

# Argentina Regulatory Framework GMO and NBT

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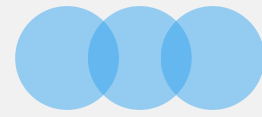
Ministerio de Economía  
Argentina





# **GMO Regulatory Framework**



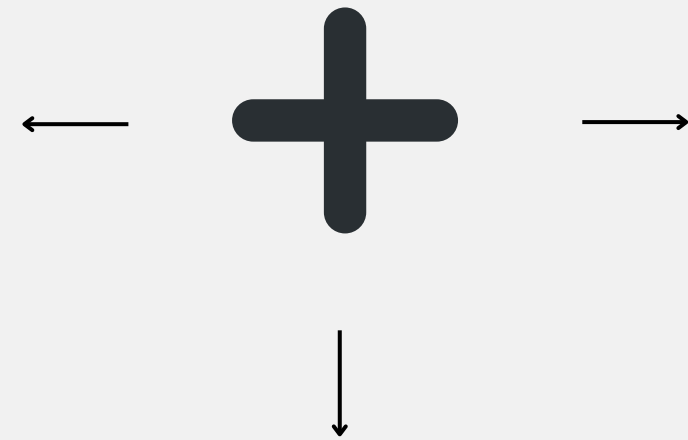


# Authorisation for production and marketing

## Undersecretariat for Food, Bioeconomy and Regional Development

### SAGyP

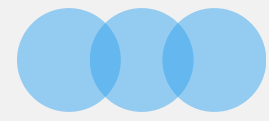
**SAFETY FOR HUMAN AND ANIMAL CONSUMPTION**  
SENASA Advisory Committee on the use of GMOs



