7th Seed Congress of the Americas

Promoting Seed Business in the Americas

September 9 - 11, 2019
Buenos Aires, Argentina

Regulatory policy in Argentina and cooperation with other regulatory agencies

SAA
Seed Association of the Americas

Lic. Agustina Whelan

“**CONABIA** milestones”

1991
Creation of **CONABIA**

GM crops field trials.

1996
First commercial approval of a GM crop (soy)

approvals of GM corn and cotton, counter-season...

2005
First field testing of a GM animal (cattle)

Biotechonology Directorate

2011
First field testing of a GM animal (cattle)

Biotechonology Directorate

2014
FAO Center of Reference

-Novel traits, RNAi.

-Regulation on constructs.

2015
-Regulation on GENE EDITING.

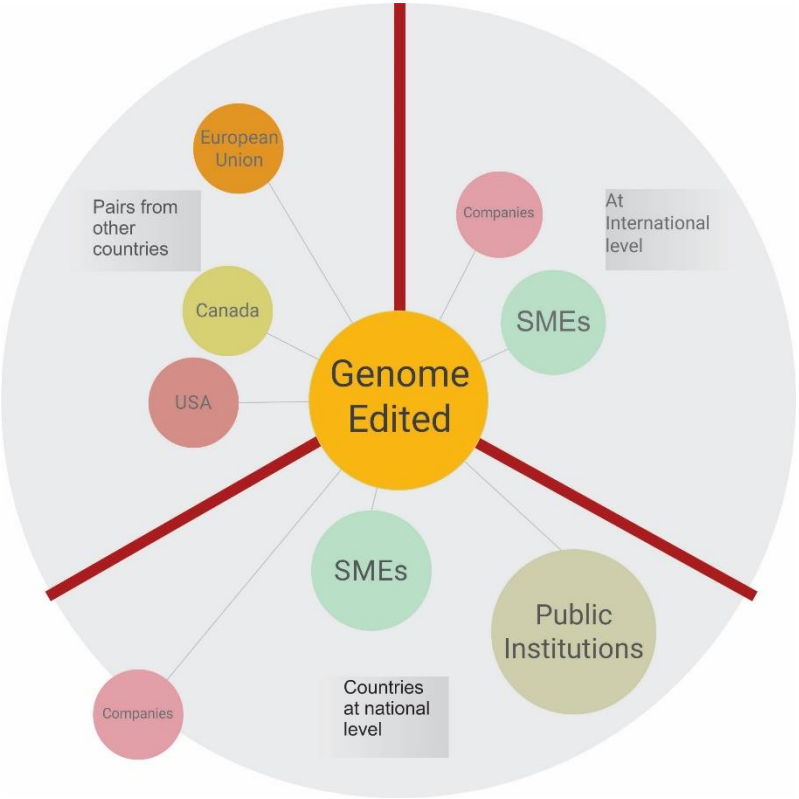
2019
56 commercial approvals, 6 spieces (soybean, alfalfa, corn, cotton, potato, cartamo)

“Reference center”

ARGENTINA worldwide REFERENCE in GMO BIOSAFETY

In 2014, CONABIA was recognized as a GMO Biosafety Reference Center by the Food and Agriculture Organization of the United Nations (FAO).

“**Collaboration** of sectors”



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

Argentina pioneer in the creation of a specific regulation for the use of genetically edited products

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“**GMO** definition”

Genetically Modified Organism: Organism that has a ***combination of genetic material*** obtained through the application of ***modern biotechnology”.***

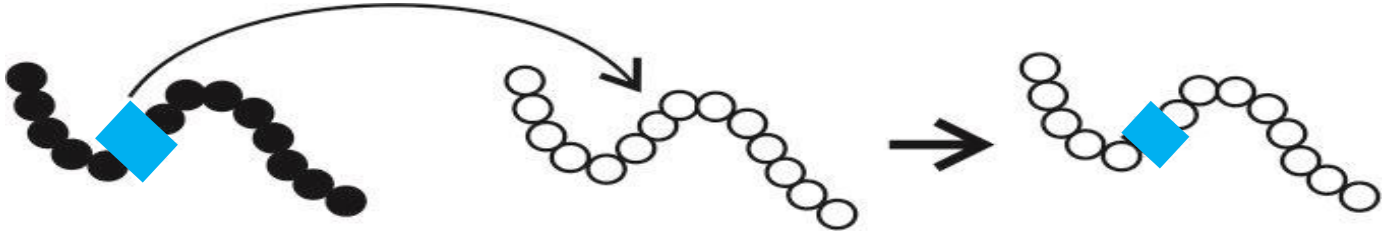
Same as in Cartagena Protocol for LMOs

“GMO”

