

# How are NBTs regulated outside the EU & potential impact on commodity trade

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## Three sectors

- Industrial biotechnology / White: Industrial processes
- Healthcare biotechnology / Red: Pharmaceuticals
- Plant biotechnology / Green: Agriculture/ seeds

## Wide Network

- 55 corporate members (Healthcare + Industrial + Ag)
- 15 associate members and Bioregions
- 17 national biotech associations = +1800 biotech SMEs

## 10 ag biotech member companies





**EU = heavy importer** of many ag commodities

**GMO experience shows:**

- dysfunctional EU authorization system for cultivation: no access for EU farmers
- partly dysfunctional system for imports: risks disruptions, delays farmers' access elsewhere

**Plant Breeding Innovation is different:**

- NBT-derived crops often indistinguishable
  - More players (smaller companies & public)
  - More crops, more traits (incl. fruit & veg)
- Different regulation per country **likely to cause greater trade problems** than for GMOs



## Delayed Import Approvals

- Imports approvals take 6 ½ years on av. (incl 4 ½ Y for EFSA, but rapidly increasing)
- Member States divided
- GM Cultivation: dysfunctional – 1 product
- National bans on EU approved GMOs
  - In place for cultivation
  - Proposed for imports



**6.5 y for approval**  
(4.5 y EFSA + 2 y political)





Disclaimer: preliminary info!

## USA

- Likely most NBT crops do/ will not lead to GMO
- Ht canola (ODM) no GMO, being cultivated
- Waxy maize & mushroom (both CRISPR) no GMOs
- Review of biotech regulatory system ongoing, with a view to encouraging innovation

## Brazil

- Mutagenesis exempt
- likely gene-edited crops no GMO
- Some cisgenesis-derived crops likely no GMO



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## Argentina

- GMO definition & new regulation for NBTs put more emphasis on product than process
- No transformation event = no GMO
- Most gene-editing techniques likely not lead to GMOs (if no transformation events inserted)
- Cisgenesis, ZNF3 likely lead to GMOs

## Canada

- Biotech regulation is triggered by product/ trait novelty ('Plants with Novel Traits', not process)
- In principle, no authorization needed if NBT-derived crop has a trait which existed in before 1996 (grandfather clause)



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## China

- Similar to EU in terms of timelines for GMO import approvals
- Strong process (not product) focus
- No clarity - similar to EU

## Japan

- Comparatively efficient on GMO imports
- No clarity on NBTs, but SIP (strategic innovation promotion program) developed by the cabinet office is working on development, regulatory consideration and public communication of NBT incl. genome editing).



1. Divergent NBT regulation between countries will likely mean **bigger trade problems** than for GMOs
2. **Exporting countries likely to treat many NBT-derived crops as conventional**
  - USA & Canada: likely treat most NBT derived crops as conventional crops
  - Brazil & Argentina: legislation more similar to EU, but application in practice most likely rather pragmatic.
3. **Other importing countries uncertain**
4. **Need for international alignment**