



# Global Regulatory Landscape for Animal Biotechnology: Agricultural Applications

**Diane Wray-Cahen, PhD**

Senior Advisor/Office of the Chief Scientist

Senior Trade Advisor/Foreign Agricultural Service

*diane.wray-cahen@usda.gov*



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# Multiple Roles of REGULATIONS:

- Protect health & safety of humans, animals, and environment
- Instill trust in the food supply
- Encourage development of new ideas and innovations



# Different Countries – Different Regulatory Approaches

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- Differences in existing regulatory structures and legal enabling authorities
- Different regulatory triggers: product vs. process (e.g., GMO)
  - Most countries → new GMO Laws (Argentina & Brazil)
  - Using Existing Laws – United States
  - Novelty – Canada (“novel” covers conventional breeding)
- **General agreement on what needed for safety evaluations**  
(i.e., similar criteria for rDNA/GMO products, but sometimes different requirements)

# Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from rDNA Animals (2008)

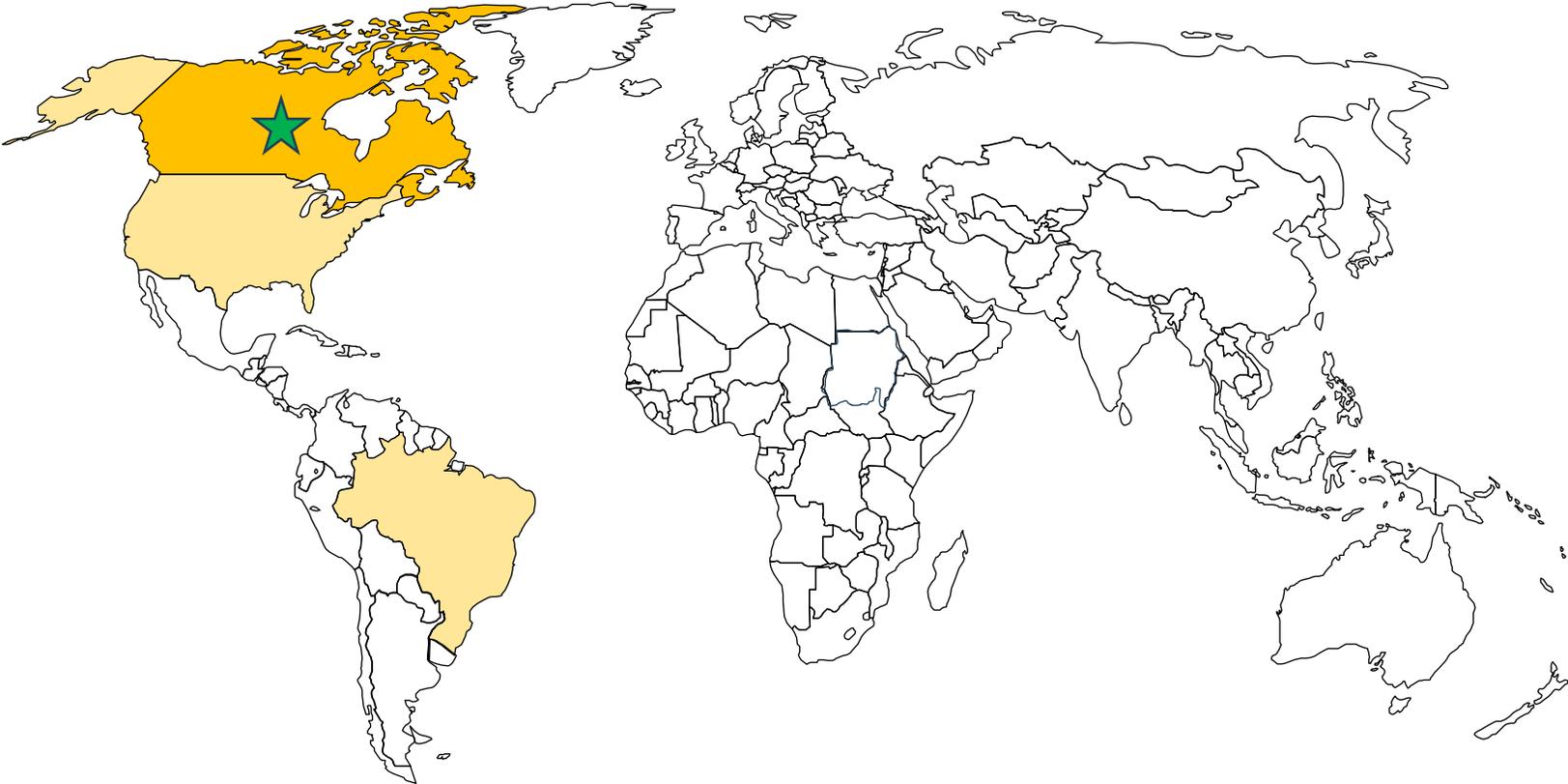
- Recommends approach for food safety assessment where a conventional counterpart exists and identifies data applicable to making such assessments:
  - The nature of the rDNA construct and its expression
  - The health status of the rDNA animal
  - The composition of food products produced
- Useful for standardizing **food safety assessments** and potentially for harmonizing trade in foods derived from rDNA animals
- Addresses food safety and nutritional aspects only\*



\* Guideline does *not* address animal welfare; ethical, moral, and socioeconomic aspects; environmental risks. It also does not address “efficacy” of the trait, but does address impact of any antibiotic marker genes on therapeutic efficacy of orally administered antibiotics.

