Global Regulatory Landscape for Animal Biotechnology: Agricultural Applications

February 2025

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

- 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 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 Recombiant-DNA Microorganisms	TFFBT
CXG 68-2008	Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals	TFFBT

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*

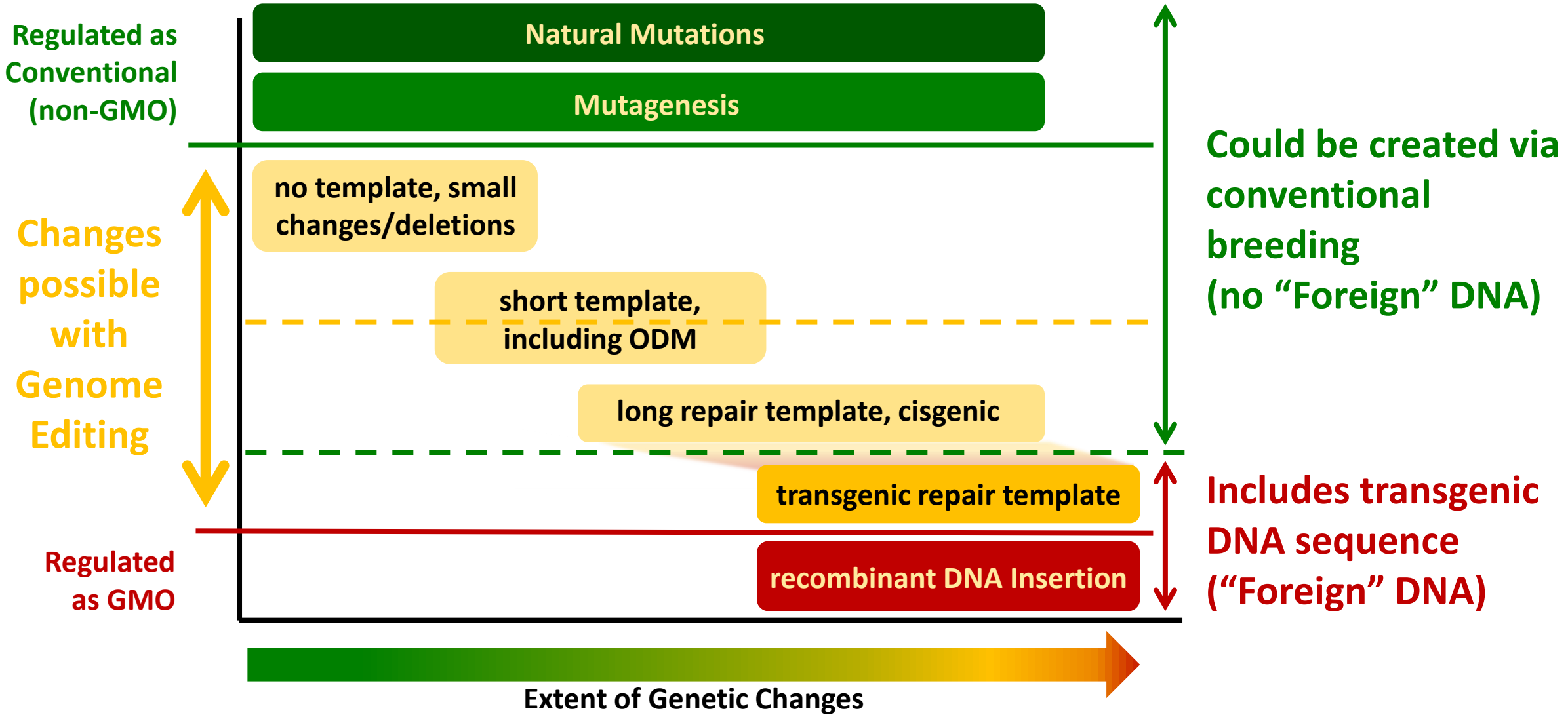
* Guideline does *not* address animal welfare; ethical, moral, and socioeconomic aspects; environmental risks. It also does not address "efficacy" of the trait, but does address impact of any antibiotic marker genes on therapeutic efficacy of orally administered antibiotics.


