

A Quick Introduction to the Global Regulation of Animal Biotechnology

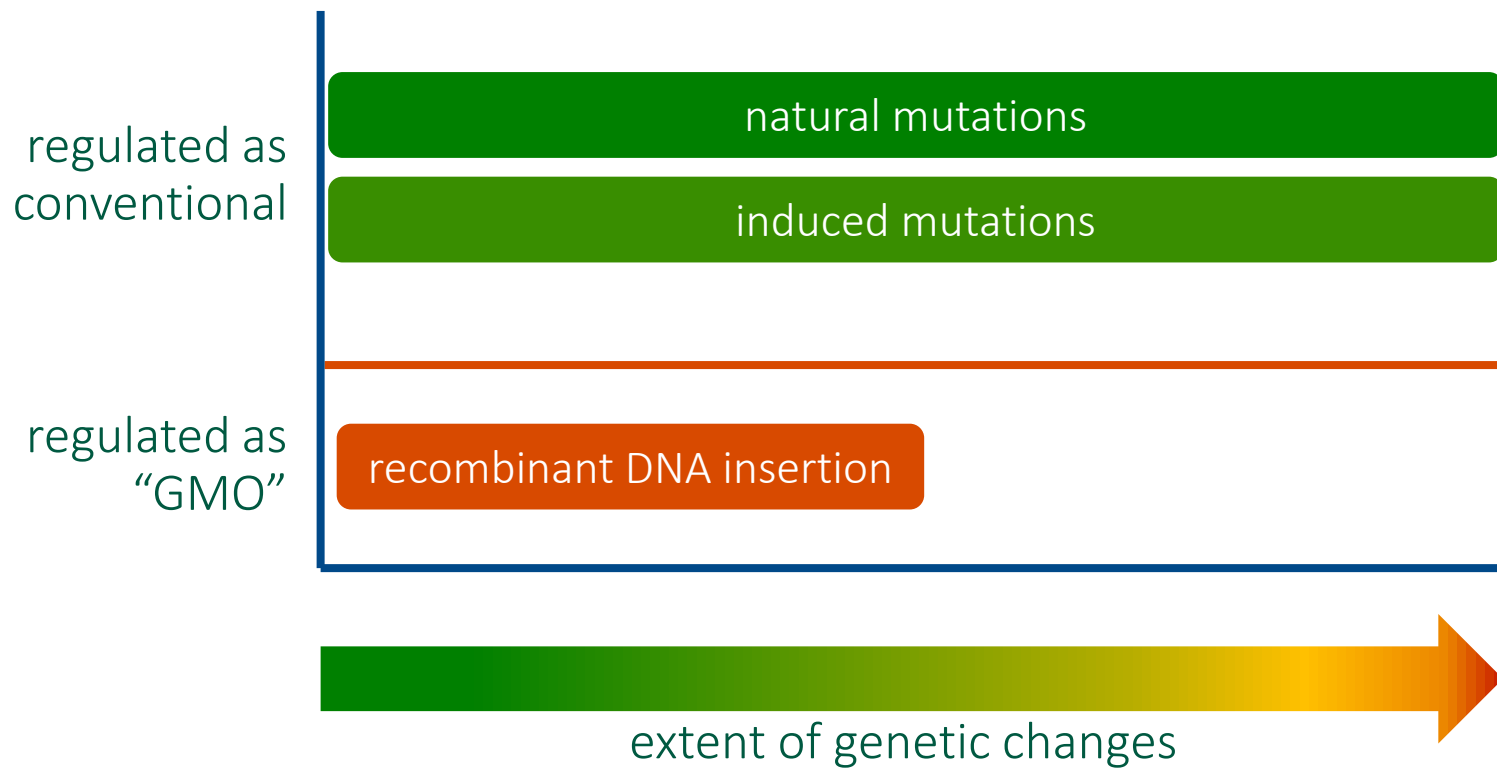
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Genetic Engineering: Huge Dividends, Huge Costs