# Global Regulatory Landscape for Animal Biotechnology

2011  
Argentina  
Workshop



-  Countries with regulatory policy with exclusions
-  Countries with **pending** policies, regulations, or legal rulings
-  Countries with GMO only policy with no exclusions
-  Countries with regulatory policy with exclusions (plants only)
-  Regulatory approvals for rDNA animals



# Global Regulatory Landscape for Animal Biotechnology

2014  
Brazil  
Workshop



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A landscape photograph showing a green pasture in the foreground with four sheep grazing. Behind the pasture is a field of golden-brown crops, and in the background are rolling hills under a clear sky. The text "Changing Scientific & Regulatory Landscapes" is overlaid in the center.

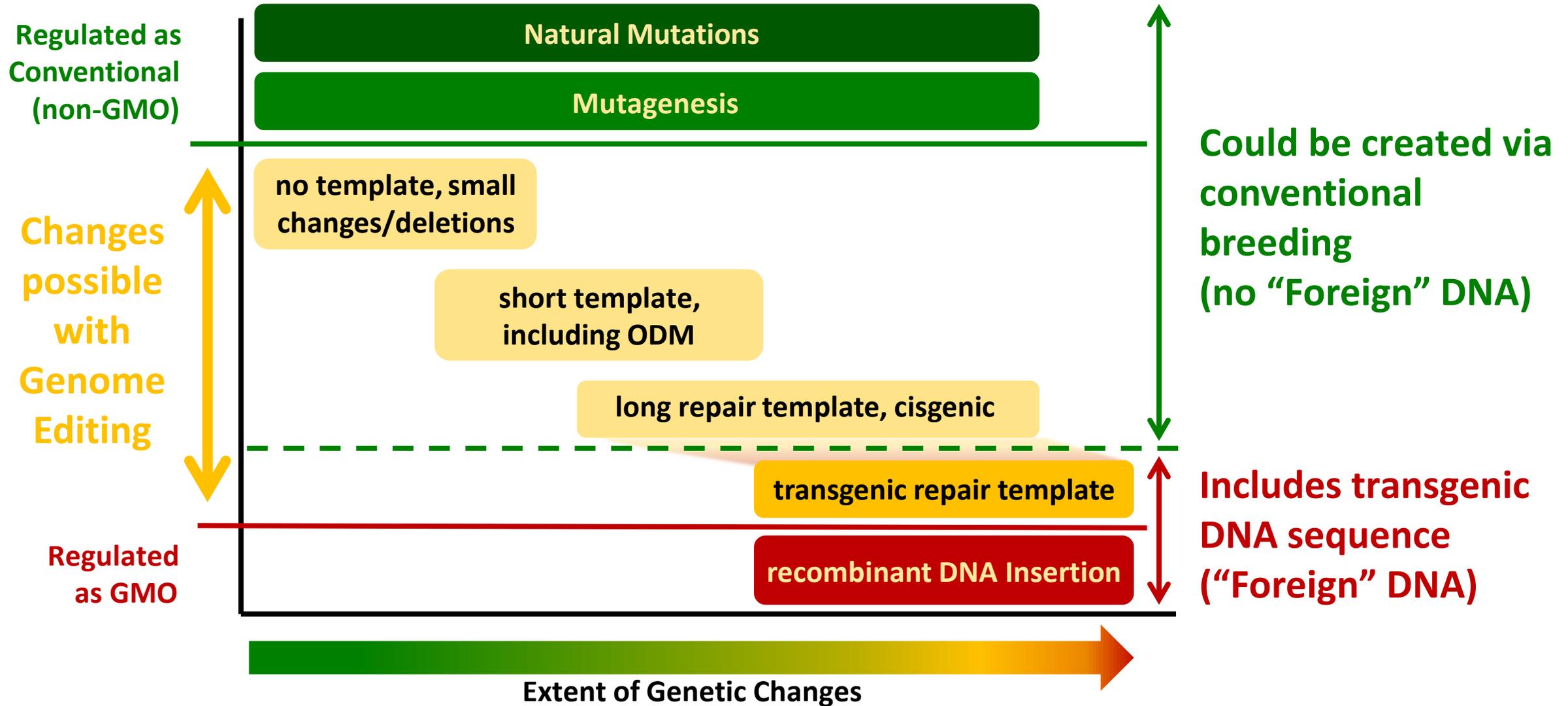
# Changing Scientific & Regulatory Landscapes

# Modernizing Regulatory Approaches

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- Protection goals remain the same - all products (biotech or conventional) safe for humans, animals, and the environment
- Regulatory approaches that reflect **characteristics** and **potential risk** of **products** of new technologies (focus on product, not technology)
- Encourage creation of new innovative **safe** agricultural products to address growing global challenges and threats
- Facilitate getting new precision breeding tools to farmers, for use within **current** production systems and husbandry practices (equitably)

# “When to Regulate as GMO?”



# Definition of LMO in Cartagena Protocol

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## Article 3 (Use of Terms)

- (g) "**Living modified organism**" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
  
- (i) "**Modern biotechnology**" means the application of:
  - a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
  - b. Fusion of cells beyond the taxonomic family,  
that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

