

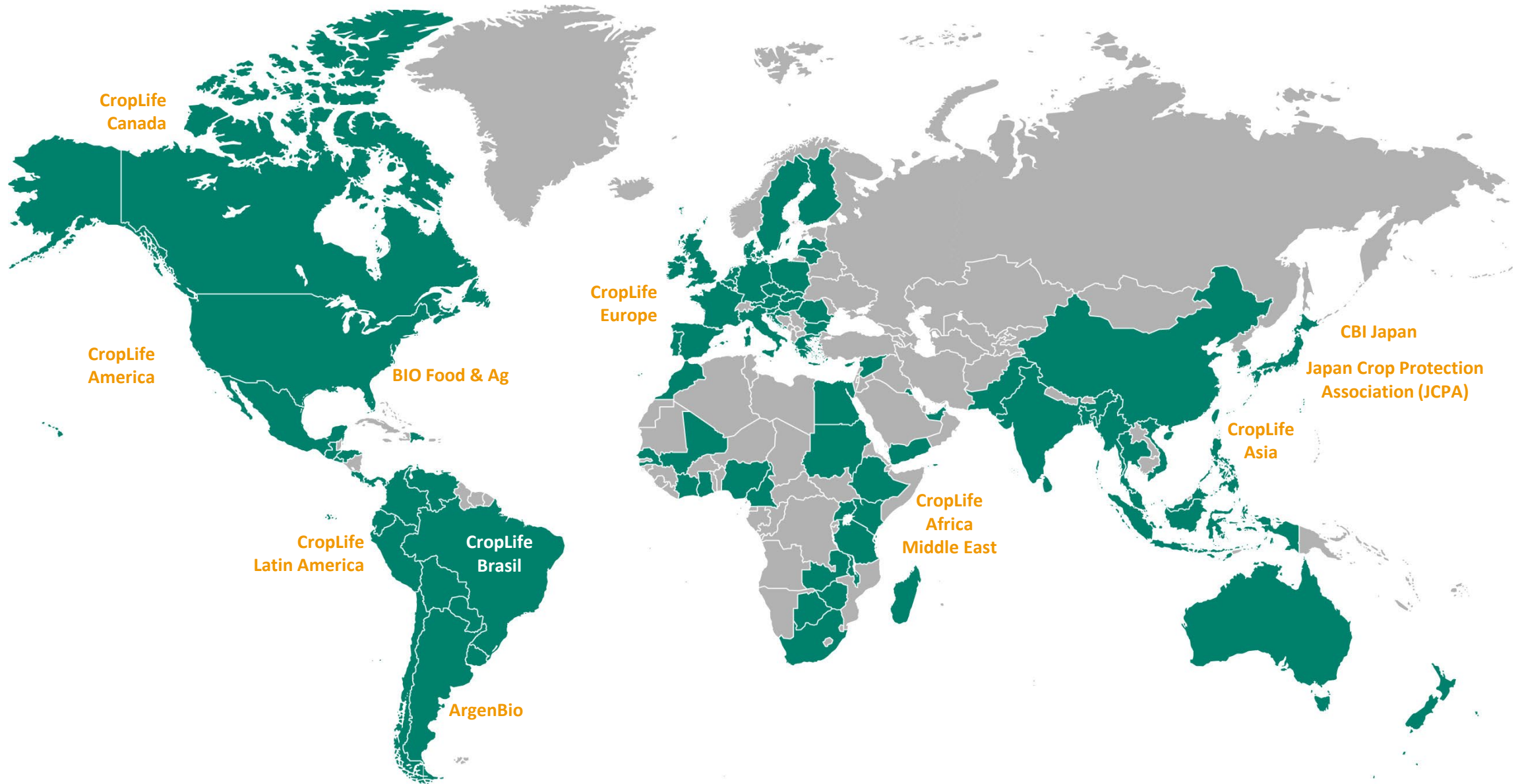
Trade in Genome Edited Products

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Member Companies



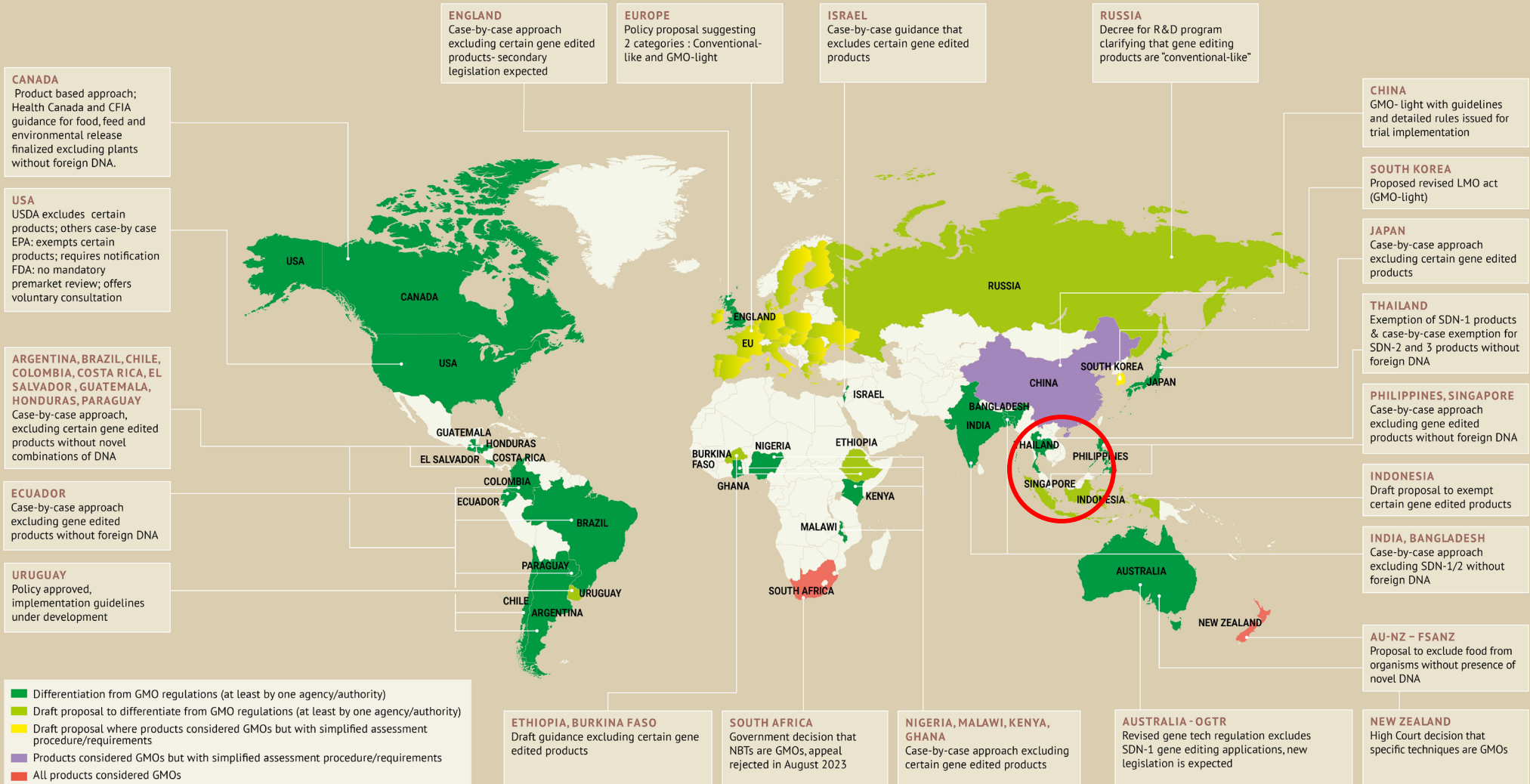
Member Associations



Policy Map Updates

Policy developments around the world 08/2024

ISF International Seed Federation
Seed is Life



Trade Considerations – Overall



From a global trade overarching perspective, **functionally no different** to have country-specific, case by case "exclusions" for products developed using genome editing as compared to case by case approvals of GMO's.

Trade Considerations – Specifics



- From a compliance side for growers/developers/traders standpoint, more complex than current GMO as a result of:
 - a) Inconsistent definitions and regulatory triggers
 - b) Differences in Post Market Requirements
 - c) Rapidly advancing applications of the genome editing technology
 - d) Technical limitations for detection methods
 - e) More developers utilizing the tools

Definitions & Triggers

Europe

China

India

LATAM

Regulatory Triggers

Some predefined number of genetic changes (?)

