Stepping Forward: Regulatory Policy Approaches that Encourage Innovation in Animal Biotechnology

Diane Wray-Cahen, PhD

Senior Advisor for Animal Health and Production, and Animal Products

USDA Office of the Chief Scientist

diane.wray-cahen@usda.gov

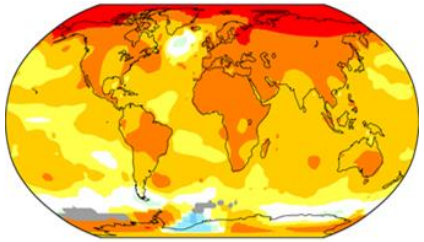
USDA United States Department of Agriculture

Asia Regional Virtual Workshop
September 2021

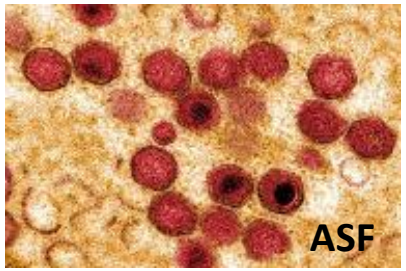
Future of Animal Agriculture

Unprecedented agricultural challenges globally:

- Prepare for climate change
- Emerging disease threats
- Increase agricultural production
- Reduced land and resources

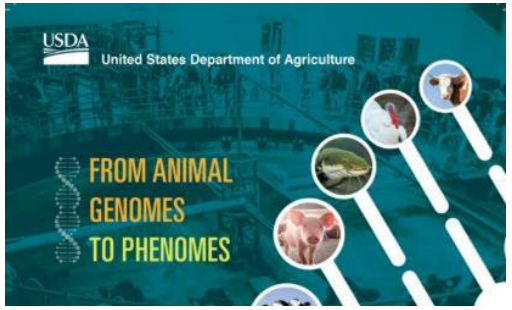


2011-2020 average vs 1951-1980 baseline



Need to transform agriculture and make it more resilient

Biotechnology tools would enable animal scientists and breeders to solve many agricultural challenges and address many threats more quickly and sustainably.



Opportunities and Potential for Animal Agriculture

Disease and Pest Control (reduce antibiotics and insecticides)

- Disease resistance – African Swine Fever, PRRS, avian influenza, foot and mouth disease, trypanosomiasis, mastitis, TB, BSE (prion-free), etc.
- Insect control – disease vectors (mosquitoes, ticks), plant/animal pests

Environmental Protection and Adaption for Climate Change

- Reduced environmental impact, less GHG
- More efficient feed use, extract more nutrients from feed
- Climate resilience – heat and humidity tolerance, coat color

Animal Welfare

- Sex selection (laying hens), polled dairy cattle, castration-free pigs

Food Health, Safety, and Production

- Healthier food products, safer food products (anti-salmonella)
- Production traits - growth, milk, wool

. . .

What tools are available
in the animal breeding toolbox . . .

Old and New

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

Hallmarks of Effective Regulatory Approaches

- Science-based, risk-proportionate and defensible
- Credible to the public – may have non-scientific, values-based issues
- Timely and predictable (important for innovation)
- Appropriate for intended use (e.g., food vs. biomedical)
- Transparent to all

Effective regulations

- Protect humans, animals, and the environment
- **Allow production and marketing of safe products**

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 harmonizing trade in foods derived from rDNA animals

* Guideline does *not* address animal welfare; ethical, moral and socioeconomic aspects; environmental risks; safety of rDNA animals used as feed, or safety of animals fed with rDNA feedstuffs

No “Best” Approach: Different Countries – Different Effective Regulatory Approaches

- Differences in existing regulatory structures and legal enabling authorities, as well as different philosophies
- Different regulatory triggers: product vs. process (GMO)
- Oversight by different authorities (ministries):
  - Agriculture (or Fisheries), Environment, or Food
  - Shared oversight by multiple ministries or even multiple countries
- **General agreement on what needed for evaluations**

  (i.e., similar criteria for rDNA/GMO products, but sometimes different requirements)

Transgenic Animals for Commercialization (with inserted rDNA constructs)

Research

Transgenic models
(rodents, fish, pigs, etc.)

Vector Control

Oxitec mosquito
(2014 Brazil)

Food

AquAdvantage Salmon

(2015 US, 2016 Canada, 2021 Brazil)

Currently:
on market in
Canada and US

Pets

GloFish (2003 US)
~15% of U.S. market

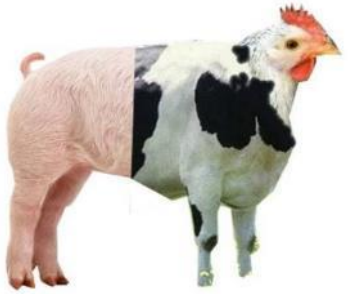
Medical + Food

GalSafe Pig: (US 2020)
Food Use of Biomedical

Challenges and Barriers

- Focus on production processes, not product safety
  - *Products treated differently because of how traits were introduced*
- Political involvement (or pressure) in regulatory decisions

- Additional public acceptance challenges:
  - Emotional connection to animals
  - Unfamiliarity with animal agriculture
  - Dis-information campaigns

