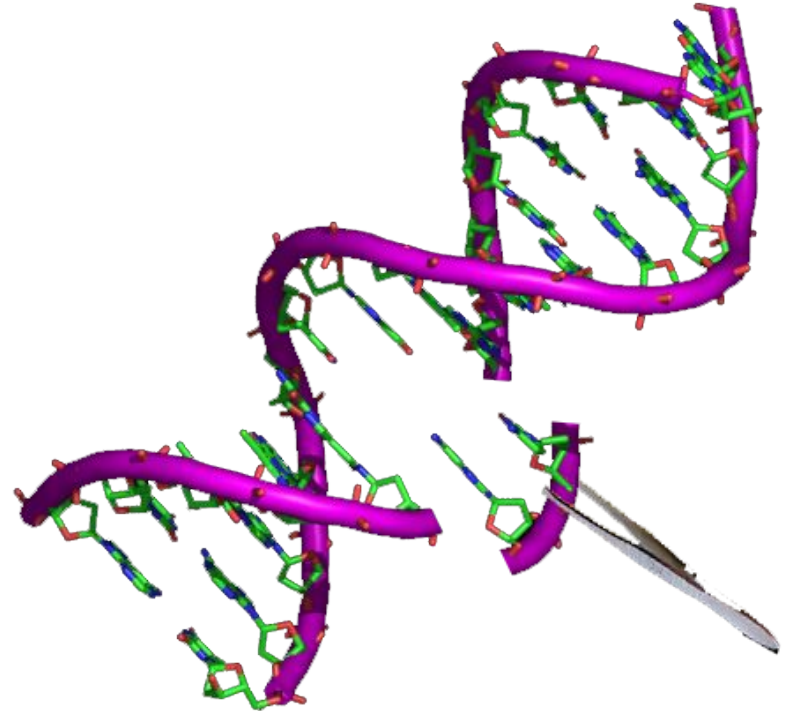


Genome Editing for Food Security  
and Environmental Sustainability



# Genetic Engineering: The new paradigm of Agriculture

- 190 Million ha of GM crops grown globally
- 25 years of significant public and private research
- New technology provides new opportunities for editing



# The Incongruence Between Development and Regulation

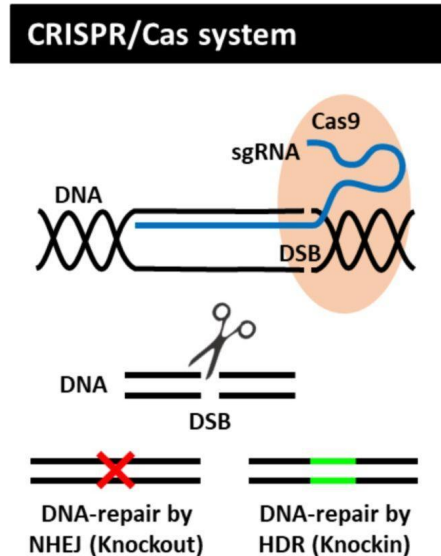
- Regulation influenced by:
  - Political interest
  - Public interest
  - Researchers and experts
  
- Difficulty in commercializing GM products:
  - Financial barriers
  - Intellectual property conflict
  - Lack of regulatory harmonization
  - Lack of clear definition between GM and gene editing



