

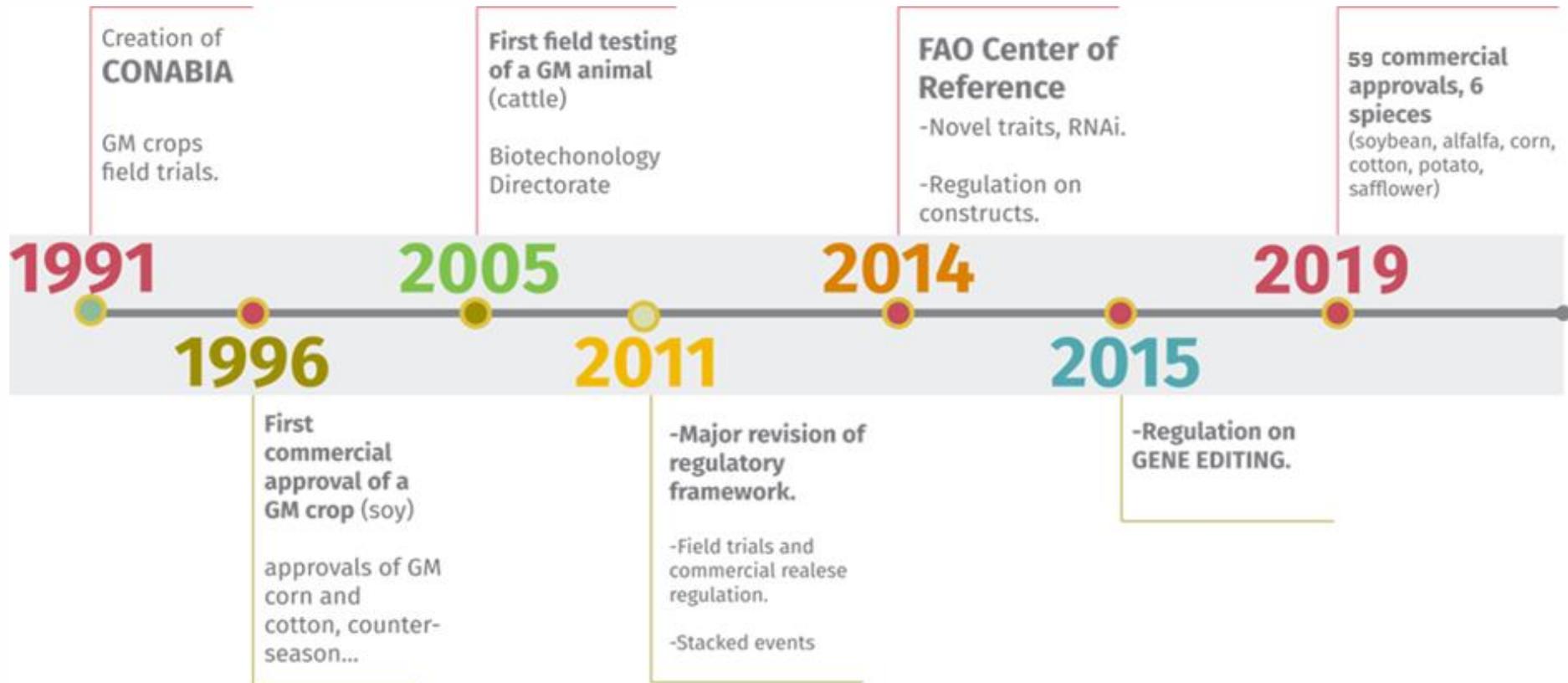
Regulatory Approaches



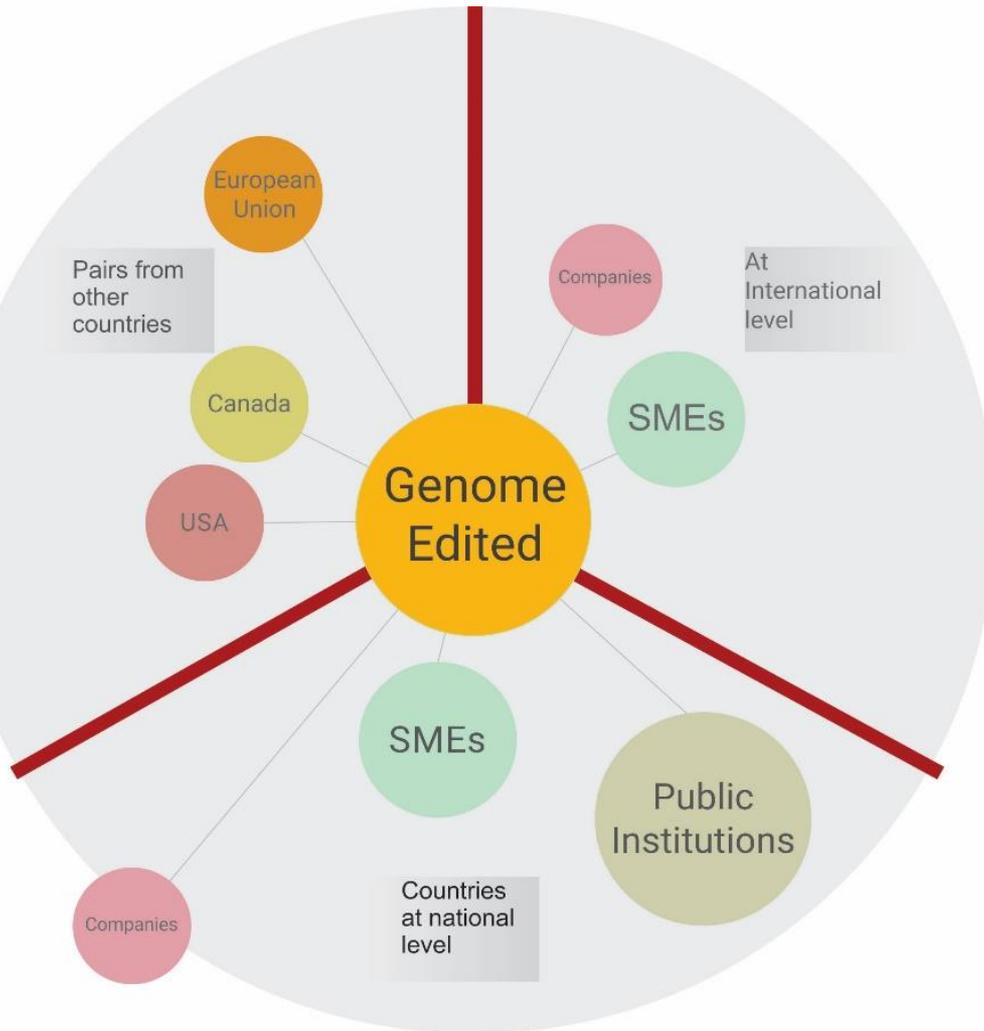
Ministerio de Agricultura,
Ganadería y Pesca
Argentina

CONABIA's milestones

CONABIA: National Advisory Commission on Agricultural Biotechnology



Collaboration Sectors



How do we accompany the emergence of these techniques with an appropriate Regulatory Framework?



2015: Argentina pioneer in the creation of a specific regulation for the use of gene edited products

GMO definition (Cartagena Protocol)



Genetically Modified Organism:

Organism that has a ***combination of genetic material*** obtained through the application of ***modern biotechnology***".