**ENVIRONMENTAL AND ECOSYSTEM SAFETY**  
CONABIA and Coordination of Innovation and Bioenergy

**IMPACT ON THE COUNTRY'S POTENTIAL EXPORT MARKETS**  
Sub-Secretariat for Agricultural Markets





# GMO Risk Assessment: The comparative approach

**Agronomic parameters (morphology, reproduction, performance), composition, nutritional suitability...**

**NON GM**



**GM**



**As safe as and no less nutritious than its conventional counterpart with history of safe use**



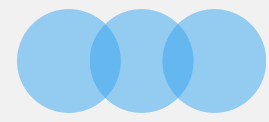
# Regulatory framework



QR code to the  
GMO  
regulations

## Genetically Modified Organisms (GMOs)

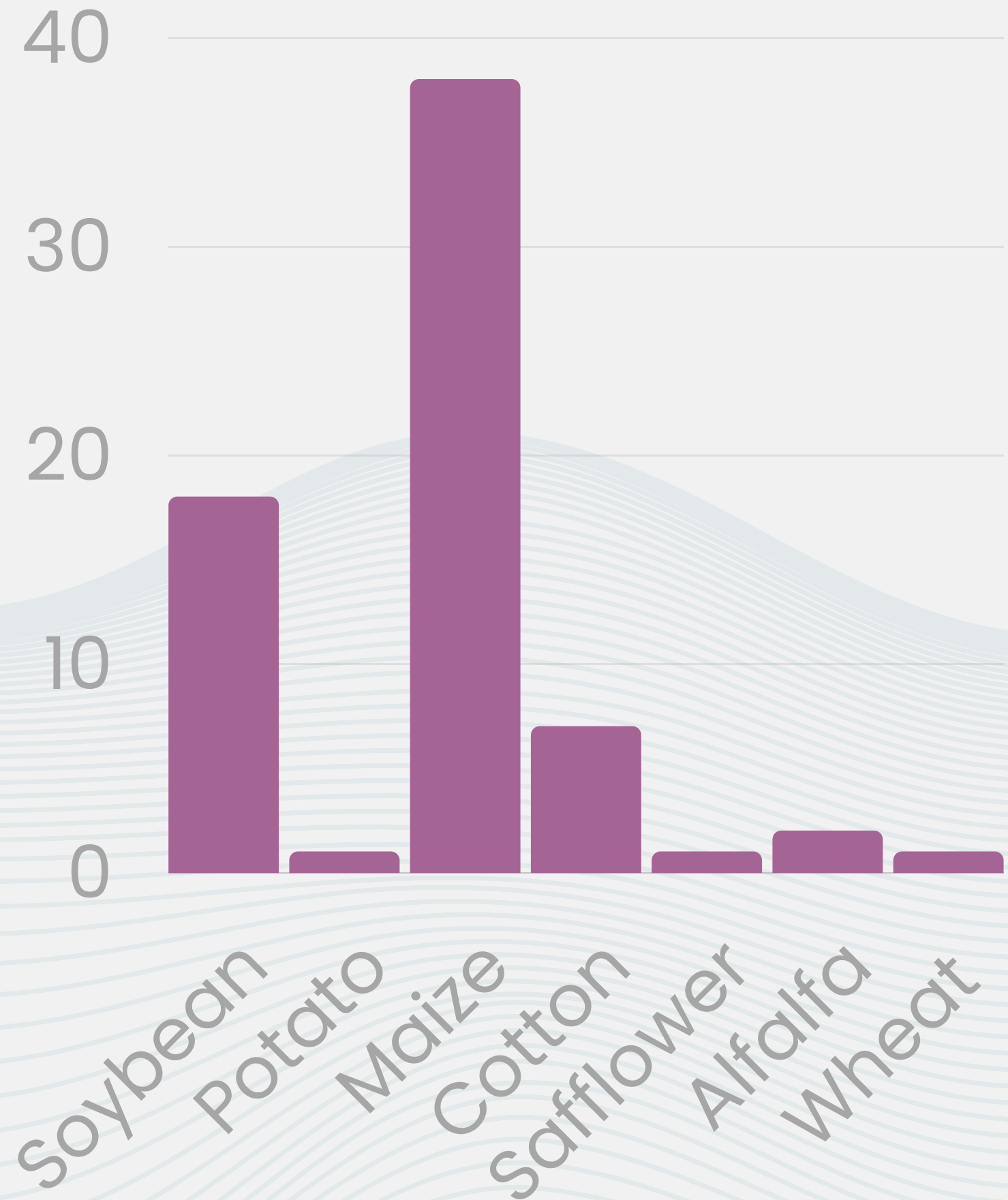
GMO Vegetable	resolution
EVALUATION OF ACTIVITIES CONTAINED OR CONFINED WITH REGULATED PLANT GMOs	<a href="#">Resolution N°45/22 + 8 annexes</a>
INSULATION CONDITIONS FOR TESTS WITH REGULATED GM MATERIALS	<a href="#">Resolution N°19/2021 + 1 annex</a>
RISK ANALYSIS OF PLANT GMOS, AS A PREREQUISITE TO REQUEST COMMERCIAL AUTHORIZATION	<a href="#">Resolution N°32/2021 + 3 annexes</a> <a href="#">CIRCULAR CIyB_N° 2_HDUS</a> <a href="#">CIRCULAR CIyB_N° 1_ENOI</a>
INSECT RESISTANCE MANAGEMENT PLAN (PMRI)	<a href="#">Resolution N°49/21 + 3 annexes</a>
animal gmo	resolution
EVALUATION OF THE CONFINED RELEASE OF GMOs AND/OR GM BIOLOGICAL MATERIAL WITH REPRODUCTIVE CAPACITY UNDER CONFINED CONDITIONS	<a href="#">Resolution N°79/17 + 2 annexes</a>
RISK ANALYSIS OF ANIMAL GMOs, AS A PREREQUISITE TO REQUEST COMMERCIAL AUTHORIZATION	<a href="#">Resolution N°63/19 + 2 annexes</a>
GMO Microorganisms	resolution
EVALUATION FOR THE CARRYING OUT OF EXPERIMENTAL ACTIVITIES UNDER CONTROLLED CONDITIONS WITH MGM	<a href="#">Resolution N°5/18 + 2 annexes</a>
REQUESTS FOR THE EVALUATION OF COMMERCIAL RELEASE OF GENETICALLY MODIFIED MICROORGANISMS (GGM)	<a href="#">Resolution N°52/19 + 2 annexes</a>



# GM crops approved for commercial use



You can consult the GM crops approved for commercial use in the following QR code





# **NBT Regulatory Framework**





# A little bit of history

How do we support the emergence and **evolution** of these techniques with an **appropriate regulatory framework?**