# Gene editing vs Genetic Modification

## Gene Editing

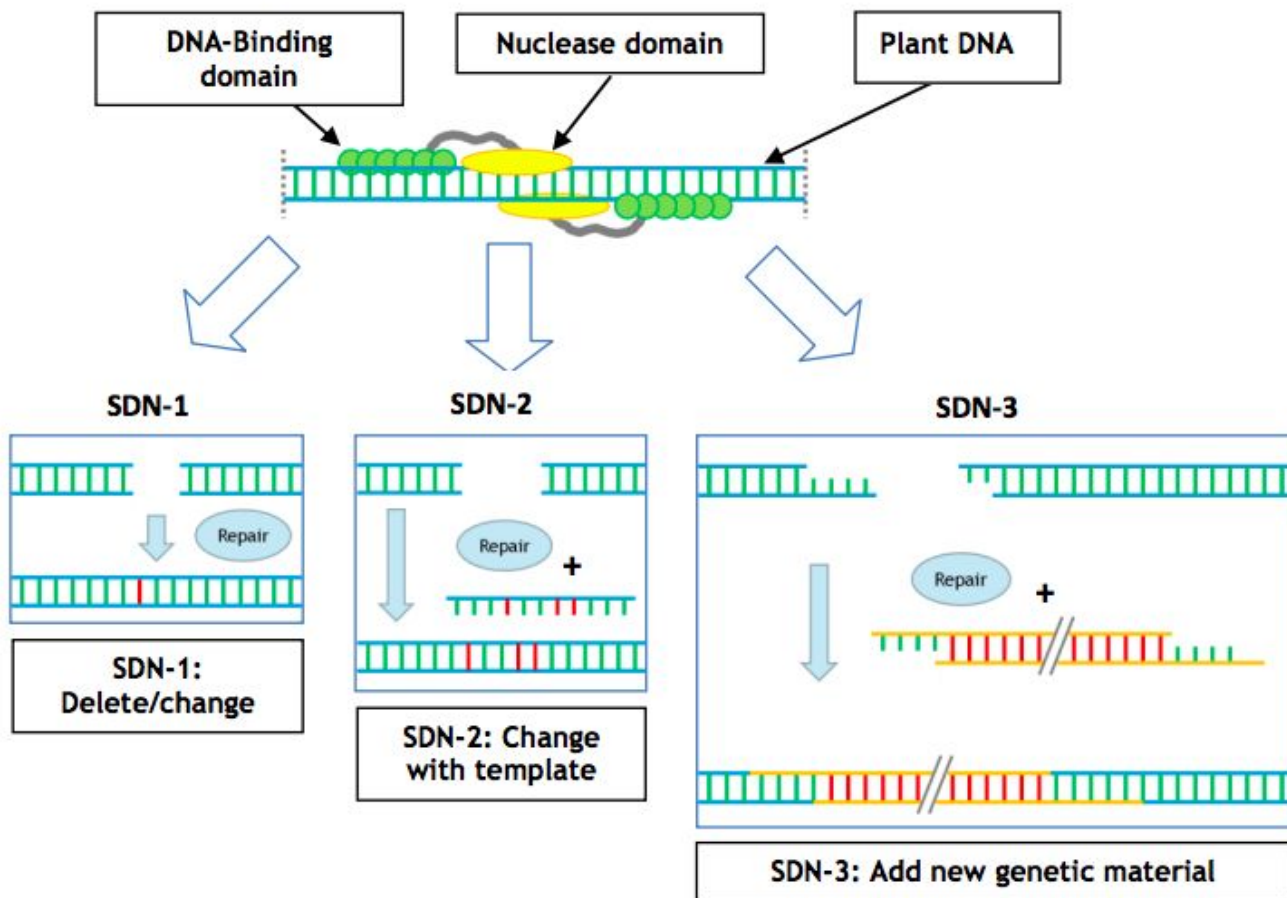
The use of new breeding technologies (e.g. CRISPR) to generate precise alterations to a gene, creating a new phenotype.



## Genetic Modification

The insertion of foreign genetic material into an organism with the intention of generating a novel trait.

# Site-Directed Nucleases and Recombinant DNA

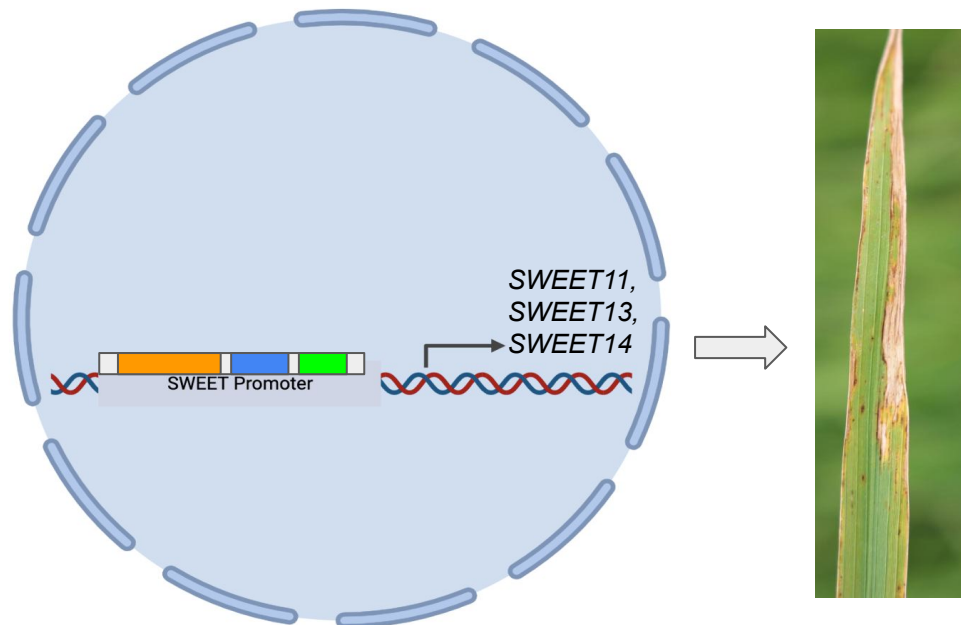
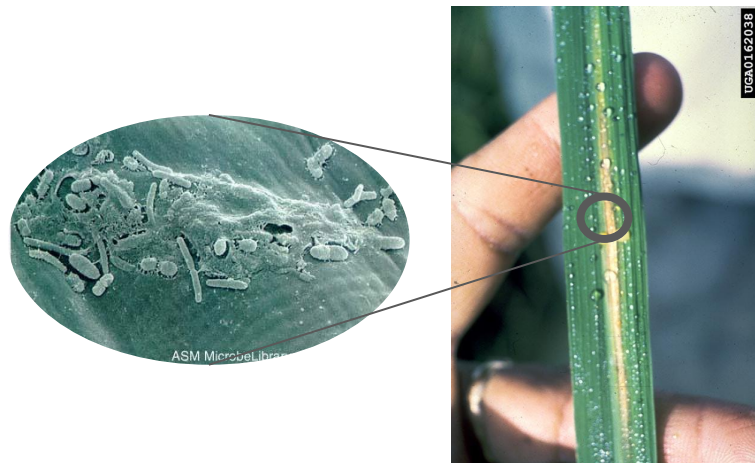