Modern biotechnology:

- *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles or:
- Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Argentina pioneer in Latin America



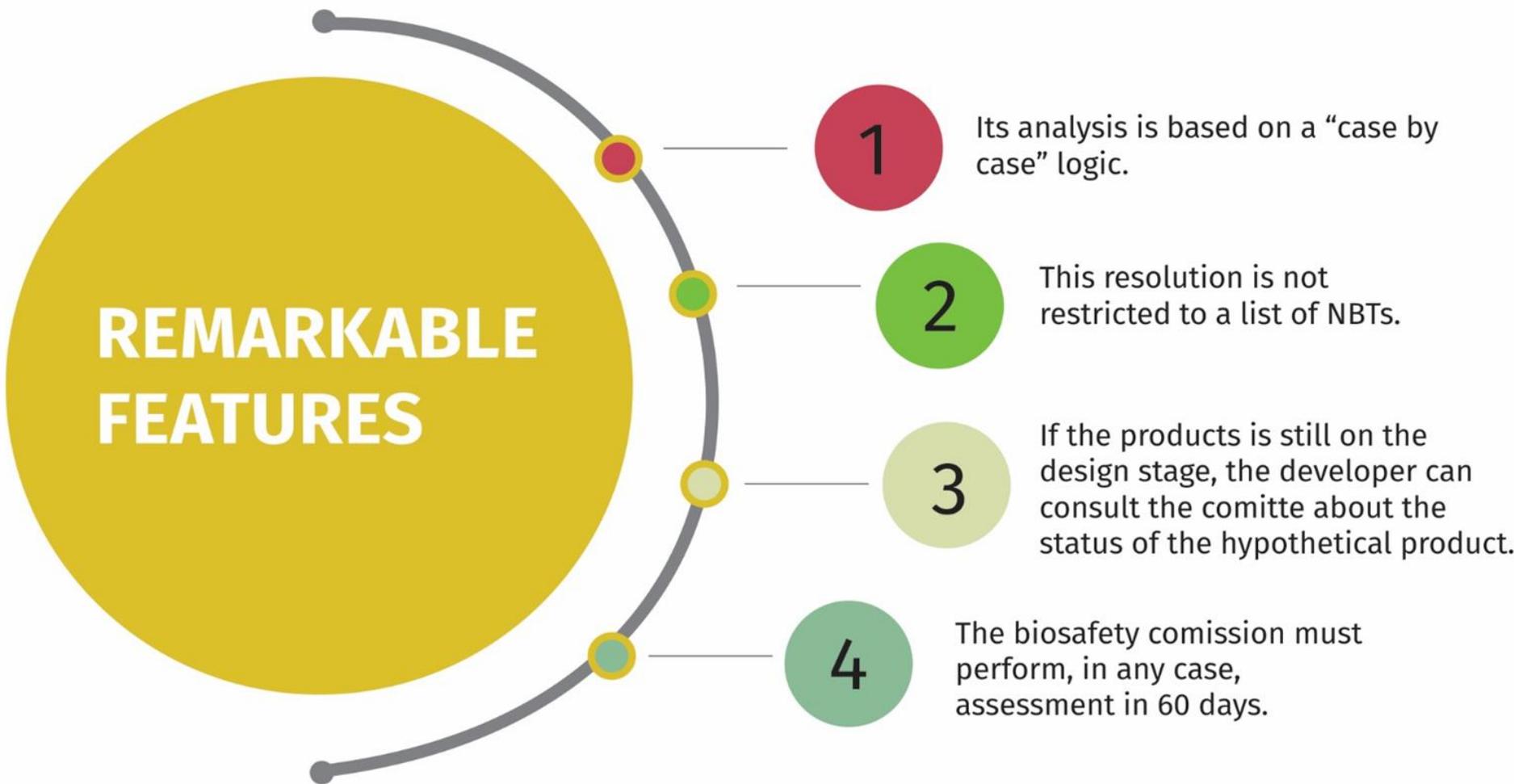
- **2013** - CONABIA Started to work on NBTs Regulation.
- **2015** - **Res. 173/15** Became official.

Procedure to determine if a product obtained using NBTs would be under the GM regulation or not.

- **2020**- The NBTs Regulation is being updated, it will contain specific annexes for each organism (plants, animal and microorganisms).

Res. N° 173/15- Remarkable Features

REMARKABLE FEATURES



1

Its analysis is based on a “case by case” logic.

2

This resolution is not restricted to a list of NBTs.