## Partners from other countries

European Union, United States and Canada



## At national level

Public institutions, SMEs and big companies



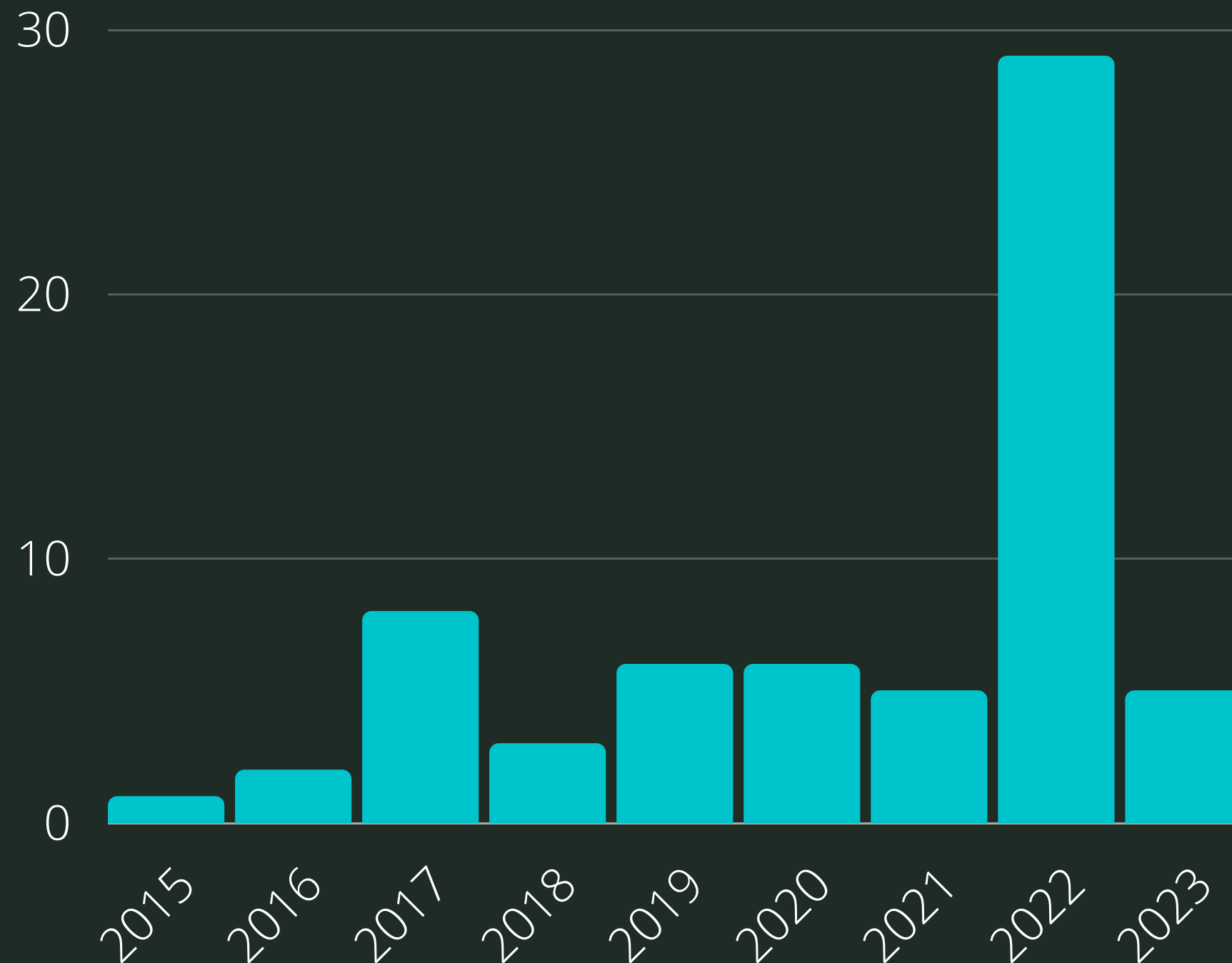
## At international level

Big companies and SMEs (Small and Medium-sized Enterprises)



# Evolution of the Regulatory Framework

**ARGENTINA IS A PIONEER IN THE CREATION OF SPECIFIC REGULATIONS FOR THE USE OF GENE EDITING PRODUCTS.**



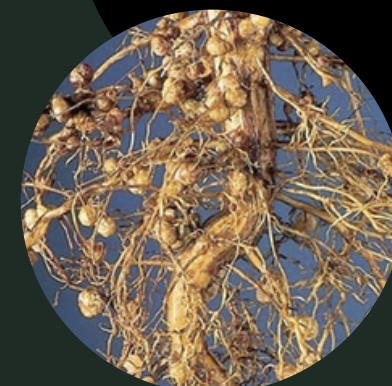
- **2013** The Directorate conducted a survey on the state of the art of NBT development in the world.
- **2015** Official publication of the first NBT regulation (only for plants).
- **2019** Official publication of NBT regulations for **animals and microorganisms** and update of vegetable regulations.
- **2020** **Unification and update** of the NBT regulations.
- **2021** **Official publication** of the update of the NBT regulations Res. N°21/2021.
- **2023** So far, 65 PCIs have been carried out for different organisms.





# Highlights of Resolution No. 21/21

- Procedure to determine whether a product obtained by NBT could be in the scope of the GMO regulation or not (**Cartagena Protocol definition of GMO**).
- The analysis is performed on a **case-by-case** basis.
- It is not restricted to a specific list of techniques.
- Allows for consultation when the **product** is at the **design stage (hypothetical product)**.
- The Commission must provide a response to the interested party within **80 working days**.
- **Specific annexes** for animals, microorganisms and plants.







# Applied criteria

## Cartagena Protocol definition of GMOs

Any living organism that possesses a new combination of genetic material obtained through the application of modern biotechnology.

## Definition of "New combination of genetic material"

Change produced in the genome of the organism by the incorporation, in a stable and joint form, of ONE (1) or more genes or nucleic acid sequences that form part of a defined genetic construction