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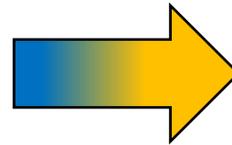
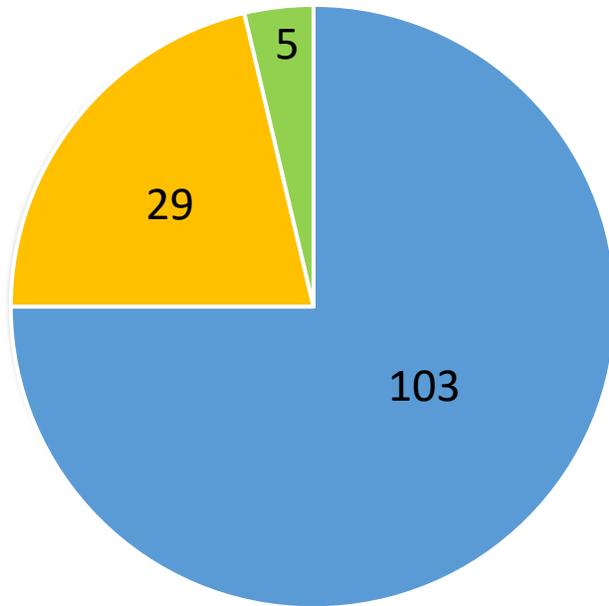
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**AND ALSO**



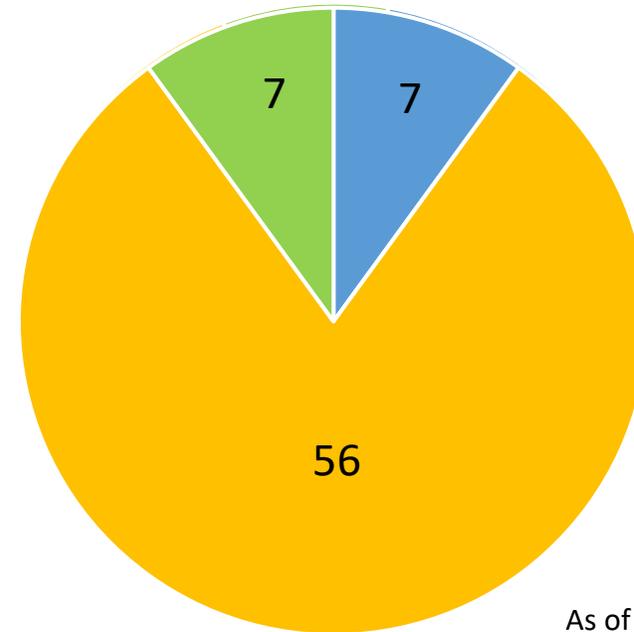
# Impact of APHIS Regulatory Status Review Process