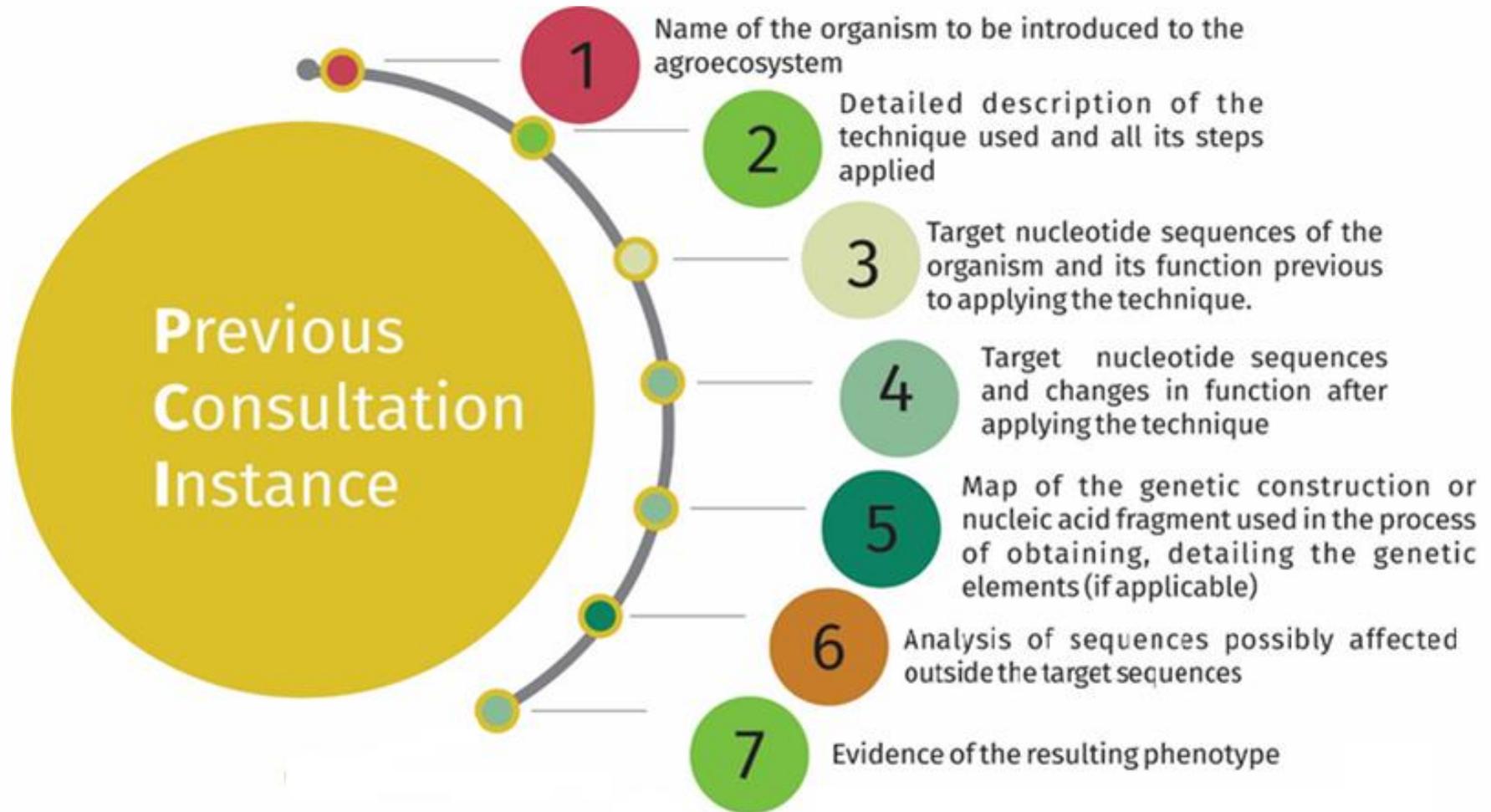
3

If the products is still on the design stage, the developer can consult the comitte about the status of the hypothetical product.

