

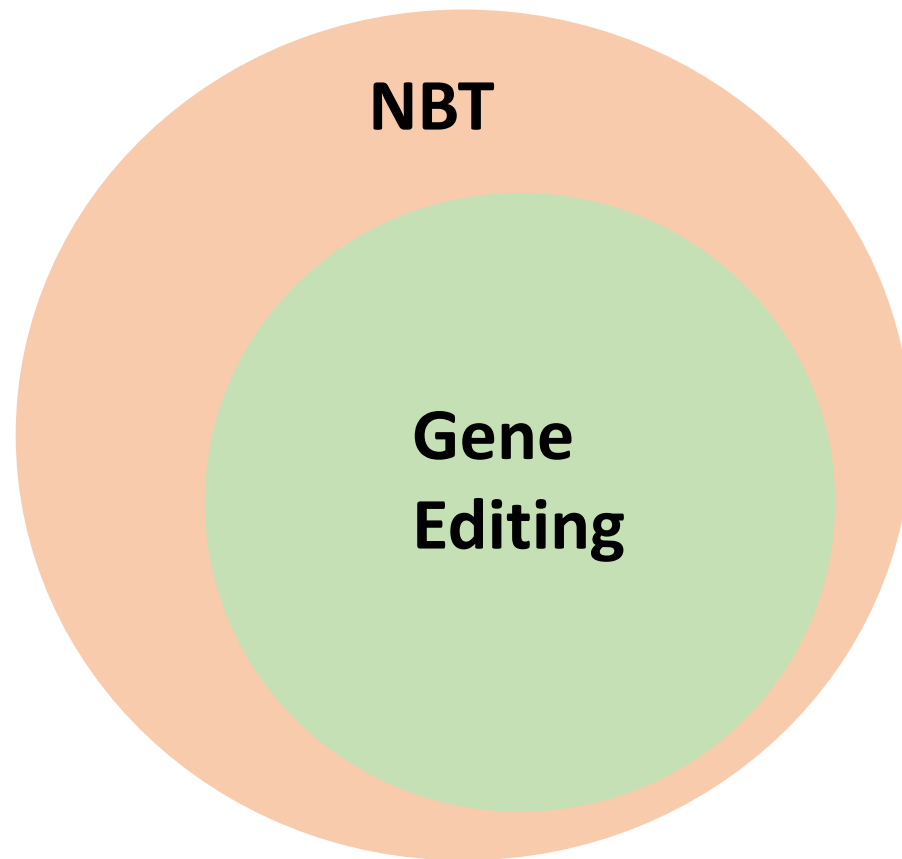
Argentine Regulatory Framework for Genome Editing

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“Application in Agriculture and Regulations on Food
Derived from Gene Editing Technology”
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Argentina started discussing how to address the products obtained by NBTs in 2013



- “New Breeding Techniques” (NBTs) include a diverse range of techniques that are new and different from the “conventional” breeding methods
 - Gene Editing includes different techniques allowing to make highly specific changes in the DNA sequence of a living organism

