International Seed Federation
Seed is Life

Plant breeding innovation: Global Industry Perspective

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Plant Breeding Innovation Defined

Plant breeding innovation:

- describes the constantly evolving ideas and practices which enhance the field of plant breeding
- is the way to adapt crops to local needs
- reflects the continuum of innovation in plant breeding.
- does not focus on any particular group of techniques, nor is it defined by them
- **Current policy focus is on gene editing**

Plant Breeding Innovation: Background

- Plant breeders continue to develop methods to safely increase precision and efficiency of breeding.
- Creating variability: the source material for new plant characteristics
  - inherent genetic diversity in a plant's gene pool
  - naturally occurring and induced variations of existing genes
- Latest breeding methods, such as genome editing, also use genetic variability as source material.
- **The plant varieties developed using these new tools could, in most cases, be developed through traditional breeding.**

Impact of Public Policy

- Regulatory policy will determine utilization of methods across companies and across crops
- Overly high regulatory burden
  - Limit utilization to largest companies
  - Limit utilization to highest value crops (e.g., corn, soybeans) and to limited number of traits (e.g., herbicide tolerance)
- Importance of science based, consistent policies across countries

Current Situation

- Differing definitions, legal frameworks and approaches around the world for biotech regulations
  - Limited use of the technology
  - Trade implications

- How to move toward consistent, science based, policies for plant varieties developed through newer breeding methods such as gene editing?

Common Themes and “Watch Outs”

- “Regulation” means pre-market review and approval process
  - All new plant varieties are subject to seed laws and regulations
- Do not want to create a third class of products
- Plant breeders continue quality practices
- Not talking about all applications of gene editing

Factors Affecting Predicability

There are two essential factors affecting the predictability of the policy approach for the regulatory oversight for products developed using tools of PBI:

- **Agreement on criteria to determine scope of regulation**
- **Alignment around implementation of the criteria**

ISF Concept Paper: How to Approach Scope of Regulatory Oversight

Goal: Consistent, science-based approach to the scope of regulatory oversight for products of plant breeding innovation

- Agreement among countries on the criteria that would be used to determine the scope of regulatory oversight

Underlying principle for determining the criteria:

"Plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier breeding methods."

Consistent Criteria for Regulatory Oversight

The resulting product would not fall under the current scope of GMO regulation if:

- it does not contain a novel combination of genetic material (*there is no stable insertion in the plant genome of one or more genes that are part of a designed genetic construct*); or
- the final plant product solely contains the stable insertion of inherited genetic material from sexually compatible plant species; or
- any form of mutagenesis is involved.

Application of Criteria

Targeted deletion via site directed nucleases

- No novel genetic combination
- Solely contains inherited genetic material from sexually compatible plant species
- Any form of mutagenesis in involved
- ***Not under GMO/Biotech regulation***

Targeted gene edit via site directed nucleases or ODM

- No novel genetic combination
- Solely contains inherited genetic material from sexually compatible plant species
- Any form of mutagenesis in involved
- ***Not under GMO/Biotech regulation***

Application of Criteria

Replacement of allele at naturally occurring location using site directed nucleases

- No novel genetic combination
- Solely contains inherited genetic material from sexually compatible plant species
- ***Not under GMO/Biotech regulation***

Addition of allele not at naturally occurring location using site directed nucleases

- Novel genetic combination—Parties to Cartegena Protocol
- Is under GMO/Biotech regulations—Parties to Cartegena Protocol
- ***Under GMO/Biotech regulations***

Introduction of transgene

- Does not meet any of the criteria
- ***Under GMO/Biotech regulations***

Implementation of Criteria

- The process used to determine whether a product is within or outside the scope of existing biotech/GMO regulations.
- The primary benchmark is to avoid having a policy or procedure that creates a new (third) category of products.
- In other words, a product should either fall under existing biotech/GMO regulations, or be excluded from them and treated as a conventional product in terms of testing, registration, certification and marketing.

General Trends

- More governments now developing and policy, including reviewing and interpreting their current regulations: e.g., Argentina, Brazil, Chile, Colombia, US, Japan, Australia
- Growing consensus that targeted mutations (deletions and small edits) should not be treated as GMOs
- Novel genetic combination used as trigger in a number of countries
- No “foreign DNA” in final product also used as trigger
- Alignment among countries in S. America
- Case-by-case approach and exemptions

Importance of Alignment around Criteria and Implementation

Negative impact of differing processes across countries on

- global seed movement
- exchange and access to germplasm globally
- agricultural trade
- research collaborations

Clear Guidance on

- scope of regulatory oversight
- timelines and requirements

Consideration of the existing regulatory mechanisms for new plant varieties

- variety registrations
- national seed laws and regulations
- phytosanitary regulations

Lessons from the Past

The risk is to create another system of patchwork regulations and asynchronous decisions repeating some of the mistakes of GMO regulation

1. Only the largest seed companies will have the financial capability to manage the costs related to regulation.
2. Only a limited number of crops will benefit from breeding innovations.
3. The accessibility of these tools to the academic community, national agricultural research organizations, and international agricultural research centers / CGIAR centers will be restricted.
4. Global economic activity in the seed and grain trade will decrease.
5. Research cooperation and germplasm exchange for global breeding will become more challenging.
6. Increasing productivity in a sustainable way will become more challenging.

Conclusion

Latest breeding methods provide opportunities to target global challenges as well as local needs and can help us achieve our common vision.

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