Modern biotechnology application

New combination of genetic material

Transgenesis



DNA 1

1	Donor organism **Desired feature**

DNA 2

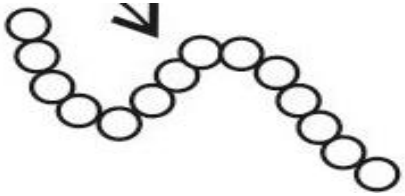
2	Receiving organism

DNA 2 + gene DNA1

3	**GMO product**

“**Genome** editing”

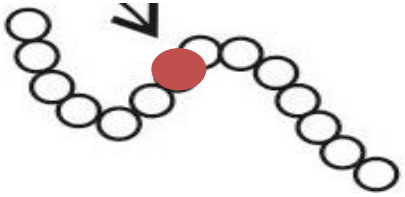
Modern biotechnology application



1 Organism ***receiver***

Gene editing techniques

There is **NO new** combination of genetic material

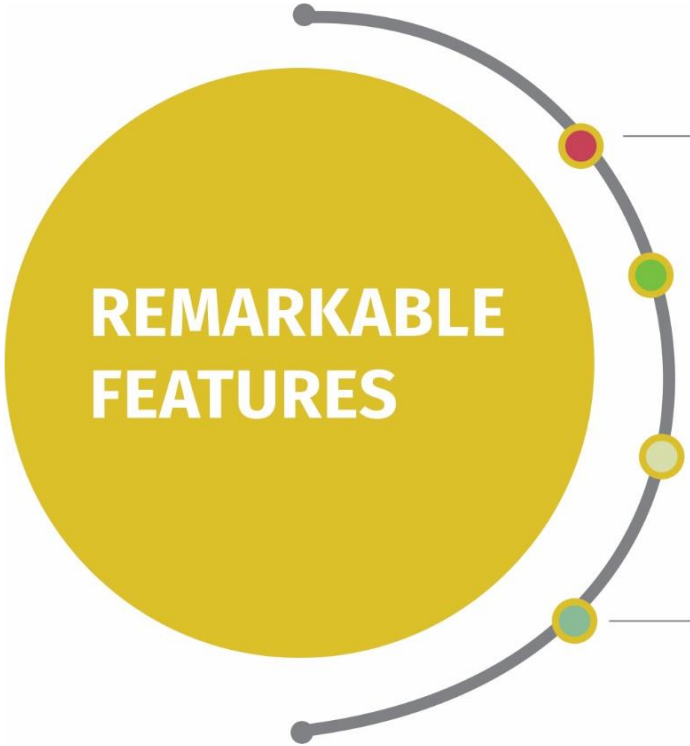


2 Gene editing ***product***

“**ARGENTINA** pioneer in Latin America”