Regulatory framework for New Breeding Techniques (NBTs) in Argentina

2013

State-of-the-art
survey on NBTs

2019

Regulations for animals
and microorganisms
obtained by NBTs

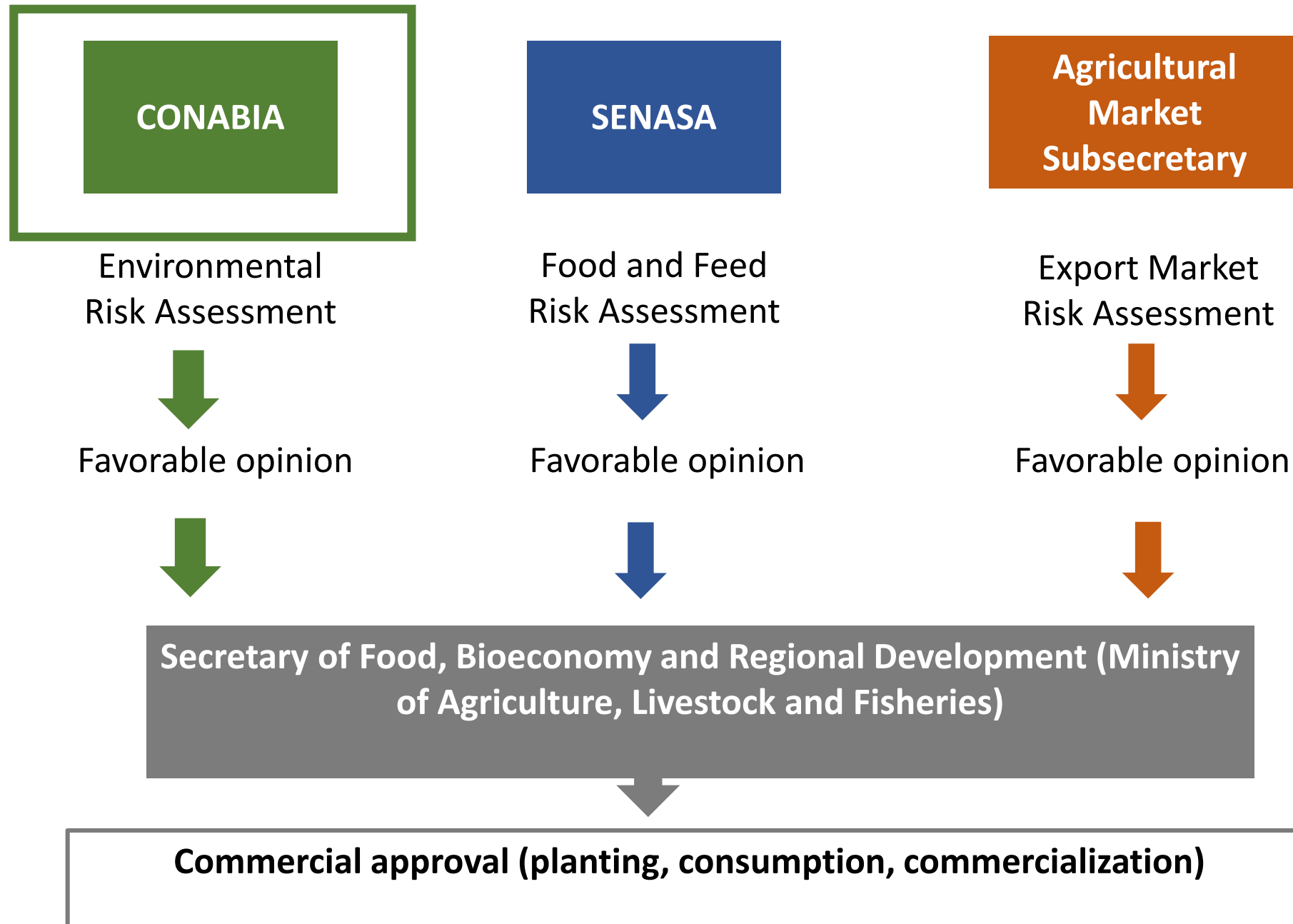
2015

First regulation for
plants obtained by NBTs

2021

Updated (current) regulation
for plants, animals and
microorganisms obtained by
NBTs (Res. 21/2021)