- **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

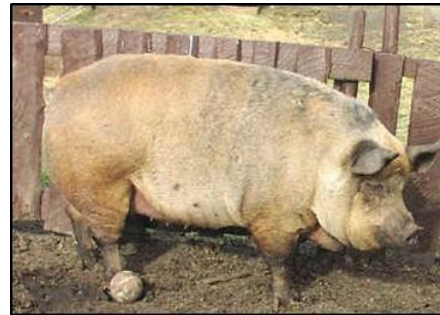
Domestication



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

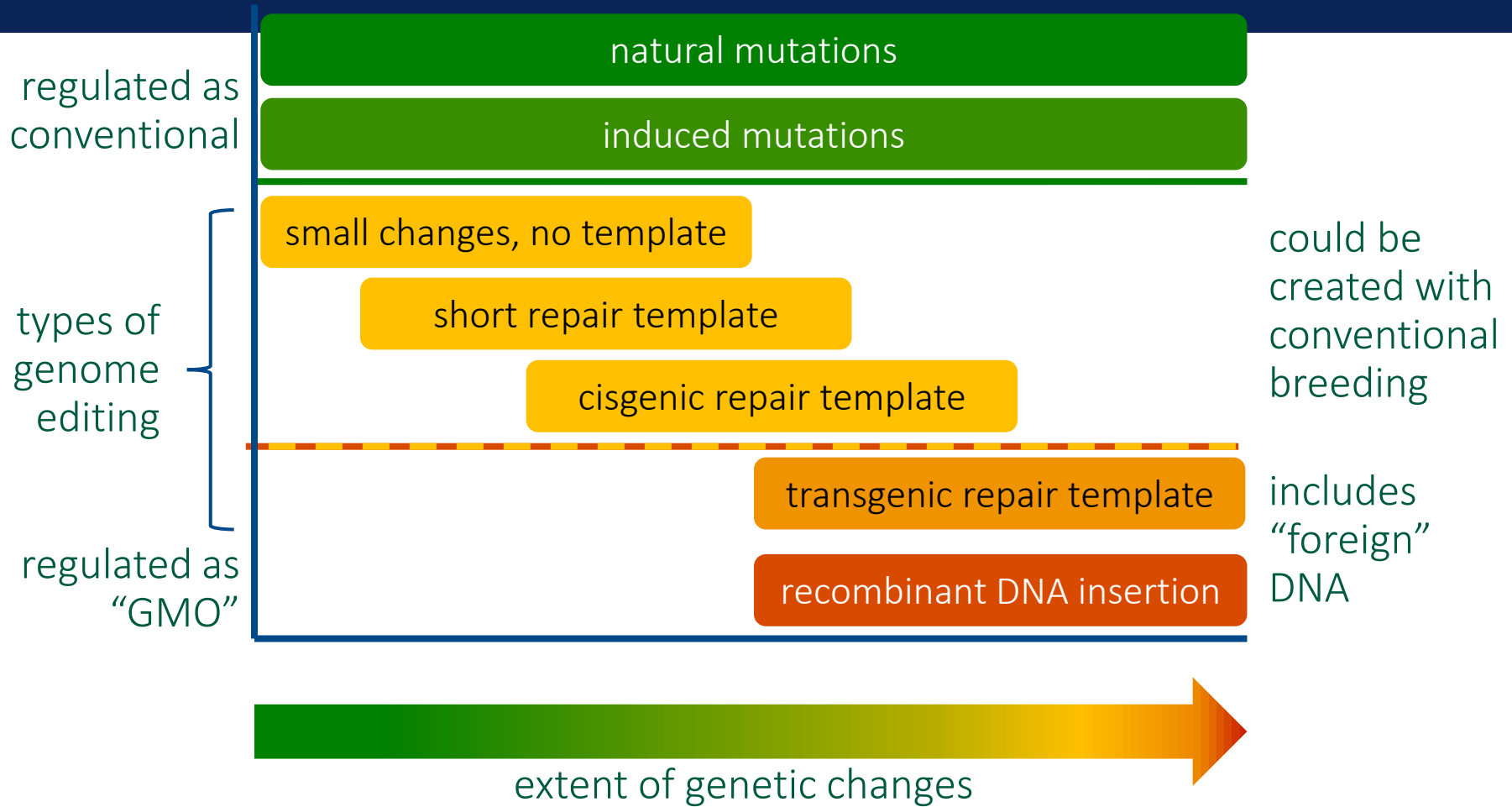
- The old GE/GMO paradigm is not a good fit for many anticipated applications of genome editing
- Pre-market: risk-proportionate regulatory review is needed for genome editing applications that could have been achieved through conventional breeding
- Post-Decision: if it could have been achieved through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