# PCI: PRIOR CONSULTATION INSTANCE

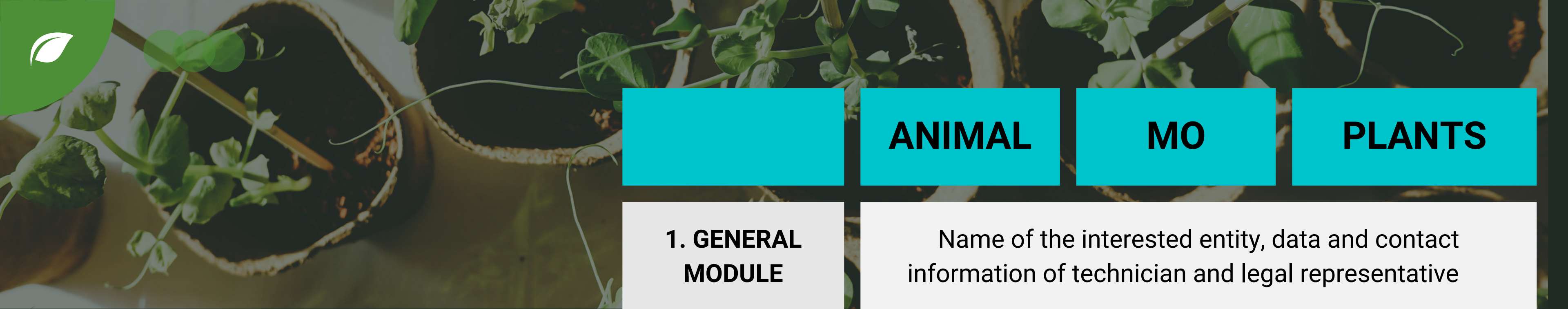
APPLIED  
METHODOLOGY

GENETIC  
CHANGES  
IN THE  
NEW  
PRODUCT

NEW TRAIT

EVIDENCE  
OF  
TRANSGENE  
DELETION  
(IF NECESSARY)





# Specific annexes for each organism



QR code to the NBT regulations

	ANIMAL	MO	PLANTS
1. GENERAL MODULE	Name of the interested entity, data and contact information of technician and legal representative		
2. ORGANISM MODULE	Taxonomic description, name assigned to the genotype		
3. MOLECULAR BIOLOGY MODULE	It is described in more detail below		
4. PROOF OF THE PHENOTYPE	Not applicable	Requested according to the technique	Not applicable



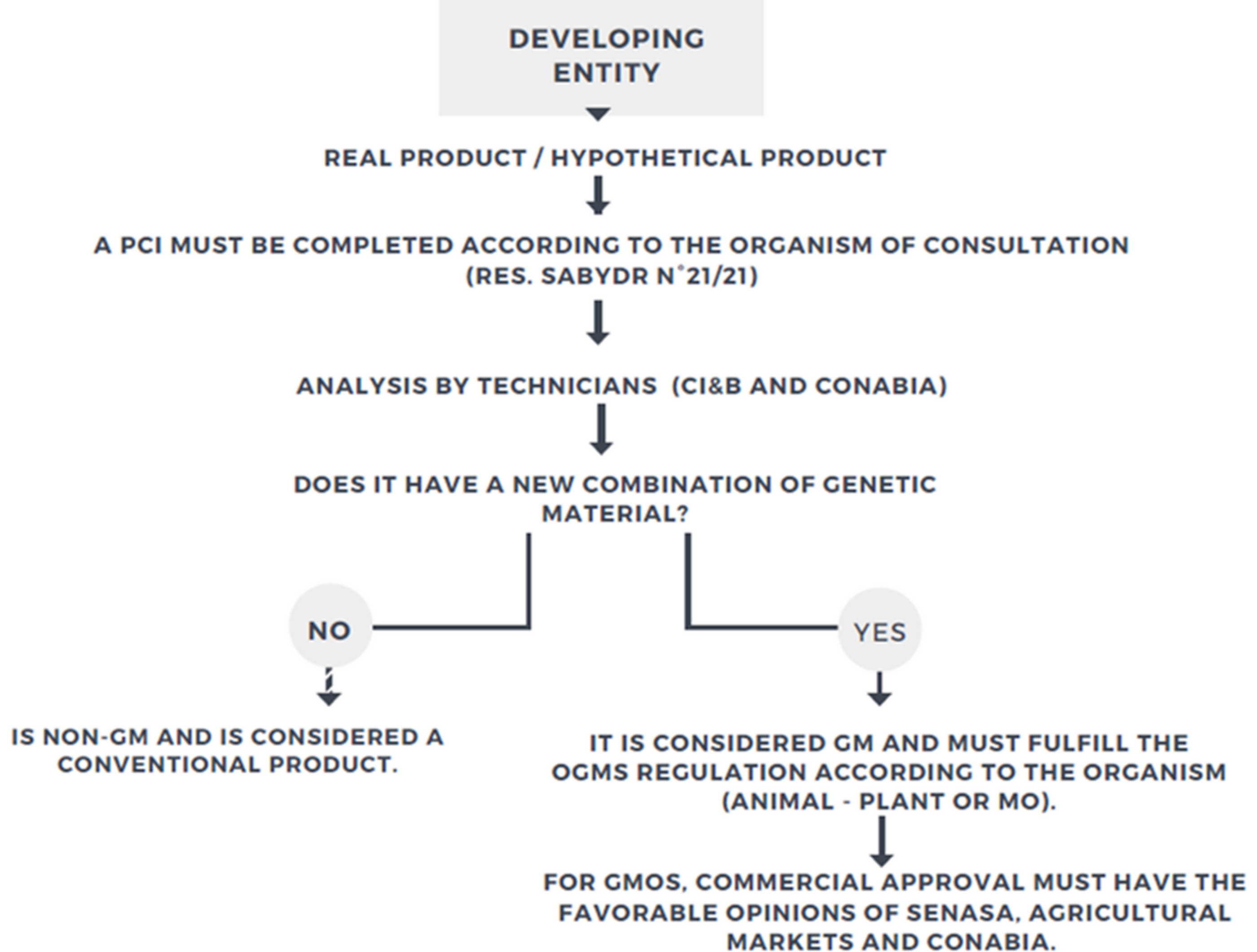


# Molecular biology module

- Detailed description of the technique used and all its steps applied in the case submitted.
- Molecular description of the target nucleotide sequences of the organism, in its state before and after applying the technique.
- Function of the sequences in their state prior to applying the technique and after applying the technique.
- Map of any genetic construct or nucleic acid fragment used in the generation process, detailing the genetic elements (if applicable).
- Analysis of possibly affected sequences outside the target sequences (not to be submitted for plants).
- Evidence demonstrating that the product obtained does not present new combinations of genetic material.