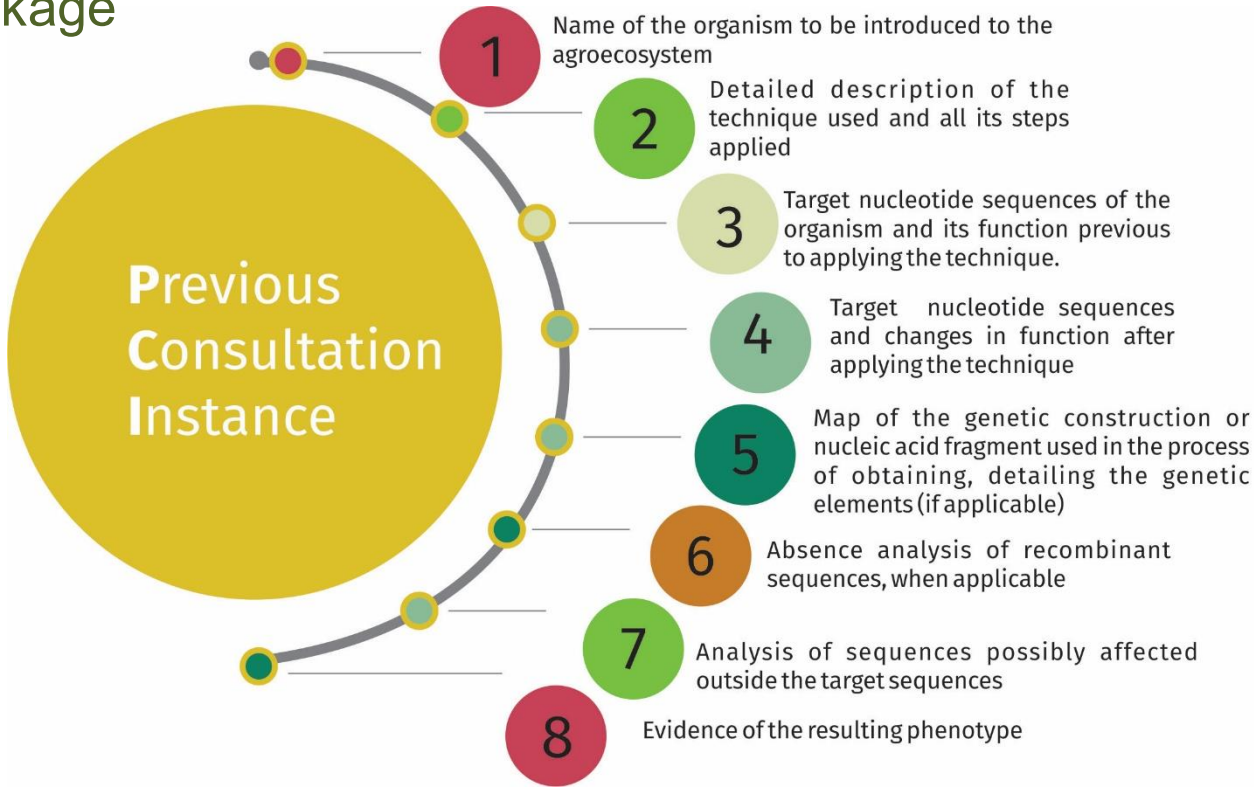
- **2013 -** CONABIA Started to work on NBT´s Regulation.
- **2015 - Res. 173/15** Became official. (Plants)
- Procedure to determine if a product obtained using NBTs would be under the GM regulation or not.
- **2019- Res. 36/2019** Form for the presentation of Prior Consultation Instances for plants, animals and microorganisms obtained through New BreedingTechniques.

RES. 173/15- Remarkable Features



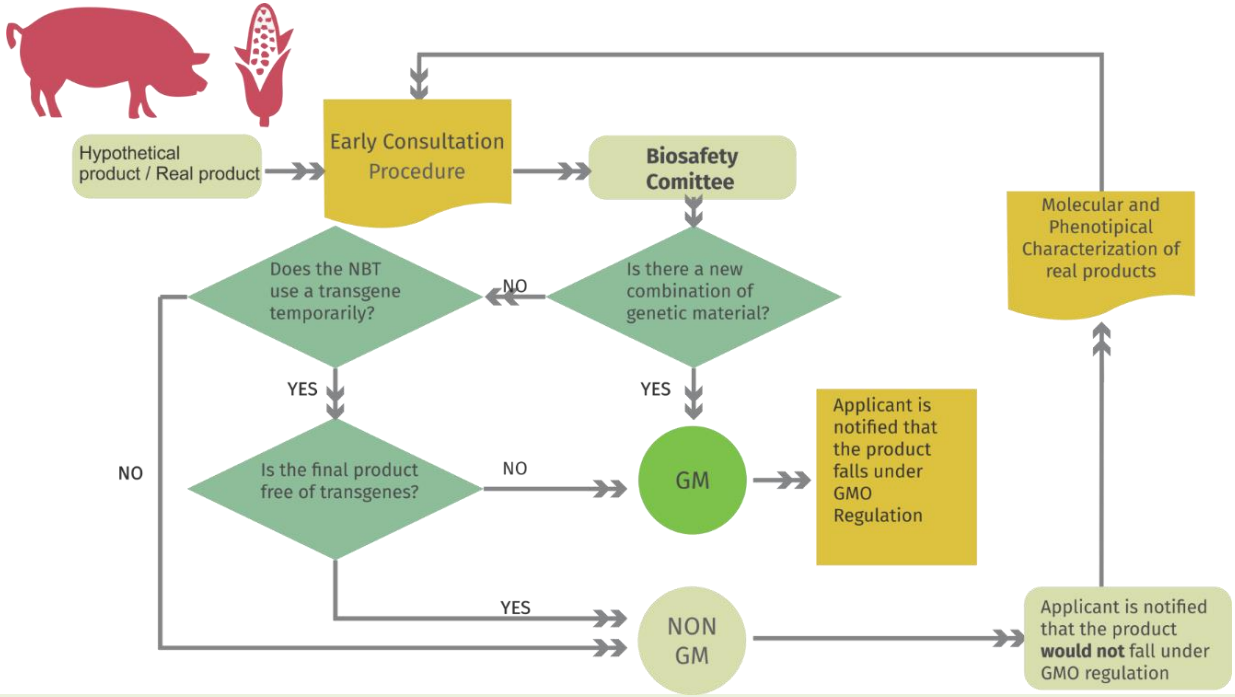
1. Its analysis is based on a “case by case” logic.
2. This resolution is not restricted to a list of NBTs.
3. If the products is still on the design stage, the developer can consult the comitte about the status of the hypothetical product.
4. The biosafety comission must perform, in any case, assessment 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... "