4

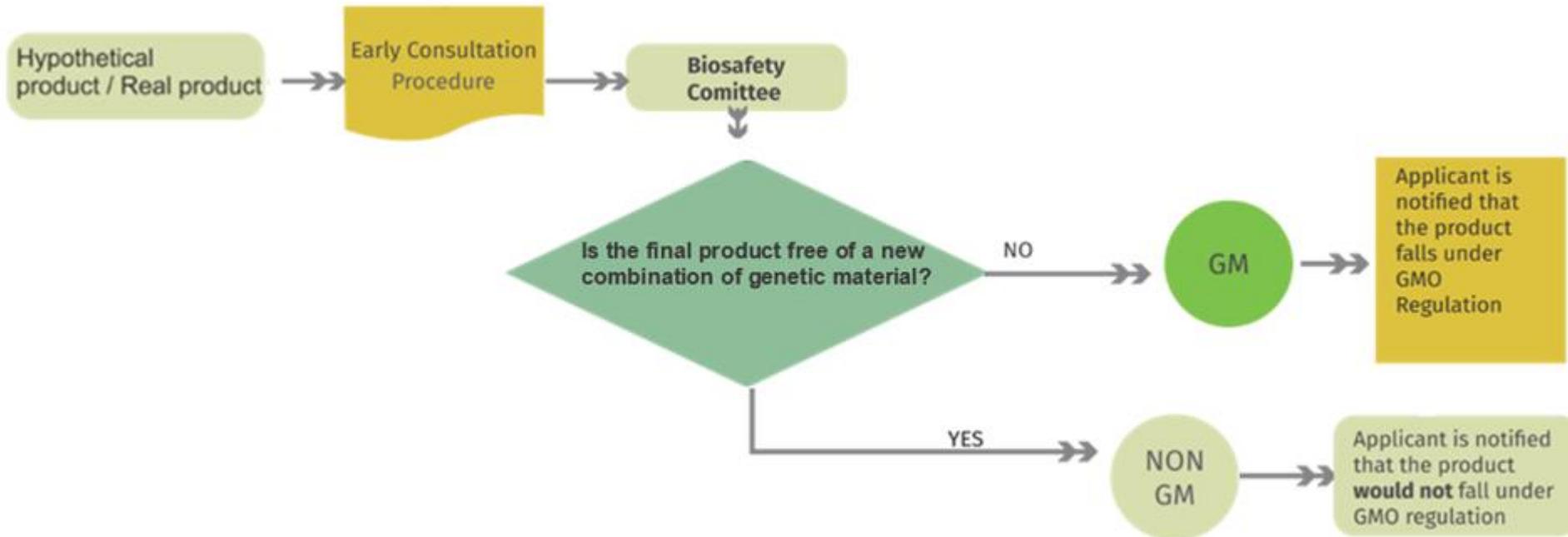
The biosafety comission must perform, in any case, assessment in 60 days.

DATA Package



Biotechnology Directorate and CONABIA may request the applicants to file additional data and information in order to complete their assessments.

REAL and HYPOTHETICAL products



If the Product does not contain a new combination of genetic material In the genome generated by NBT's , the product is not considered a GMO... "

