



Agriculture Division of DowDuPont

Regulatory and Stewardship Management of CRISPR and Other Gene Editing Technologies

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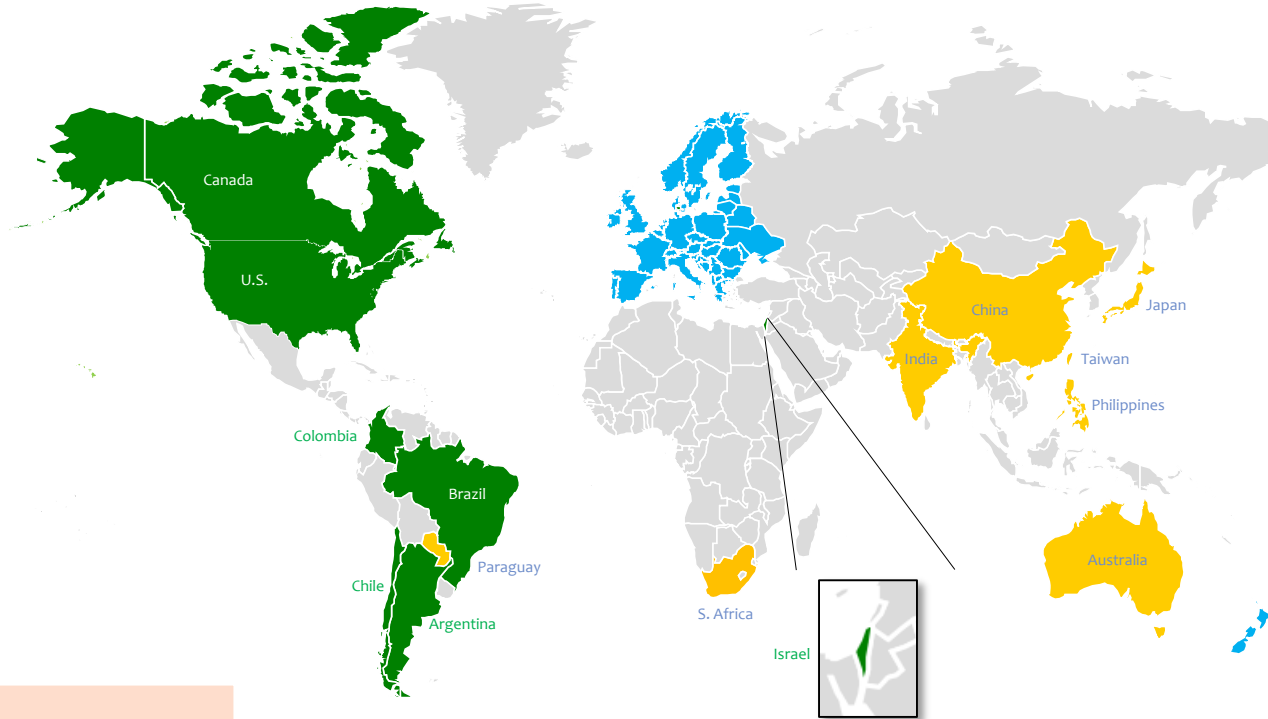
Overview

- Regulatory status of CRISPR and other gene editing technology
- Implications of current regulatory reality
- Guidance on responsible stewardship practices of gene edited plants
- Moving forward

Regulatory status of CRISPR and other gene editing technologies

- Global regulatory policy development
 - Currently a variety of policies with few having been utilized or established via legislation
 - USDA, BRS has clarified they do not plan to regulate certain types of gene edited plants if no plant pest trigger
 - Several nations have developed case by case consultation processes (Argentina, Chile, Brazil, Colombia): non-GMOs if no new combination of genetic material
 - European Court of Justice ruled that organisms obtained by “new mutagenesis techniques” are, under certain circumstances, subject to GMO regulatory obligations
 - Policies are in development in Japan, Australia, China, Philippines

Global Regulatory Policies for Gene Editing



Key 2018 developments

- USDA clarification
- Policy adoption in Brazil and Colombia
- European Court of Justice ruling
- Japan policy - in development

  in place  in development



Secretary Perdue Statement, March 28th, 2018

. Summary

- “Under its biotechnology regulations, USDA does not currently regulate, or have any plans to regulate plants that could otherwise have been developed through traditional breeding techniques as long as they are developed without the use of a plant pest as the donor or vector and they are not themselves plant pests. This can include plant varieties with the following changes:”

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- **Deletions**—the change to the plant is solely a genetic deletion of any size.
- **Single base pair substitutions**—the change to the plant is a single base pair substitution.
- **Insertions from compatible plant relatives**—the change to the plant solely introduces nucleic acid sequences from a compatible relative that could otherwise cross with the recipient organism and produce viable progeny through traditional breeding.
- **Complete Null Segregants**—off-spring of a genetically engineered plant that does not retain the change of its parent.

Implications of Current Regulatory Reality

- The proper stewardship of traits developed using gene editing is important!
 - Many traits in development may not be regulated in the U.S. by the USDA, BRS
 - However, a developer may consider, for example, its business model, the nature of the crop it's working with and the products potential markets as it designs and implements its stewardship activities
 - Specific stewardship practices a developer may consider for corn gene edits may be quite different than crops with differing biology or markets

Stewardship Considerations of Gene Edited Plants

- Regulatory status in country or countries of development
- Markets for the crop, domestic or international
- Biology of the crop
 - Reproductive mode
 - Annual vs perennial
 - Equipment cleaning
 - Records management of documentation
 - Relationships with third party collaborators
 - Business model

Moving Forward

- The regulatory environment continues to evolve
 - Remain vigilant and informed
- USDA and other regulatory bodies globally are actively developing updated regulatory frameworks
- A developer may consider many factors as it develops and designs stewardship practices (e.g. regulatory, species, trade)
- Traits are being developed in plant species that were not previously economically viable and by smaller, less experienced organizations
- Public acceptance of new technology may be impacted by our industries responsible use and transparency

Summary

- Proper stewardship is a component of successfully bringing the promise of gene editing into reality
- Scientists and regulators alike are generally positive about the potential gene editing presents
- Public acceptance is important
 - Trust
 - Transparency
- Only in collaboration with stakeholders can we be successful