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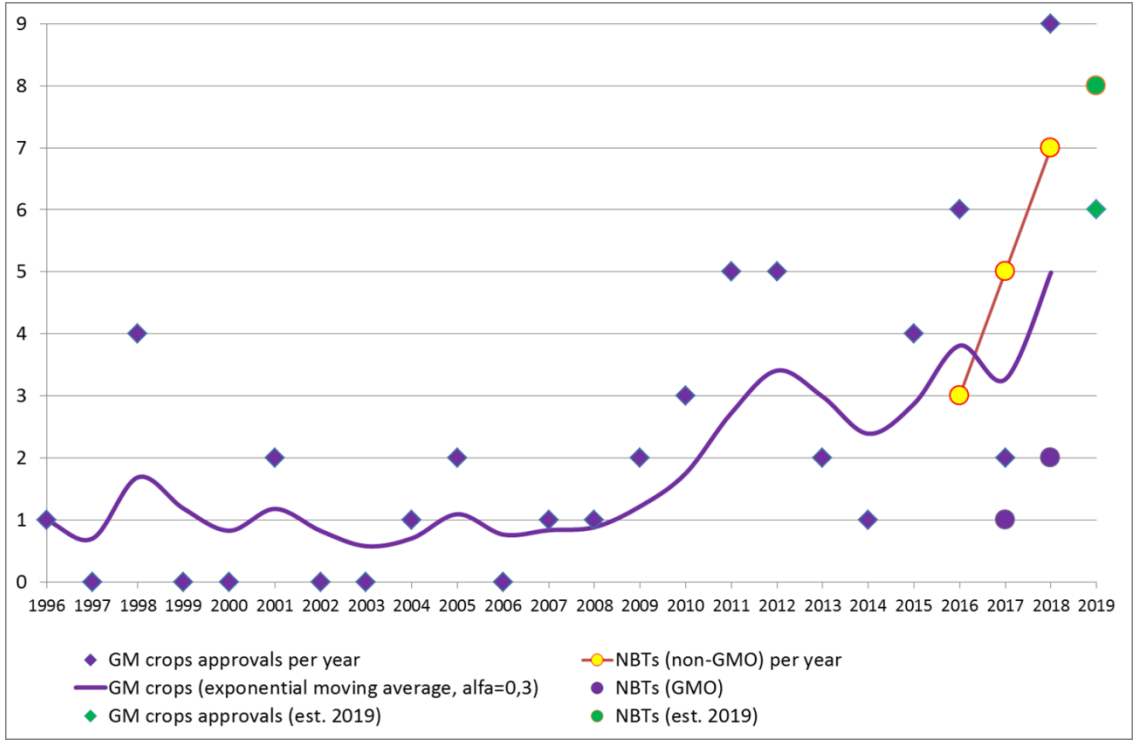
1. Innovation Speed of Gene Editing Products



