



Global Regulatory Landscape for Animal Biotechnology: Agricultural Applications

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August 2024

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 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*

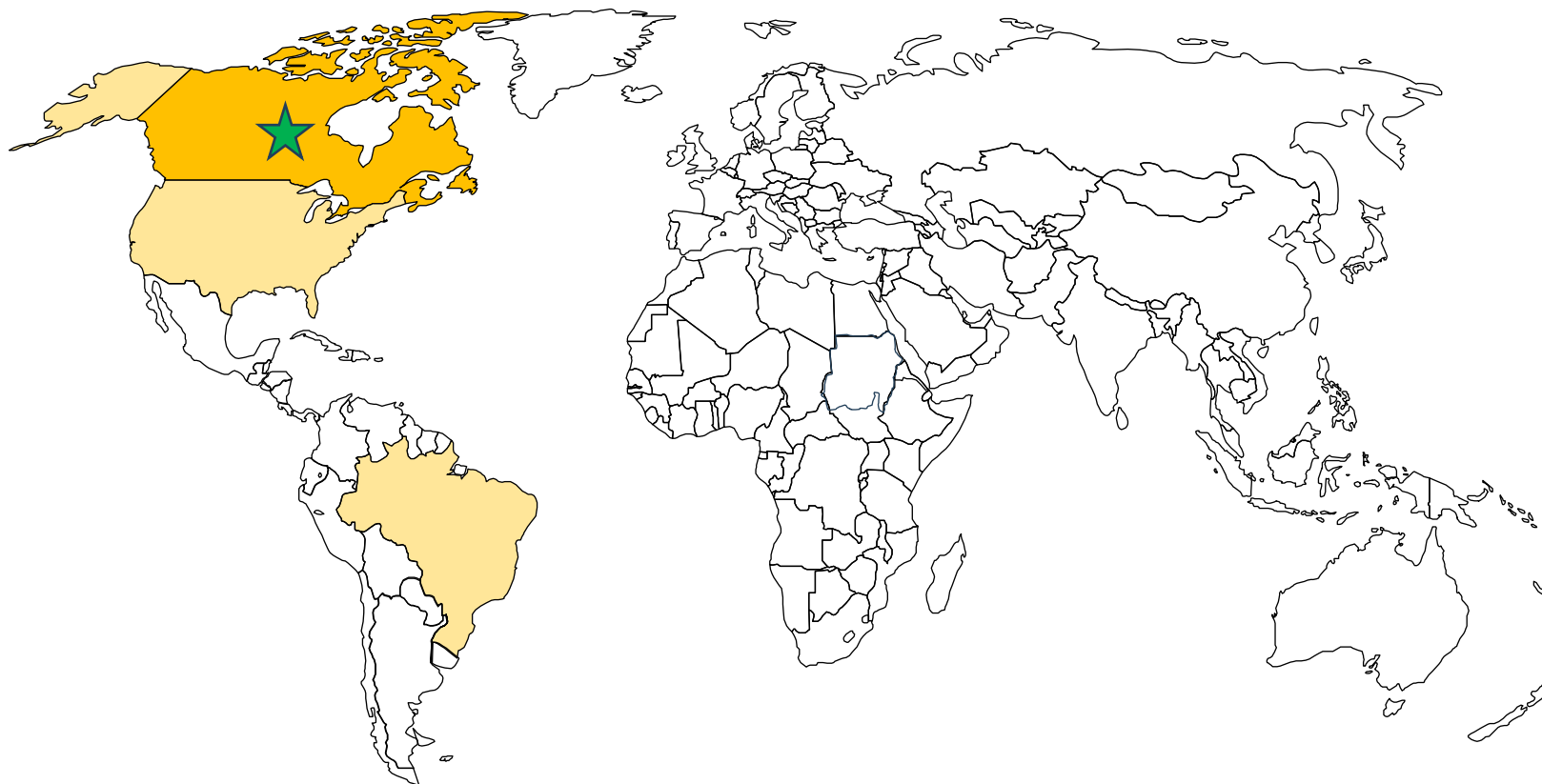


* Guideline does *not* address animal welfare; ethical, moral, and socioeconomic aspects; environmental risks. It also does not address “efficacy” of the trait, but does address impact of any antibiotic marker genes on therapeutic efficacy of orally administered antibiotics.

