Argentina Regulatory - New Breeding Techniques (NBT)

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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 the national level

Public institutions, SMEs and big companies

At the 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. So far, 45 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.
- ✓ 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

*(*Res. 21/21 of NBT of the Ministry of Agriculture, Livestock and Fisheries.)

Specific annexes for each organism

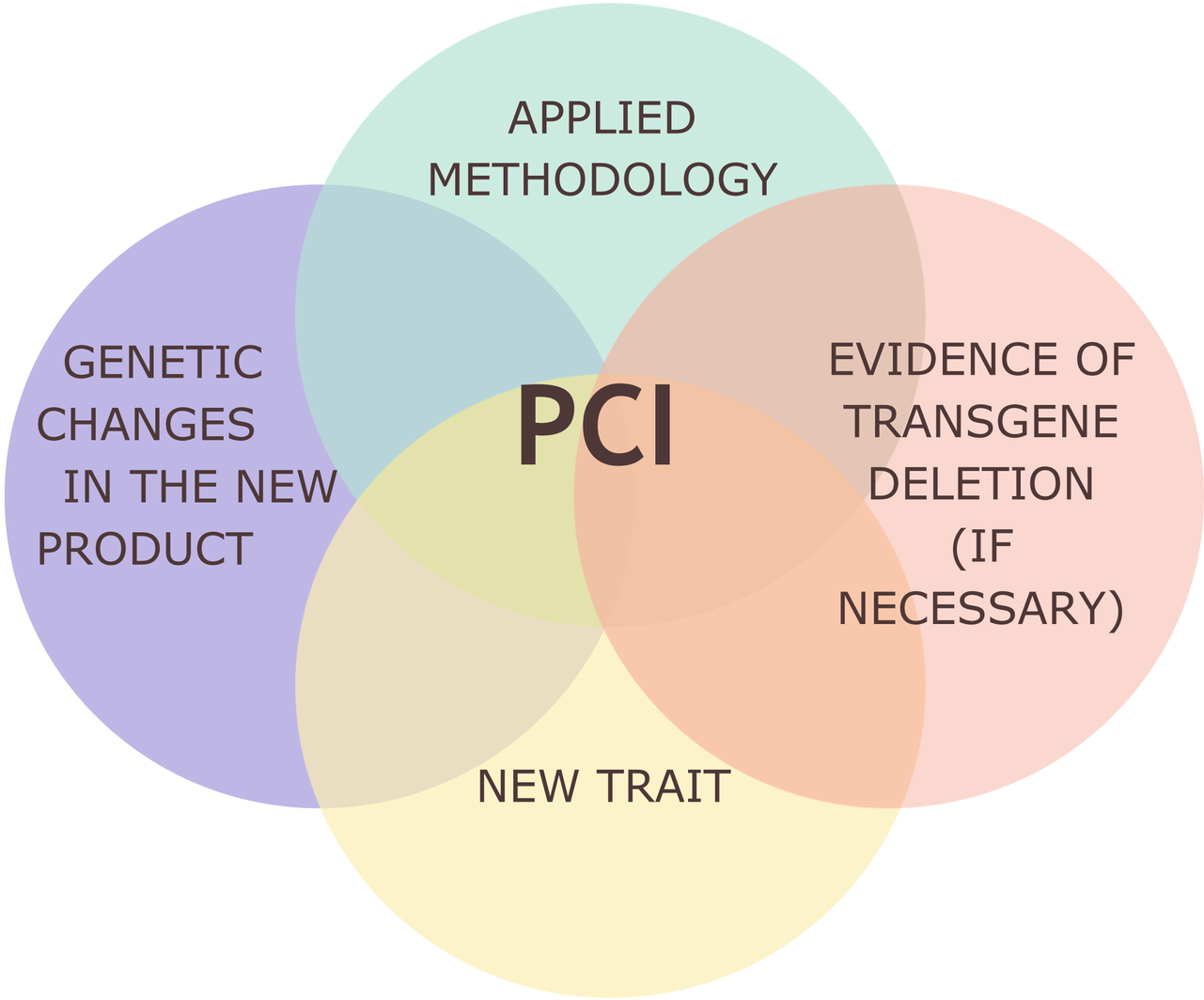
	ANIMAL	MO	PLANTS
1. GENERAL MODULE	Name of the interested entity, data and contact information of technician and legal representative		
2. ORGANISM MODULE	Taxonomic description, name assigned to the genotype		
3. MOLECULAR BIOLOGY MODULE	It is described in more detail below		
4. PROOF OF THE PHENOTYPE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