# Case Study: *Xanthomonas oryzae* Blight in Asia and Africa

- *Xanthomonas Oryzae* pv. *Oryzae* (Xoo)
- One of the most damaging forms of bacterial infection in rice.
- Lesions and damage in growth.
  - Can cause up to 70% crop loss
- Grown in sub-saharan Africa and Asia.



# Xoo's SWEET infection



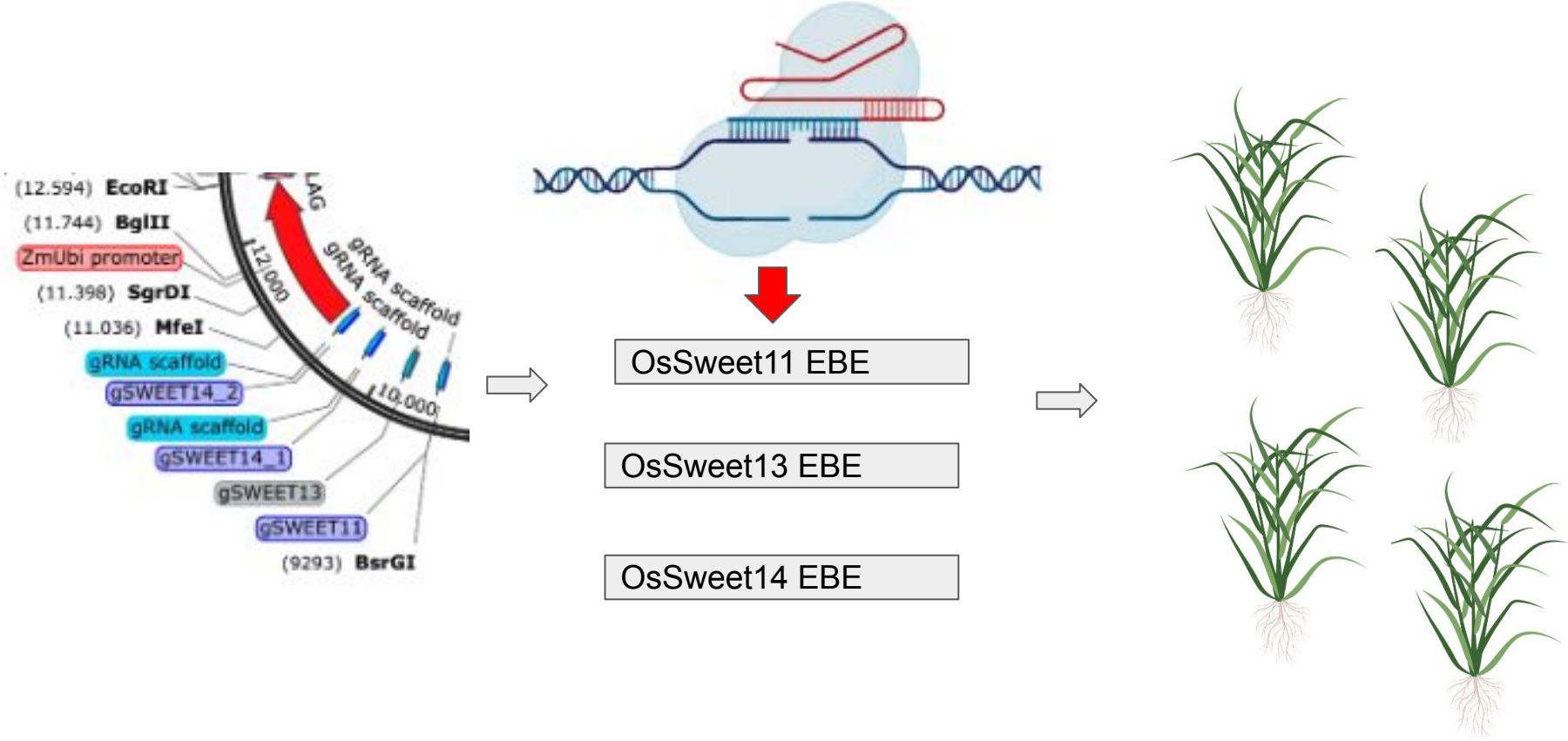
Transcription Activator Like Effectors (TALEs)