Global Regulatory Landscape for Animal Biotechnology

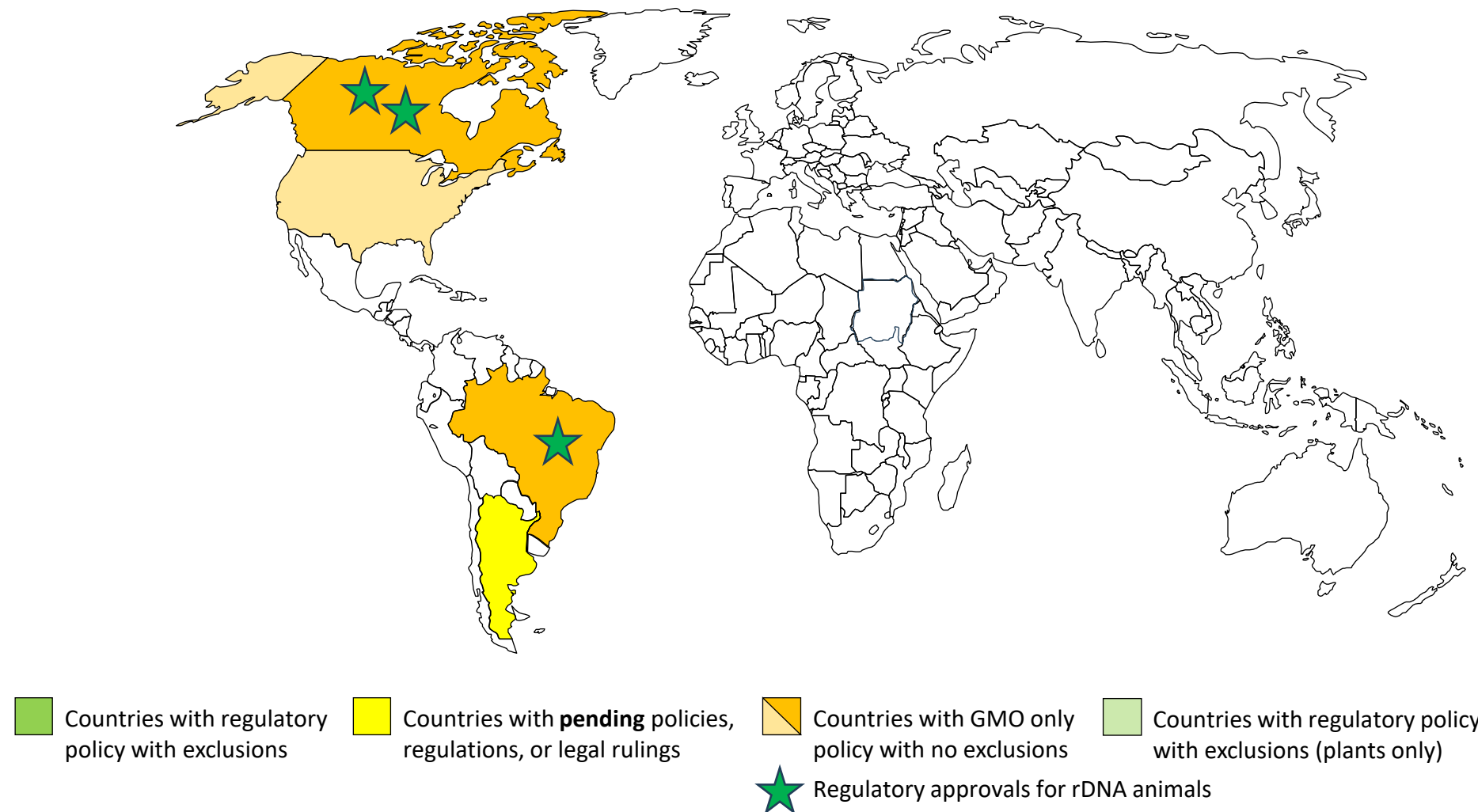
2011


Argentina
Workshop



Global Regulatory Landscape for Animal Biotechnology

2014
Brazil
Workshop



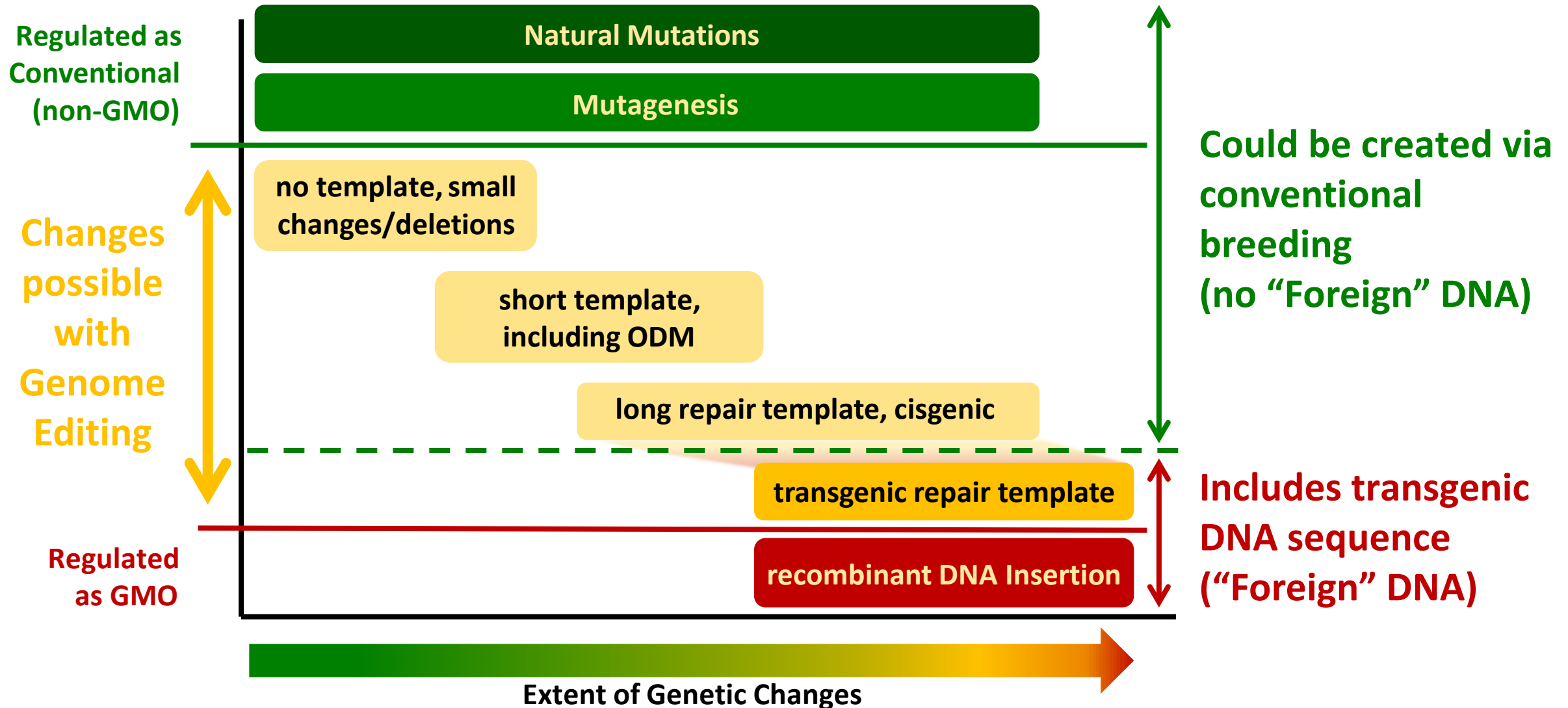


Changing Scientific & Regulatory Landscapes

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;