Molecular biology module

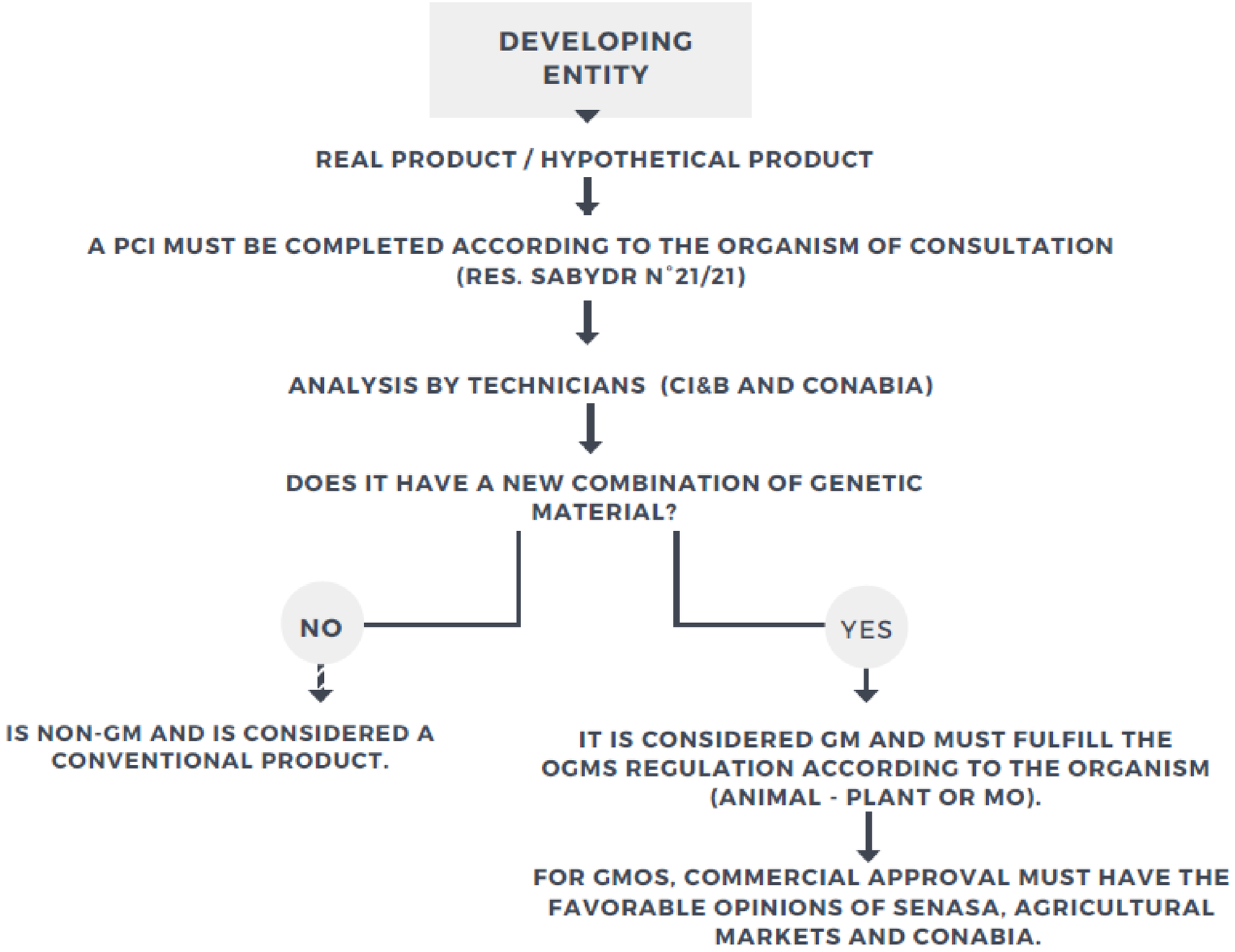
- Detailed **description of the technique** used and all its steps applied in the case submitted.
- **Molecular description** of the target nucleotide sequences of the organism, in its state before applying the technique.
- **Function of the sequences** in their state prior to applying the technique.
- **Molecular characterization** of the target sequences after applying the technique (genotype obtained/expected).
- **Expected/obtained changes** in the function of the sequences and phenotype, 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.