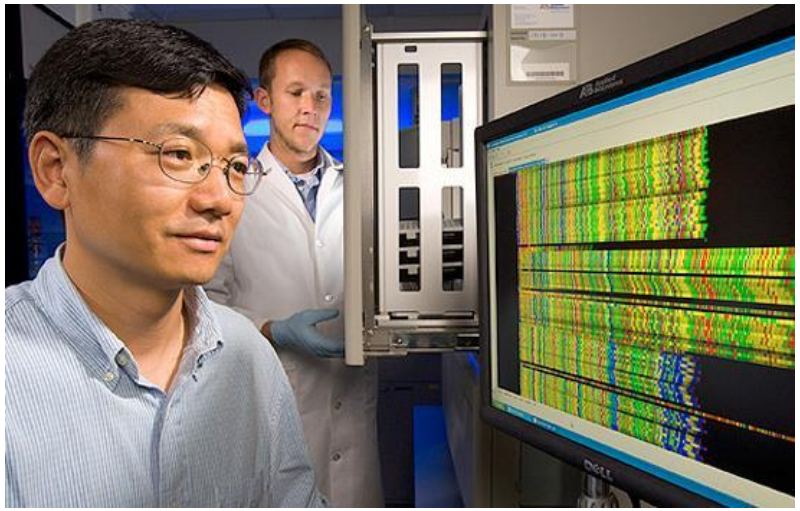


(Dis)Perception

Reality

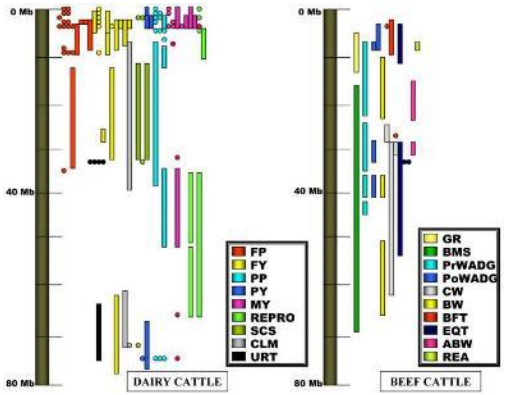

Changing Scientific &
Regulatory Landscapes

Scientific Advances:
New Opportunities and New Tools



Agricultural Animal Genomes Mapped

- Identify DNA sequences associated with valued traits
- Quicker and less expensive
  - Genomic selection
  - More breeds and species

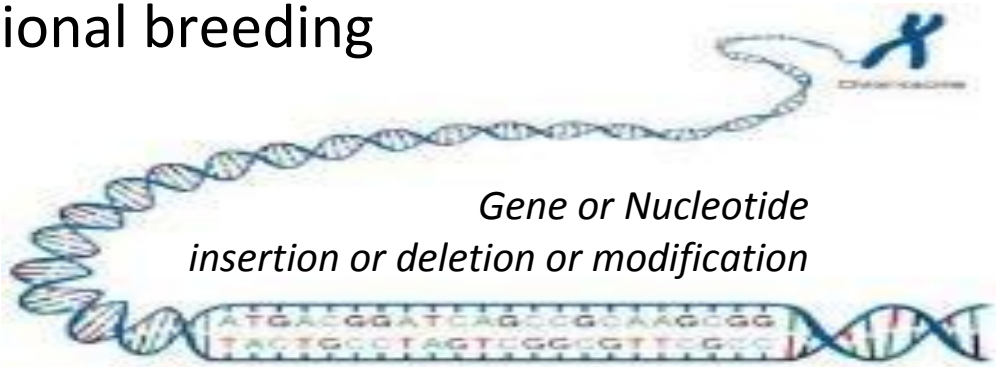


Genome Editing (esp. CRISPR)

- Easy, efficient and inexpensive
- Add new traits while preserving diversity of livestock breeds

Why Use Genome Editing Instead of Conventional Breeding?

- Introduce traits not available via conventional breeding
- Overcome otherwise low heritability
- Separate “linked” genes
- Target only genes of interest



- Protect animal/breed diversity when introducing valued traits
- Increase precision and efficiency of introducing desirable traits (*conventional breeding results in random combinations*)

- Reduce the generation time necessary for genetic advancement of a breed or variety

Creating a New Breed

5/8

3/8

Many Generations Later . . .