Changing Scientific &
Regulatory Landscapes

Modernizing Regulatory Approaches

- 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

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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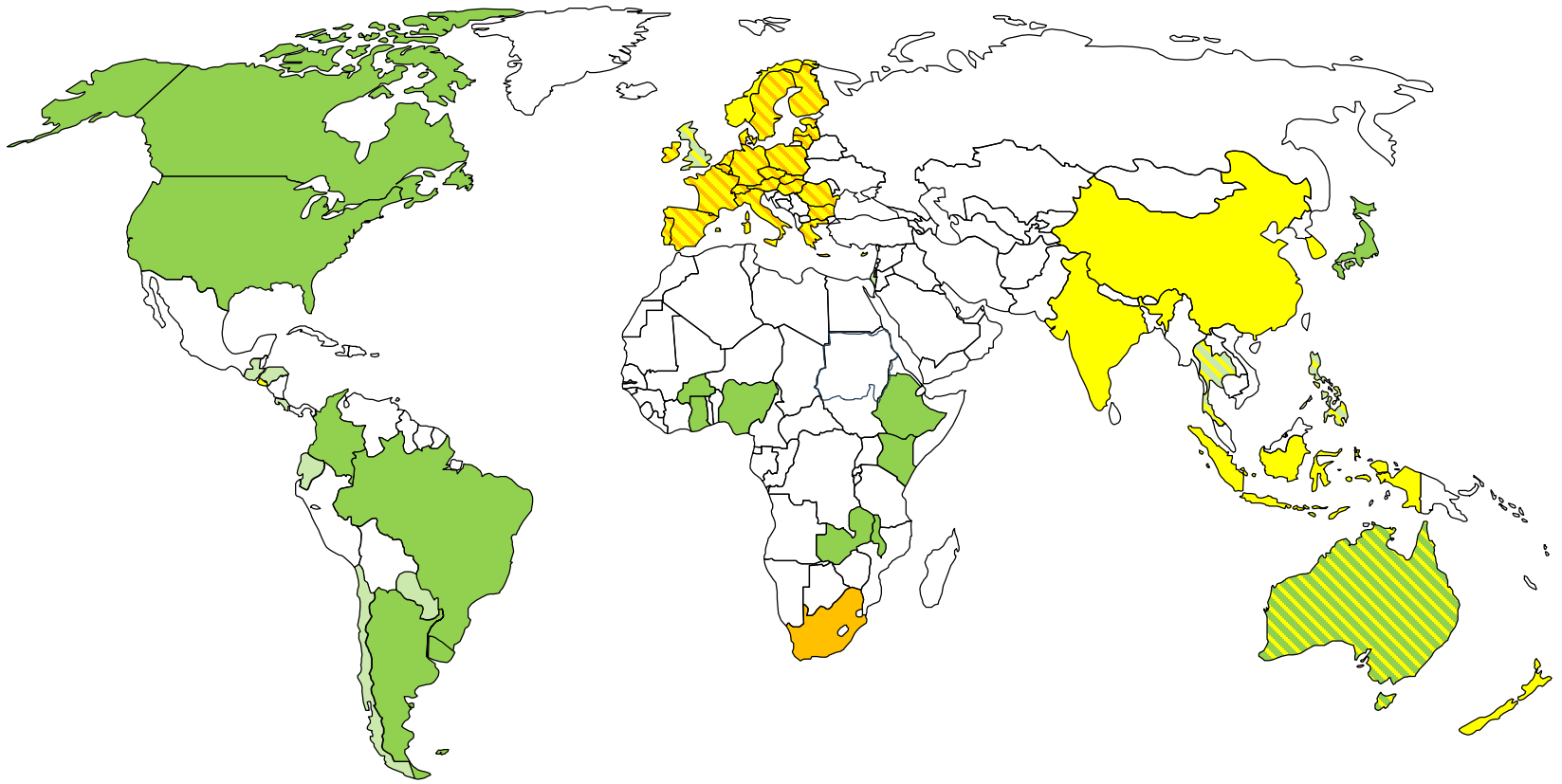
Global Regulatory Landscape for Products of Genome Editing



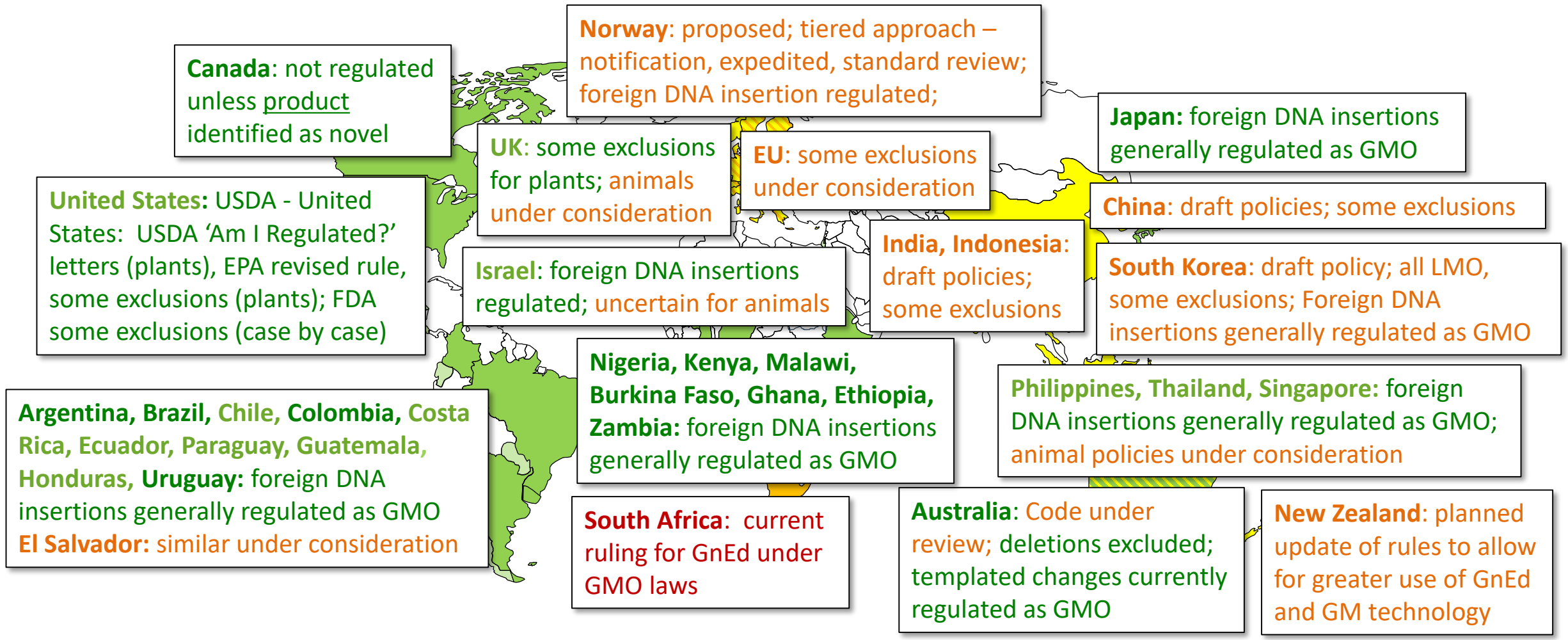
Countries with regulatory policy with exclusions