This graph represent the acceleration of Gene Editing products compared to GMOs

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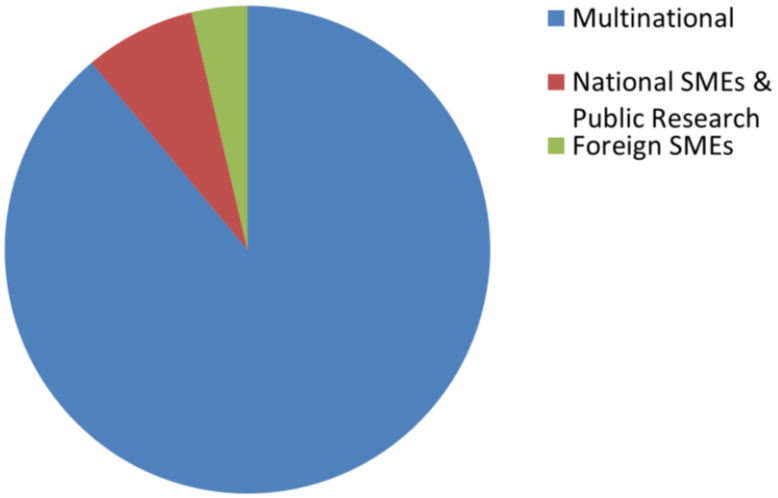
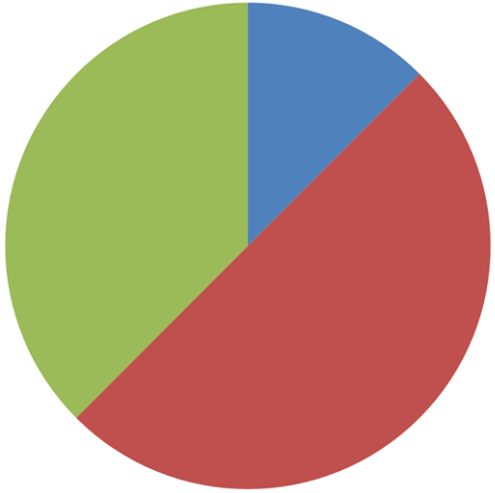
2. Opportunity for new developers

TOTAL QUANTITY OF PRODUCTS





The public sector and small businesses presented the majority of edited cases

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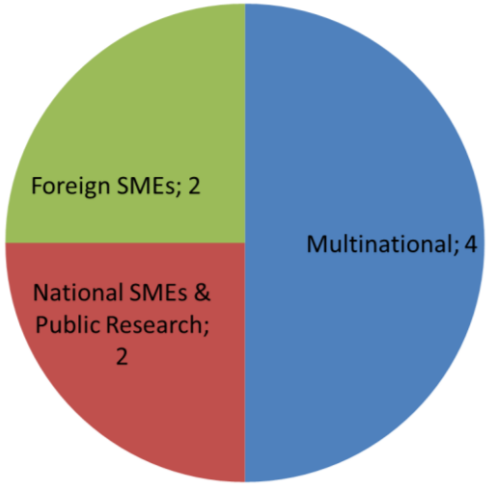
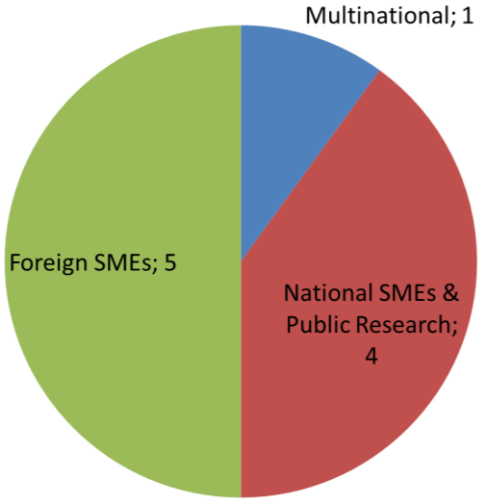
2. Opportunity for new developers

TOTAL QUANTITY OF DEVELOPERS

GM crops approvals in 23 yrs.