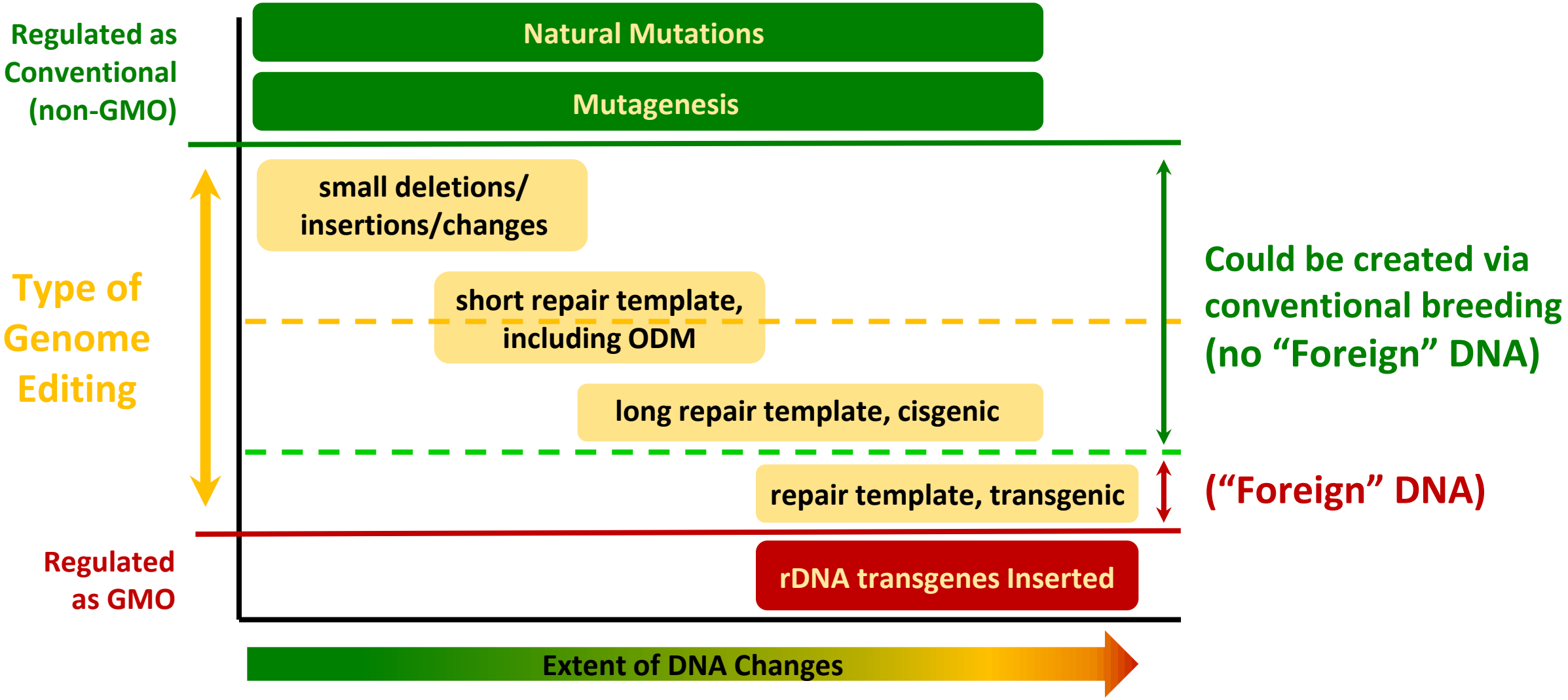
(1912-1949)

