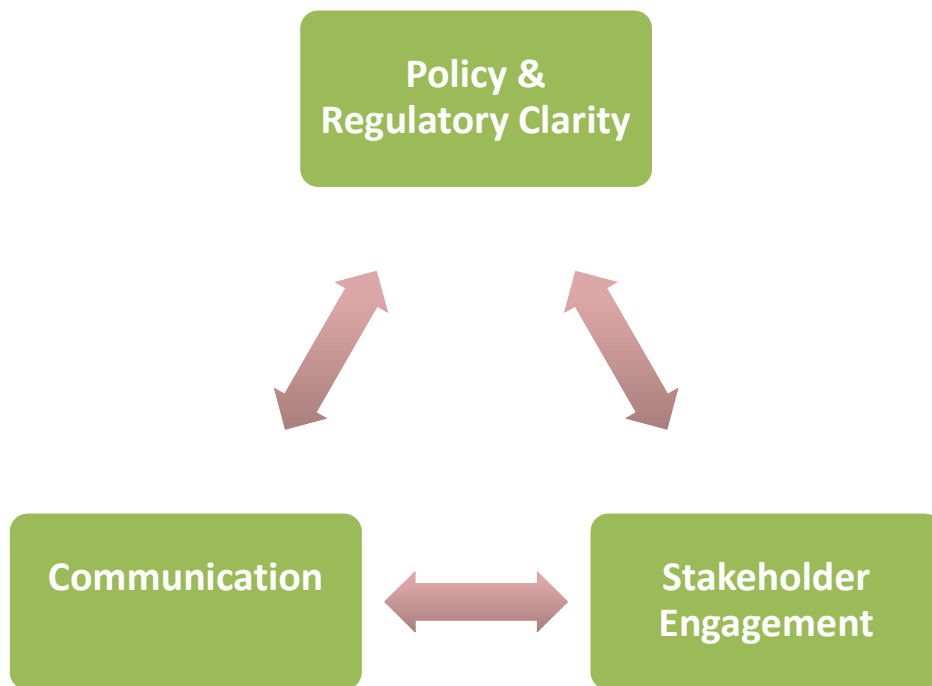


# Global Policy and Regulatory Overview

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# ISF Focus



- Importance of policy alignment
- Communication is a key component
- Outreach to stakeholders—our customers, the agriculture value chain, governments and the public

## Plant Breeding Innovation: Goals of Global Seed Sector

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



## Impact of Public Policy Around the World

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)
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# Basic Approach

- **Goal:** Consistent, science-based approach for regulatory oversight
  - Agreement among governments on the criteria to determine the scope of regulatory oversight

Underlying principle:

*Like products should be treated the same under the law.*



# Alignment around Criteria for Scope of Regulatory Oversight

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## ISF Concept Paper:

The resulting product would not fall under the current scope of GMO regulations 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.

# Alignment on information requirements for determination of regulatory status

In countries where consultation procedure in place to determine if a products falls under the GMO/Biotech regulation,

- International alignment should be established on the type of information requested from the developers
- The requested information should be restricted to only those that are relevant for the scope determination
- Excessive information needs put unnecessary administrative and/or financial burden on developers



# Essential Factors

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Three essential factors affect predictability of policy approach

1. Agreement on criteria to determine scope of regulatory oversight
2. Agreement on information requirements for determination of regulatory status (if applicable)
3. Agreement around implementation--timelines and any requirements



# All New Seed Varieties are Regulated

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Important to recognize existing regulatory mechanisms for plant varieties

- variety registration
- seed laws and regulations
- phytosanitary regulations
- general environmental safety/liability laws and regulations
- general food/feed laws and regulations



## Policy developments around the world (09/2021)

**Canada:** Product based approach;  
[Health Canada draft guidance](#)  
released, under review

**US:** Final USDA revised  
biotechnology regulation  
exempts certain products; EPA  
proposed rule exempt certain  
products; FDA conducted  
request for information from  
the public, policy TBD

**Argentina, Chile, Brazil, Paraguay**  
**Colombia, Honduras, Guatemala:** Case-  
by-case approach, excluding certain  
edited products  
**Costa Rica:** draft regulation excluding  
certain edited products

**Israel:** guidance that  
specific techniques  
outside GMO scope

**Nigeria:** high level act  
final, guidelines  
excluding certain edited  
products  
**SA:** discussions ongoing,  
draft expected 2021

**Europe:** ECJ decision that genome  
targeted mutagenesis products are  
GMOs, but legal initiative to update  
law announced by EU Commission  
**Norway:** discussion of a "tiered"  
approach  
**UK:** positive draft Ag bill, [public  
consultation](#)

**Russia:** decree for R&D program  
clarifying that genome editing  
products are "conventional-like"

**China:** unofficial "GMO-lite"  
proposal  
**Taiwan/South Korea/**  
**Thailand:** discussion of  
options  
**Indonesia:** growing consensus  
to exempt certain gene  
editing appl.  
**Singapore:** draft proposal to  
exempt certain edited  
products under consultation