### Completed Petitions



- Major Biotech
- Other Companies
- Public

### Regulatory Status Reviews (RSR)



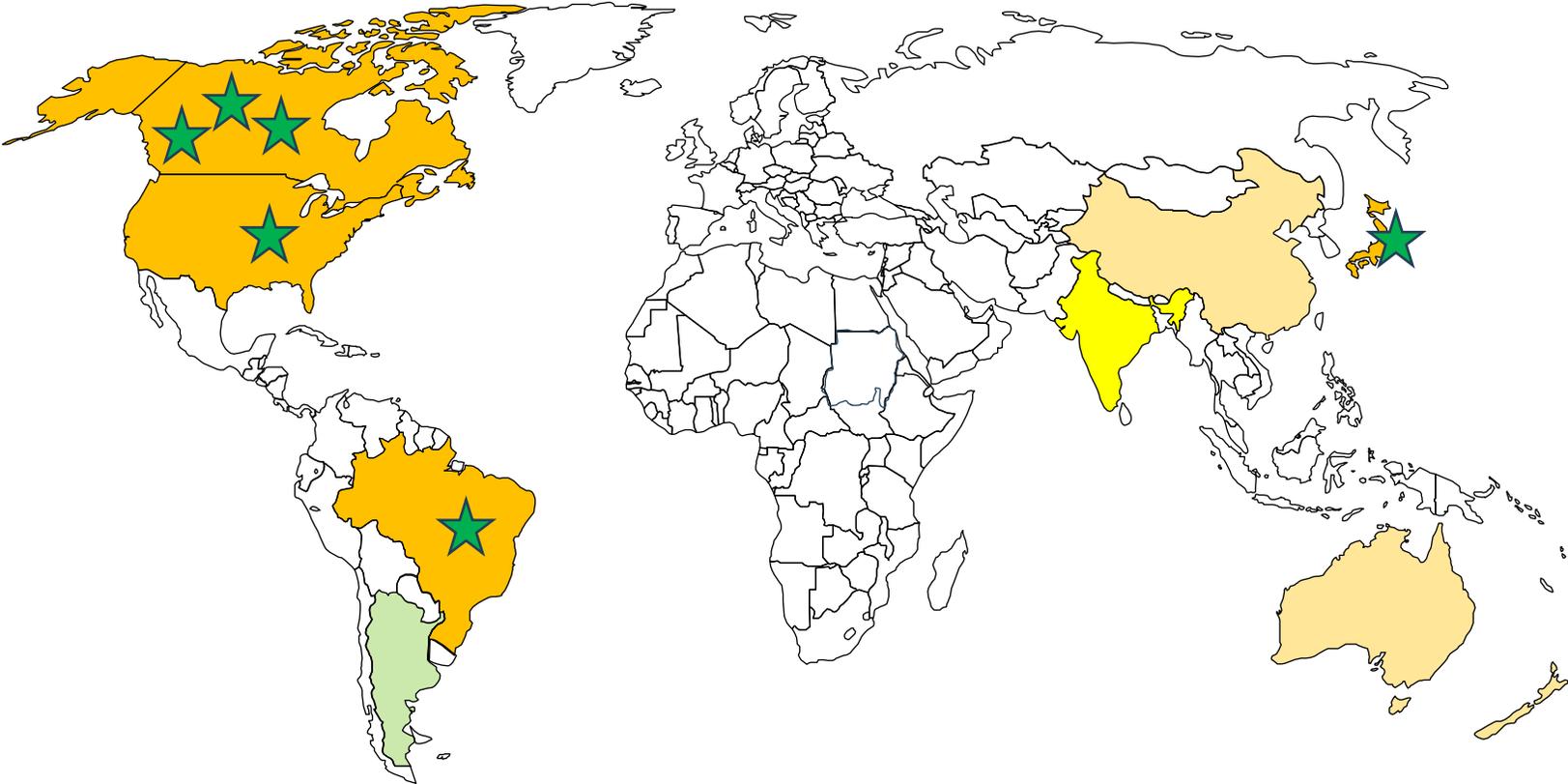
As of  
August 12, 2024

**19 Crops/137 Decisions**  
**1992-2020 (28 years)**  
*(most recent decision: 2023)*

**20 Crops/70 Decisions**  
**2021-Present (3 years)**  
*(97 Confirmation Letters; <5% Major Biotech)*

# Global Regulatory Landscape for Animal Biotechnology

2017  
United States  
Workshop

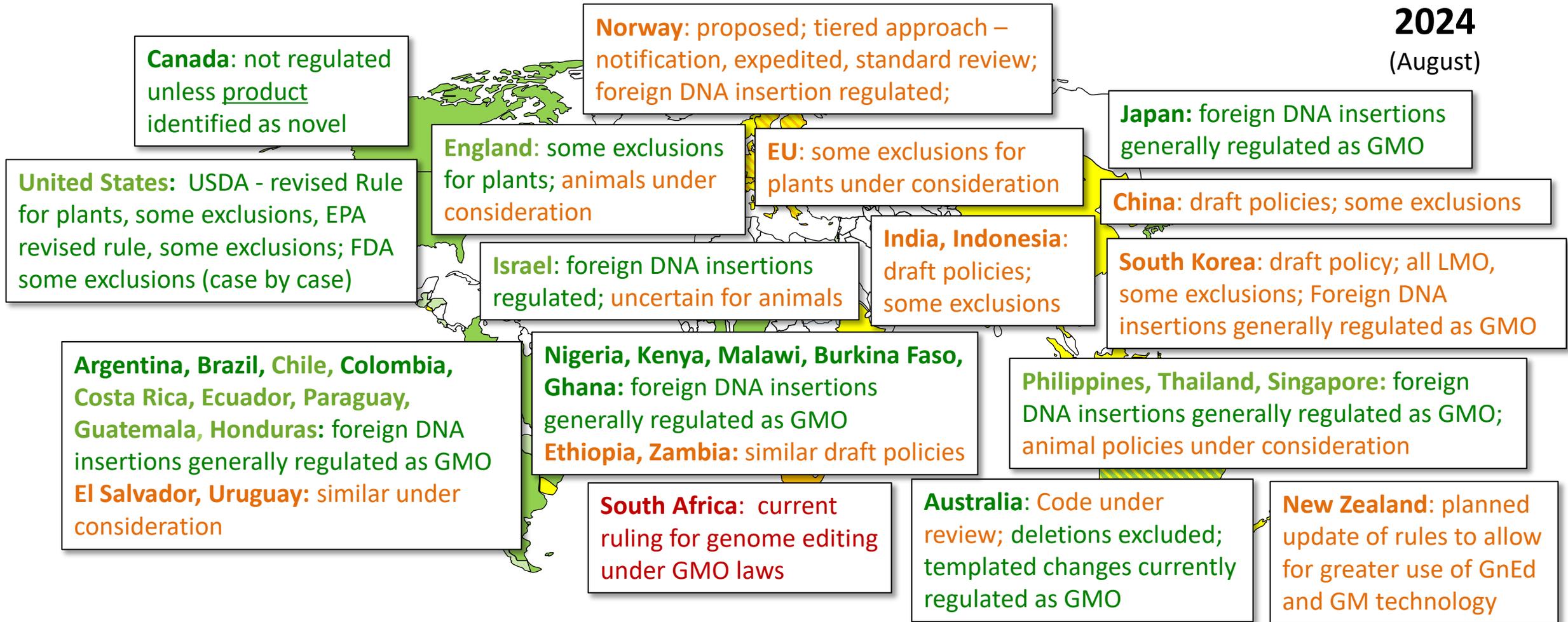


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# Global Regulatory Landscape for Products of Genome Editing

**2024**  
(August)



 Countries with regulatory policy with exclusions

 Countries with **pending** policies, regulations, or legal rulings

 Countries with GMO only policy with no exclusions

 Countries with regulatory policy with exclusions (plants only)

# Two Regulatory Scenarios:

## Opportunities Lost or Gained

Regulations and how they are applied or implemented . . .

Shape what products are developed and who can afford to use these new technologies

### **“No Exclusions” Approach (Status Quo – GMO Rules Apply)**

- Large multinational companies (plants)
- Developers from very few countries
- Dominated by row crops, high return traits
- Very few food animals
  - Unmet needs of conventional farmers
  - Many lost opportunities