## ● Infection

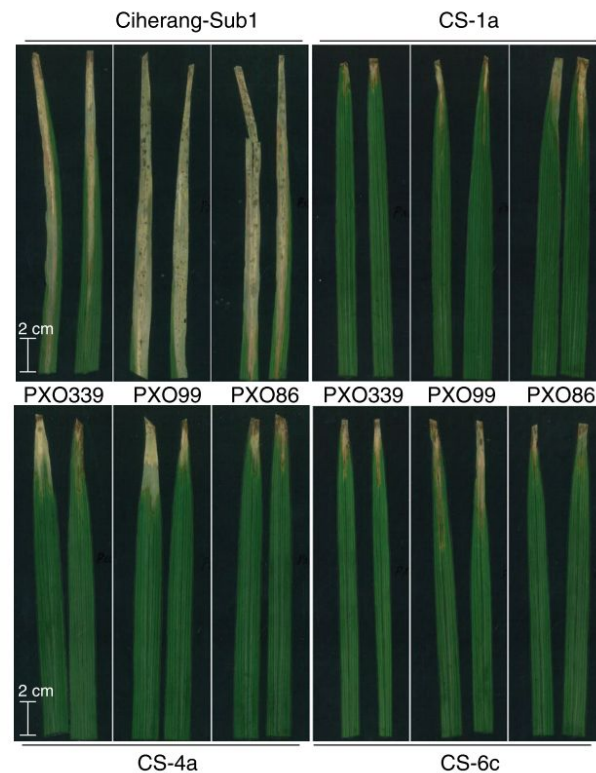
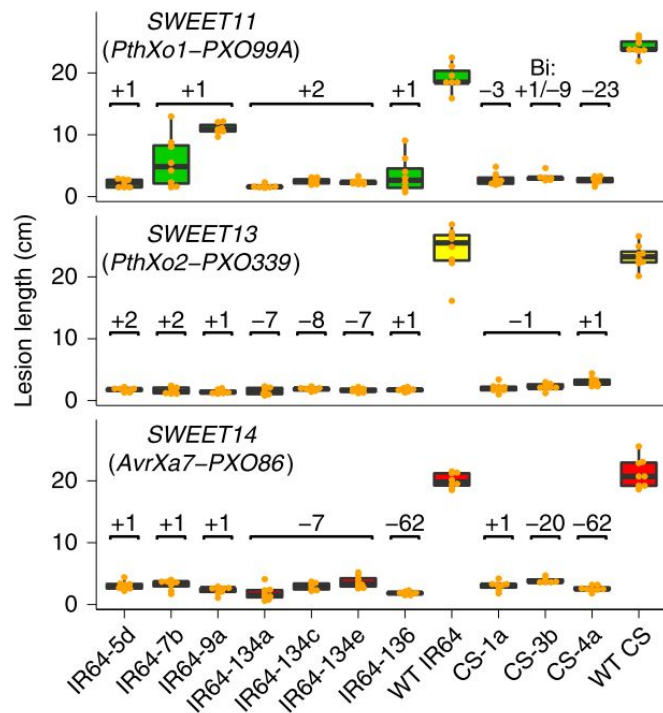
- Transcription activator like effectors (TAL) secreted into the host
- Bind to SWEET effector binding element (EBE)
- Induce expression to upregulate sugar transport
- Increase in apoplastic sugar concentration -> increase in virulence

