Overview of biosafety regulations to support the future regulatory status of precision breeding products in some non-EU countries

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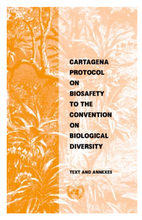
What is a Living Modified Organism?

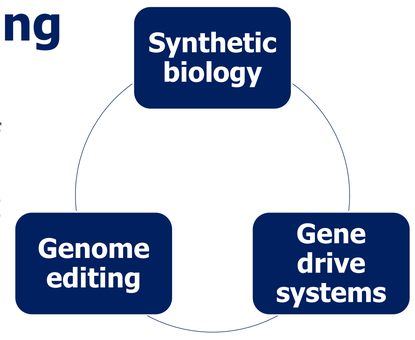


According to the Cartagena Protocol on Biosafety, a Living Modified Organism (LMO) is any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. LMOs are regulated under international and national biosafety law.

Product-based approach + **Process-based approach** = **LMO**

Precision breeding

No international consensus on its definition. Some of these technologies may result in organisms that cannot be distinguished from their conventional counterparts. Techniques:



Are precision breeding products subject to regulation?

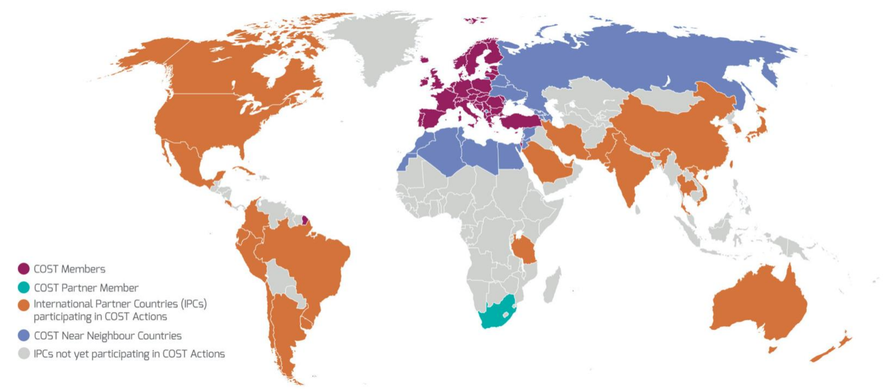
It is still uncertain. Most countries require legal clarity to the regulatory status of precision breeding. For example, if the breeding process has not resulted in the incorporation of any novel genetic combination, is the final product not considered as LMO?

Precision breeding products ⟷ **LMOs**

Biosafety and precision breeding matters in countries near the European Union

1. Targeting countries

27 countries near the European Union (12 non-EU COST Members and 15 COST Near Neighbor Countries).



2. Methodology

- Biosafety legislation, regulations

Revision of legal material

Stakeholder consultation

- Online survey to regulators and researchers

3. Clustering of countries

The key criterion for the clustering of countries is whether the national legislation has adopted the legal definition of LMO under the Cartagena Protocol on Biosafety or the Genetically Modified Organism (GMO) definition under EU law, Directive 2001/18/EC.

4. LMO regulatory experience

Decisions for the use of LMOs have been made in few countries. A ban for LMO import and cultivation is imposed in most COST Near Neighbor countries. Authorized activities with LMOs include:

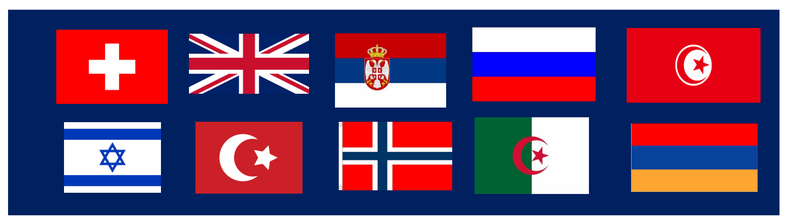
- **In contained use (lab, greenhouse, glasshouse)**
- **Importation for food purposes**
- **In confined use (confined field trials)**
- **Importation for feed purposes**

5. Regulatory matters on precision breeding

Israel

- In Israel, genome edited plants resulting only in a deletion of nucleotides and with no insertion of foreign DNA, are not considered to be transgenic and are not be subjected to the Israel's Seed Regulations No.5765.
- In 11 targeting countries, initials discussions are currently being made.

6. R&D activities on precision breeding



Crops: **cereals, tobacco, fruits and berries, pulses, oil crops, roots, tuber crops, forage crops, fiber crops.**

Technologies: **Agroinfiltration, ODM, SDN, RNAi, synthetic biology, reverse breeding, grafting, RdDM.**

Conclusions

- Initial efforts are being made to assess the regulatory status of precision breeding in few countries, and some institutions in selected countries are carrying out R&D activities using precision breeding technologies. The need to assess the regulatory status of precision breeding is strongly connected to the role of biotechnology in these countries, considering their economic and socio-political contexts.

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