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# Creating an Enabling Environment for Innovation

A plant biotechnology perspective

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# What is innovation?

- **Oxford Dictionary – new method, idea, product, etc.**
- **Difference between innovation and invention?**
  - First cell phone (invention), smartphone (innovation)
- **Innovation as a driver**
  - Economic growth
  - Societal change



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# Enabling Environment

**Invention** —→ **Innovation** —→ **Positive Change**



National strategy, policy framework

Research and development

Entrepreneurship

Intellectual property

Oversight / regulation

*No magic formula!*

# Enabling Environment

## Confidence – clear pathway to market

- Consistency
- Transparency
- Predictability
- Functionality

## Beyond national policy –

- Trade (seed, food/feed/processing, product derived from)
- Cross border technology transfer



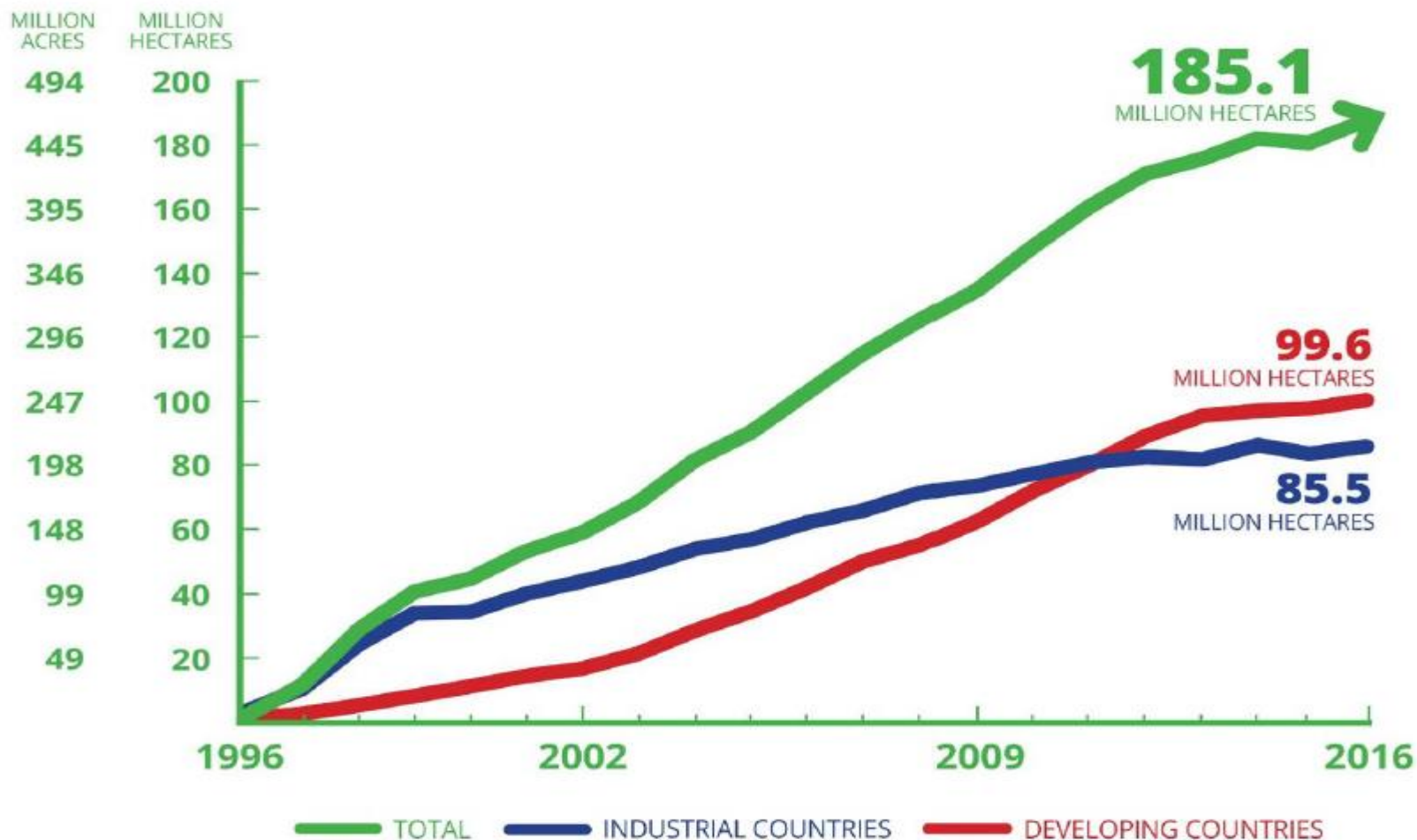
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# Plant Biotechnology – success