# Multiplex Cas9 for the generation of SNP sweet Rice (Olivia et al., 2019)

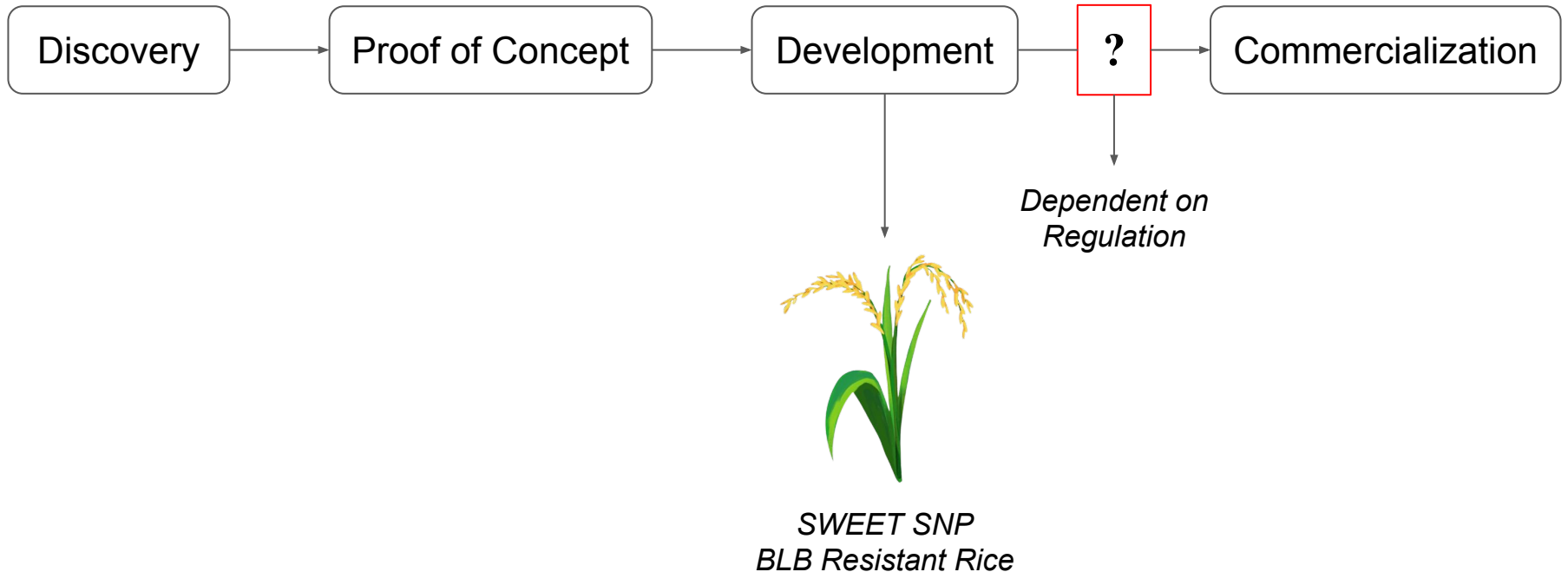




# IR64/Ciherang mutant lines resistant to *Xoo* infection



# Role of Regulation



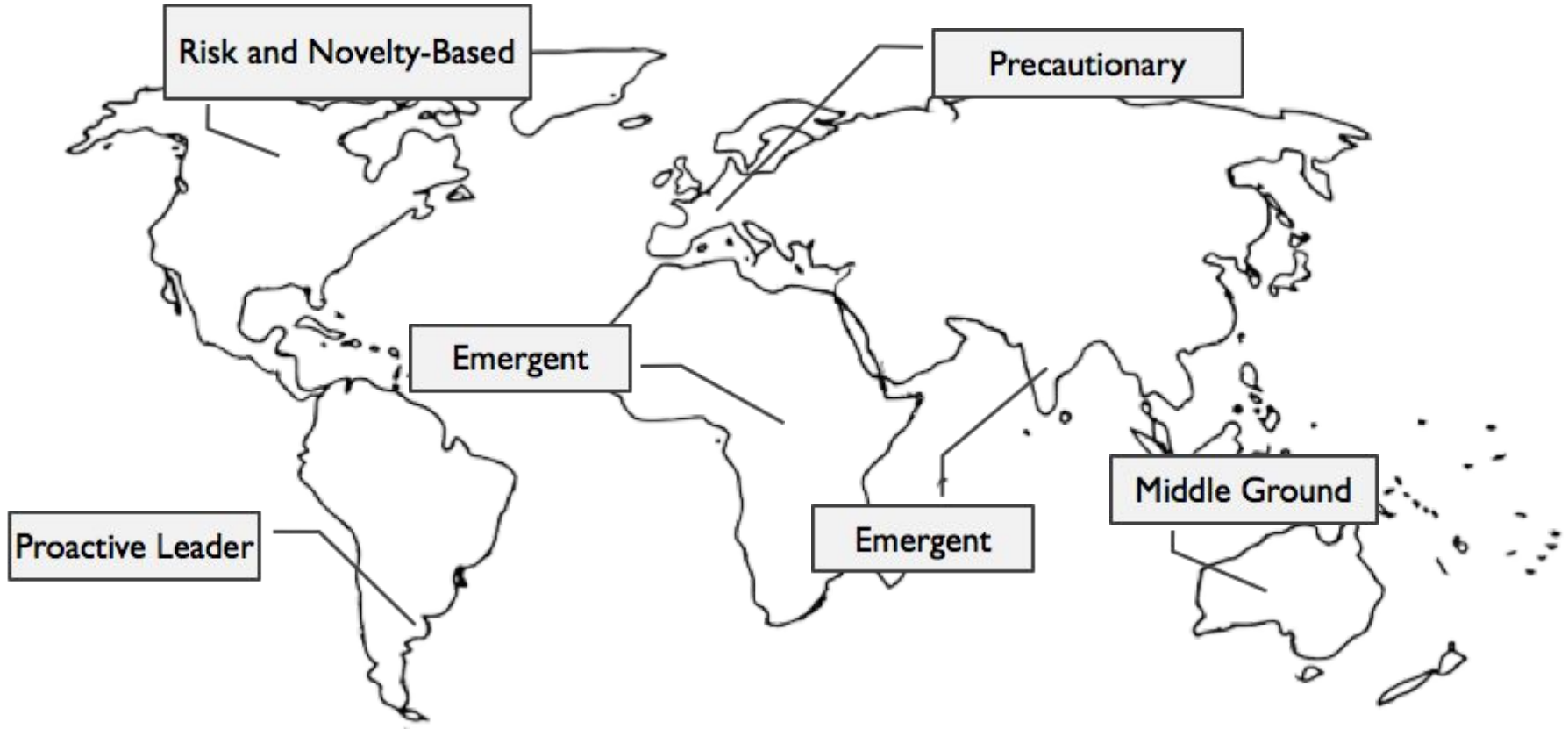
# Regulation

Processes that are influenced by local and global policy decisions.

Has implications for the research and commercialization of gene editing.



# Global Regulatory Approaches to Gene Editing



# Regulation in Canada



- Based on the novelty of the trait rather than the process by which it was created.
- If a novel trait is determined to be present, product undergoes pre-market assessment.



Environment and  
Climate Change Canada

## Participation in International Regulation

World Trade Organization	✓
Codex Alimentarius	✓
Cartagena Protocol on Biosafety	X

# Regulation in the European Union



- 2018 ruling by the EU Court of Justice: Gene edited products are subject to the same regulations as transgenic GMOs.
- Independent risk assessment required.
- Strict traceability and labelling requirements.

## Participation in International Regulation

World Trade Organization	✓
Codex Alimentarius	✓
Cartagena Protocol on Biosafety	✓

# Regulation in Argentina



- Recognized internationally as a regulatory pioneer.
  - First country in the world to introduce gene editing-specific regulation in 2015.
- Case by case assessment based on use of recombinant DNA.
  - **SDN-1**, **2**, and **3**.
- Anticipatory.

## Participation in International Regulation

World Trade Organization	✓
Codex Alimentarius	✓
Cartagena Protocol on Biosafety	✓

# Regulation in Australia



- ‘Middle ground’ approach between the North America and the EU.
- Gene editing techniques that do not introduce foreign genetic material are deregulated.
  - **SDN-1**, **2**, and **3**.



**Australian Government**

**Department of Health**

Office of the Gene Technology Regulator

## Participation in International Regulation

World Trade Organization	✓
Codex Alimentarius	✓
Cartagena Protocol on Biosafety	X



# Regulation in the African Union



African Biosafety Network  
of Expertise (ABNE)

- Regulatory field is emergent - harmonization strategies underway.
- Nigeria and Kenya have published specific biosafety guidelines for gene edited crops.
  - Case by case basis assessment based on recombinant DNA.
  - **SDN-1**, **2**, and **3**.

## AU Member State Participation in International Regulation

World Trade Organization	44 / 55
Codex Alimentarius	49 / 55
Cartagena Protocol on Biosafety	49 / 55