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;

AND ALSO

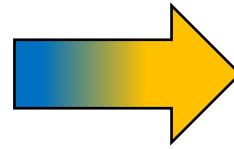
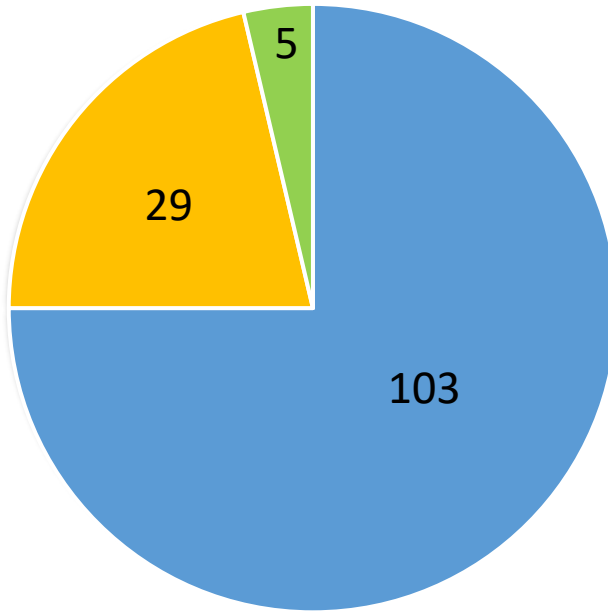


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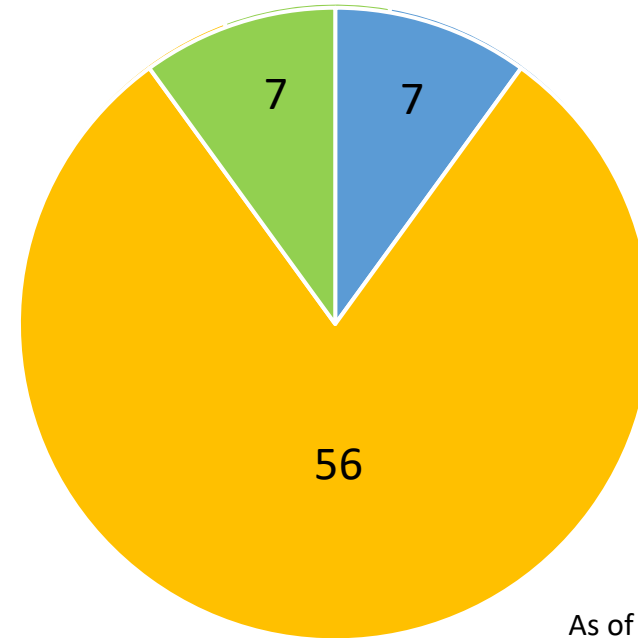
Impact of APHIS Regulatory Status Review Process

Completed Petitions



- Major Biotech
- Other Companies
- Public

Regulatory Status Reviews (RSR)