All are GMO, interpretations of elevated levels food safety and environmental risk affects submission

“SDN1 and SDN2” products are non GMO

Novel combination of DNA / Foreign DNA



Future Proofing Policy

Early examples using genome editing in a SDN1/2/3 nomenclature (“delete”, “edit”, “add”)

Pipeline from our members, what is published in the literature goes well beyond

Policy perspective, essential that triggers and processes can handle these evolving applications – **prevent future trade concerns**



Knockouts

Insertions / Deletions

Copy number variation

Inversions

Translocations

Duplications

Epigenetics

Guided Recombination

Differences in Post Market Requirements

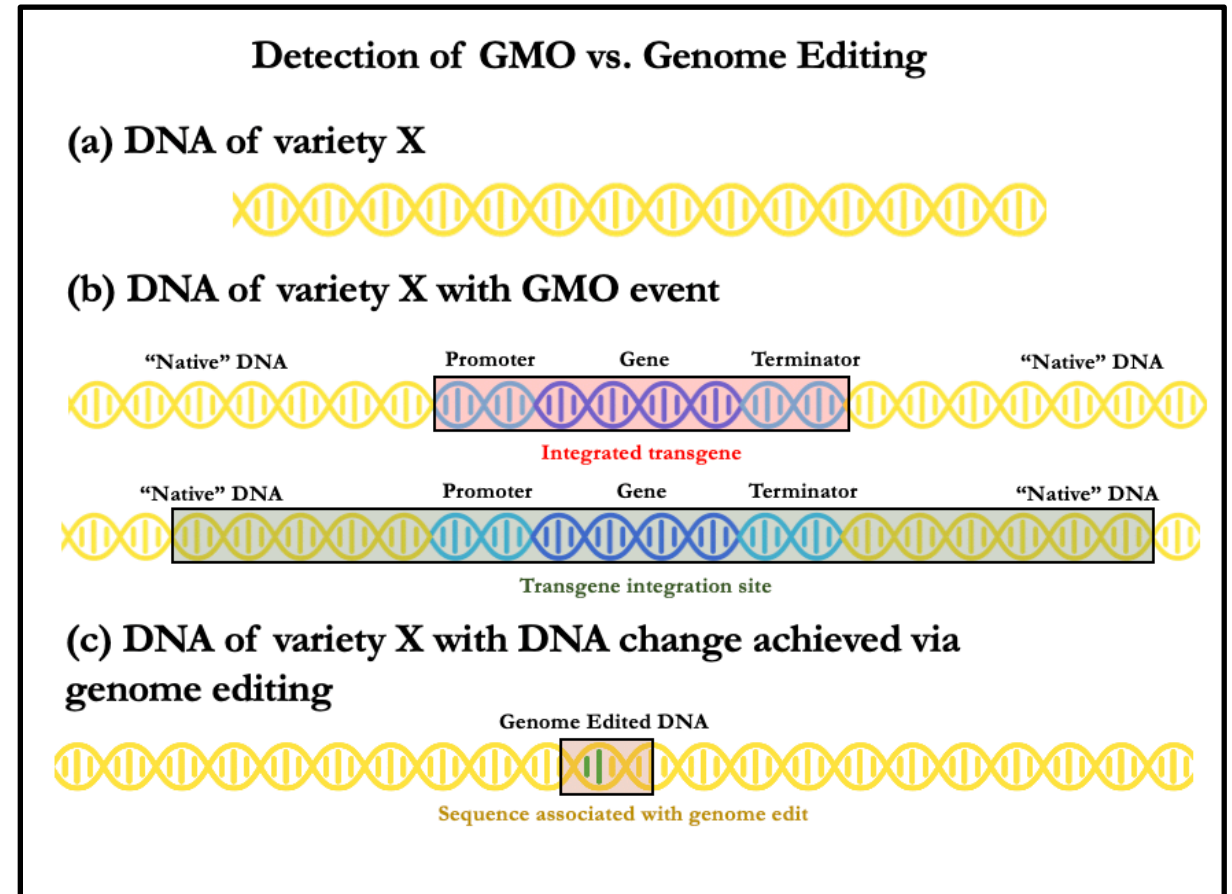


Exempting genome edited products from GMO regulations but then still applying unique post-market conditions to “conventional” products affects global utility. This includes