Risk Assessment for Genome Edited Animals

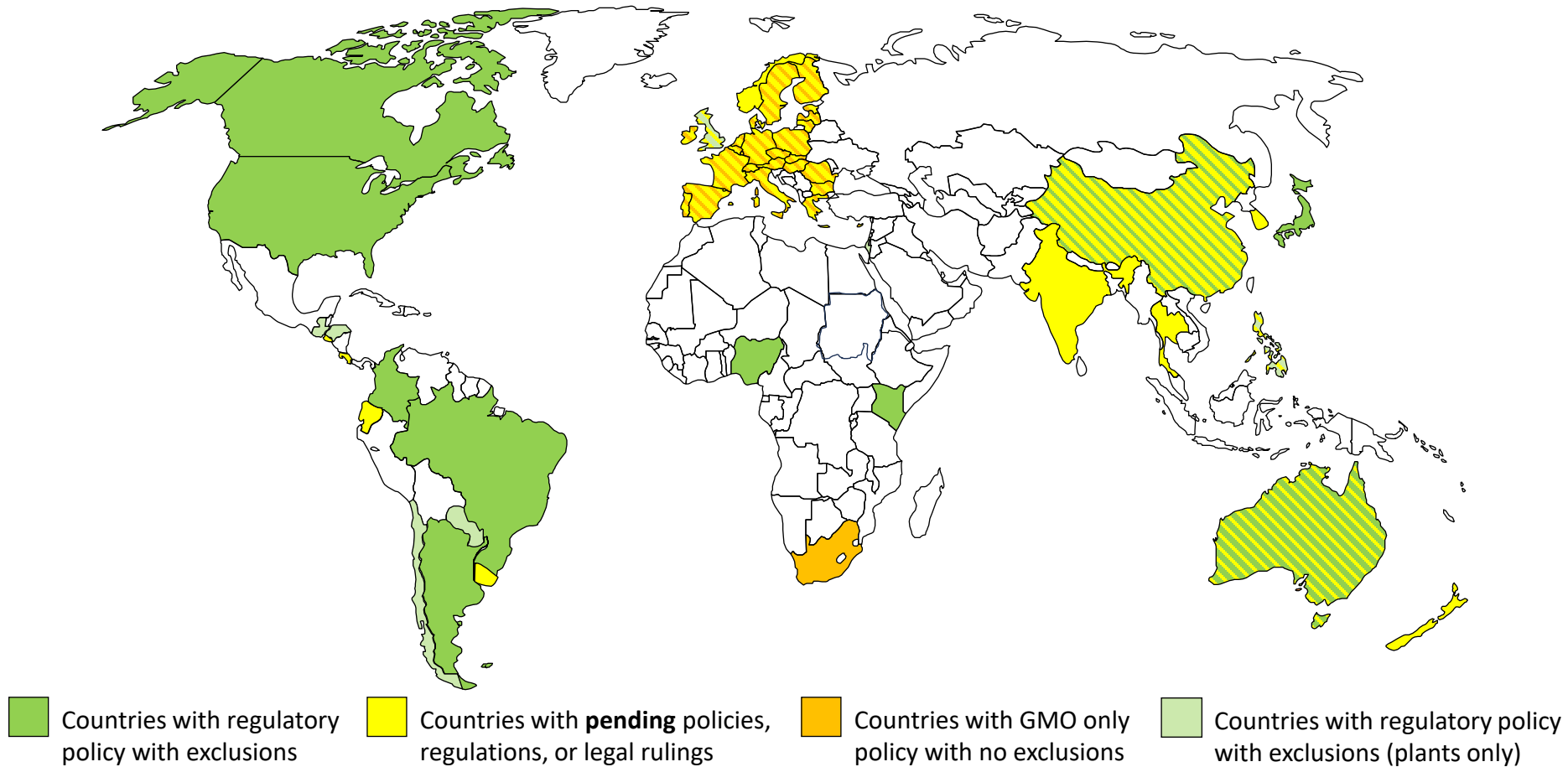
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Can this be justified from a risk management perspective?

The new global paradigm?



Global Regulatory Status of Agricultural Genome Editing



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



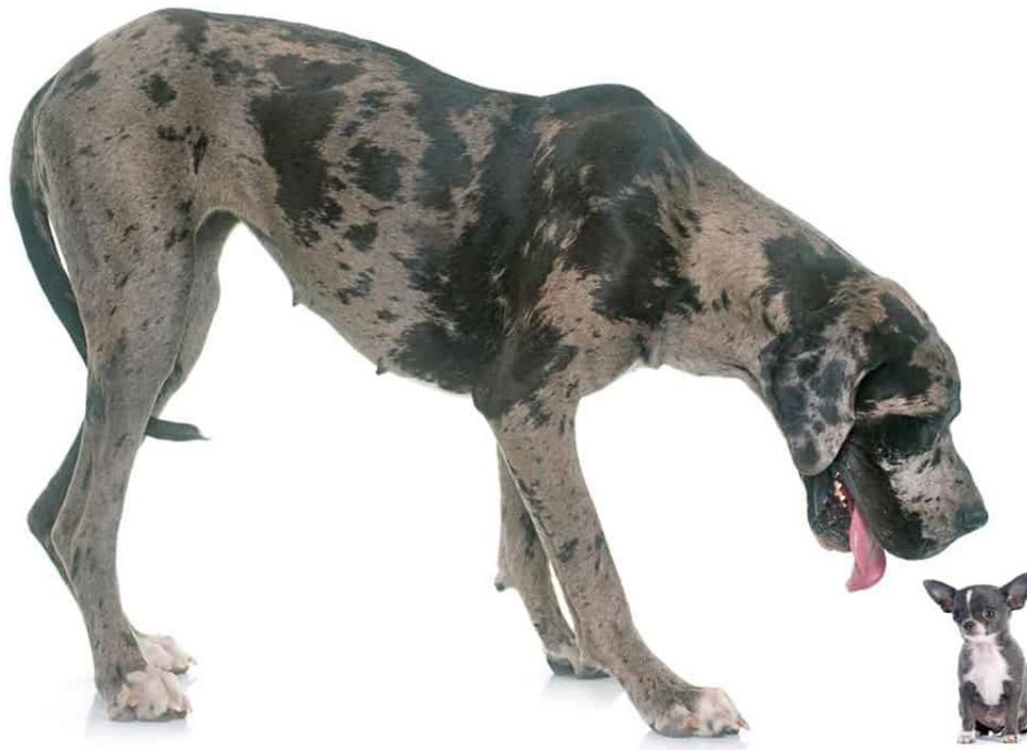
Regulation Impacts Accessibility



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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