## Global Area of Biotech Crops: 1996 - 2016





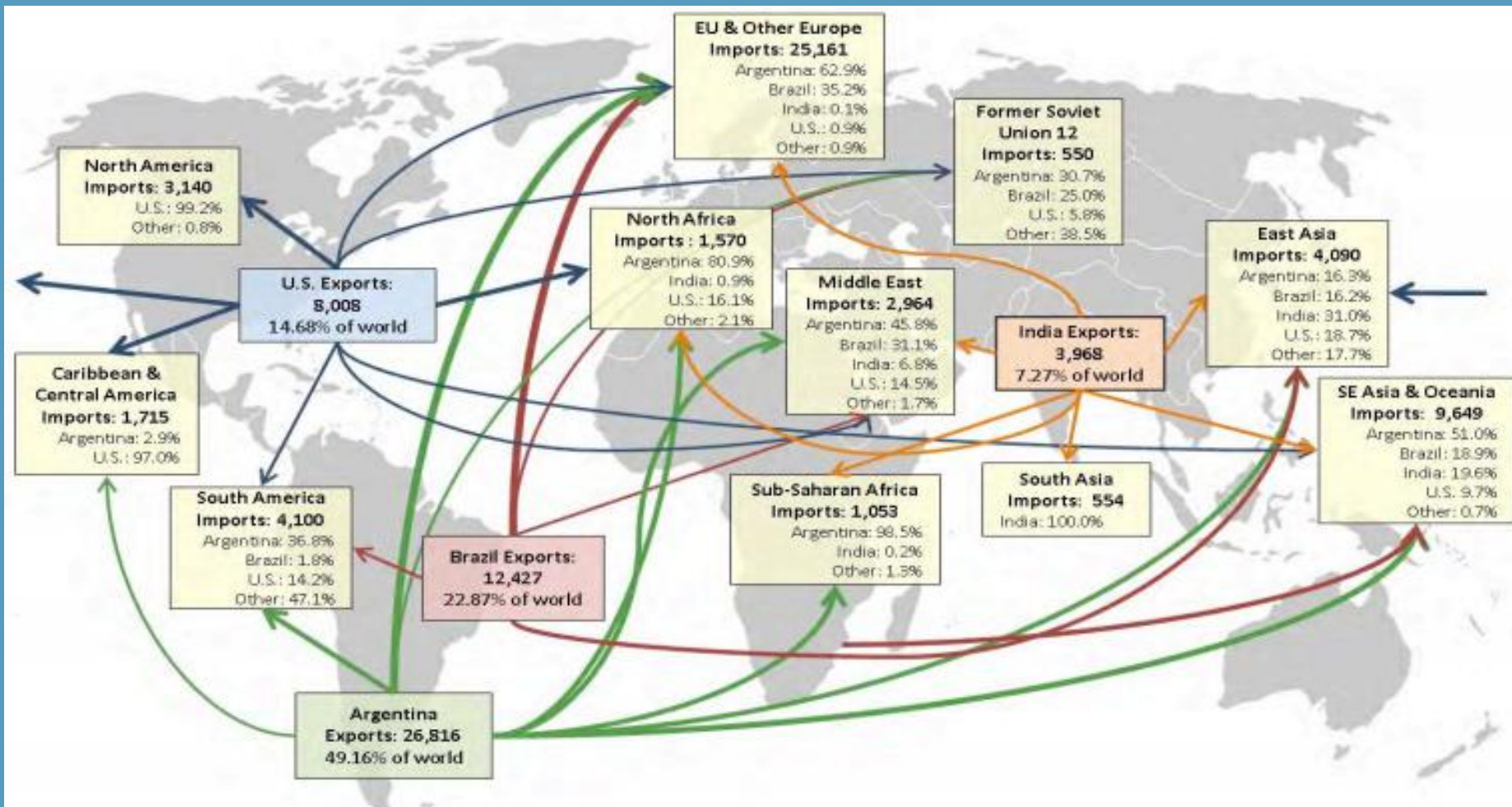
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# Plant Biotechnology – success

Seed, Grain and Food are Traded and Move Internationally





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# Plant Biotechnology – success

## Global Approval (1996 – 2016)

- **Food Use – 1,777**
- **Feed Use – 1,238**
- **Cultivation – 753**

Source: ISAAA 2016



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# Plant Biotechnology – limited success

- **Main growers – US (38%), BRA (27%), ARG (13%), CAN (6%), IND(6%),**
- **Main crops – soy, corn, cotton, canola**
- **Main traits – herbicide tolerant, insect resistant**
- **Main technology developers – big 6 (3)**





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# Reflect - Evolve

- **Entering into 21 years of regulating GE plants**
- **Thousands of safety assessments completed by multitude of regulatory agencies around the world**
- **Record of safe use – cultivation, consumption**

*Is it time to modernize – innovate ?*



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# Looking forward

## Can we improve?

- **Traditional GE crops**
  - Use of familiarity
  - What is new?
- **Products of newer innovations in breeding– genome editing**