Brangus

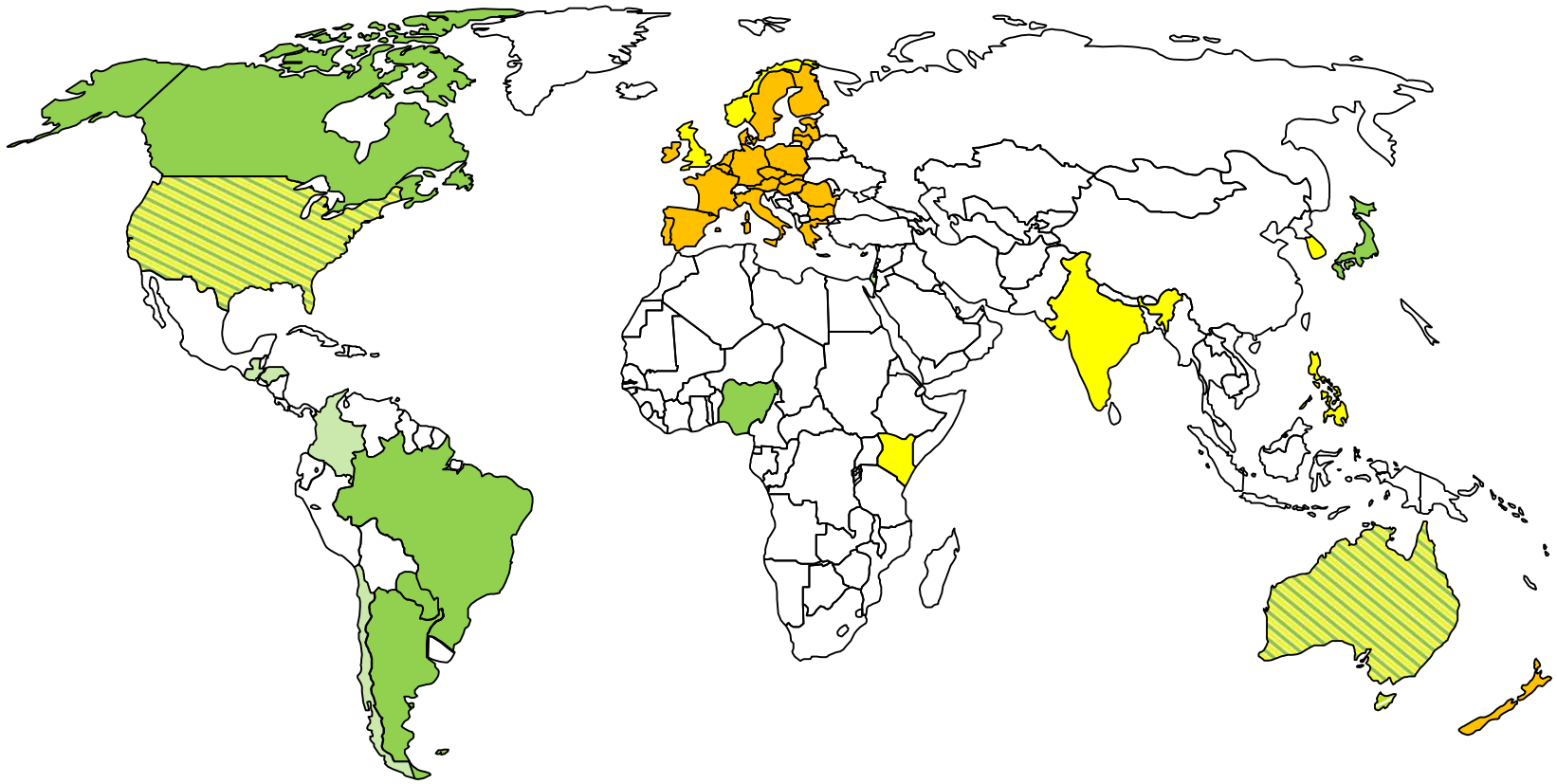
Modernizing Regulatory Approaches

- 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 (product, not technology, triggers)
- Encourage creation of new innovative **safe** agricultural products to address growing global challenges and threats

Global "When to Regulate as GMO?" Debate



Global Regulatory Landscape for Products of Genome Editing



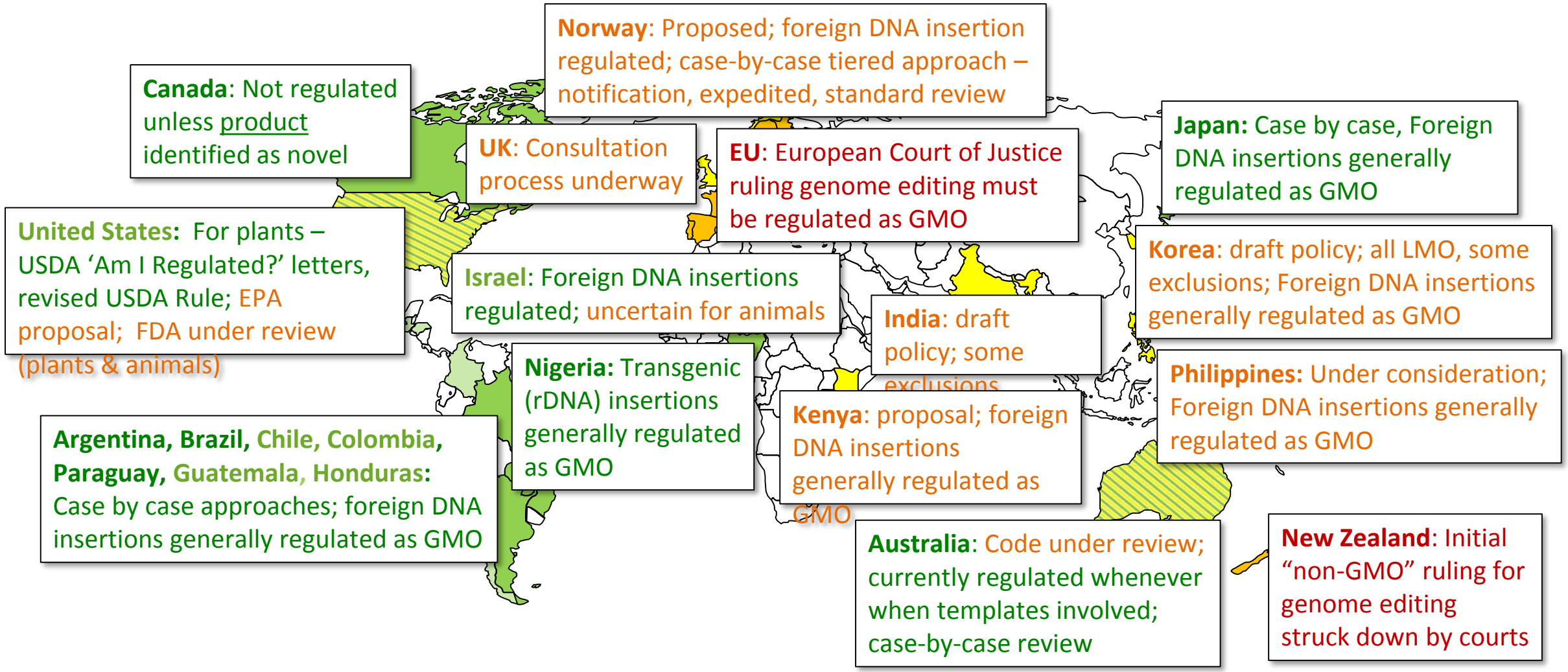
Countries with regulatory policy with exclusions

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



Example: Argentina's Approach to Genome Edited Organisms

GE animal: Applicant´s previous consultation

↓

CONABIA

↓

Is there a new combination of genetic material?