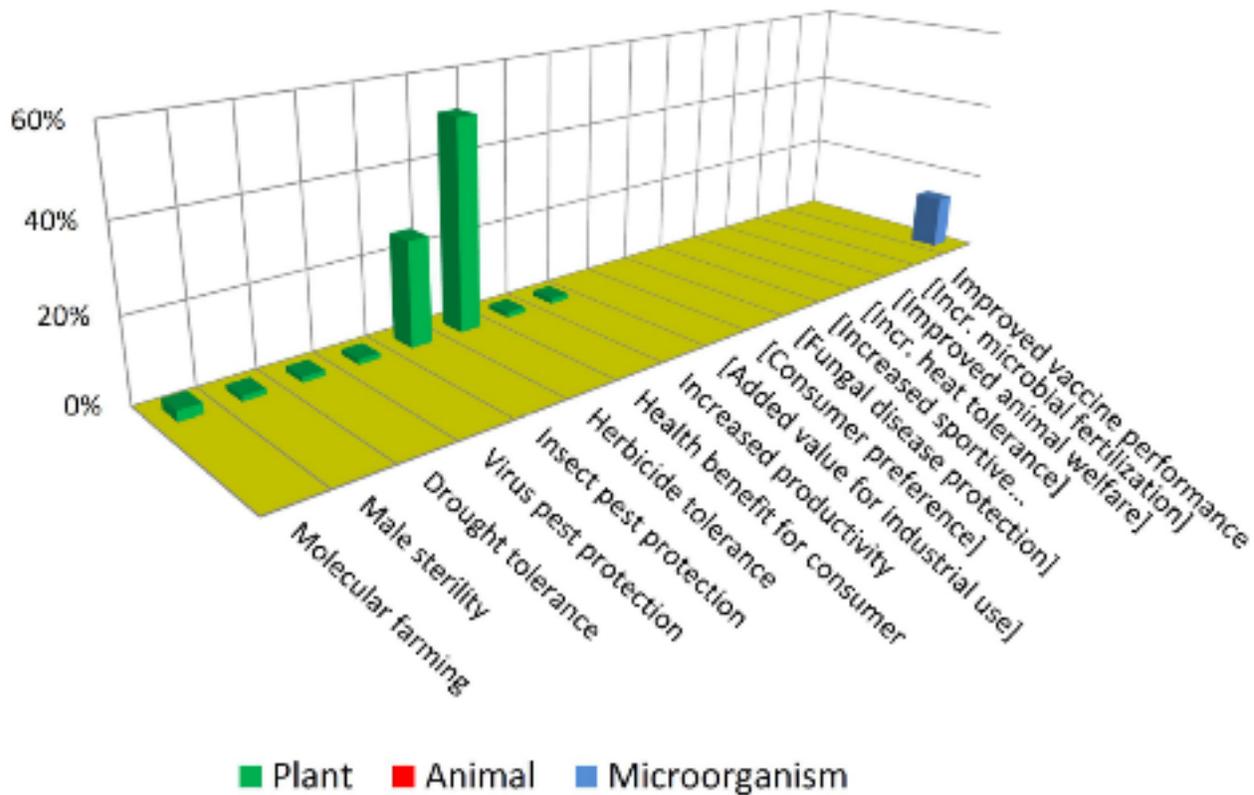
vs

### **“Exclusions” Approach (Some GmEd as “Conventional”)**

- Public research, small and medium enterprises (SMEs)
- More countries involved
- Livestock, fruits, vegetables, flowers
- Consumer oriented traits
- Quicker solutions to regional problems

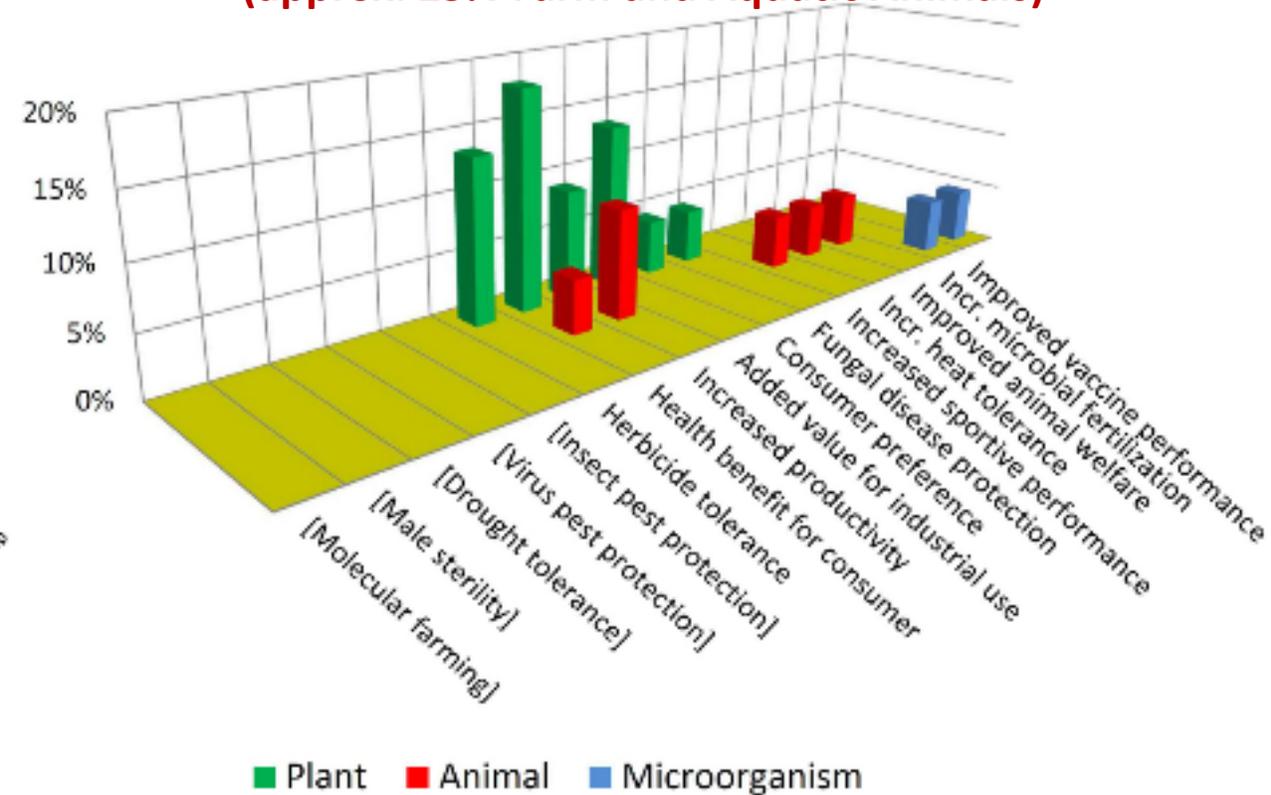
# Increased Diversity of Organisms & Traits (Argentina)