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# Principles for Regulation

- **Decisions should be based on best available science**
- **Regulation should be developed with transparency**
- **The cost of regulation should be justified by the benefits of regulation**
- **Regulation should promote innovation while addressing goals of protection environment and health**
- **Decision to NOT regulate should be an option if no significant oversight issues can be identified**
- **Regulation should be predictable and flexible to accommodate new evidence**



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# Government initiatives

- **R&D investment**
- **Expert Group Reports**
  - Japan, U.S., European Union, EU member states, etc
- **Consider revision to regulation?**
  - Australia, US
- **Fit into current framework**
  - Argentina
- **Information sharing**
  - G to G; Multilateral fora (OECD, APEC)

# Private Sector Initiative

- **International Seed Federation (ISF)**
- **Convened two Chatham House rule discussions in 2015 and 2016.**
- **Goal: Consistent 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



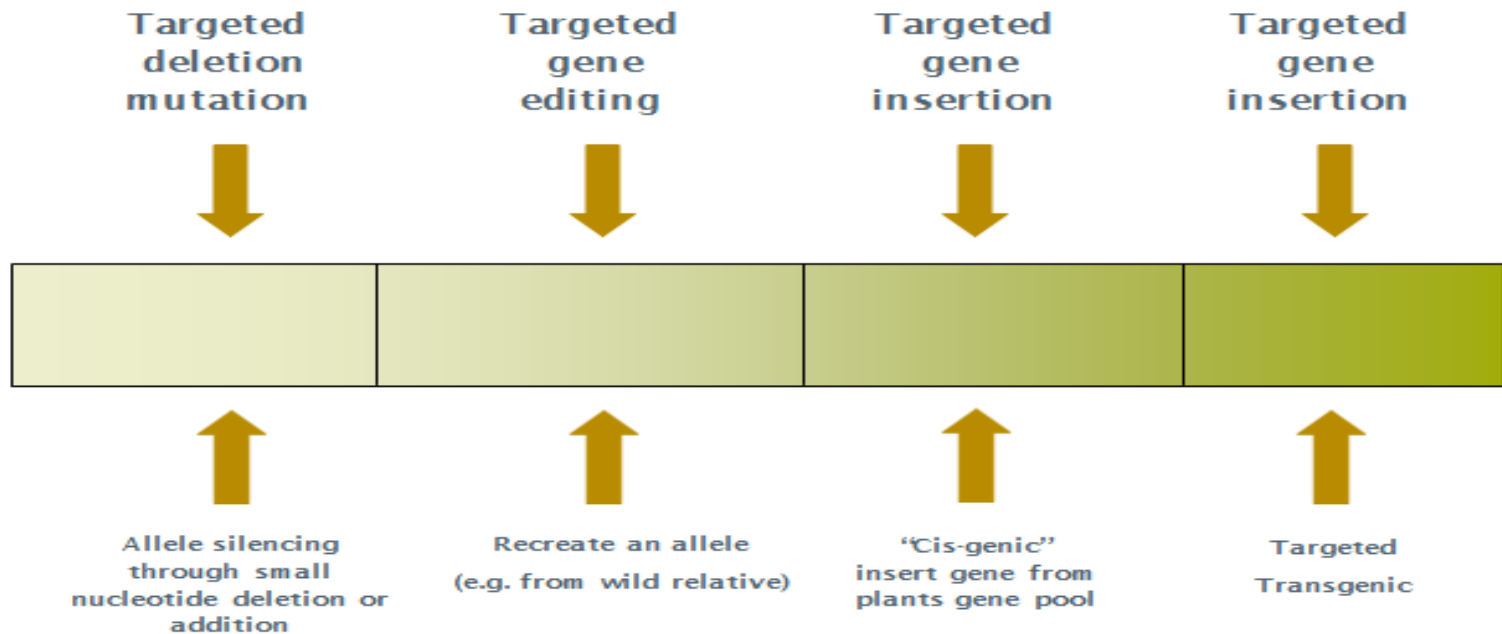
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# ISF Approach

## Genome Editing: A Continuum



Where to Draw the Line?



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# ISF Approach

**An 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.***



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# ISF Criteria

**The genetic variation in the final plant product would not be under the scope of existing biotech/GMO regulations for plants if:**

- 1) there is no novel combination of genetic material;  
or**
- 2) the final plant product solely contains the stable insertion of inherited genetic material from sexually compatible plant species; or**
- 3) the genetic variation is the result of mutagenesis--spontaneous, induced or targeted.**

*Novel combination of genetic material means the stable insertion in the plant genome of one or more genes that are part of a designed genetic construct.*





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# ISF – Next steps

- Differing definitions, legal frameworks and approaches around the world - given
- How countries implement the criteria important
- Planned 3<sup>rd</sup> meeting in 2017



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# Looking forward

- **Differing processes across countries could have negative implications for:**
  - Trade in commodities
  - Movement of seed
  - Research collaborations



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# Looking forward

## Confidence – clear pathway to market

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# Thank you

## Questions?