

Part II. Challenges and efforts towards social implementation
(including regulatory considerations)

14:10-14:40 Plant breeding innovation: A Concept Paper

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Internationally, there is a patchwork of national GMO regulations. Some countries regulate specific technologies through GMO definitions. Other countries regulate based on the characteristics of the final product. Additionally, definitions for 'GMO', 'biotechnology', 'genetic engineering' and 'bioengineering' are not consistent across countries. Due to these differences, products developed through the latest plant breeding methods may be subject to different requirements for pre-market assessments and other requirements. Consistent policies among governments for products of the latest plant breeding methods, such as gene editing, would facilitate the development and uptake of advanced, innovative breeding applications by both industry and public breeders in developed and developing countries. The seed industry is therefore focused on achieving a consistent approach among governments to the scope of regulatory oversight for products of plant breeding innovation.

Plant breeding innovation: A Concept Paper

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COI Disclosure Information

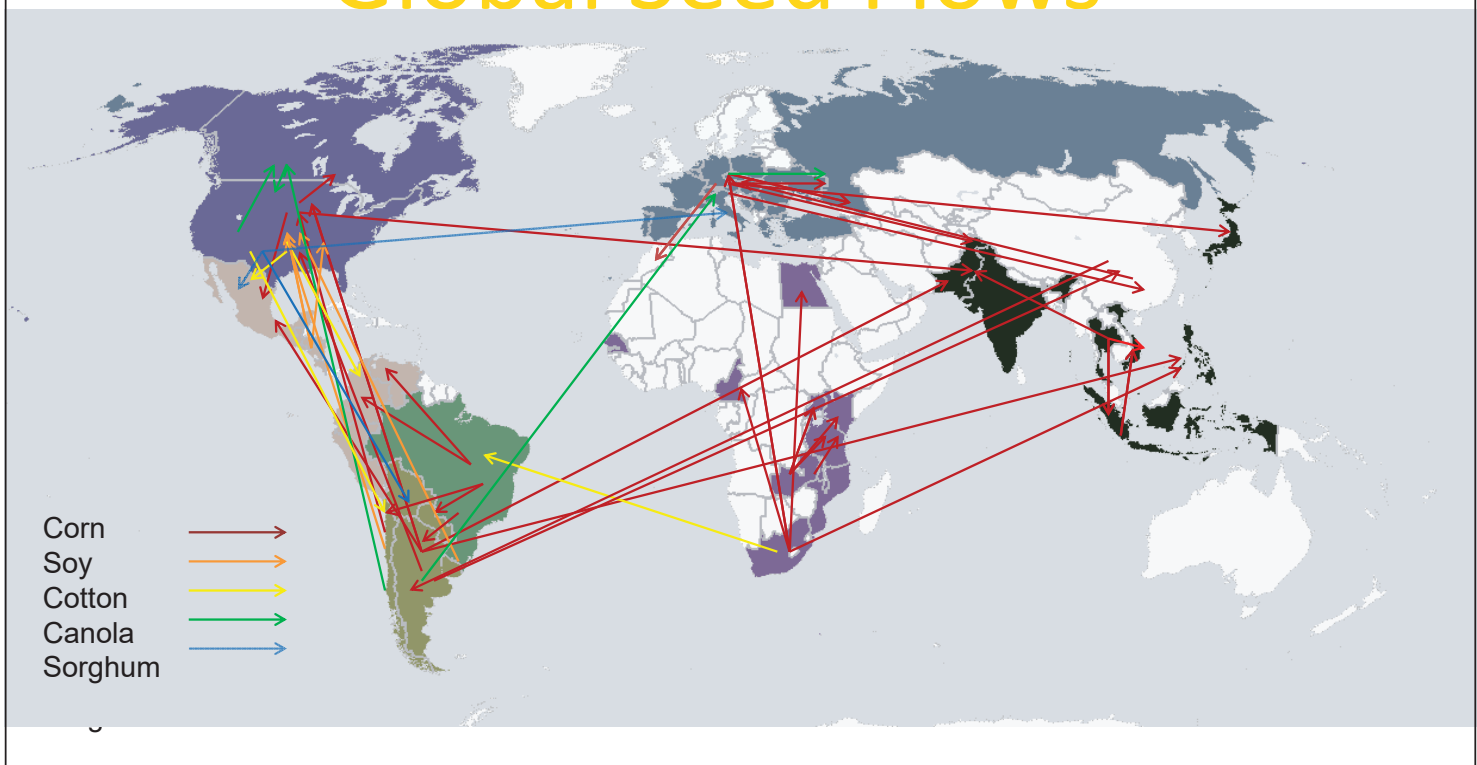
Bernice Slutsky

I have no financial relationships to disclose.