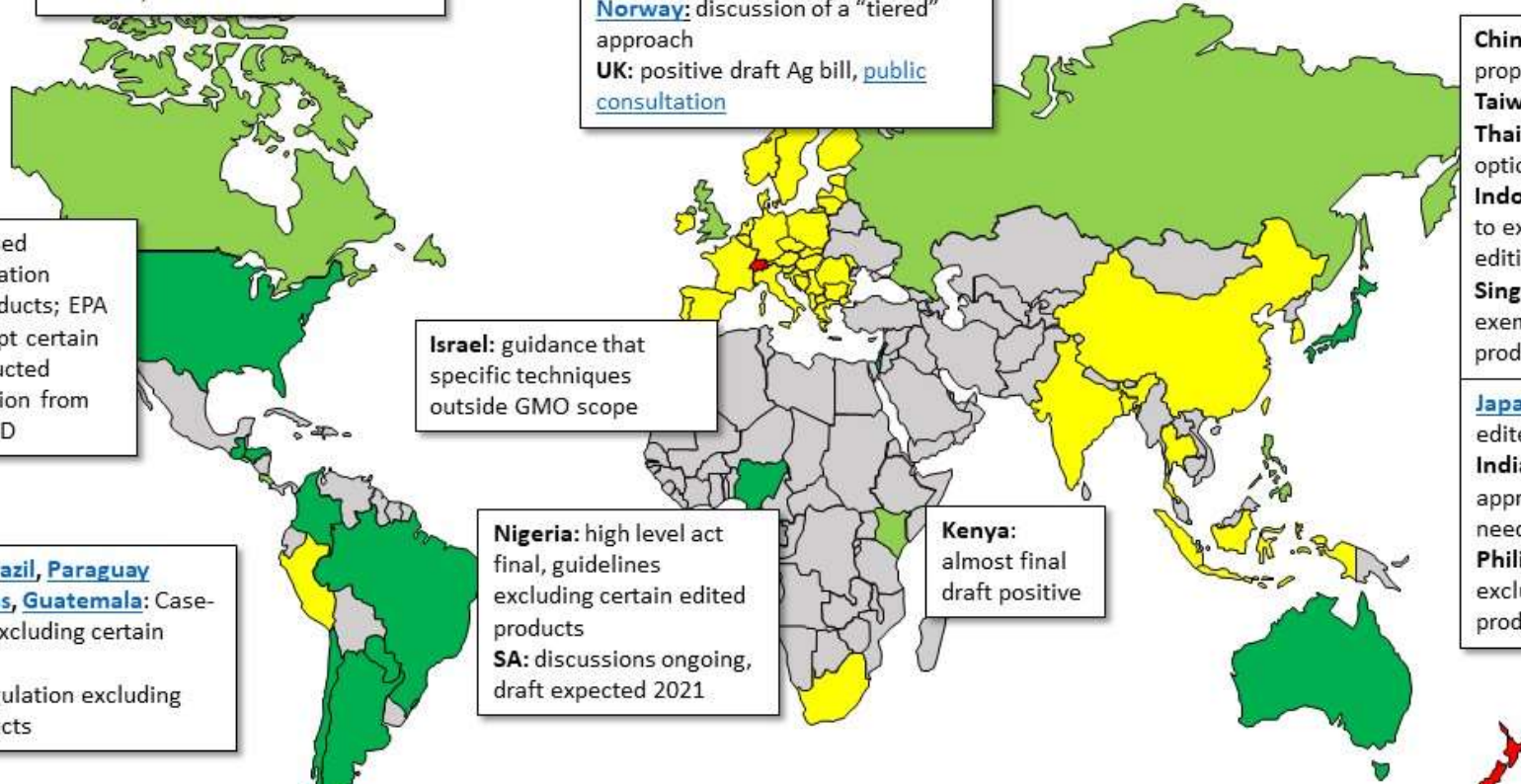
**Japan:** excluding certain  
edited products  
**India:** draft guidelines, tiered  
approach, too excessive info  
needs  
**Philippines:** draft guidance  
excluding non-transgenic  
products

**Kenya:**  
almost final  
draft positive

**Australia:** Revised gene tech  
regulation excludes *some*  
gene editing applications

**NZ:** High Court decision  
that a few specific  
techniques are GMOs

**Positive Decision**  
**No formal Decision, but positive Direction**  
**Discussion started, direction unclear**  
**Restrictive Decision**





## Moving Forward: Some Key Considerations

- Growing recognition that categories of gene products should not be treated as GMOs
- Importance of developing policy that is flexible enough to keep pace with the science
- All new plant varieties are regulated
- Breeders will continue using robust quality management processes, regardless of breeding method used
- The seed industry and agriculture are global-alignment is critical



# Seed is Life