PCI: PRIOR CONSULTATION INSTANCE

The applicant must provide information on:



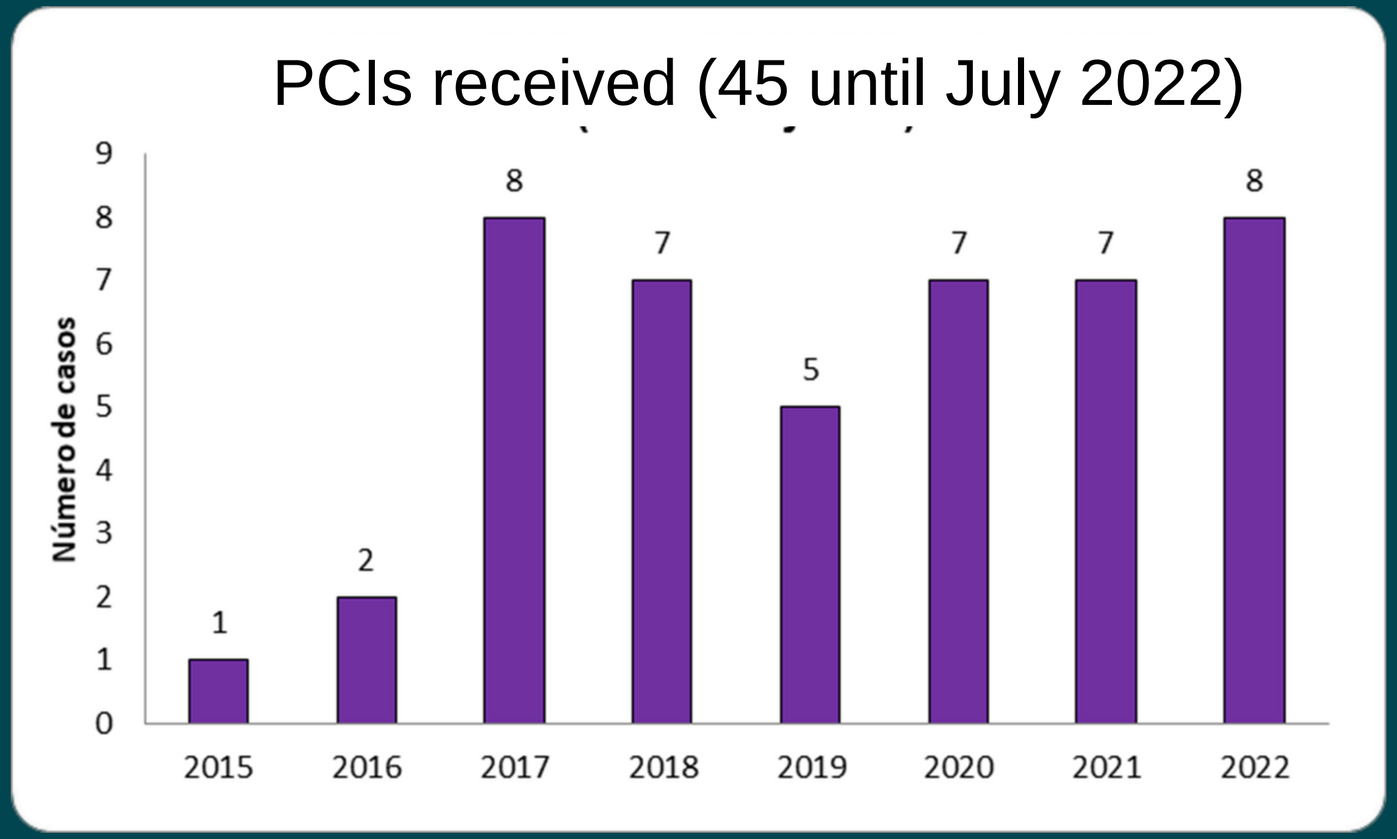
Route of analysis of a product derived from NBT