» CONABIA will determine **if the final product has a new combination of genetic material.**

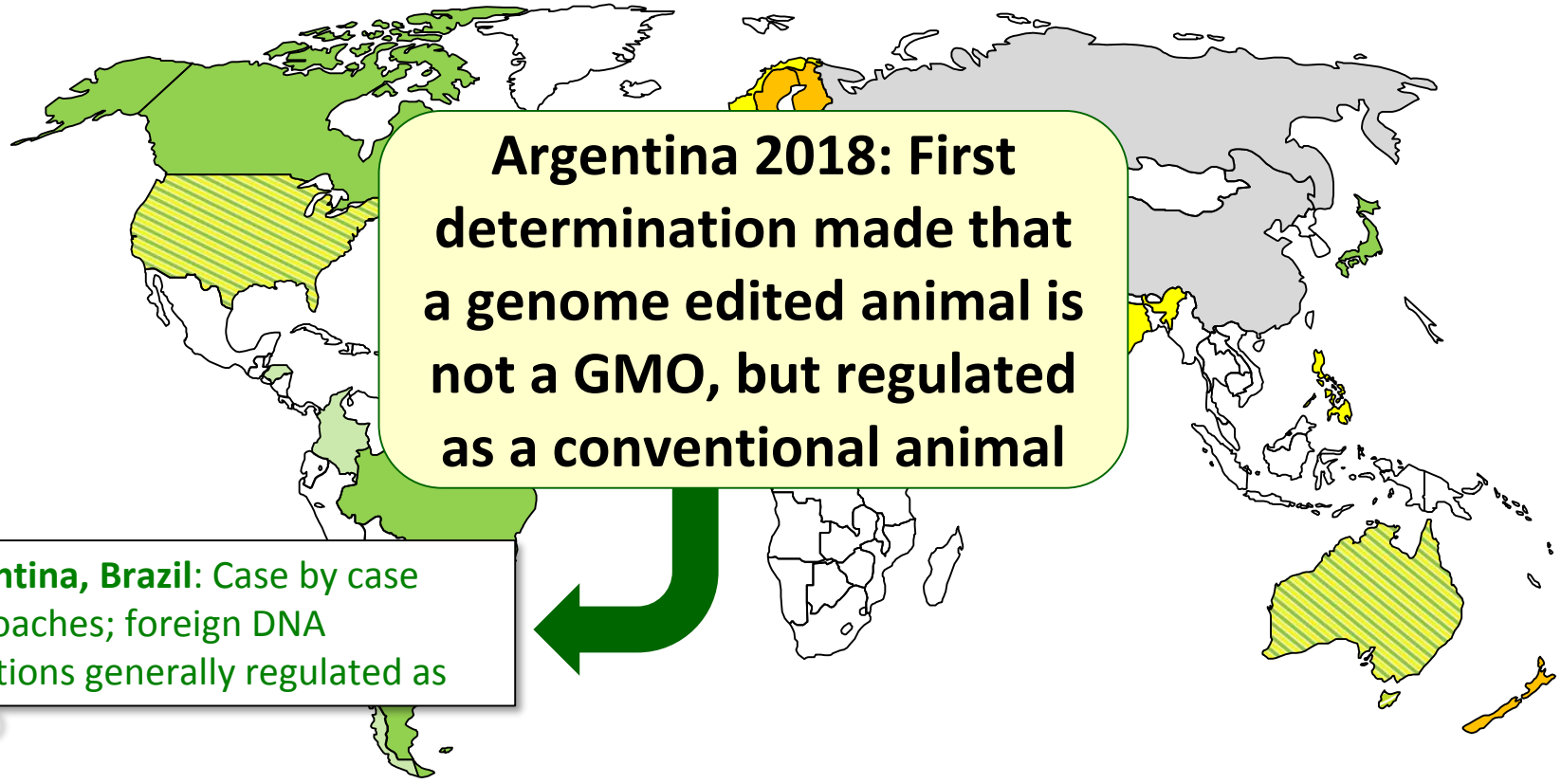
X **If it does not**, the Applicant will be informed that the GE animal **does not fall under GM-Animal Regulations.**

✓ **Otherwise**, the GE Animal product will have to **go through the regulatory process.**

→ NO → Non GMO → GE animal does not fall under GMA Regulations

→ YES → GMO → GE animal falls under GMA Regulations

Countries are Moving Forward with Path for GnEd Animal Commercialization



Argentina 2018: First determination made that a genome edited animal is not a GMO, but regulated as a conventional animal

Argentina, Brazil: Case by case approaches; foreign DNA insertions generally regulated as GMO