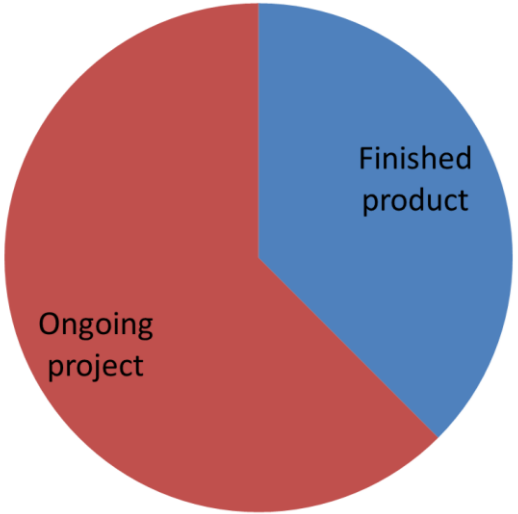


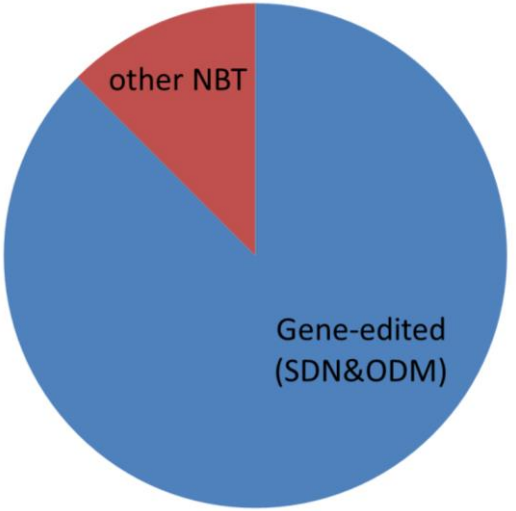
NBT products (non GMO) in 3 years



A large part of the GE consultations carried out by CONABIA belonged to SMEs, public institutions while a small proportion corresponded to multinational companies.

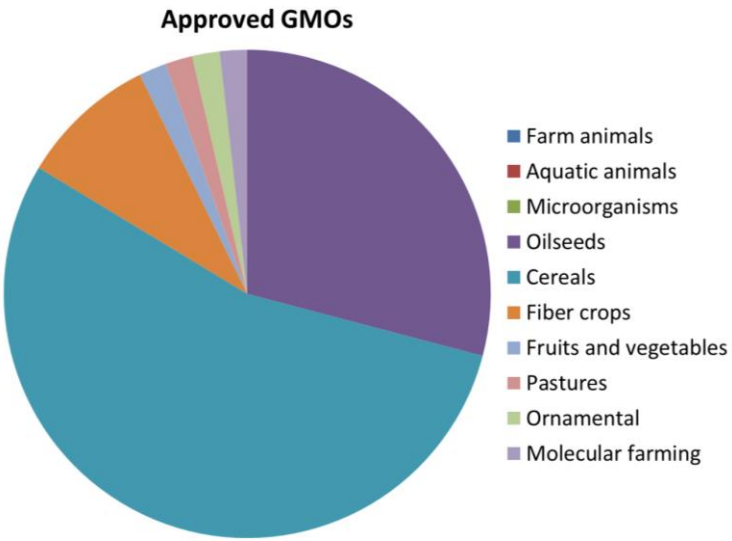
3. Investment predictability

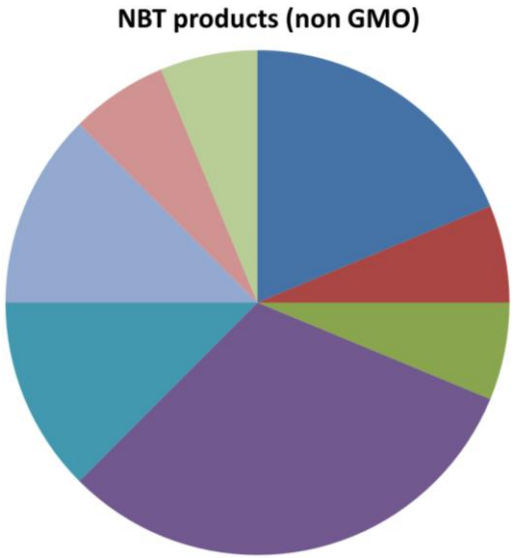




Products that made prior consultation with CONABIA according to the development status

