

# A Quick Introduction to the Global Regulation of Animal Biotechnology

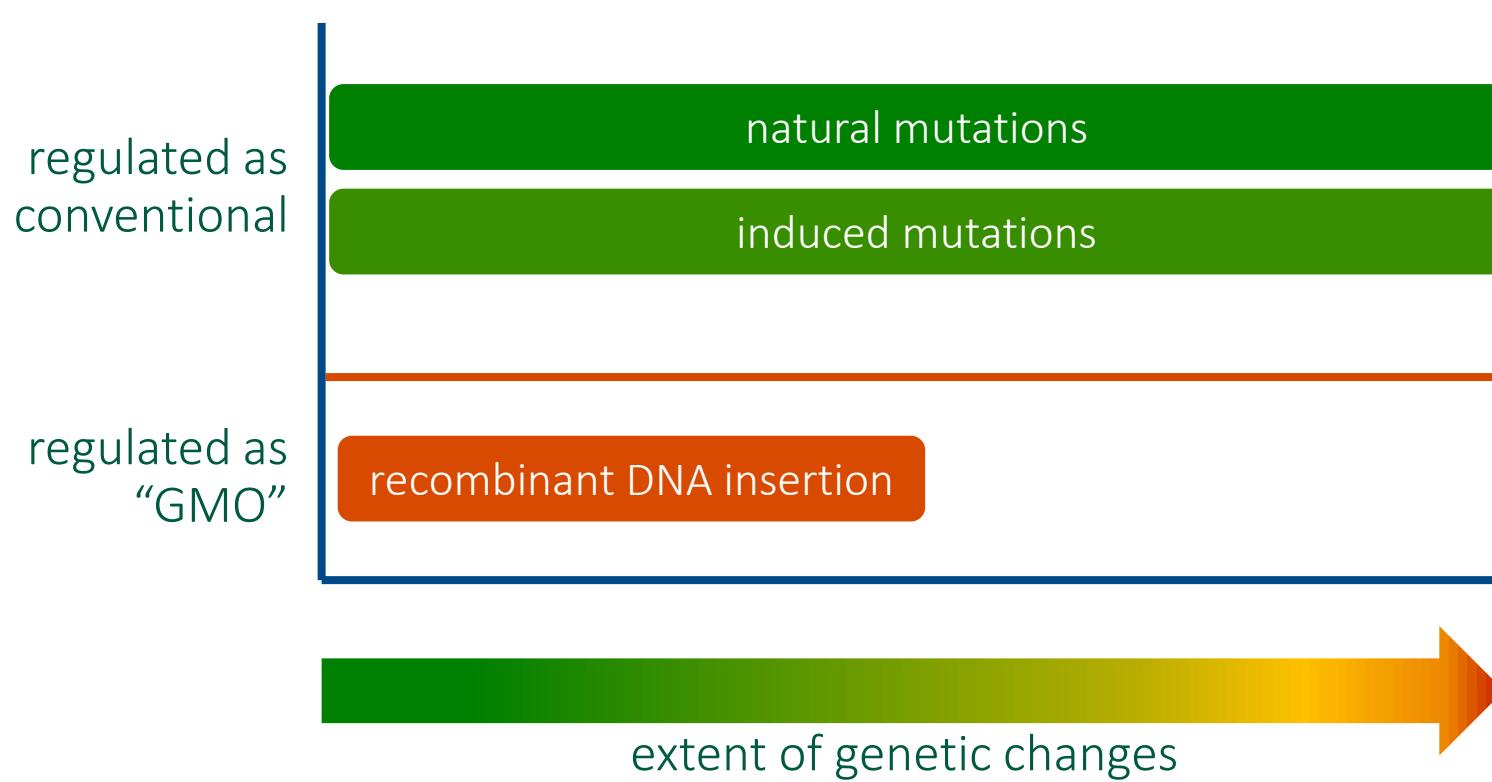
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# Genetic Engineering: Huge Dividends, Huge Costs

- **Development:** The tools of genetic engineering utilized blunt tools to randomly insert DNA requiring significant time and resources
- **Deployment:** Significant regulatory costs associated with approval and cultivation