As of
August 12, 2024

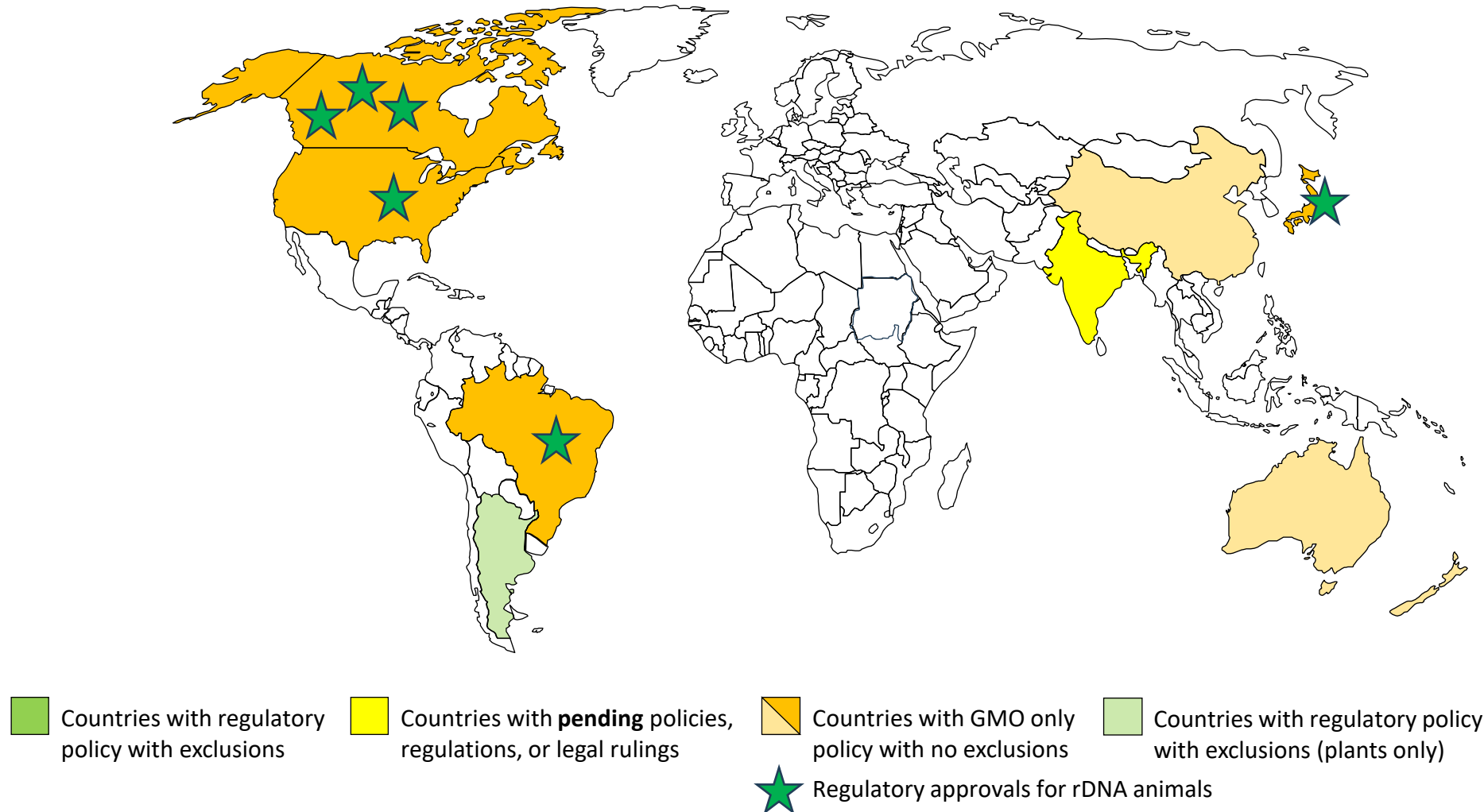
19 Crops/137 Decisions
1992-2020 (28 years)
(most recent decision: 2023)