# Route of analysis of a product derived from NBT



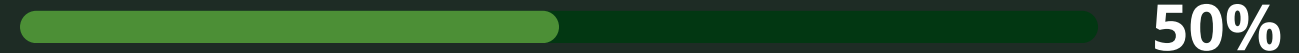




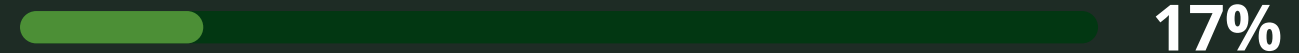
# Techniques most commonly used in product development



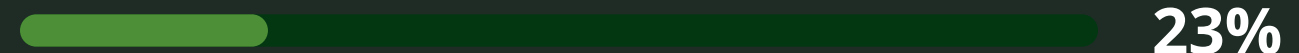
CRISPR Cas9 + plasmid



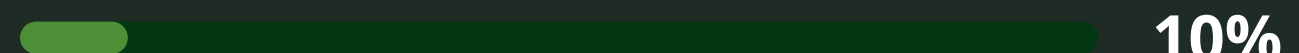
Base Editing



Ribonucleoproteins



Other

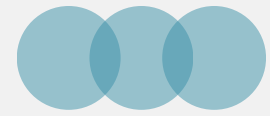






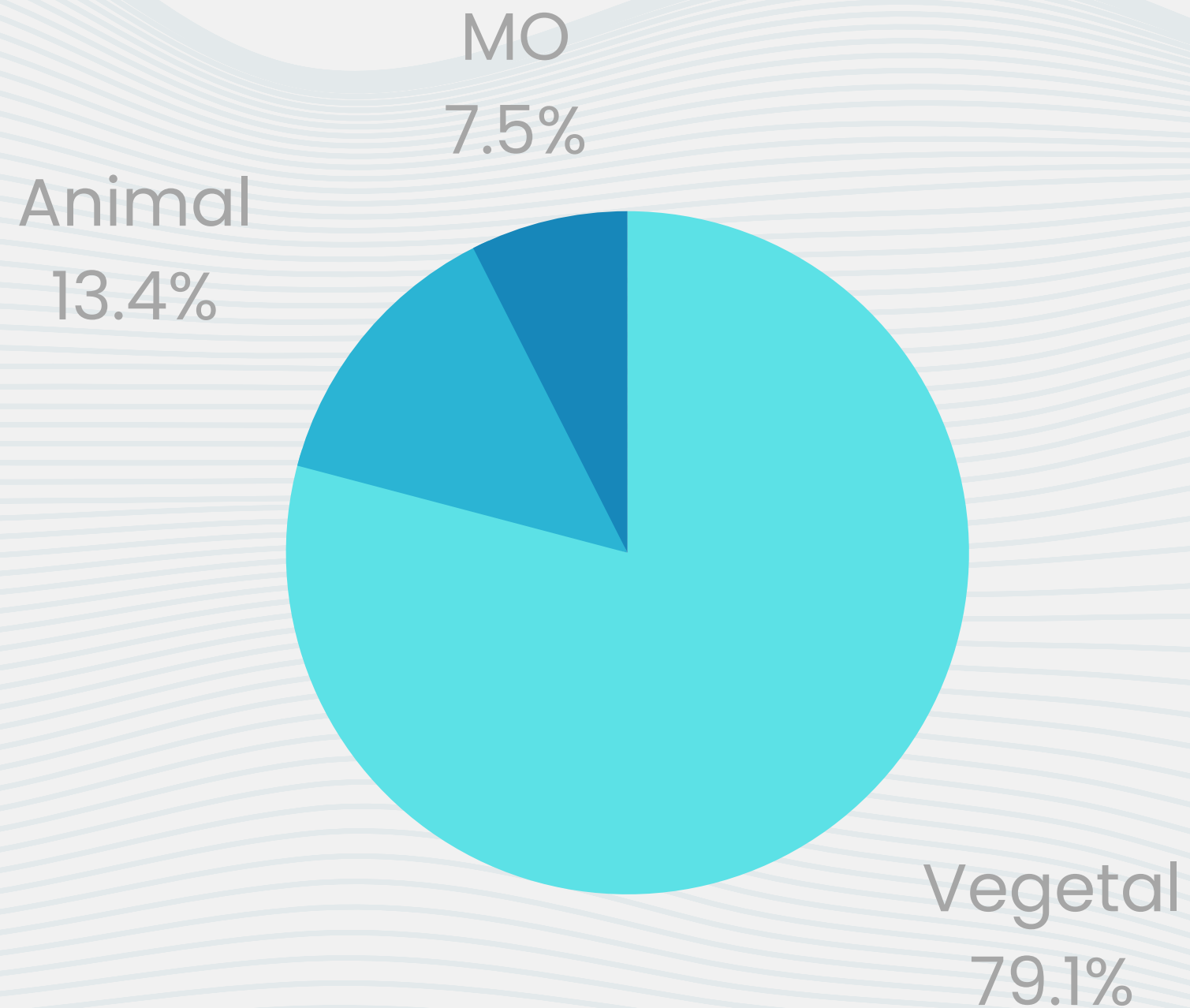
**In any case, the final product must be free of a new combination of genetic material to be considered conventional.**