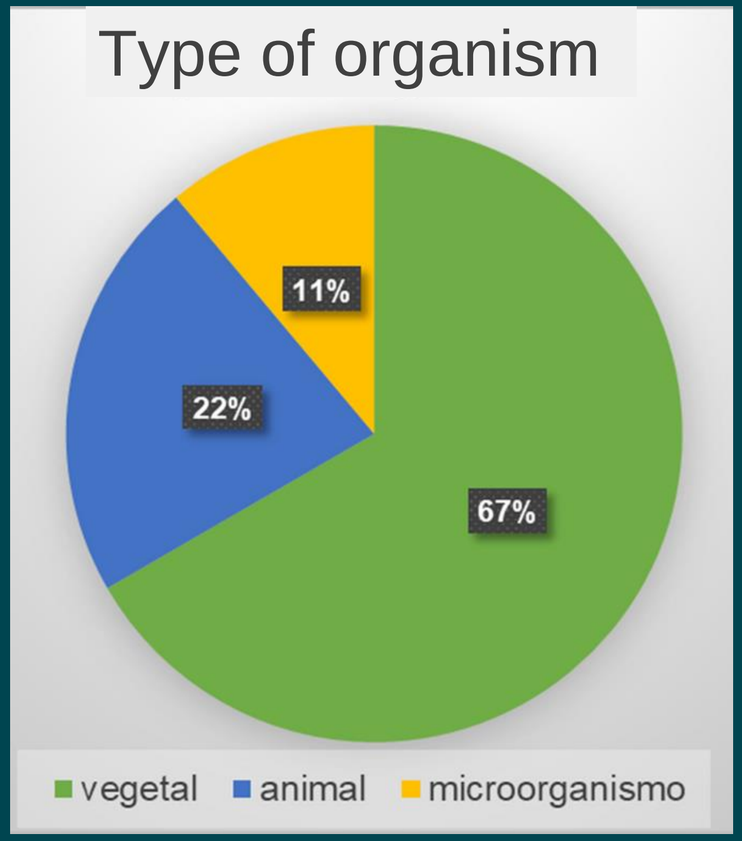


Characteristics of the received PCIs → for animals:

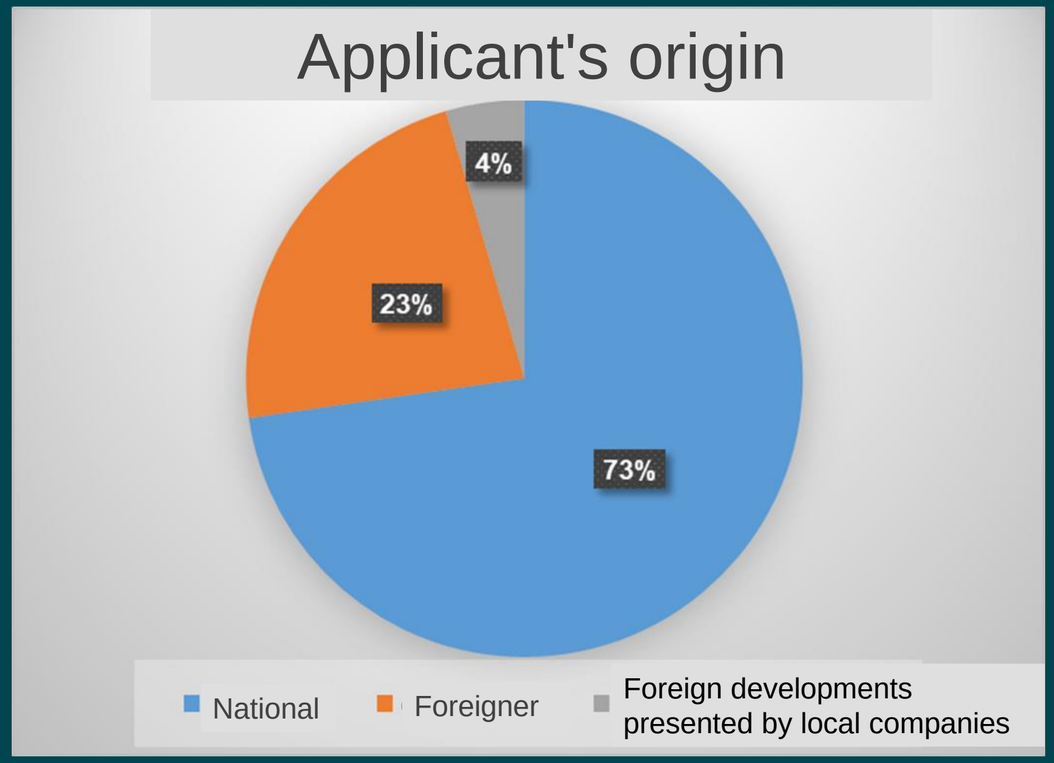
- Cattle: hypoallergenic milk - increased muscle mass - polled - thermal tolerance (hypothetical products)
- Equine: increased muscle mass (hypothetical product)
- Fish (Tilapia): improvement in fillet yield/double steak - real product
- Pigs: for xenotransplantation (hypothetical product)