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

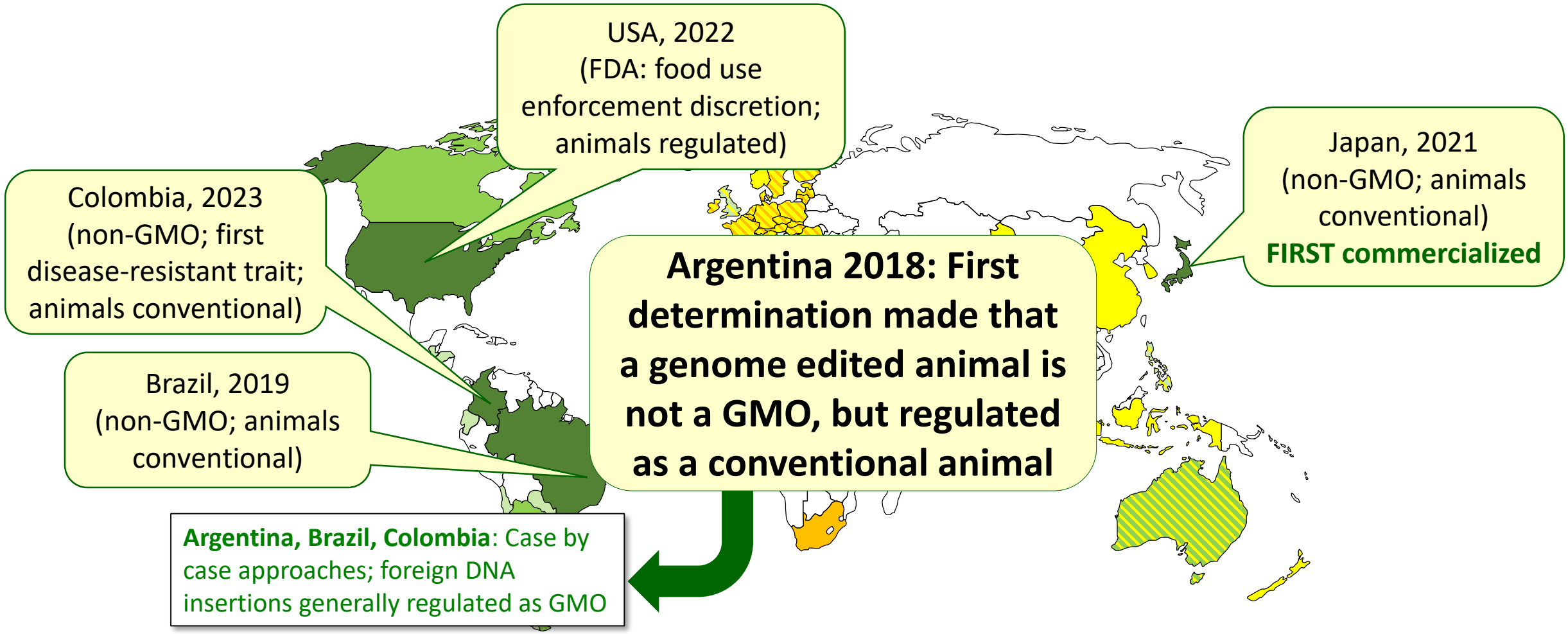
Countries with GMO only policy with no exclusions

Countries with regulatory policy with exclusions (plants only)