Two Theoretical 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

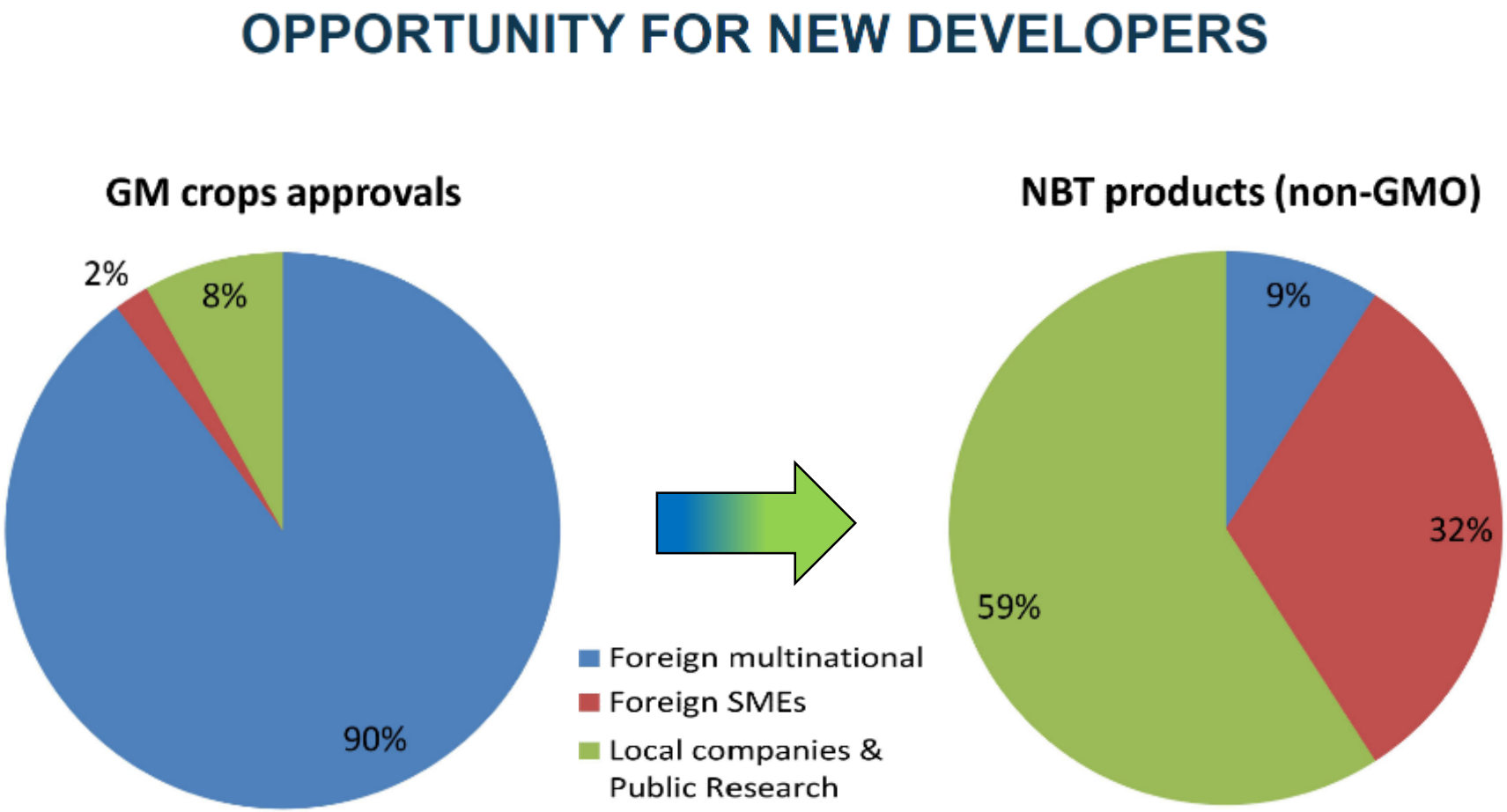
"No Exclusions" Approach
(Status Quo)

- Large multinational companies
- Developers from very few countries
- Dominated by row crops, high return traits
- Only 2 food animals (in >25 years)
  - none available to conventional farmers
  - many lost opportunities

"Foreign DNA" Approach
(Some GnEd as "Conventional")