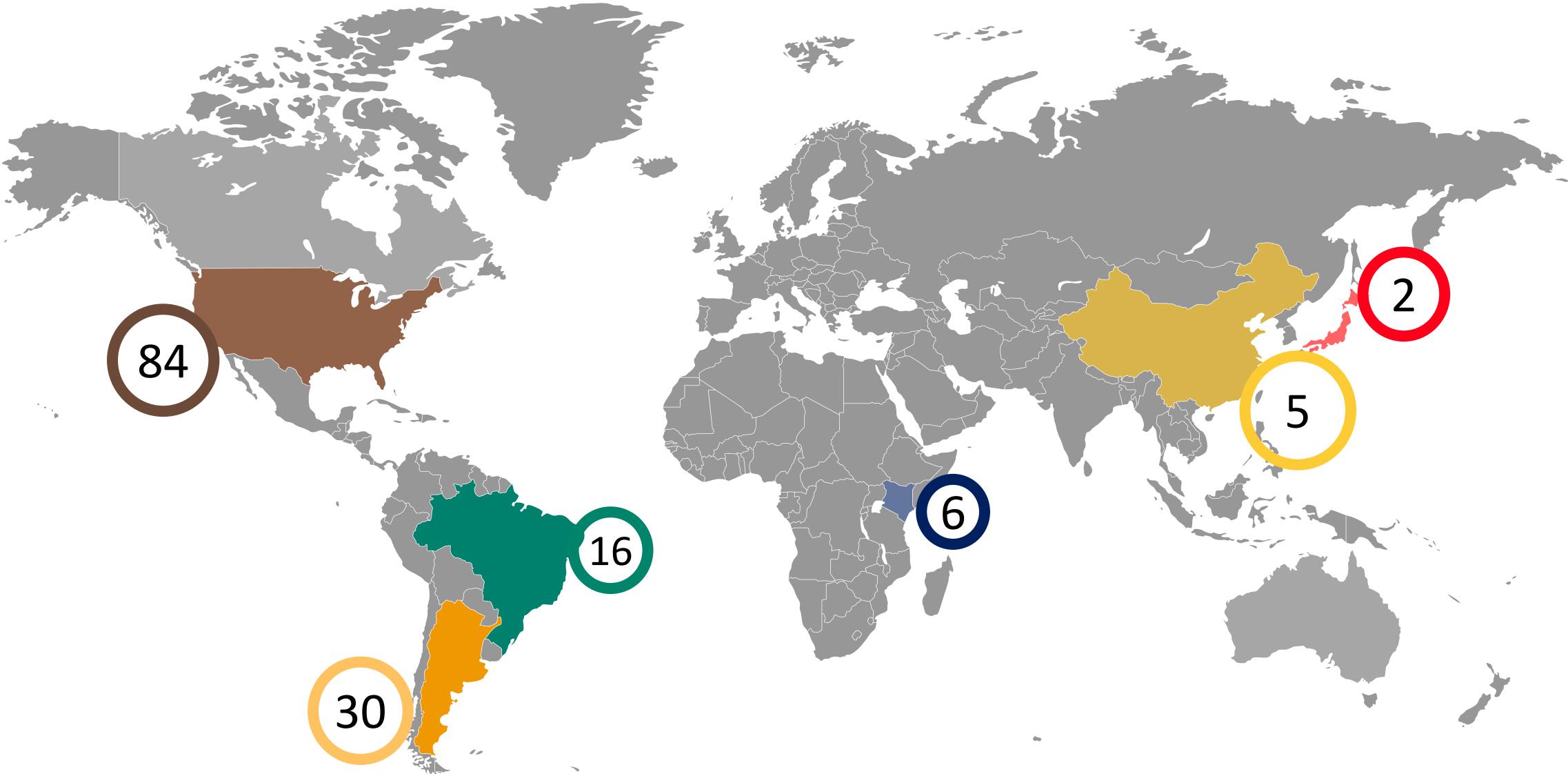
- Modifications to the variety registration process
- **Requiring segregation, traceability, testing, surveillance**
- Mandatory stewardship (above and beyond conventional seed)
- **Mandatory labelling of harvested products**

Technical Limitations for Detection Methods

- Many genome editing applications **do not** result in “events” with a specific genetic fingerprint in the same manner as GMOs
- GMOs contain a relatively large and unique DNA sequence based on the junction created between the DNA inserted and adjacent endogenous plant DNA. This provides unique sequence for the development of a DNA-based detection method that is specific for the specific transformation event. **Genome editing may not result in a DNA sequence change that is large enough, or unique enough to develop a detection method that is reliable or practical.**



Example Consultations (Plants considered non-GMO)



What is the potential impact of this?



For globally traded commodities without clear path for full global approvals based on these challenges, can lead to different commercial approaches

- Reluctance to launch any products that would go into a commodity stream
- Managed and limited closed loop production / distribution systems
- Providing less transparency on use of technology
- Rebalancing crops and focal areas of research using genome editing

Solutions



- As much harmonization as possible in the SAA region to engage with trading partners including
 - Alignment in how to communicate about genome editing with trading partners (terminology)
 - Alignment in how to handle current and future types of products (and communicating about this to stakeholders)
 - Support for SME and public developers in getting to market and engaging with trading partner systems