# The GMO global regulatory paradigm:



GMO plants have been a success—for those who can afford the price of entry



# GMO animals—a different story

Domestication



1800's



1940's



Today



# New Technology, New Considerations

- Genome Editing offers both tremendous **Precision and Cost Efficiency**
- Advances in genomics have identified **known targets** for genome editing
- There are encouraging signs of **public acceptance** for genome editing in agriculture

# Global Trends in Genome Editing Regulation

- The old GE/GMO paradigm is not a good fit for many anticipated applications of genome editing
- Pre-market: risk-proportionate regulatory review is needed for genome editing applications that could have been achieved through conventional breeding
- Post-Decision: if it could have been achieved through conventional breeding, treat it as conventional

# Risk Assessment for Genome Edited Animals

If it could have been achieved through conventional breeding, treat it as conventional

***Can this be justified from a risk management perspective?***

# The new global paradigm?

regulated as conventional

natural mutations

induced mutations

types of genome editing

small changes, no template

short repair template

cisgenic repair template

regulated as “GMO”

transgenic repair template

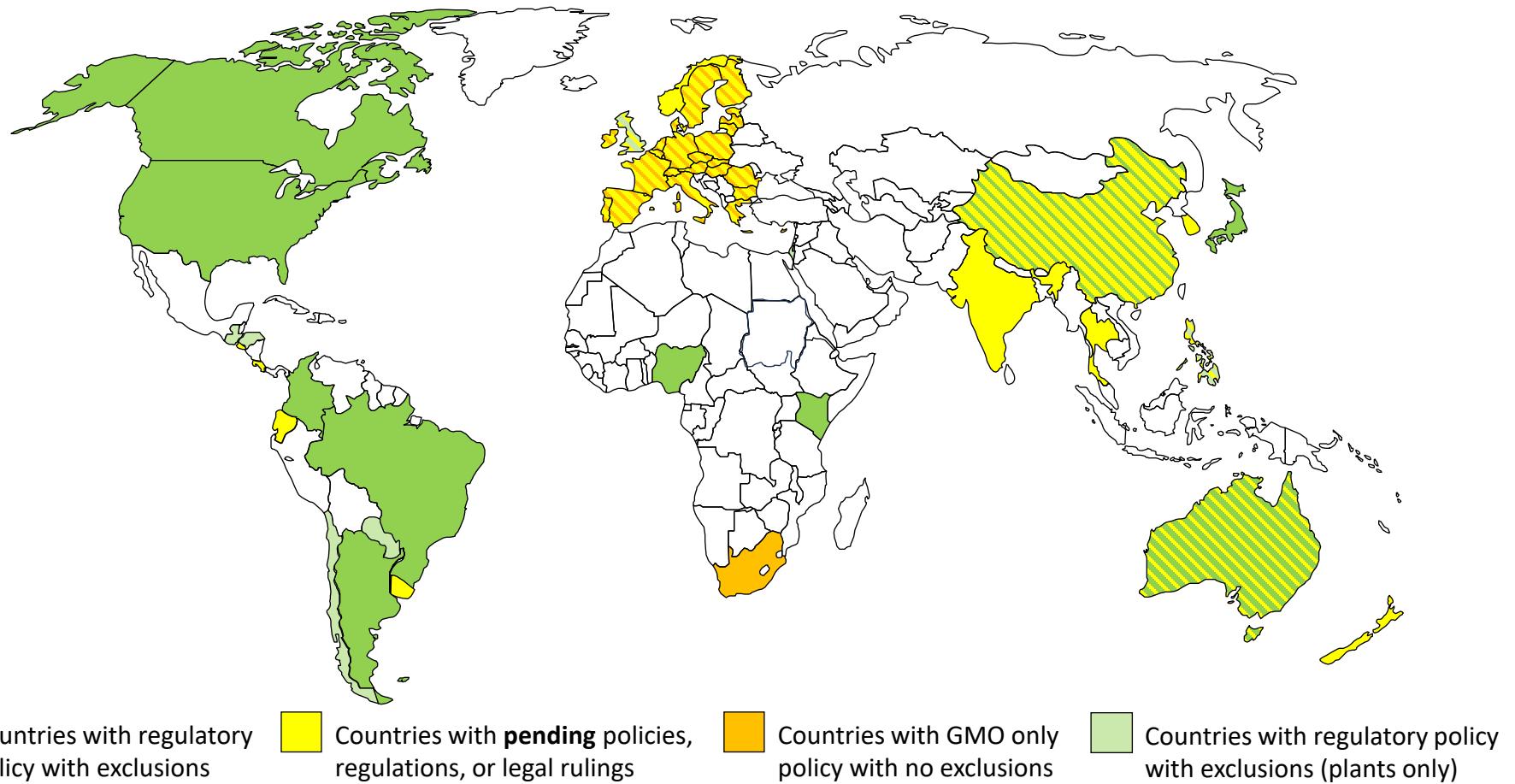
recombinant DNA insertion

could be created with conventional breeding

includes “foreign” DNA

extent of genetic changes

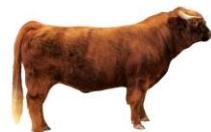
# Global Regulatory Status of Agricultural Genome Editing



# Proof of Concept, and of science and risk-based decision making



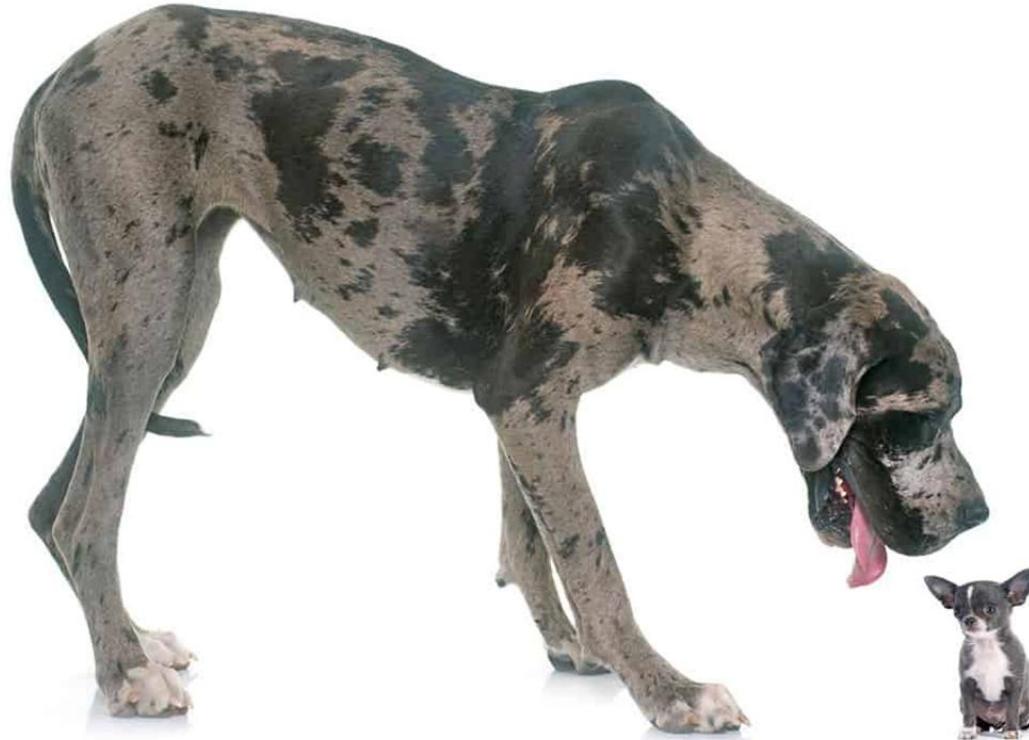
# Regulation Impacts Accessibility



# Regulatory approaches should:

- **Enable** safe products to reach the market;
- **Encourage** development of new ideas and innovations;
- and **Provide** farmers and ranchers with the best selection of tools . . .  
*to meet the challenges of the future.*

# Genome Editing—*Big Dividends from Small Changes*



Thank You

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