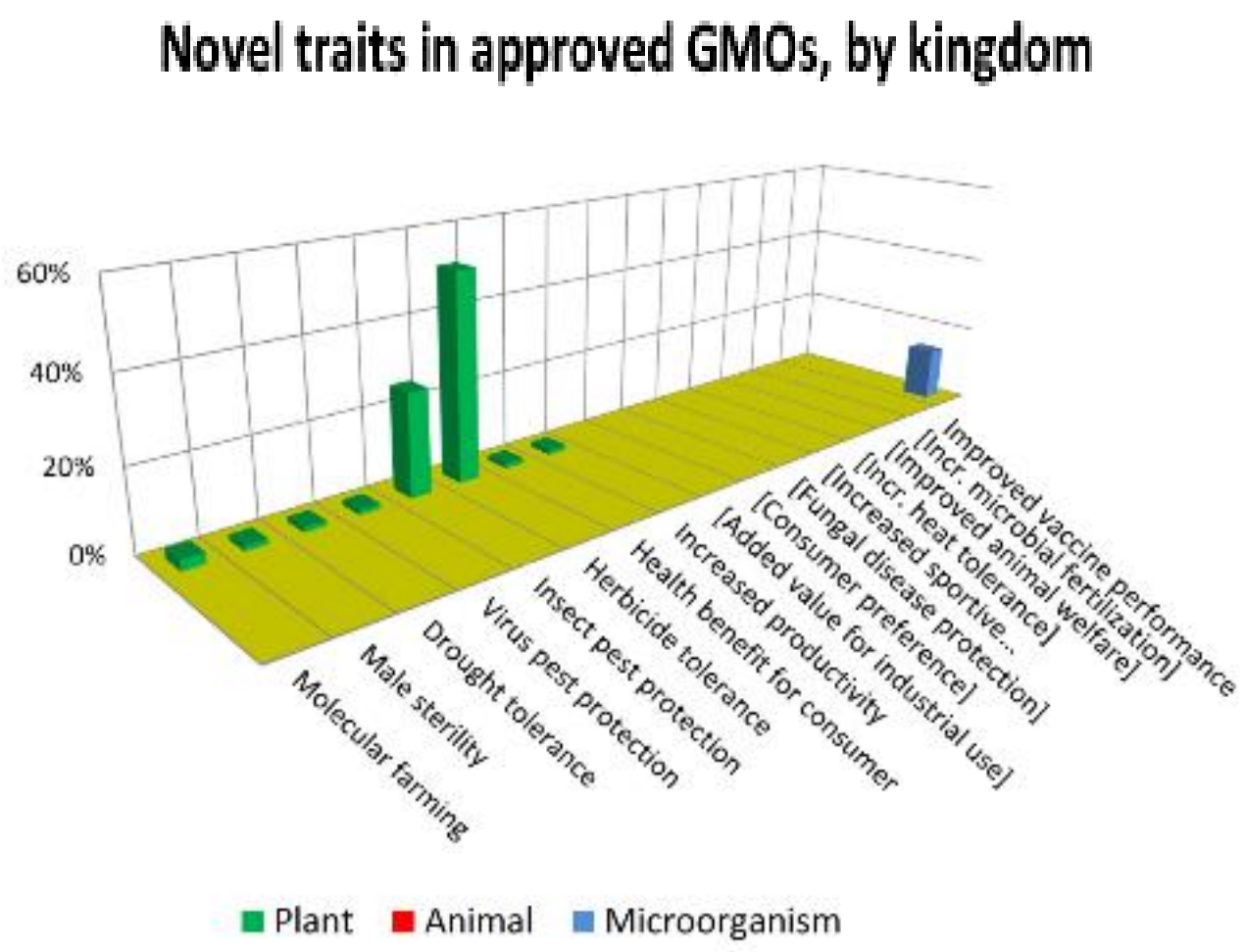
- Public research, small and medium enterprises (SMEs)
- More countries involved
- Livestock, fruits, vegetables, flowers
- Consumer oriented traits
- Quicker solutions to regional problems

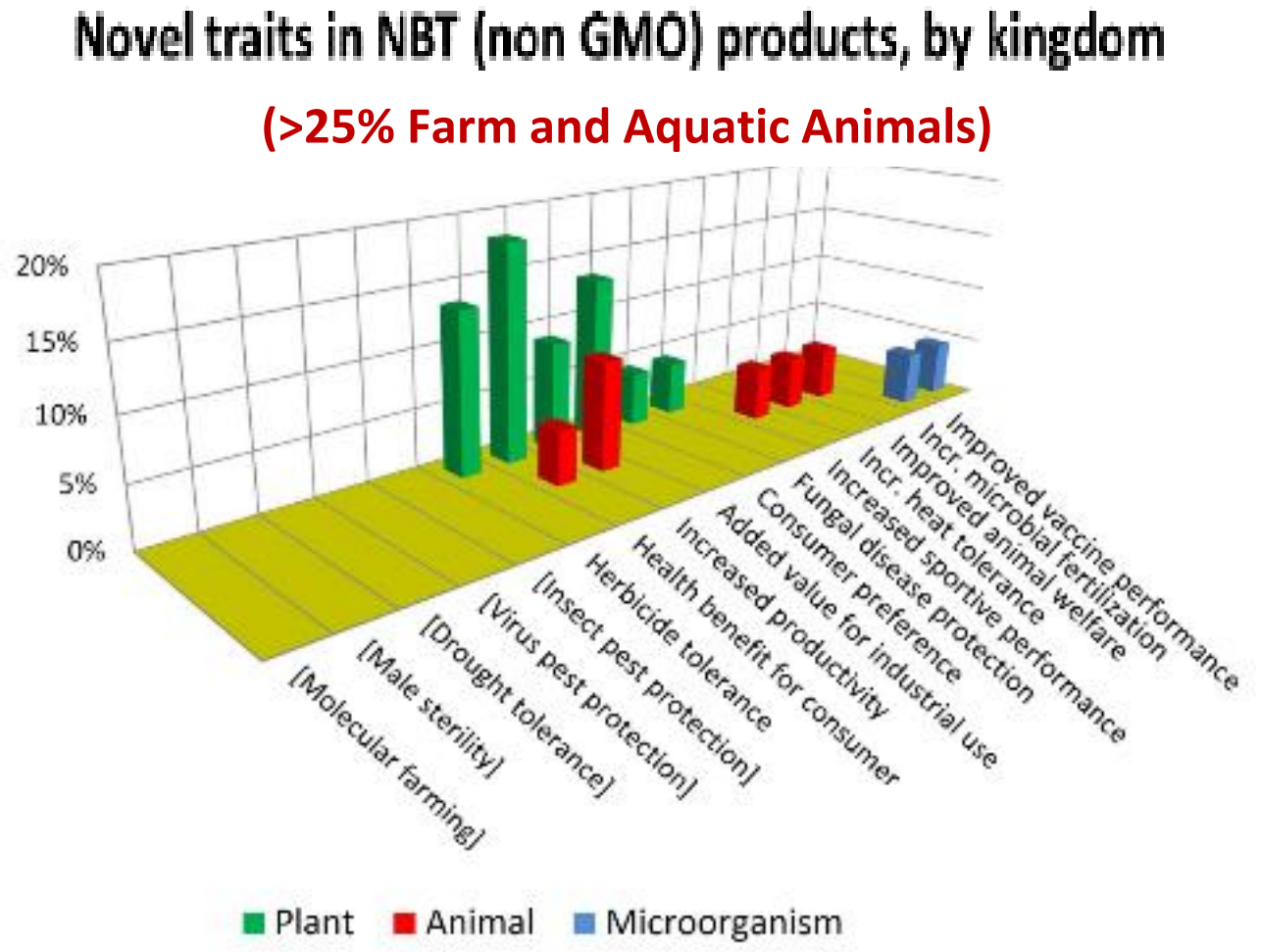
Impact of New “NBT” Regulatory Approach for Products of Genome Editing in Argentina