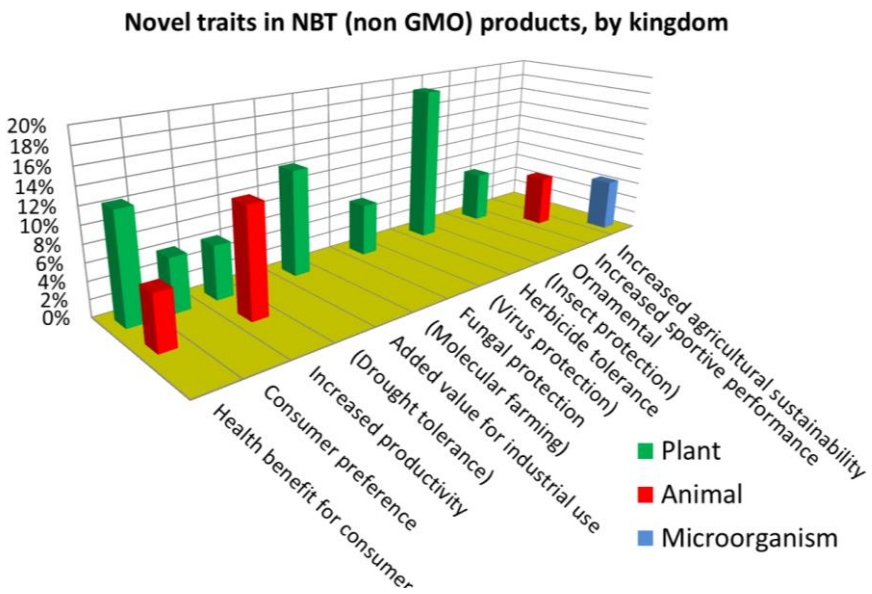
4. Diversity of type of Organisms

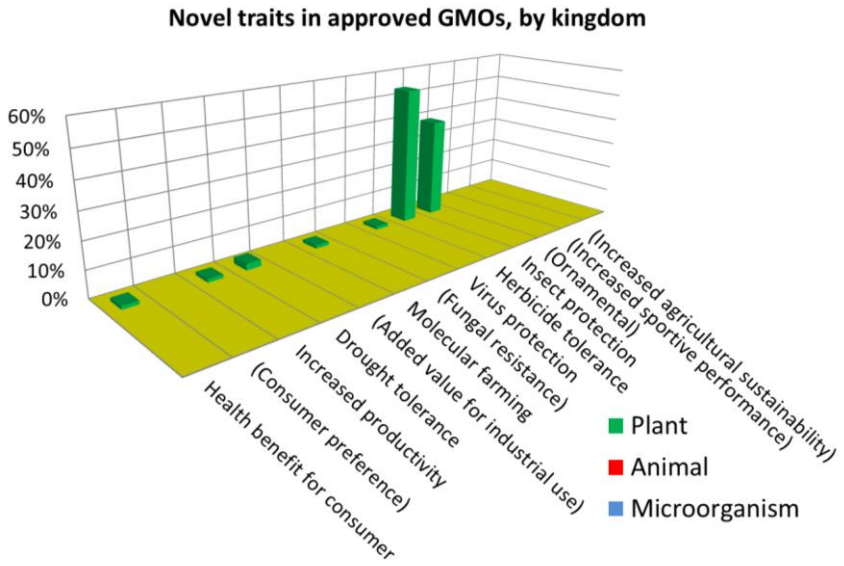




It can be assumed that the gene edition will be used in a wider variety of species compared to GMOs.

5. Greater availability of technologies in the market





Greater diversity of NBT features and developments in the animal and microbial kingdom, in addition to plants.

Remarkable Features

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

- Research and development of products obtained by state institutions and small businesses that find it difficult to go through a Regulatory System will be especially favored.

- The farmer may have more offer of products in the market of similar phenotypes with lower costs and in less time.

"Current situation of NBTs regulation in Latin America"

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“APPROACHES”

2015	ARGENTINA
2017	CHILE
2018	BRAZIL
2018	COLOMBIA
2019	PARAGUAY

These countries have very similar regulations

APPROACHES in other Latin- American Countries

REGULATION UNDERWAY PROJECT

- Guatemala
- Honduras
- Ecuador
- Costa Rica

INTERNATIONAL DISCUSSION

- México
- Uruguay

NOT WORKING ON THE ISSUE

- Bolivia
- Cuba

“GENOME EDITING for Biotechnology Regulators in the Americas “

- **Organized by *IICA*** (Inter-American Institute for Cooperation on Agriculture)
- **Main topics:**

  - Reseach and development
  - Regulatory situation
  - Cooperation among countries
  - International statement
- Policymakers and developers from public and private sector

Cali, April 3, 2018

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CAS/ COUNCIL, Statement ii(xxxv 2018)

CAS/ Consejo, Declaración II (XXXV 2018)
Buenos Aires, Argentina, 20 de setiembre de 2018
Original. Español

Declaración de los Ministros:
Los Ministros de Agricultura de Argentina, Brasil, Chile, Paraguay y Uruguay, miembros del Consejo Agropecuario del Sur (CAS), reunidos en Buenos Aires, Argentina.