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

Global Regulatory Landscape for Animal Biotechnology

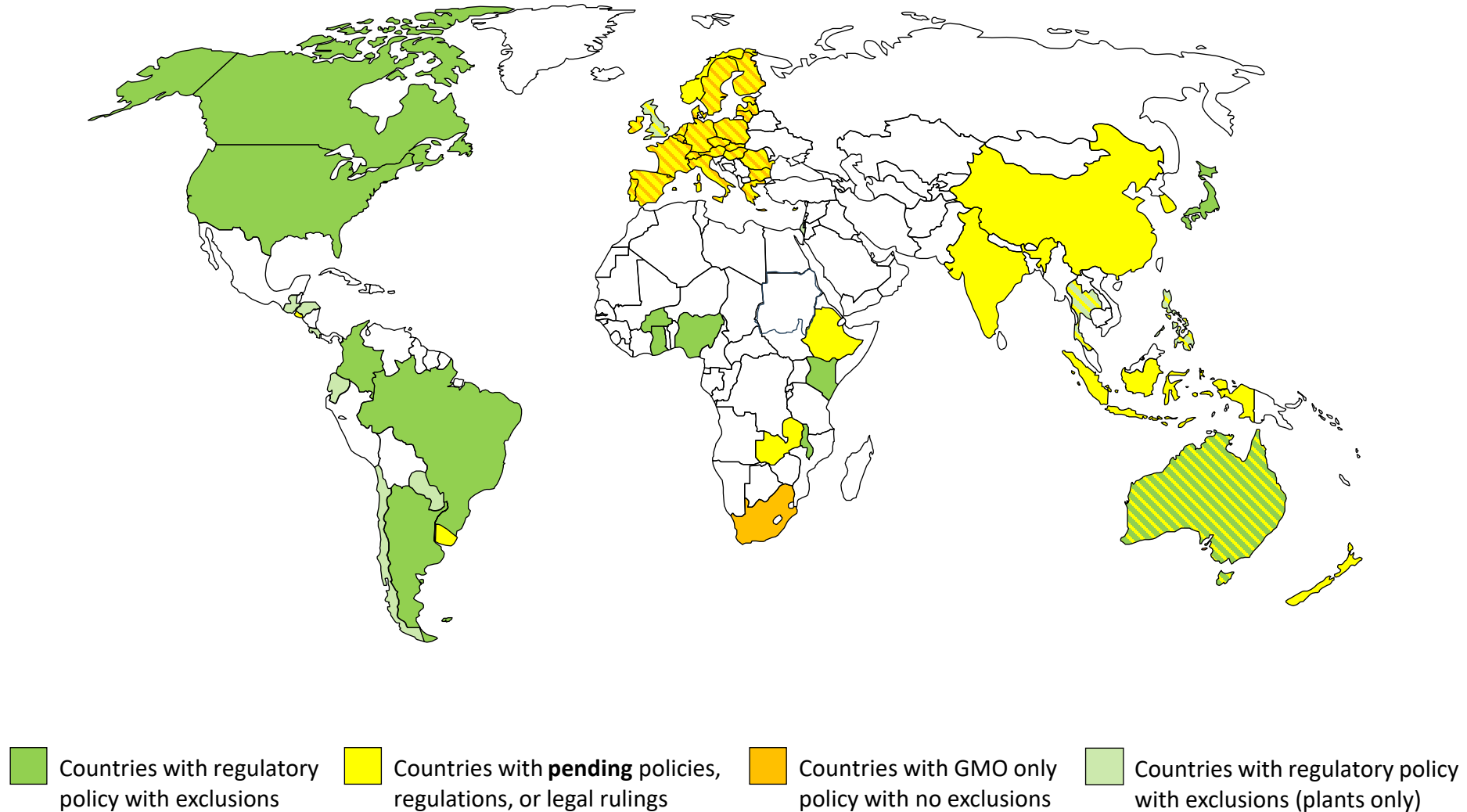
2017

United States
Workshop



Global Regulatory Landscape for Products of Genome Editing

2024
(August)



Global Regulatory Landscape for Products of Genome Editing

2024
(August)

Canada: not regulated unless product identified as novel

United States: USDA - revised Rule for plants, some exclusions, EPA revised rule, some exclusions; FDA some exclusions (case by case)

England: some exclusions for plants; animals under consideration

Norway: proposed; tiered approach – notification, expedited, standard review; foreign DNA insertion regulated;

EU: some exclusions for plants under consideration

Japan: foreign DNA insertions generally regulated as GMO

China: draft policies; some exclusions

Israel: foreign DNA insertions regulated; uncertain for animals

India, Indonesia: draft policies; some exclusions

South Korea: draft policy; all LMO, some exclusions; Foreign DNA insertions generally regulated as GMO

Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Paraguay, Guatemala, Honduras: foreign DNA insertions generally regulated as GMO
El Salvador, Uruguay: similar under consideration


Nigeria, Kenya, Malawi, Burkina Faso, Ghana: foreign DNA insertions generally regulated as GMO
Ethiopia, Zambia: similar draft policies


Philippines, Thailand, Singapore: foreign DNA insertions generally regulated as GMO; animal policies under consideration


South Africa: current ruling for genome editing under GMO laws


Australia: Code under review; deletions excluded; templated changes currently regulated as GMO

New Zealand: planned update of rules to allow for greater use of G_nEd and GM technology

 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)**

vs

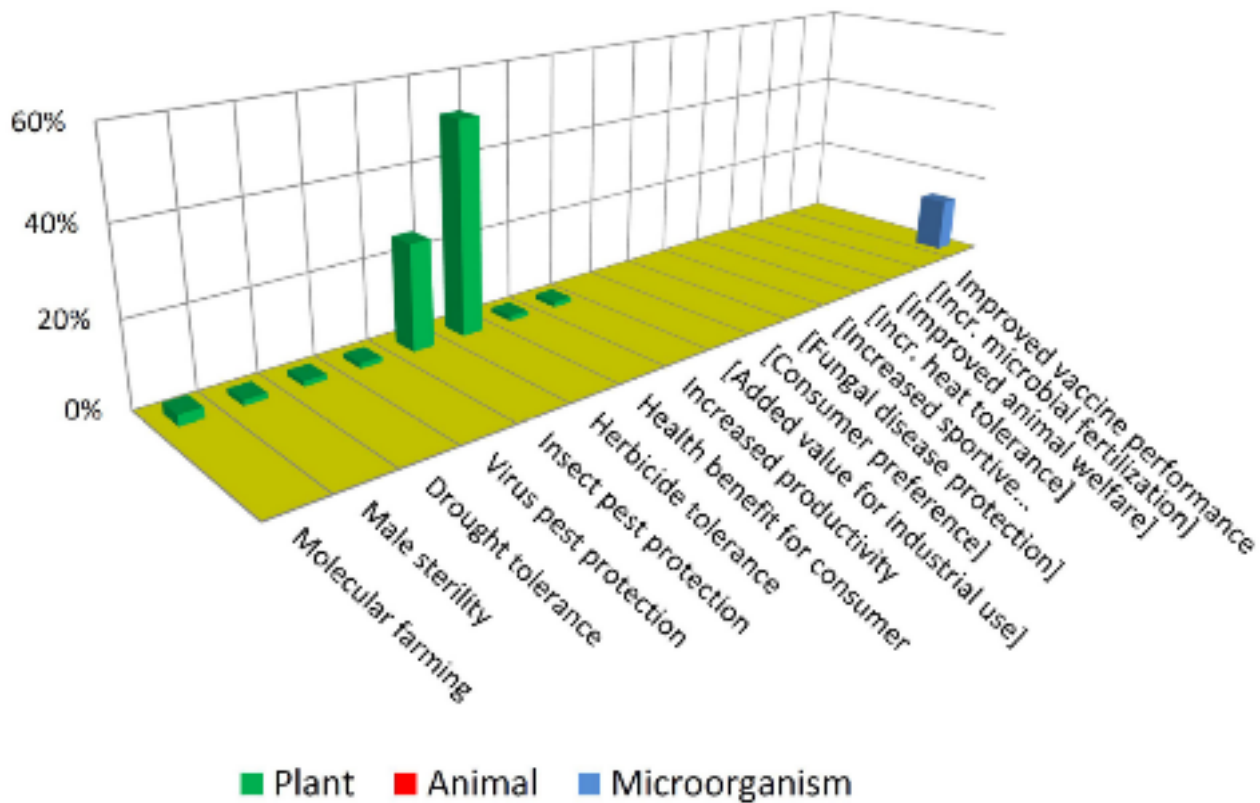
“Exclusions” Approach **(Some GnEd as “Conventional”)**