Novel traits in approved GMOs, by kingdom



Novel traits in NBT (non GMO) products, by kingdom

(approx. 25% Farm and Aquatic Animals)



# Two More Regulatory Scenarios:

## Opportunities Lost or Gained

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**“Product” Approach**  
(Status Quo)

**VS**

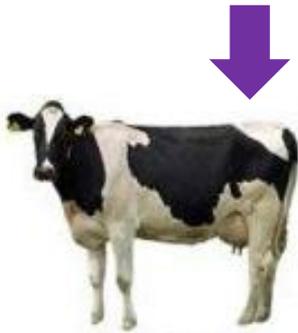
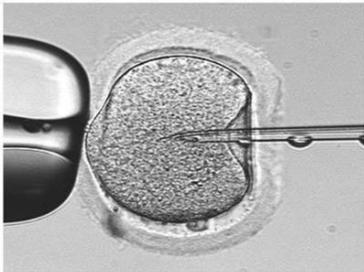
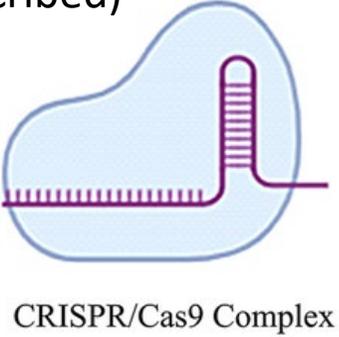
**“Breeding Tool” Approach**  
(New Breeding Opportunities)

How regulations are applied or implemented . . .

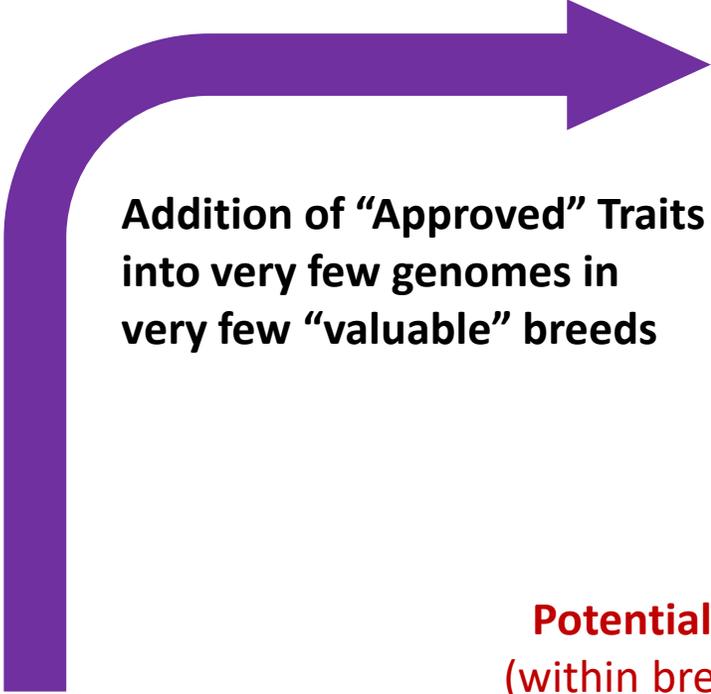
Impacts Other Protection Goals and ability to respond to threats to animal agriculture

# CREATION OF NEW PRODUCT

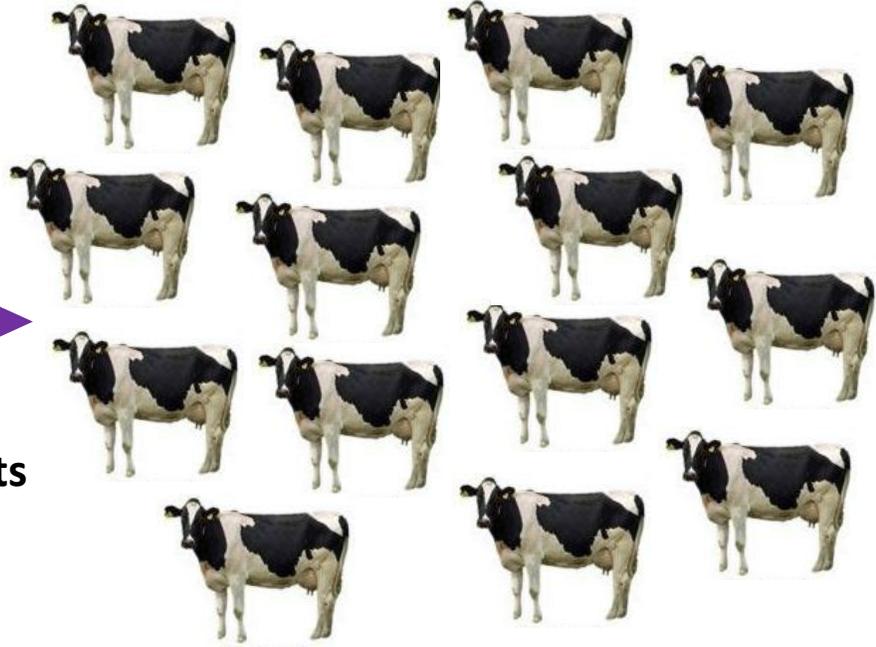
Traits "Approved" in individual animals on case-by-case basis (introduced via process described)