Global Regulatory Landscape for Products of Genome Editing



Countries are Moving Forward with Path for GnEd Animal Commercialization



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

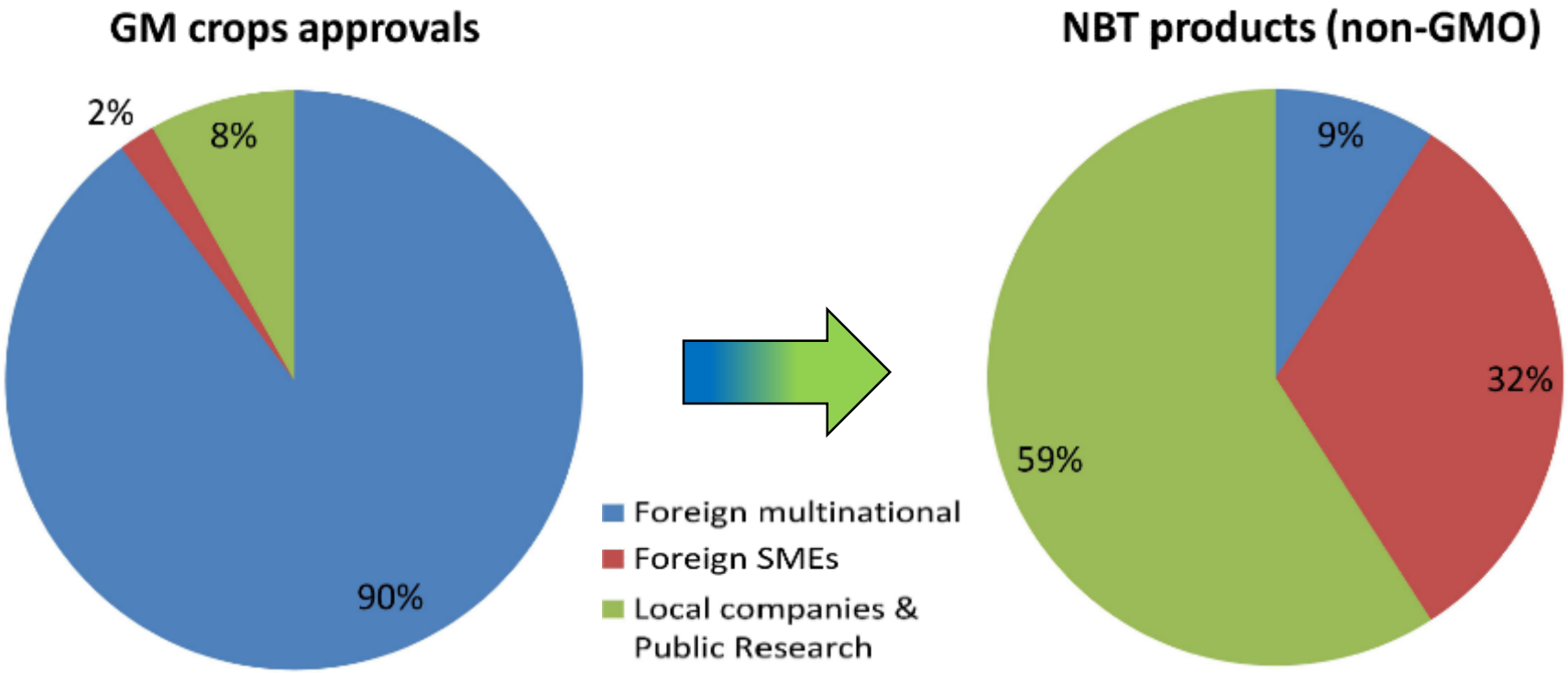
vs

"Exclusions" Approach
(Some GnEd as "Conventional")

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

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

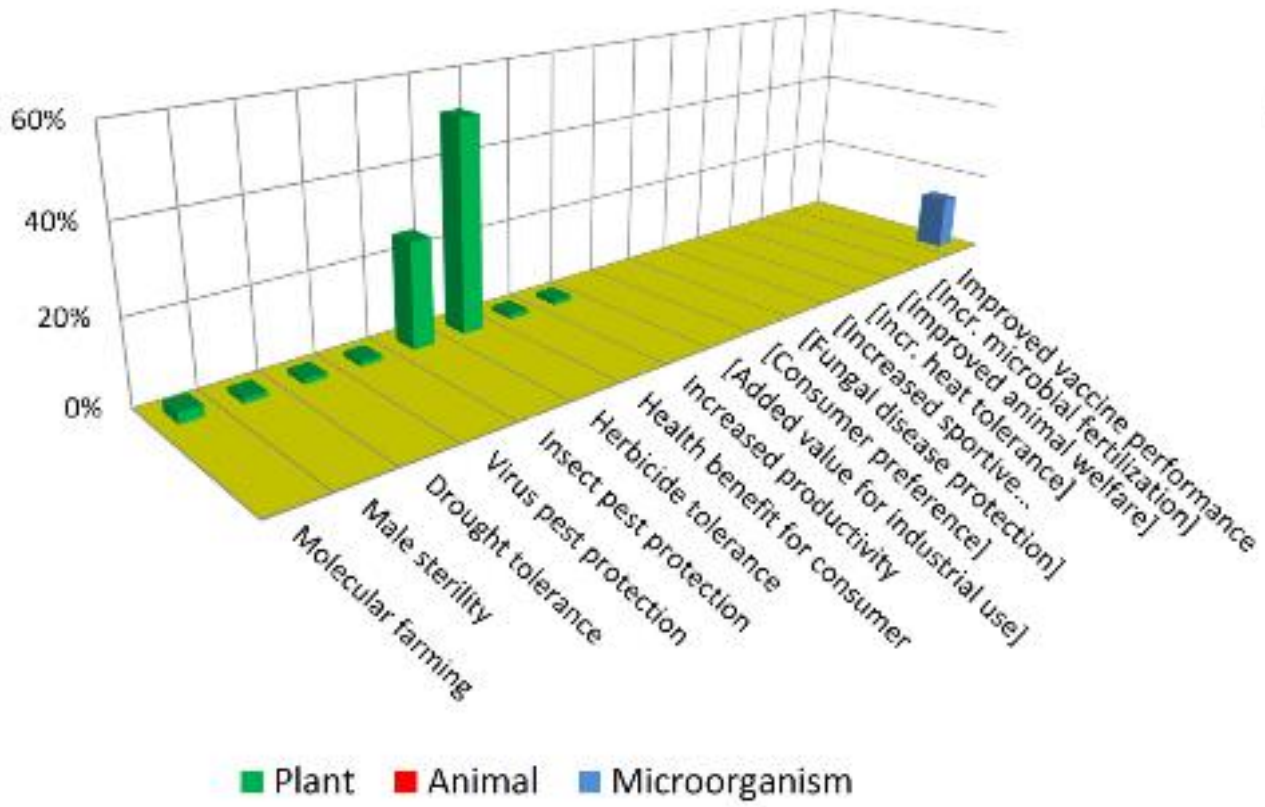
OPPORTUNITY FOR NEW DEVELOPERS



A Whelan, P Gutti, M Lema. 2020. Gene Editing Regulation and Innovation Economics. Front. Bioeng. Biotechnol., 8:303.