Approaches in other american countries

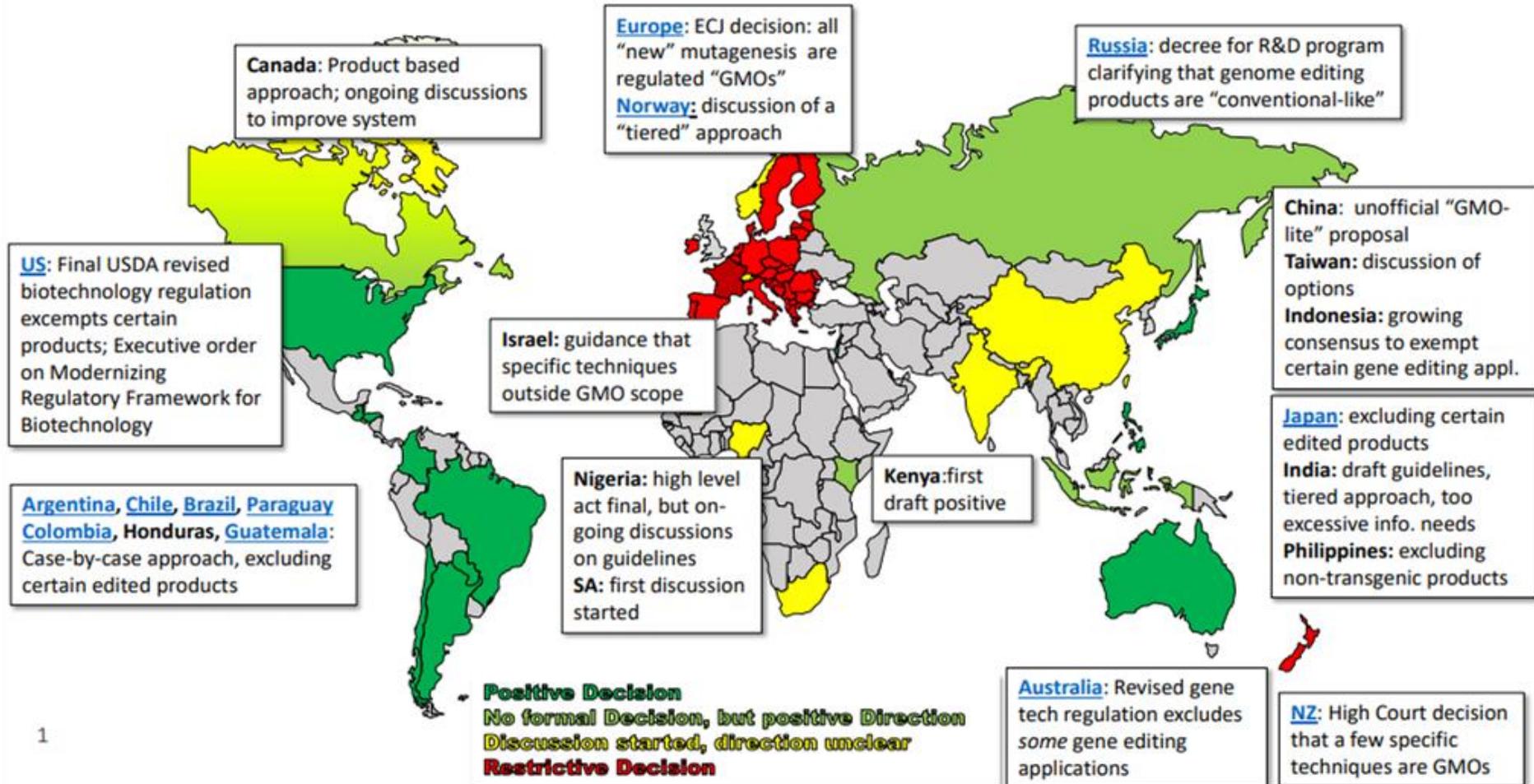


■ Harmonized Regulations
■ Similar conclusions on regulatory status

2015 **ARGENTINA**
2017 **CHILE**
2018 **BRAZIL**
2018 **COLOMBIA**
2019 **PARAGUAY**
2019 **ECUADOR**
2019 **GUATEMALA**
2020 **HONDURAS**

These countries have very similar regulations

Policy developments around the world (05/2020)