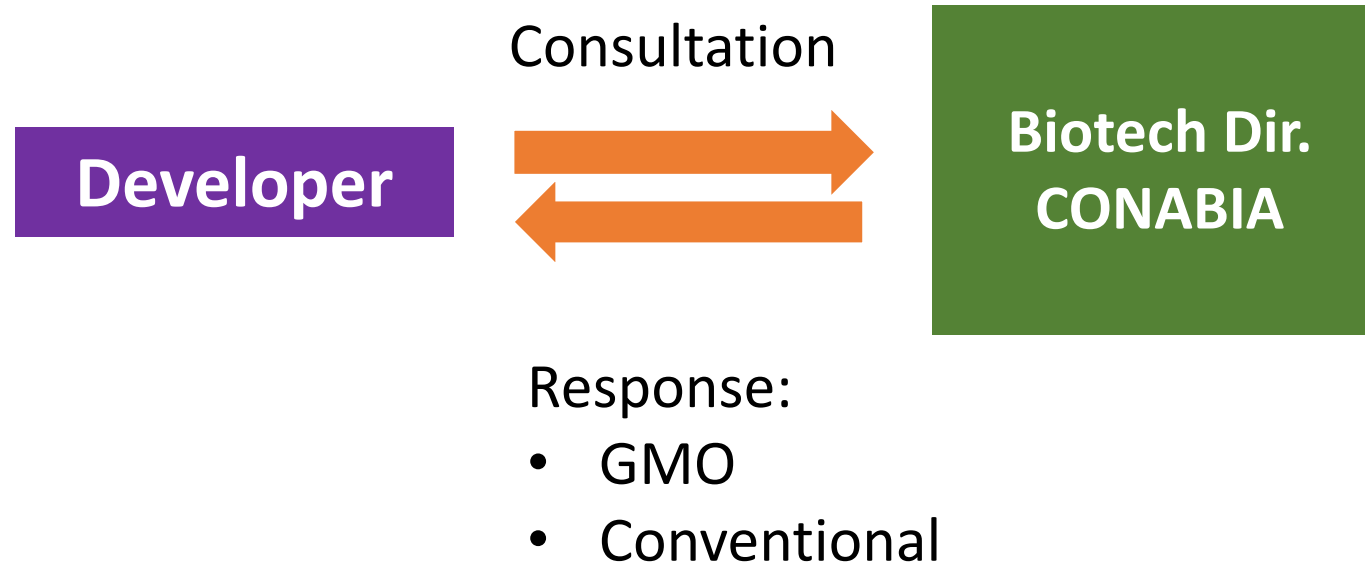
Regulatory framework for GMO in Argentina



Regulatory framework for NBTs in Argentina (Res. 21/2021)

The regulation is based on a consultation to determine whether the NBT product is a GMO or not

- (1) If not, it is considered as conventional (no further assessment is needed)
- (2) If so, it falls under the regulation for GMO (Res. 763/2011)



"Procedures are hereby established to determine when a given organism, obtained through the use of New Breeding Techniques (NBTs) falls under the scope of Resolution No. 763/2011, issued by the then MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES, and its supplementary regulations"

What is a GMO?

According to the Cartagena Protocol on Biosafety, a GMO is “*any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology*”

Where modern biotechnology is defined as the “*application of:*

- *In vitro nucleic acid techniques, including recombinant 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*”

...what is a novel combination of genetic material?

What is a novel combination of genetic material?

- NBTs can introduce changes in the genetic material that could otherwise be achieved through conventional breeding
- Similar changes pose similar risks, so they should not be regulated in a different manner
- What changes in the genetic material could not be achieved through conventional breeding?
 - A transformation event (a novel combination of genetic material)

Could the modification be achieved through conventional breeding?

(1) If so, it is not a GMO (it is a conventional product)

(2) If not, it is a GMO

- Consultation to determine whether the NBT product is a GMO or not
- Analysis of the modification introduced, on a case-by-case basis
- Not restricted to a list of techniques (open to the application of future techniques)
- Allows consultation in cases of projects that are at design phase (hypothetical products)
- Response within a period not to exceed 80 business days as from the submission

Requested information focused on:

- Description of the technique used
- Characterization of the genetic changes expected/obtained
- Proof that transgenes or foreign sequences have been eliminated

Until today...

- Most developments come from local organizations, mainly public institutions
- Most cases are hypothetical (projects in preliminary stages)
- From all NBT-derived products, around 20 gene-edited products have been considered as non-GMO (including plants, animals and microorganisms)
 - **Modifications considered as non-GMO included:**
 - **Gene KO (*indel* mutations, deletions, insertions)**
 - **Nucleotide substitution**
 - **Allele replacement**



Argentina authorities actively participate in international and regional fora...

- seeking support for science-based consideration of gene editing and other agricultural innovations
- encouraging regulatory compatibility among countries to minimize potential disruptions to trade

Thank you for your attention!

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