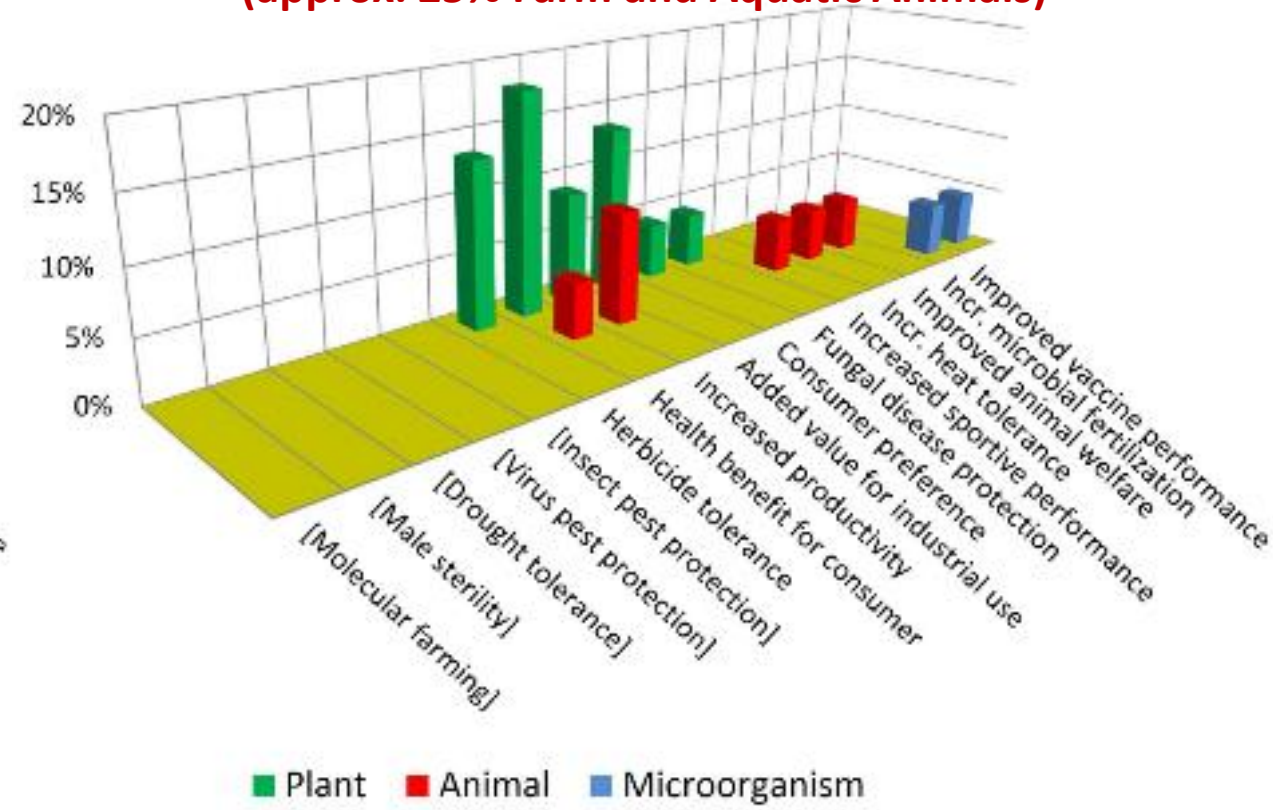
Increased Diversity of Organisms & Traits (Argentina)

Novel traits in approved GMOs, by kingdom



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

(approx. 25% Farm and Aquatic Animals)



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Two More Regulatory Scenarios:

Opportunities Lost or Gained

“Product” Approach
(Status Quo)

vs

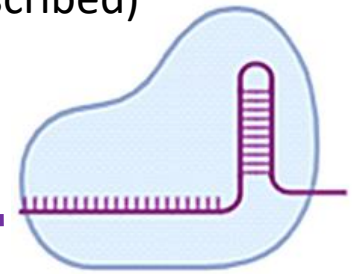
“Breeding Tool” Approach
(New Breeding Opportunities)

How regulations are applied or implemented . . .

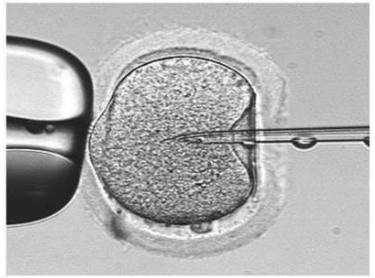
Impacts Other Protection Goals and ability to respond to threats to animal agriculture