# Regulation in India

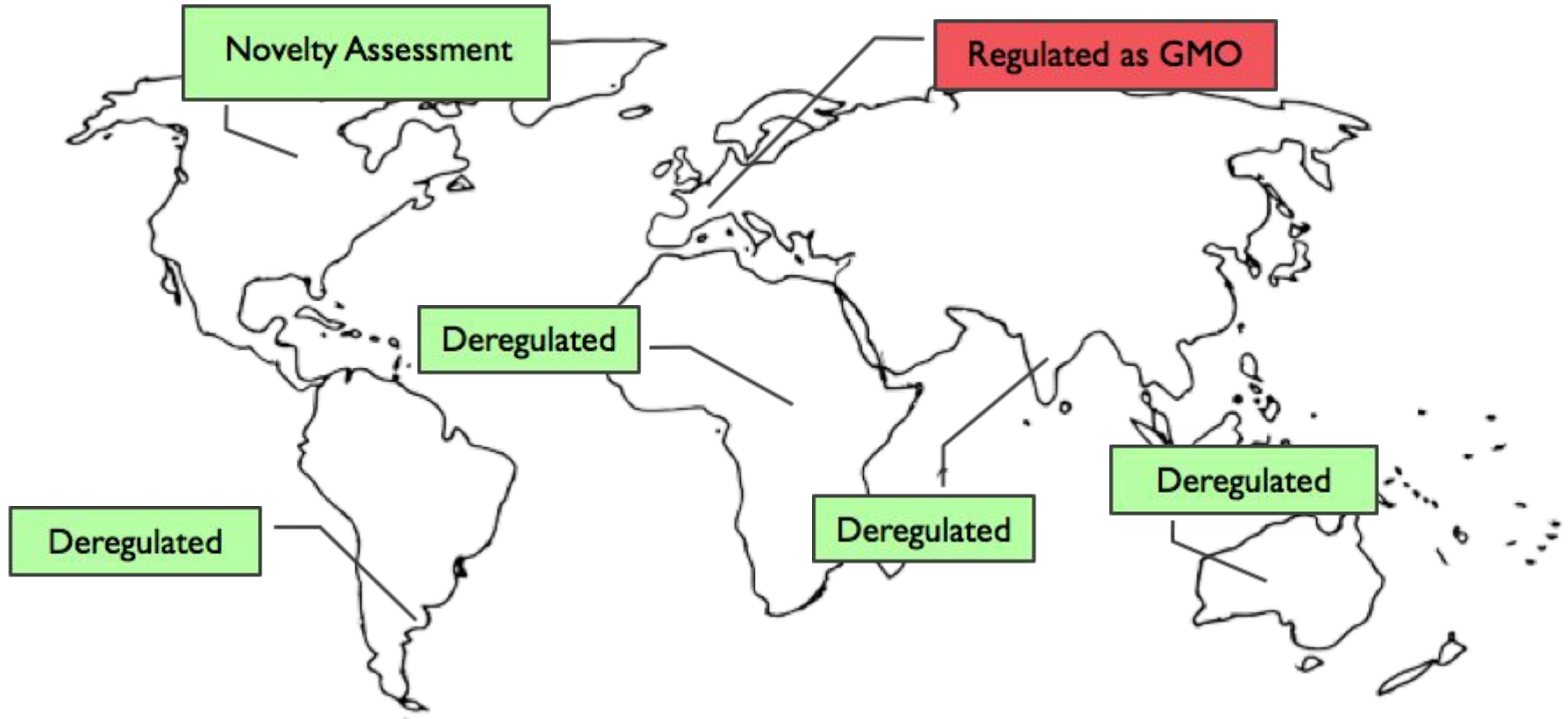


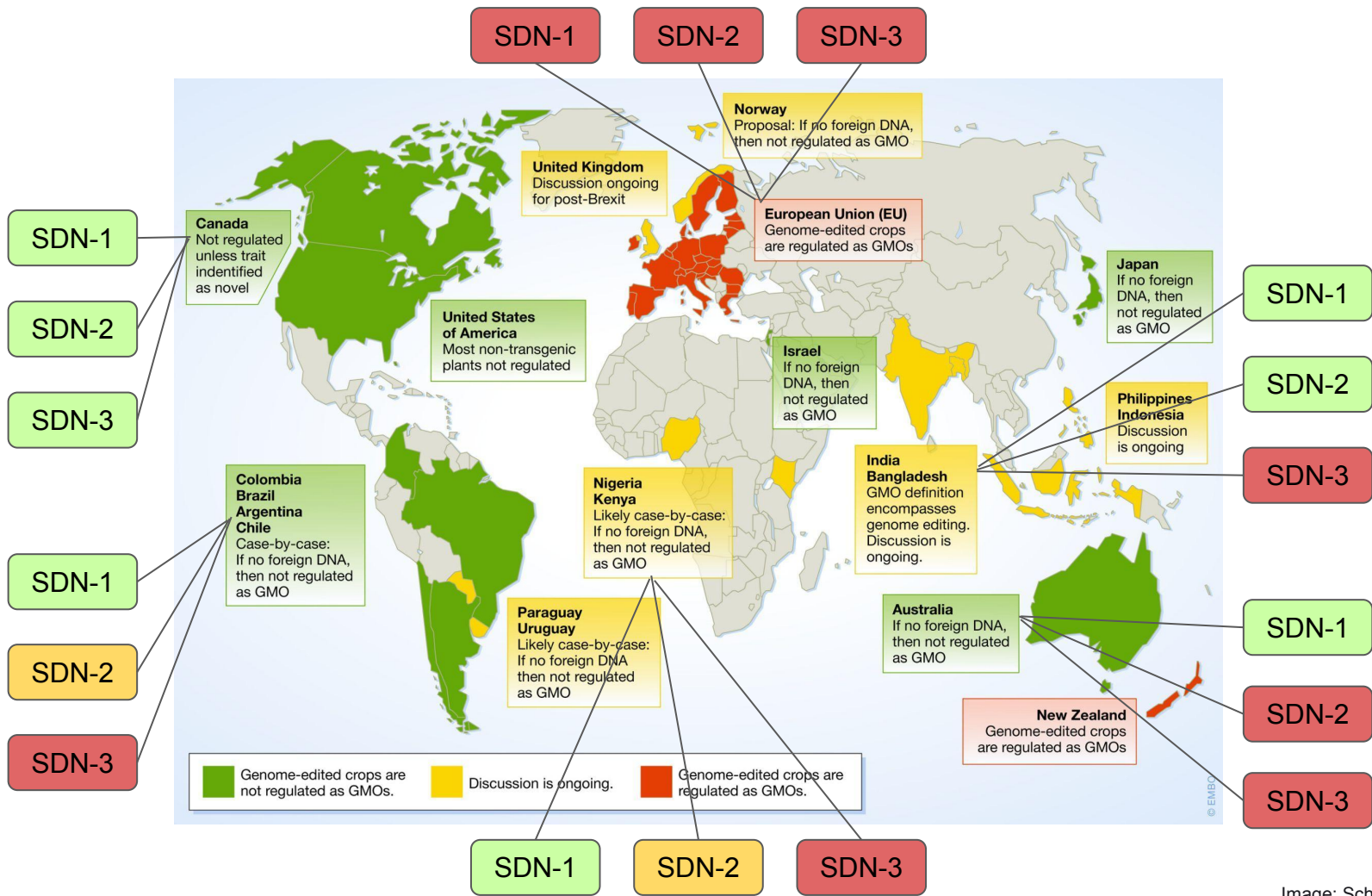
- 2022 ruling exempts gene edited products that do not involve the use of recombinant DNA from GMO regulations.
  - **SDN-1, 2, and 3.**
- Currently does not allow the commercial cultivation of genetically altered crops for food.
  - Bt Cotton is the only crop allowed to be cultivated.