Consideran que:

1. Los cultivos mejorados por edición génica tienen el potencial de desempeñar un papel fundamental para abordar los desafíos que enfrenta la producción agrícola, contribuyendo a aumentar el suministro de alimentos y otros productos agrícolas, de manera sostenible.

2. La edición génica puede generar cultivos análogos a los que se obtienen a través de otros métodos de mejoramiento convencionales.

3. Los países del CAS presentan una importante inversión pública y privada en el desarrollo de cultivos mejorados por edición génica. Esto se debe a que puede acelerar el acceso del productor agropecuario y el consumidor a nuevas características de interés productivo y agroindustrial; al tiempo que representa una oportunidad para la transferencia de tecnologías desarrolladas por los institutos nacionales de investigación agropecuaria y PyMES biotecnológicas.

4. Se deben evitar distinciones arbitrarias e injustificables entre los productos agrícolas obtenidos por edición génica y los que se obtienen a través de otros métodos de mejoramiento.

Declaran que:

1. Intercambiarán información sobre el desarrollo de productos y los marcos regulatorios existentes que les sean aplicables, explorando oportunidades con base científica para la armonización normativa regional e internacional.

2. Procurarán trabajar conjuntamente y con terceros países para evitar obstáculos sin base científica al comercio de productos agrícolas mejorados por edición génica.

Signed by the Ministers of Agriculture from **Argentina, Brazil, Chile, Paraguay and Uruguay,** members of the Agricultural Council of the South (CAS), assembled in Buenos Aires, Argentina.

Buenos Aires, Argentina,
20 September 2018,

http://consejocas.org/wp-content/uploads/2018/09/XXXVI-RO-CAS-Declaraci%C3%B3n-II.-T%C3%A9cnicas-de-Edici%C3%B3n-G%C3%A9nica.pdf

INTERNATIONAL STATEMENT On Agricultural applications of precision biotechnology

WORLD TRADE ORGANIZATION

G/SPS/GEN/1658/Rev.2

30 October 2018

(18-6816)

Page: 1/2

Committee on Sanitary and Phytosanitary Measures

Original: Spanish

INTERNATIONAL STATEMENT ON AGRICULTURAL APPLICATIONS OF PRECISION BIOTECHNOLOGY

COMMUNICATION FROM ARGENTINA, AUSTRALIA, BRAZIL, CANADA, GUATEMALA, HONDURAS, PARAGUAY AND THE UNITED STATES OF AMERICA

Revision

The following communication, received on 26 October 2018, is being circulated at the request of the delegations of Argentina, Australia, Brazil, Canada, Guatemala, Honduras, Paraguay and the United States of America.

Argentina, Australia, Brazil, Canada, Colombia, Dominican Republic, Guatemala, Honduras, Jordan, Paraguay, Uruguay, USA, Vietnam, and the Secretariat of the Economic Community of West African States)

Committee on Sanitary and Phytosanitary Measures

Ginebra, November 1st ,2018

https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(%40Symbol%3d+g%2fsps%2fgen%2f*+)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true

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STATEMENTS - Remarkable Features

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

- It is necessary to share information on product development and existing regulatory frameworks applicable to them, exploring science-based opportunities.

- Work must be done with other countries, in order to avoid trade barriers for products improved through gene editing.

REFERENCES

- Whelan, Lema (2015). **Regulatory framework for gene editing and other new breeding techniques in Argentina.** GM Crops Food 6(4):253-65**.**
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- Eriksson, Kershen….& Whelan (2018). **A comparison of the EU regulatory approach to directed mutagenesis with that of other jurisdictions, consequences for international trade and potential steps forward**. New Phytologist.
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THANK YOU!

awhelan@magyp.gob.ar

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