- 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

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

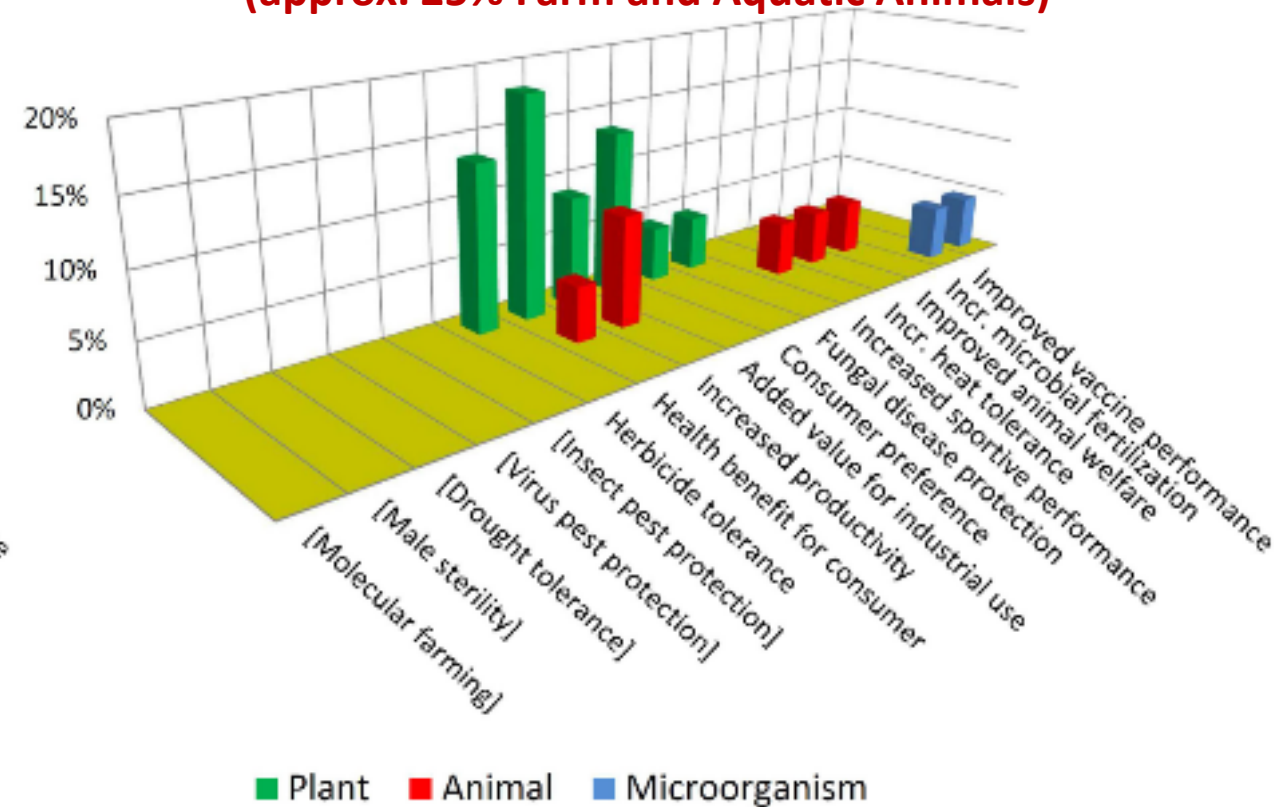
Increased Diversity of Organisms & Traits (Argentina)

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

“Product” Approach
(Status Quo)

VS

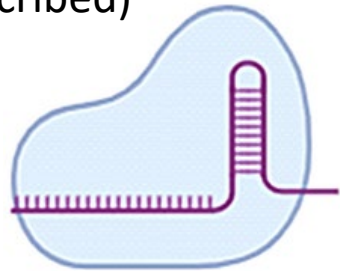
“Breeding Tool” Approach
(New Breeding Opportunities)

How regulations are applied or implemented . . .