## Participation in International Regulation

World Trade Organization	✓
Codex Alimentarius	✓
Cartagena Protocol on Biosafety	✓

# Regulatory Fate of SWEET SNP BLB Resistant Rice (SDN-1)



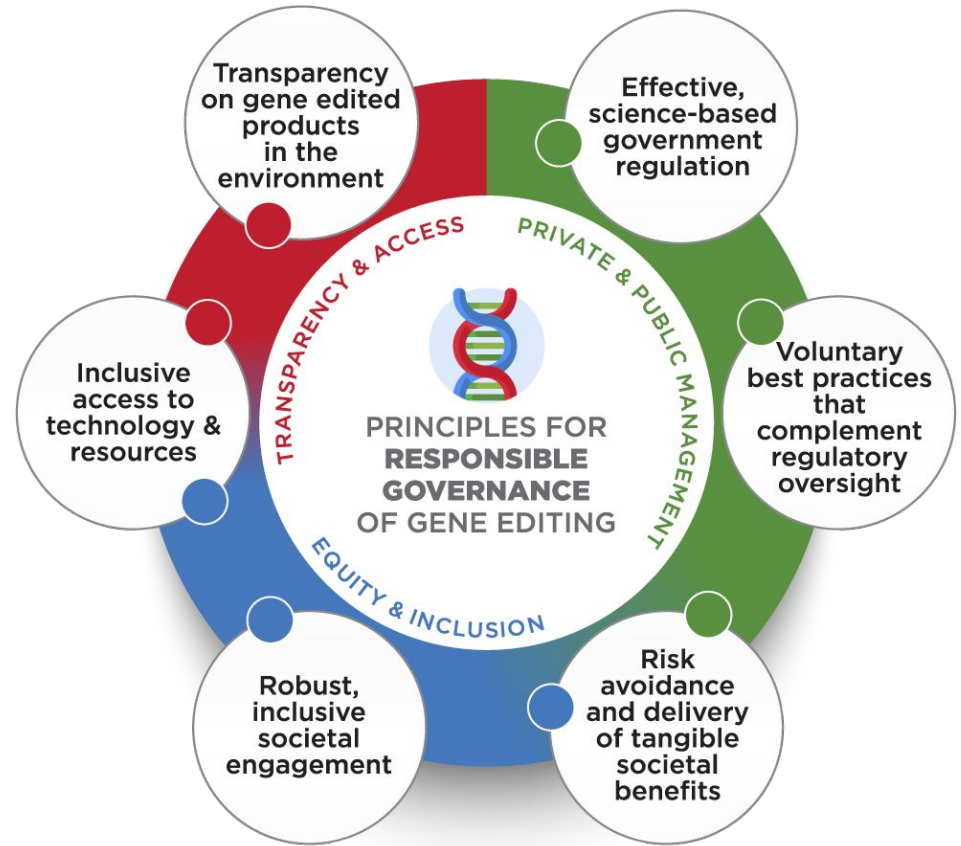


# Conclusions

- While gene editing in agriculture rapidly progresses, diverse regulation poses challenges for global coordination.
- Streamlined regulatory frameworks are straightforward, easy to comply with, enforceable, and adaptable.
- Diverse regulatory approaches reflect diverse societal values.

# Key Recommendations

- Calls for harmonization towards global equity.
- Implementation of responsible principles to realize these calls to action.



# *Global Regulatory Fates of Gene Edited Crops*

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# Thank You