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

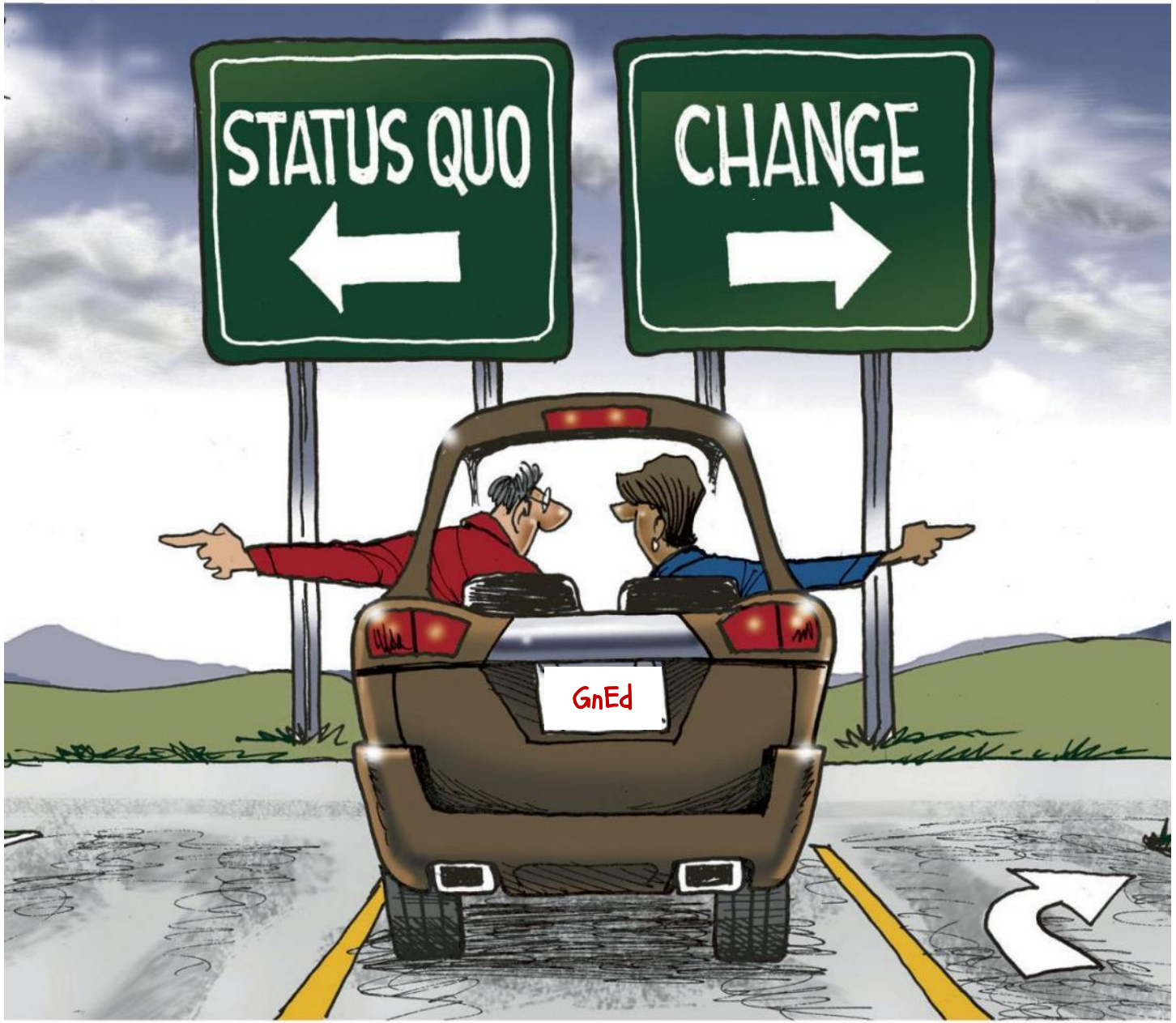
INCREASED DIVERSITY OF ORGANISMS & TRAITS





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

Regulatory Crossroads



HOPE for Future:

- Safe solutions to farmers from publicly-funded research
- GnEd solutions are available when needed to address . . .
  - Climate Change
  - Disease and Pest Threats
  - Animal Welfare
  - Food Security
- Farmers across the world have access to new technologies

Ideally, 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

Next Generation . . .
More Options, Not Fewer

"We've considered every potential risk except the risks of avoiding all risks."

Product Based, Science-Based, Risk Proportionate

Thank you!

diane.wray-cahen@usda.gov