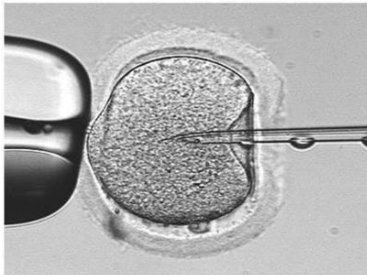
Impacts Other Protection Goals and ability to respond to threats to animal agriculture

CREATION OF NEW PRODUCT

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



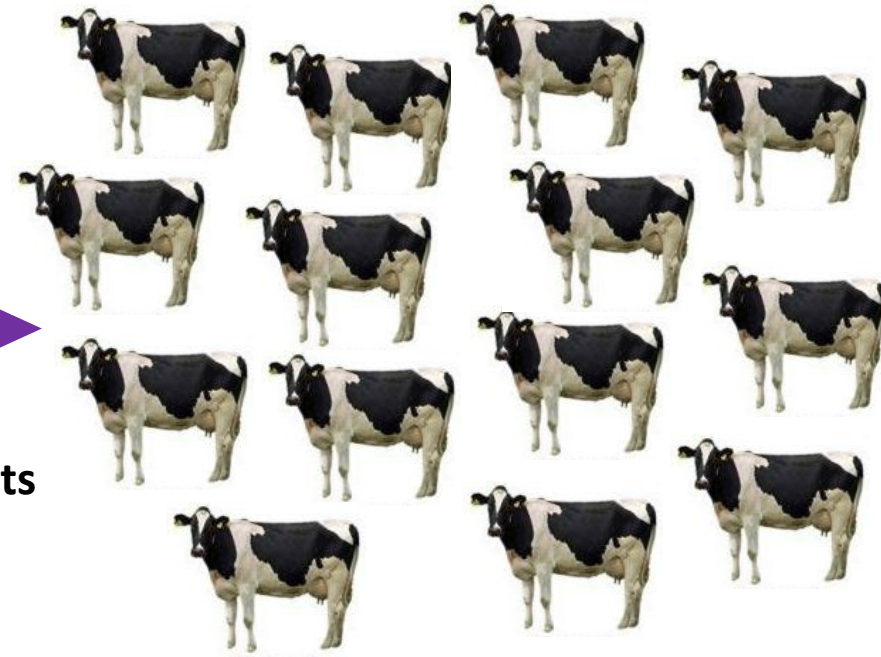
CRISPR/Cas9 Complex



Multiply approved
animal genetics



Addition of “Approved” Traits
into very few genomes in
very few “valuable” breeds

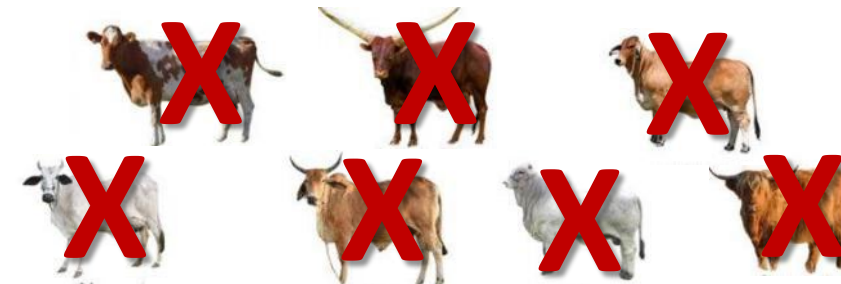


Large Companies Supply GnEd Genetics

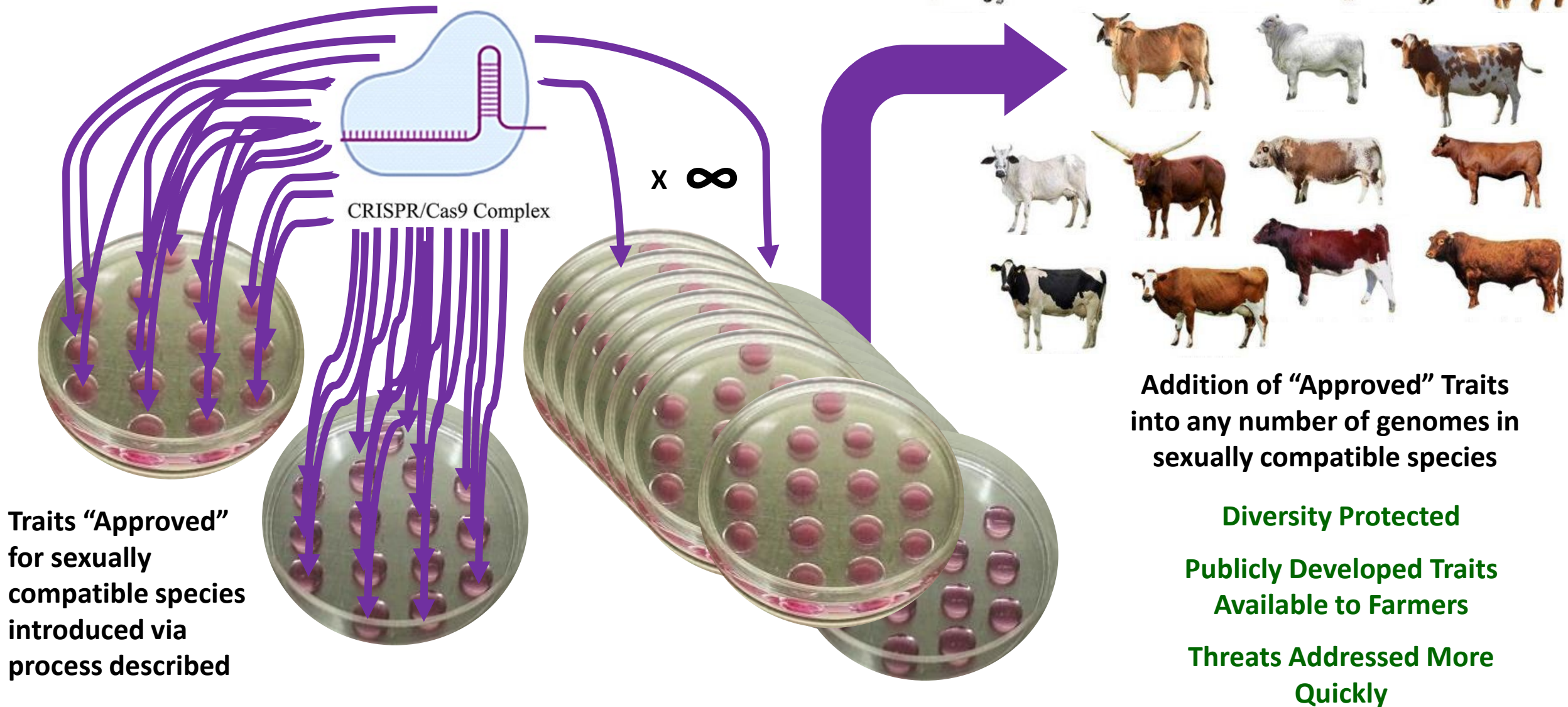
Potential Diversity Lost
(within breed and species)