CREATION OF NEW PRODUCT

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

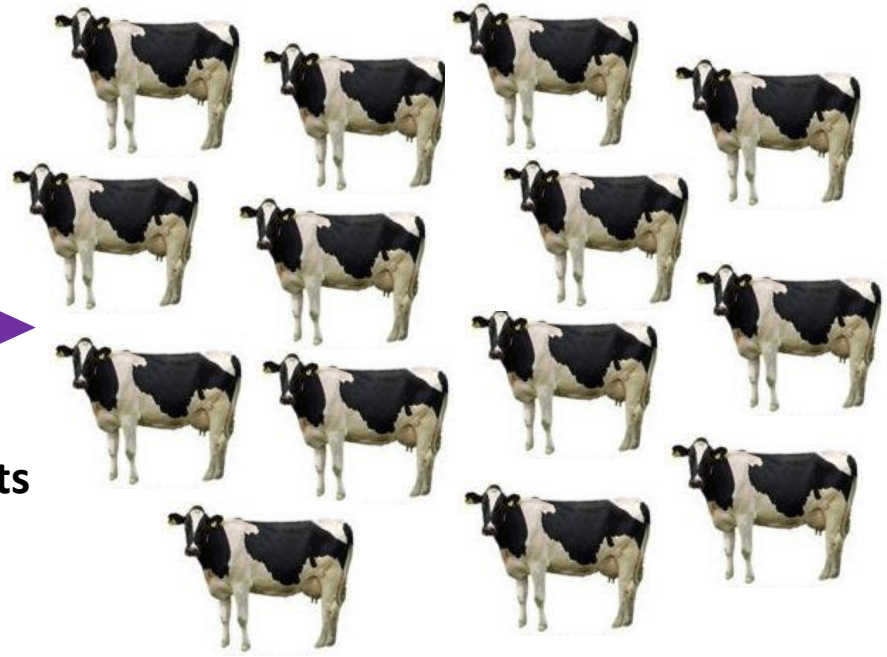


CRISPR/Cas9 Complex



Multiply approved animal genetics

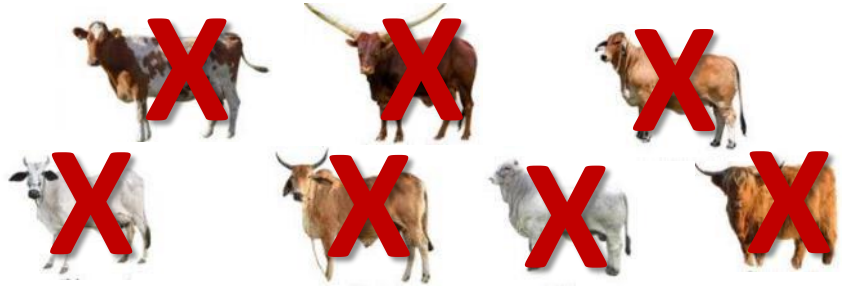
Addition of "Approved" Traits into very few genomes in very few "valuable" breeds