Multiply approved animal genetics



Addition of "Approved" Traits into very few genomes in very few "valuable" breeds

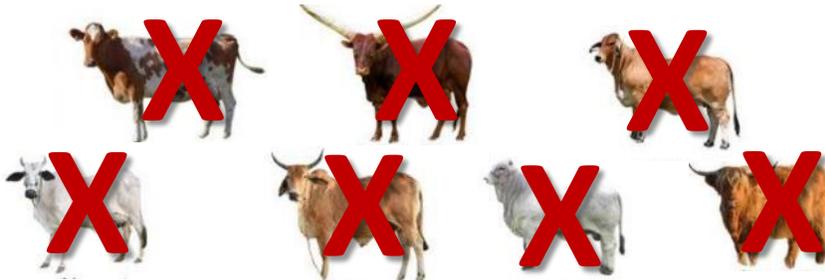


Large Companies Supply GnEd Genetics

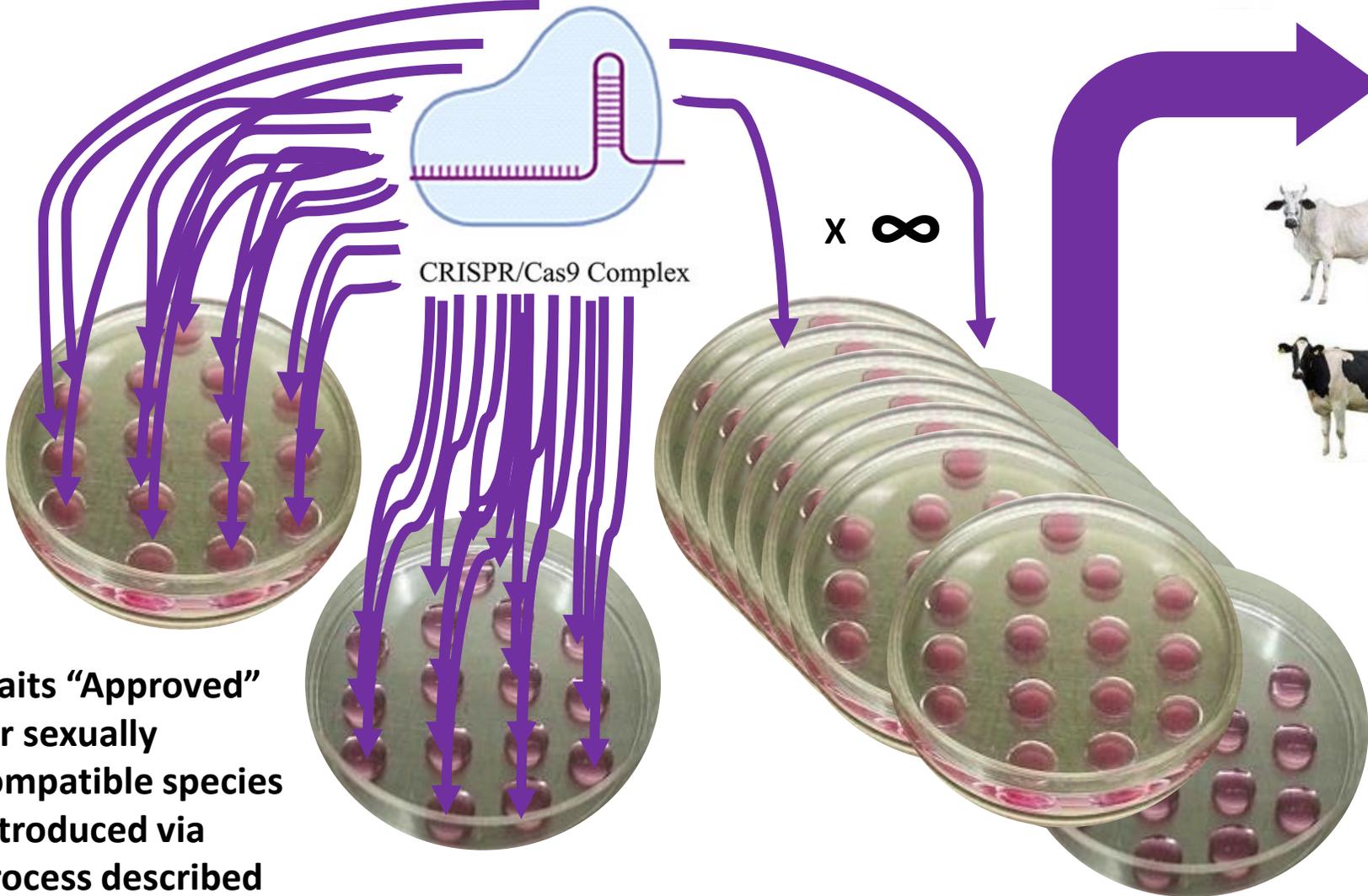
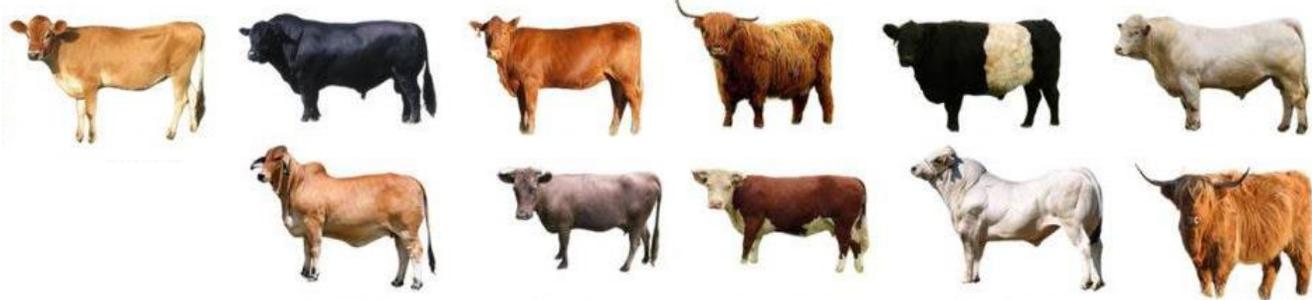
Potential Diversity Lost (within breed and species)