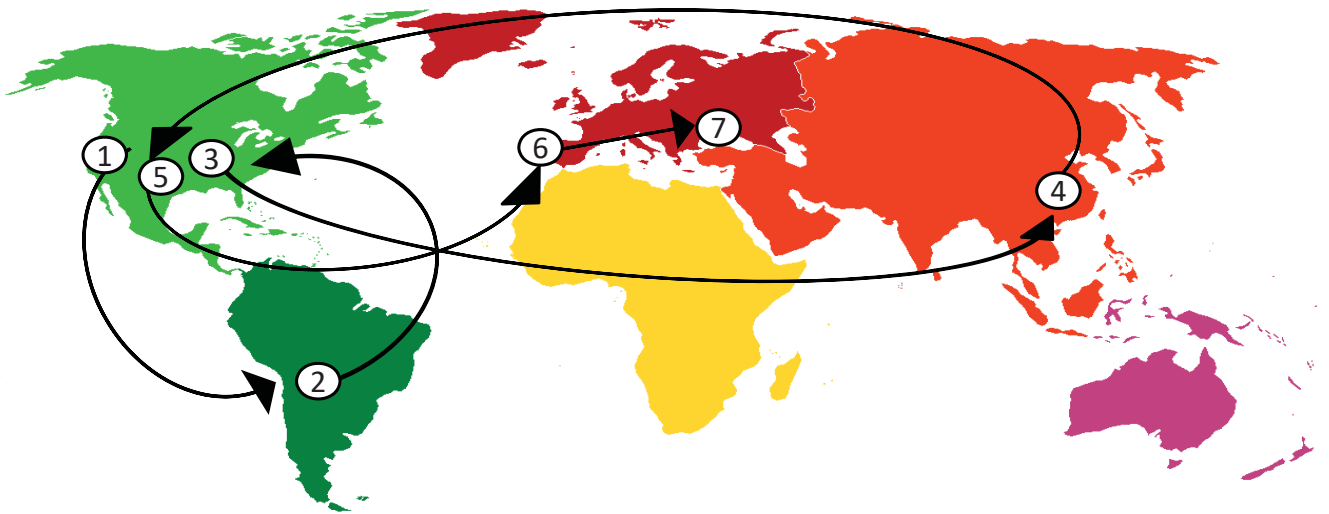
Plant Breeding Innovation: Goals of Global Seed Sector

- The seed sector and agriculture are global—what is needed?
 - Clear, scientifically based, government policy
 - Facilitation of innovation and collaboration
 - Consistent policies across countries

Global Seed Flows



Tomato Example



Goals of Plant Breeders

Plant breeders have always strived to:

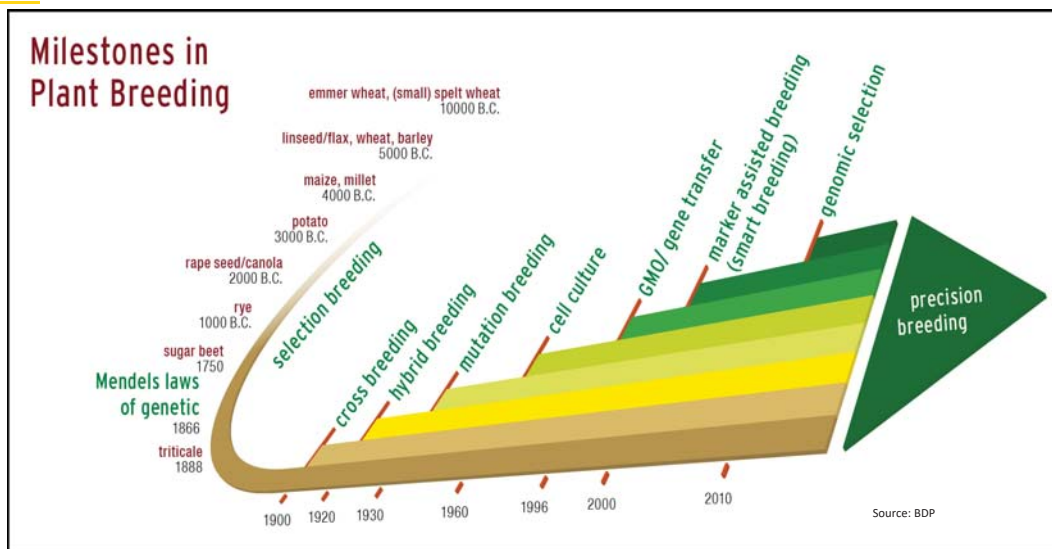
- create new variations of plant characteristics
- provide solutions for disease and pest resistance
- increase tolerance to environmental stress
- achieve higher yields
- meet consumer expectations

Plant Breeding Innovation

Plant breeding innovation can contribute to overcoming global challenges:

- Changing climate
- Limited resources (i.e. land, water, energy)
- Crop pests and diseases

Evolution of plant breeding innovation



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.
- it does not focus on any particular group of techniques, nor is it defined by them.