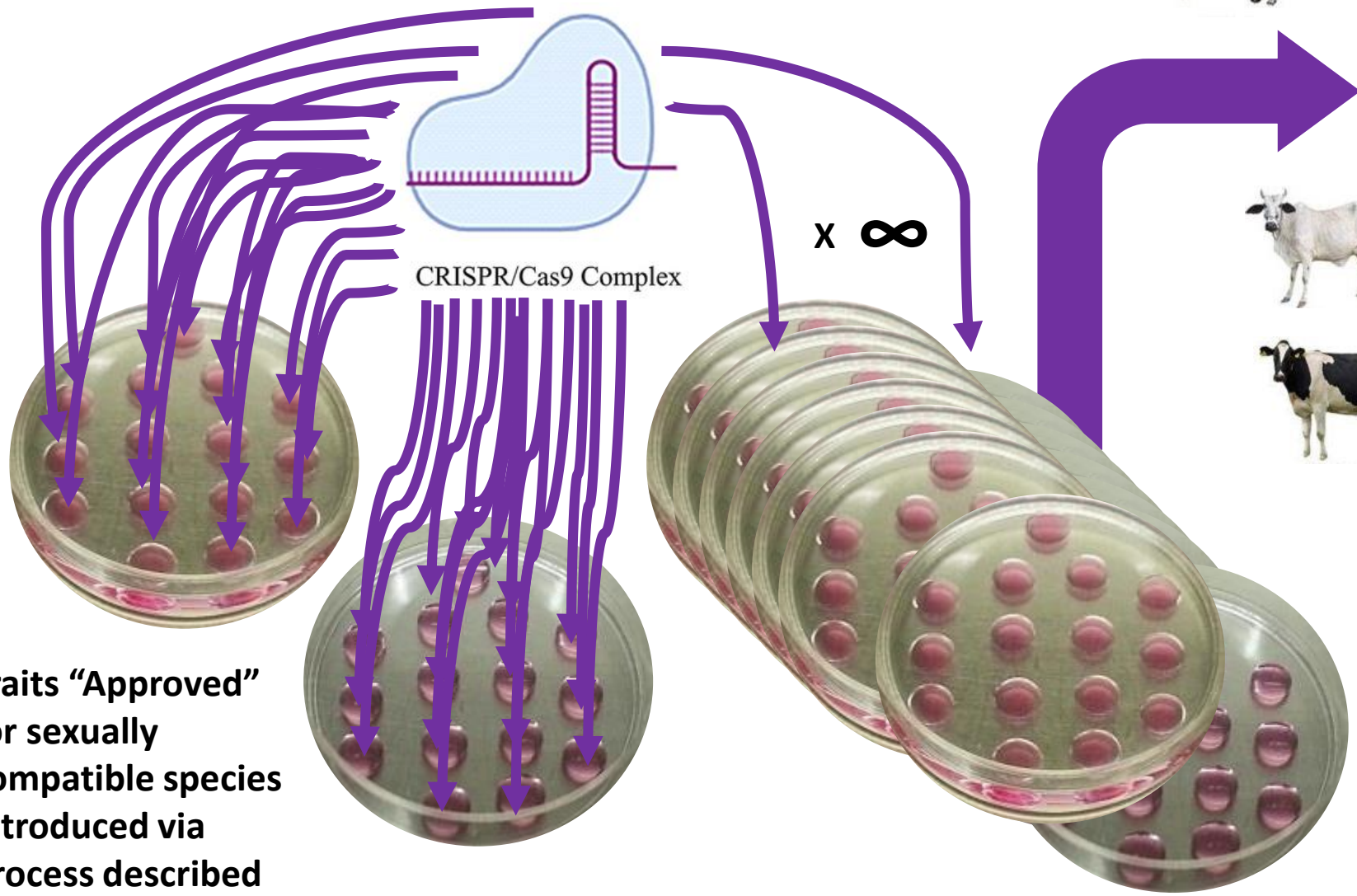
Large Companies Supply GnEd Genetics

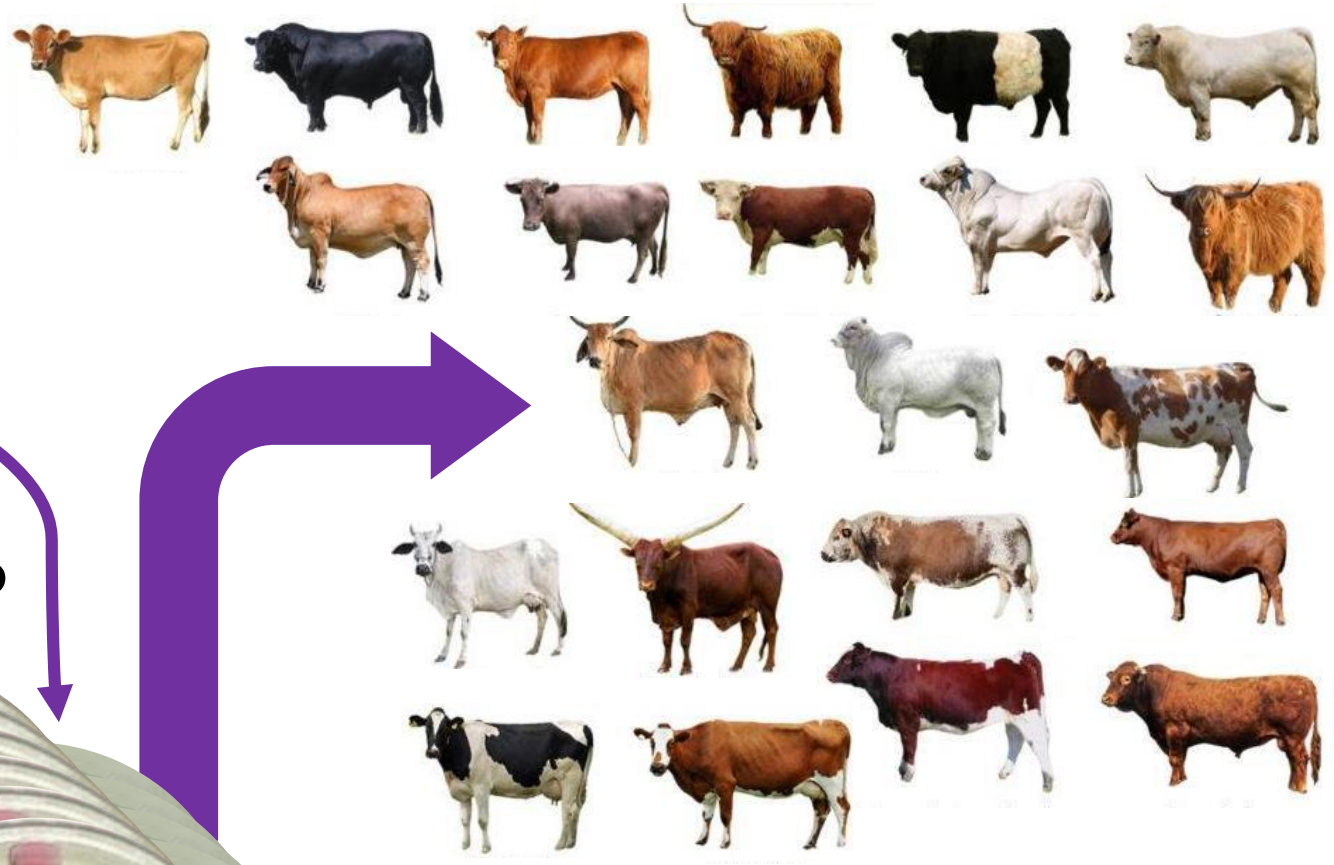
Potential Diversity Lost
(within breed and species)