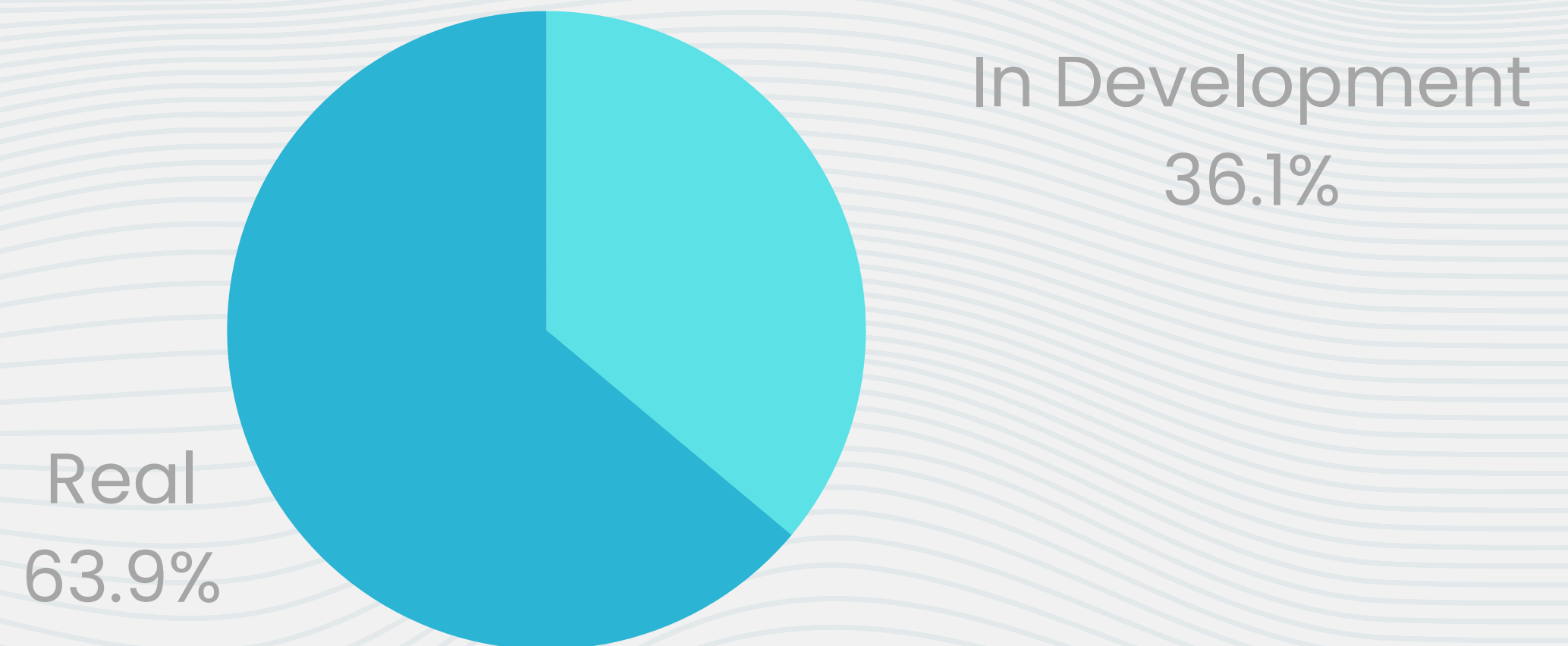


# NBT- Gene editing: PCI received

## Type of organism



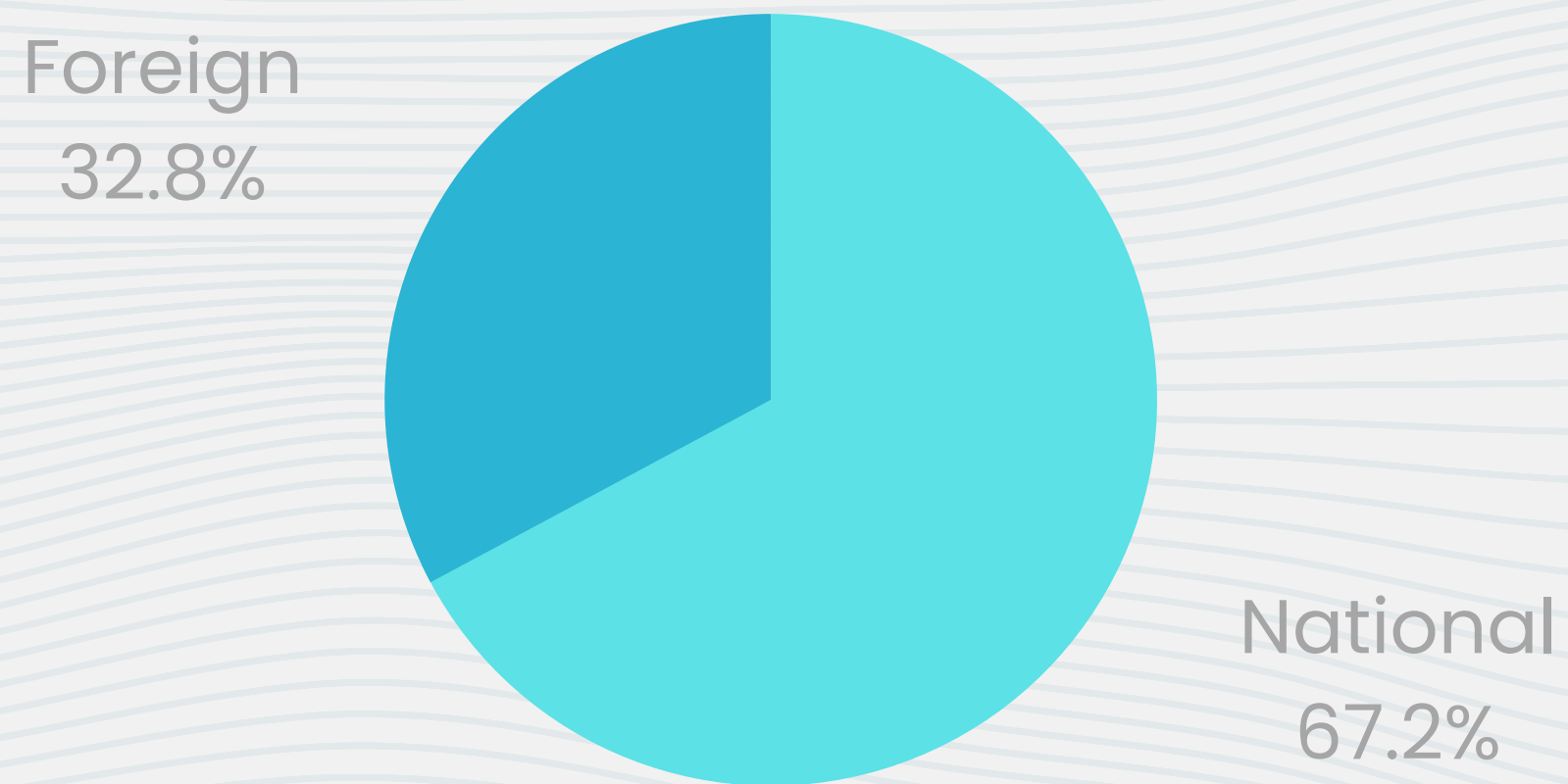
## Type ICP received



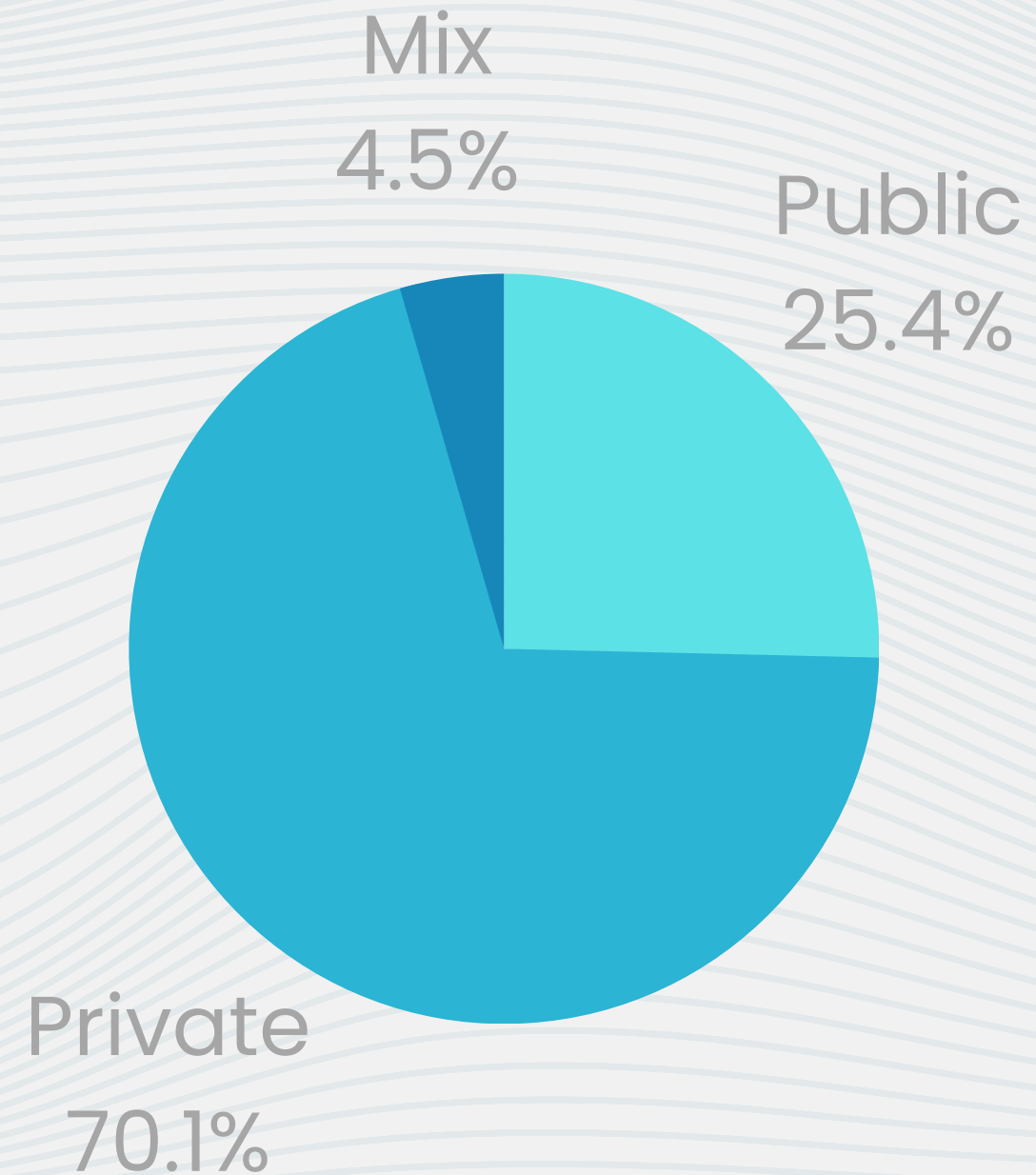


# NBT- Gene editing: PCI received

Origin of the applicant entity



Type of applicant entity







# Regulatory Framework Opportunities

- 01.** There is a greater variety of phenotypes in different crops and a higher diversity of organisms.
- 02.** It's possible to predict costs and time of the product in the design stage
- 03.** The speed of innovation is higher in relation to GMOs
- 04.** Regulations allow developers to get their product to market faster



# NBT regulations published on CONABIA's official web site

<https://www.argentina.gob.ar/agricultura/bioeconomia/biotecnologia/conabia>

## Forms and related documents

According to the type of activity to be developed, the corresponding regulation must be selected (REGULATORY FRAMEWORK). In turn, each regulation contains annexes with the form to be completed, where all the information required to carry out its evaluation is detailed.

The forms for the different activities are listed below:

**CONABIA**  
Comisión Nacional Asesora de Biotecnología Agropecuaria

- Commercial GMOs
- animal gmo
- Decision documents
- evaluations
- regulatory framework
- New Breeding Techniques (NBT)