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.**

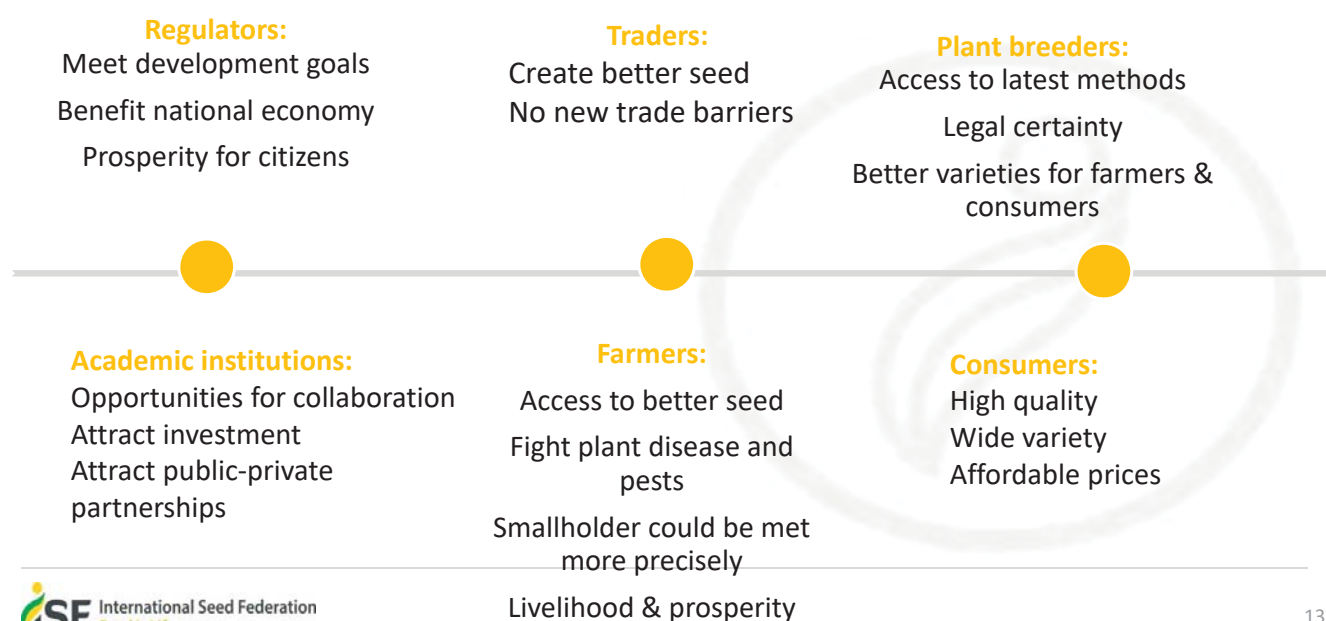
Importance of Genome Editing in Plants

- **More targeted plant breeding:** we can improve precision by making specific changes to a plant's DNA using the plant's own internal processes.
 - Activation of a beneficial characteristic (e.g. drought tolerance or increased nutrition)
 - Deactivation of an unfavorable characteristic (e.g. disease sensitivity)
 - Small changes to the DNA that reproduce a characteristic found within the plant's family – like disease resistant characteristic found in a wild relative.
- **More efficient plant breeding:** we can swiftly adapt varieties to meet the challenges of a changing world (e.g. resistance to new plant disease).

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 Consistent, Science-based Policies



So how are we going to get there?

Our “roadmap” will lead to consistent policies

- ISF Concept Paper: ‘*Consistent Criteria for 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 >> What are they?

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; 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.

Consistent Criteria for Regulatory Oversight

All new plant varieties are regulated

Question: which categories of new varieties should fall under current GMO pre-market review and approval processes

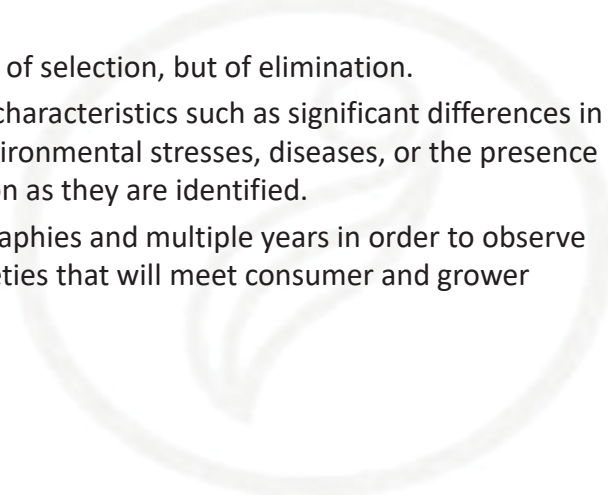
International Landscape

- Topic of discussion and policy review in a number of countries
 - Argentina
 - Brazil
 - European Union
 - United States
 - Australia
 - Israel
 - Others
- International Fora
 - OECD
 - APEC
 - FAO



Plant Breeding Practices

- Plant breeders: Product quality processes in place no matter what plant breeding method used
 - Plant breeding is often said to be a process not of selection, but of elimination.
 - Any off-types, unstable lines, or lines showing characteristics such as significant differences in nutrient content, detrimental responses to environmental stresses, diseases, or the presence of other undesirable traits are discarded as soon as they are identified.
 - The trialing process occurs over multiple geographies and multiple years in order to observe that potential variability, keeping only the varieties that will meet consumer and grower expectations.



Conclusion

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



Seed is Life