Speed of innovation

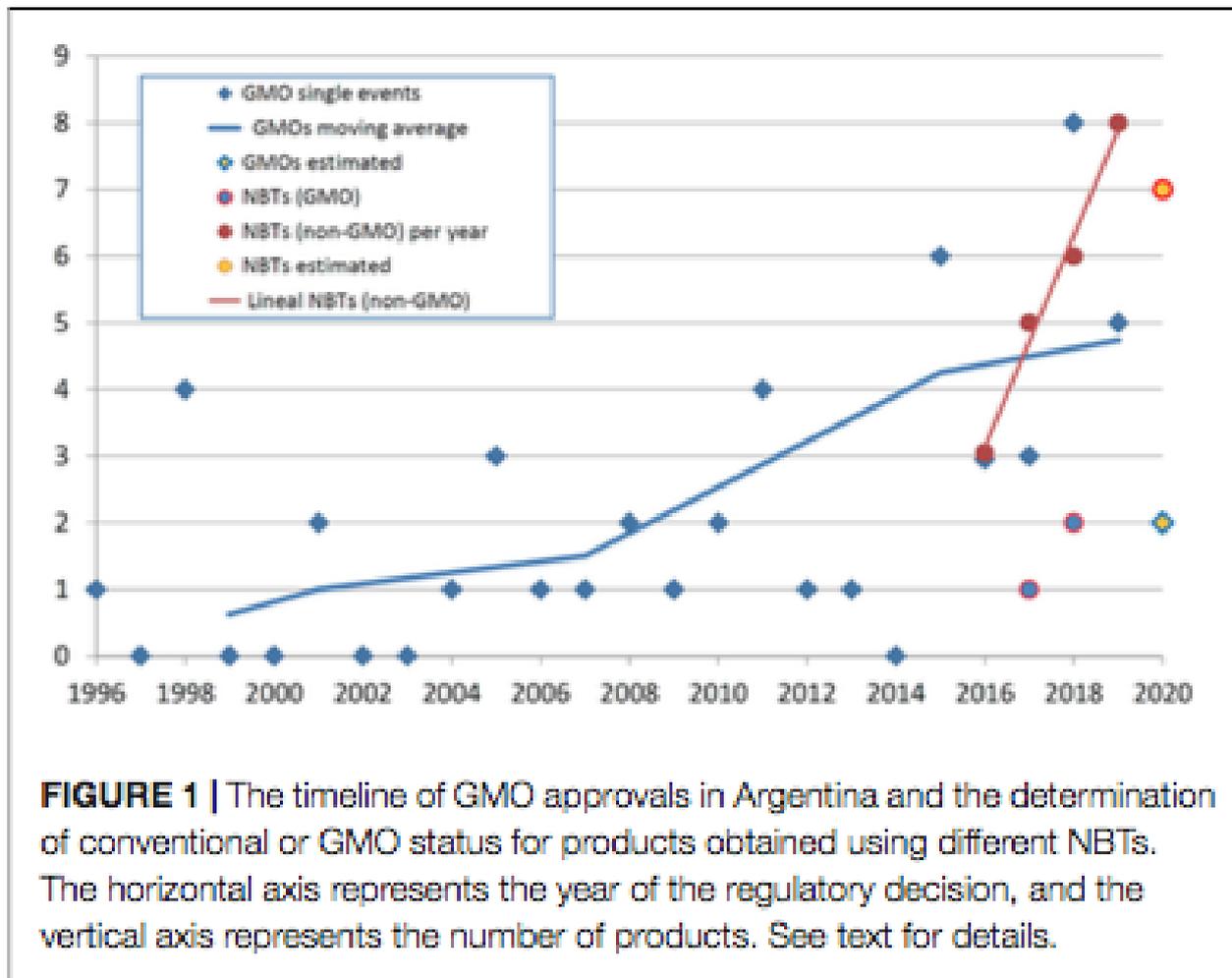


FIGURE 1 | The timeline of GMO approvals in Argentina and the determination of conventional or GMO status for products obtained using different NBTs. The horizontal axis represents the year of the regulatory decision, and the vertical axis represents the number of products. See text for details.

Speed of innovation of genetic editing products compared to GMOs

Conclusions

The crops obtained by Gene Editing have the potential to confront the challenges facing agricultural production, helping to increase the supply of food and other agricultural products in a sustainable manner.

Considering Argentina's 5 years of experience applying this criteria in the case analysis of products derived from NBTs, we can conclude that taking the definition of GMOs from the Cartagena Protocol is adequate and sufficient.



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