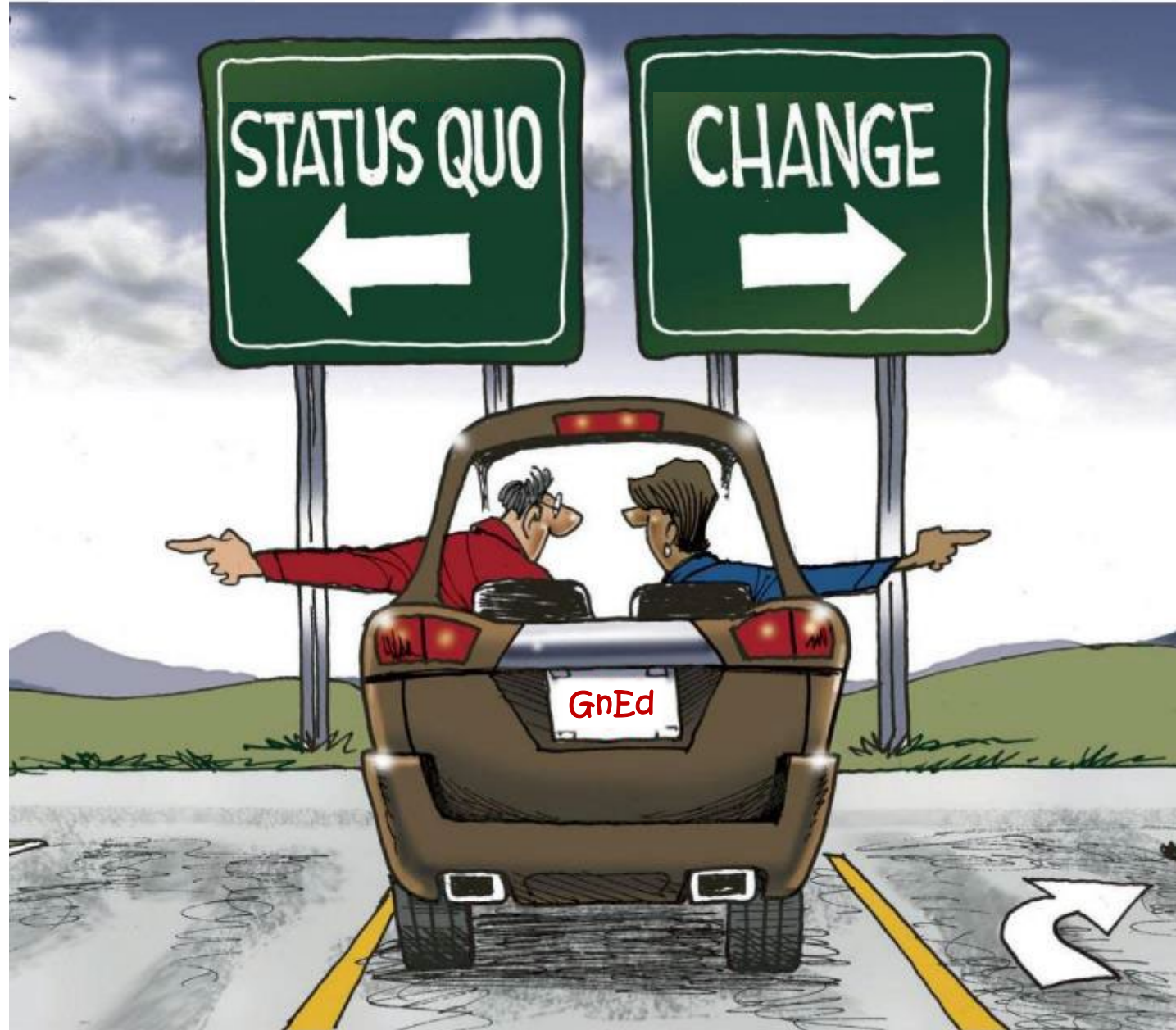
Trait not Available for Many Breeds



NEW BREEDING TOOL



Regulatory Crossroads



Thank you!

USDA



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“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