Trait not Available for Many Breeds



# NEW BREEDING TOOL

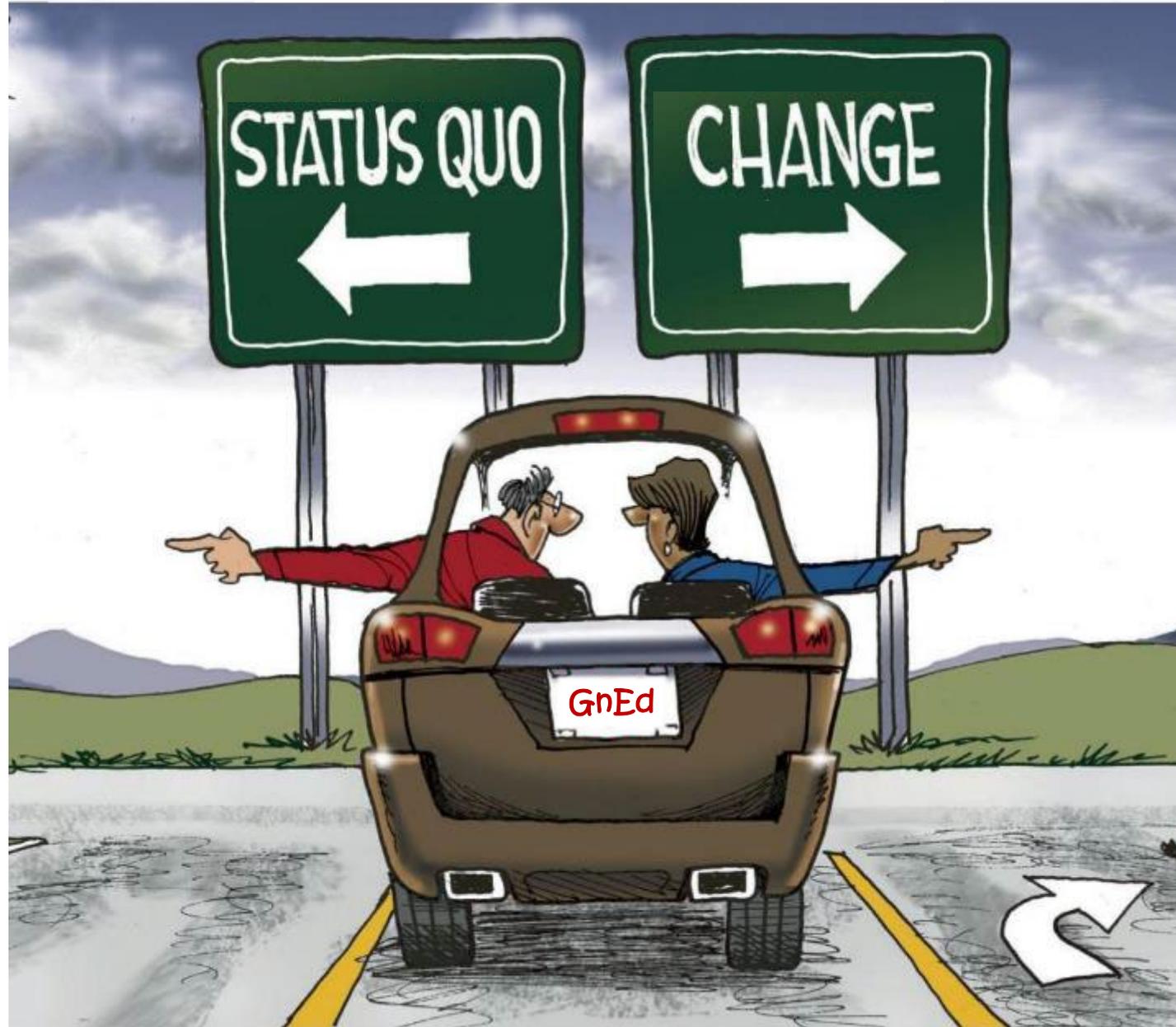


Addition of "Approved" Traits into any number of genomes in sexually compatible species

Traits "Approved" for sexually compatible species introduced via process described

- Diversity Protected
- Publicly Developed Traits Available to Farmers
- Threats Addressed More Quickly

# Regulatory Crossroads



**Thank you!**

**USDA**



[diane.wray-cahen@usda.gov](mailto:diane.wray-cahen@usda.gov)



“We’ve considered every potential risk except the risks of avoiding all risks.”





## Codex Alimentarius - FAO- WHO

Codex *ad hoc* intergovernmental task force on food derived from biotechnology (TFFBT)

Reference 	Title	Committee
CXG 44-2003	Principles for the Risk Analysis of Foods Derived from Modern Biotechnology	TFFBT
CXG 45-2003	Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants	TFFBT
CXG 46-2003	Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms	TFFBT
CXG 68-2008	Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals	TFFBT

# Impact of New “NBT” Regulatory Approach for Products of Genome Editing in Argentina

## OPPORTUNITY FOR NEW DEVELOPERS