- GM Microorganisms
- Phase 1: Contained and Confined Vegetables
- Phase 2: Risk analysis for the commercial authorization of GMOs
- Does my product have to be regulated?
- information portal



## New Breeding Techniques (NBT)

# Should my product be regulated?

Online form open for guidance inquiries

Argentina.gov.ar

Search procedures, services or areas


Ministry of Economy / Agriculture, Livestock and fishing / Food, Bioeconomy and Regional Development /

## bioeconomy

The Bioeconomy consists of the sustainable production of goods and services through the use or transformation of biological resources.



**Innovation and Biotechnology**



**bioenergy**

The bioeconomy is a paradigm of sustainable development and a state policy that includes various sectors of the agricultural and agro-industrial chain. It includes both the so-called bioproducts such as bioinputs and biomaterials, bioprocesses such as bioenergy and biotechnology as a tool applied to plant, animal and microorganism improvement in agriculture. These four sectors contribute to

Organism type:

Vegetal  Animal  Microorganism

Is the product real or hypothetical?

Real  Hypothetical

Is the product a local development or is it imported?

Local  imported

What biotechnology technique are you applying?

transgenesis  New Breeding Techniques  Other

My query consists of:

Know if my development is or is not GMO.

Request guidance on the regulations that I must attend to request an experimentation permit.

Request guidance on the regulations that I must attend to request a permit for future commercial release.

Request information on the progress status of the permit application submitted (indicate file number)





# Conclusions



The spirit of the regulation is to contemplate all the organisms under the same resolution in an independent manner without being linked to the commercial regulations for GMOs.

This regulation gives certainty to the local working groups and this can be seen in the number of developments and consultations carried out.

Argentina actively participate in international and regional forums in order to:

- seek support for science-based consideration of gene editing and other agricultural innovations
- encourage regulatory compatibility among countries.



# Our Contact Here

Website : [www.argentina.gob.ar/agricultura/bioeconomia/biotecnologia](http://www.argentina.gob.ar/agricultura/bioeconomia/biotecnologia)

Email : [nbt.biotecnologia@magyp.gob](mailto:nbt.biotecnologia@magyp.gob)

Address : Paseo Colón 922, Buenos Aires,  
Argentina





# Thank you very much

Secretaría de Agricultura,  
Ganadería y Pesca



Ministerio de Economía  
**Argentina**