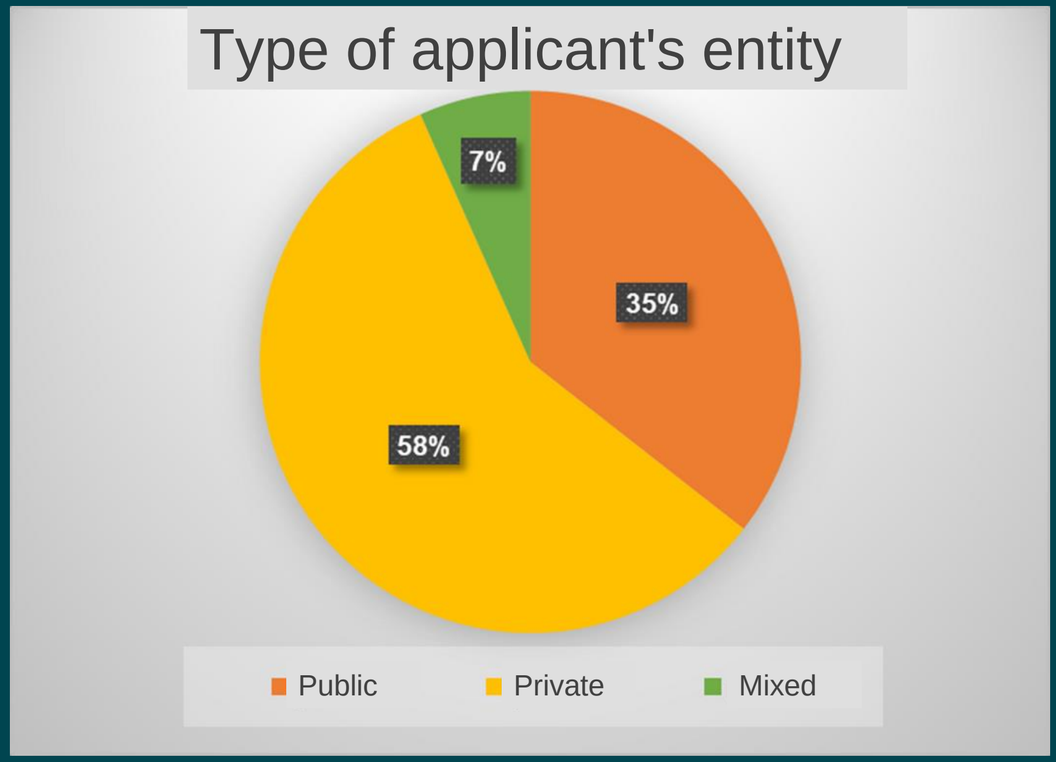
NBT- Gene editing: PCI received





NBT- Gene editing: PCI received





Regulatory Framework Opportunities

There is a greater variety of phenotypes in different crops and a higher diversity of organisms.

It´s possible to predict costs and time of the product in the design stage

The speed of innovation is higher in relation to GMOs

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

Should my product be regulated?

Online form open for guidance inquiries

- Convocatoria CONABIA
- OGM Comerciales
- OGM Animal
- Documentos de decisión
- Evaluaciones
- Marco regulatorio
- ¿Mi producto debe ser regulado?
- Portal de información

Tipo de organismo:

☐ Vegetal ☐ Animal ☐ Microorganismo

¿El producto es real o hipotético?

○ Real ○ Hipotético

¿El producto es un desarrollo local o es importado?

○ Local ○ Importado

¿Qué técnica de biotecnología está aplicando?

☐ Transgénesis ☐ Nuevas Técnicas de Mejoramiento ☐ Otra

Mi consulta consiste en:

☐ Saber si mi desarrollo es o no es OGM.

☐ Solicitar orientación sobre la normativa que debo atender para solicitar un permiso de experimentación.

☐ Solicitar orientación sobre la normativa que debo atender para solicitar un permiso para futura liberación comercial.

☐ Solicitar información sobre el estado de avance de la solicitud de permiso presentada (indicar número de expediente)

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.

Thank you very much

contact: nbt.biotecnologia@magyp.gob.ar

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