Trait not Available for Many Breeds



NEW BREEDING TOOL





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

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

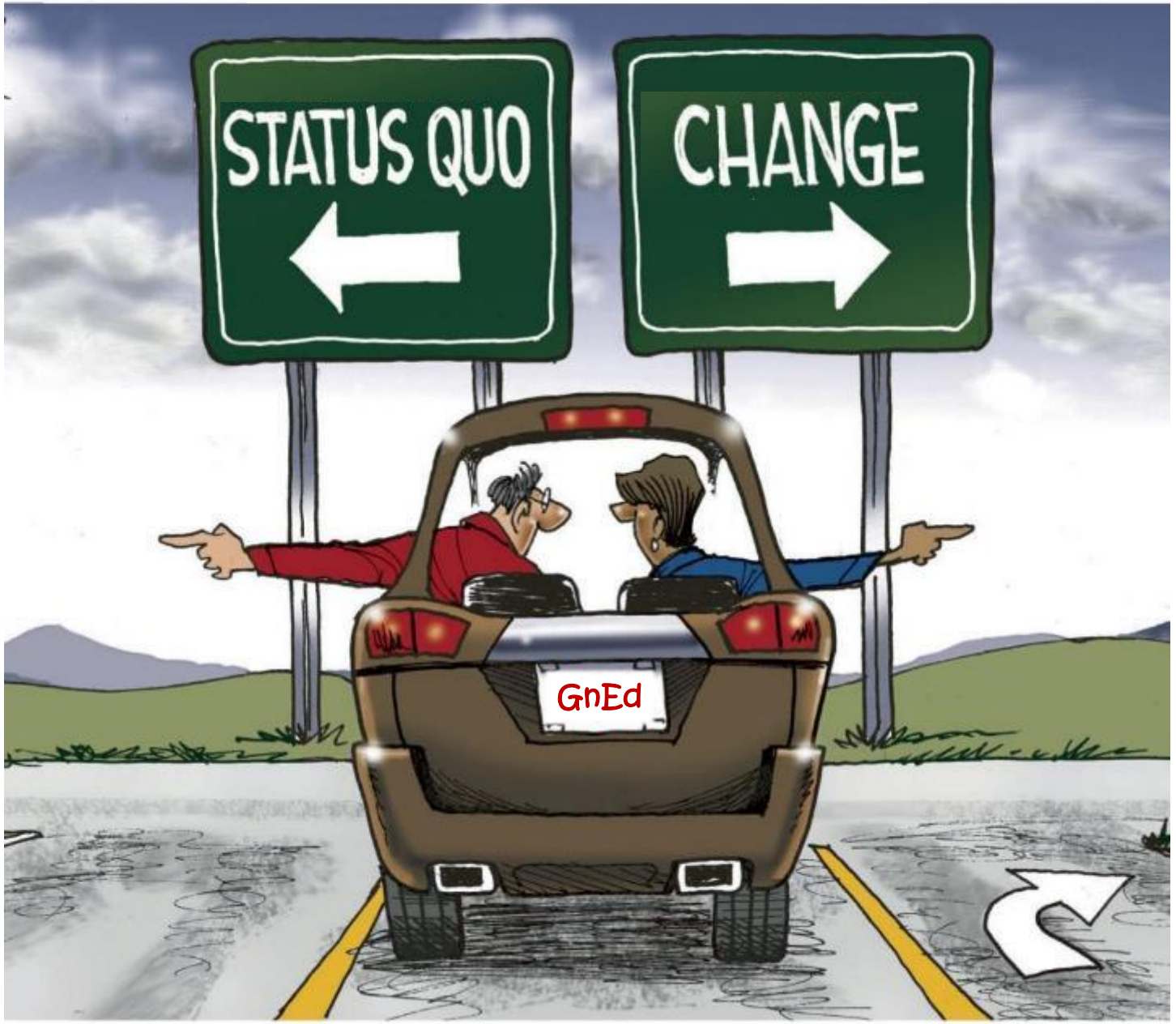
Diversity Protected

Publicly Developed Traits Available to Farmers

Threats Addressed More Quickly

Product Based, Science-Based, Risk Proportionate

Regulatory Crossroads



Risk in Context . . . Balance

Consider Future Impacts of Regulatory Approaches on Other Types of Protection Goals

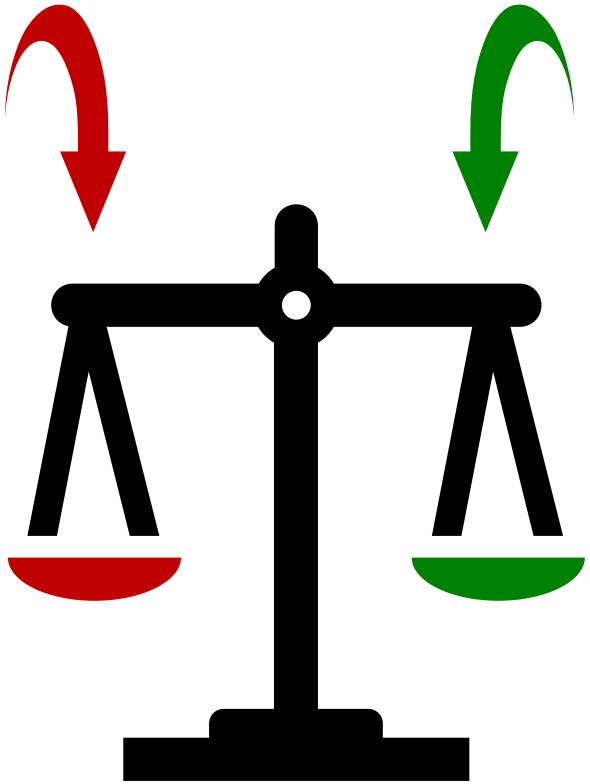
Potential Risk of Approving

Food Safety Risk of Meat from Healthy Animal?

Food Safety Risk of Milk from Healthy Animal?

Risk to Animal Health?

Increased Risk to Environment from Farm Animal?



Potential Benefit of Approving

Disease Prevention

Reduced Zoonoses

Reduce Antibiotic Use

Improve Animal Welfare

Climate Change Adaptation

Reduce Impact on Environment

Usually Not Considered: What is the Risk of NOT "Approving"?

Regulatory approaches should enable **safe products to reach the market**.

Encourage development of new ideas and innovations

Provide farmers with the **choice** of best selection of tools to better meet the challenges of the future more sustainably

Thank you!