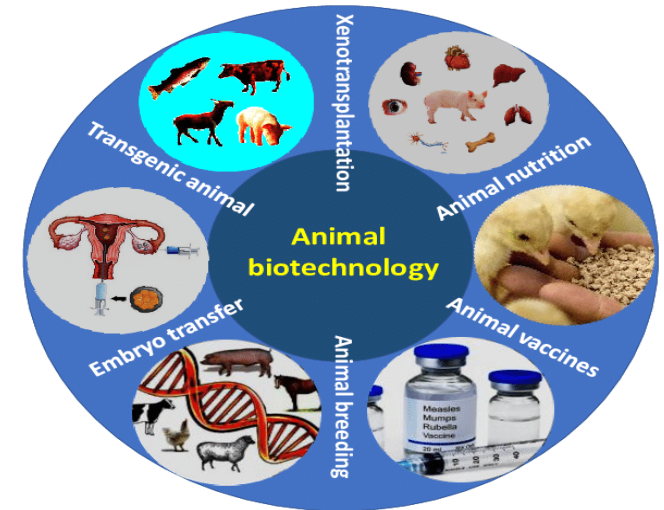


Regulatory Approach for Products of Animal and Plant Biotechnology in Colombia



Yenny Catherine Pinilla López
DVM, MSc Animal Science (Animal Genetics)
Technical Advisor in Animal Genetic Registration
Colombian Agricultural Institute (ICA)

São Paulo, Brazil
September 14, 2022

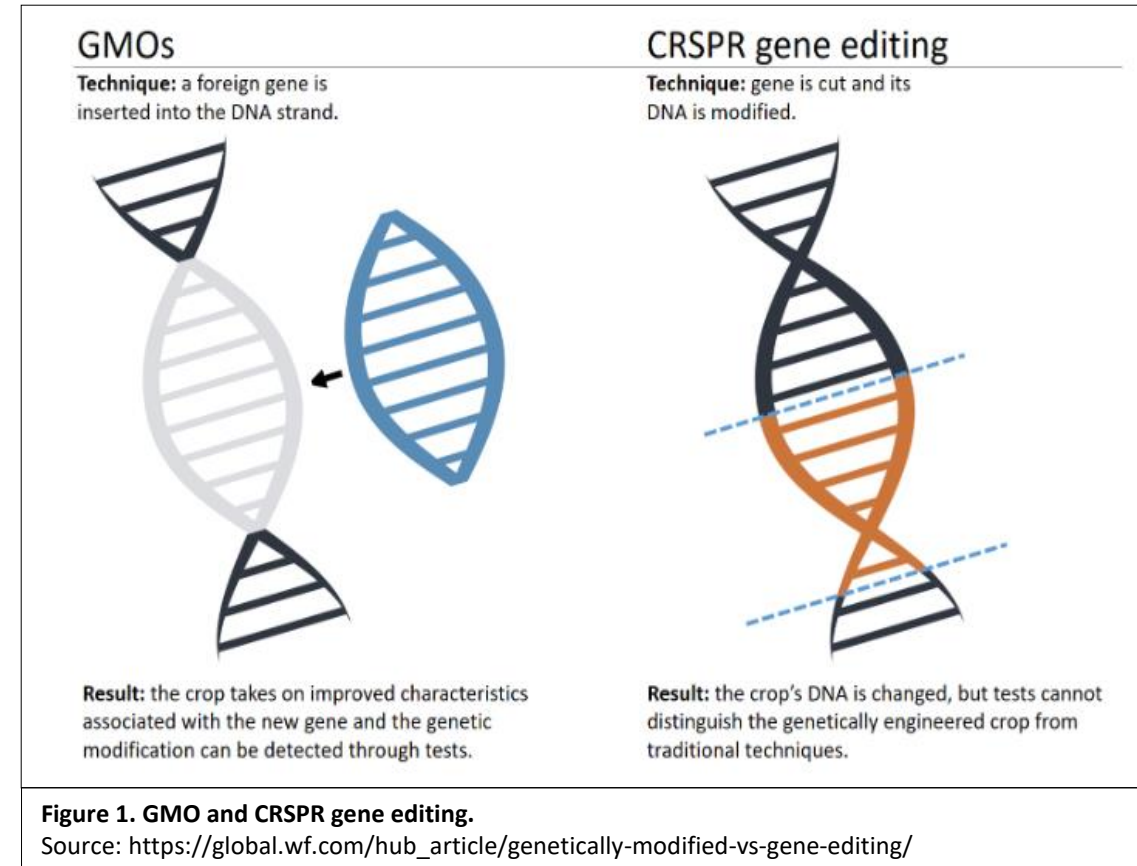
Introduction

In 2002, Colombia ratified Cartagena Protocol on Biosafety, as a supplementary agreement to the Convention on Biological Diversity, to ensure the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology. Subsequently, Government of Colombia issue second regulation which ICA (Colombian Agricultural Institute) is responsible of authorization and verify requiriments of LMOs and Conventional Organism obtained with innovative breeding techniques using modern biotechnology in case of exclusively for agricultural, livestock, fishing, commercial forest plantations and agroindustrial use, which may have adverse effects on the conservation and sustainable use of biological diversity.



Is gene editing technique considered LMOs in Colombia?

- Living Modified Organisms (LMOs): Is any organism life that contain a new combination of genetic material that has been developed through Modern Biotechnology (Cartagena Protocol on Biosafety, 2000).
- In August 2018, ICA (Colombian Agricultural Institute) issued the resolution to regulate and determine it *“if the crops has been developed with use of phytoimprovement innovation techniques through Modern Biotechnology where the final product does not contain any foreign genetic material, in order to determine if it is a living modified organism (LMOs) or not and consequently decide whether the regulations on LMOs shall be applied or not.”*
- This clarifies that gene editing will not be part of the same regulatory oversight as LMOs in **Colombia**.



Biotechnology Applications

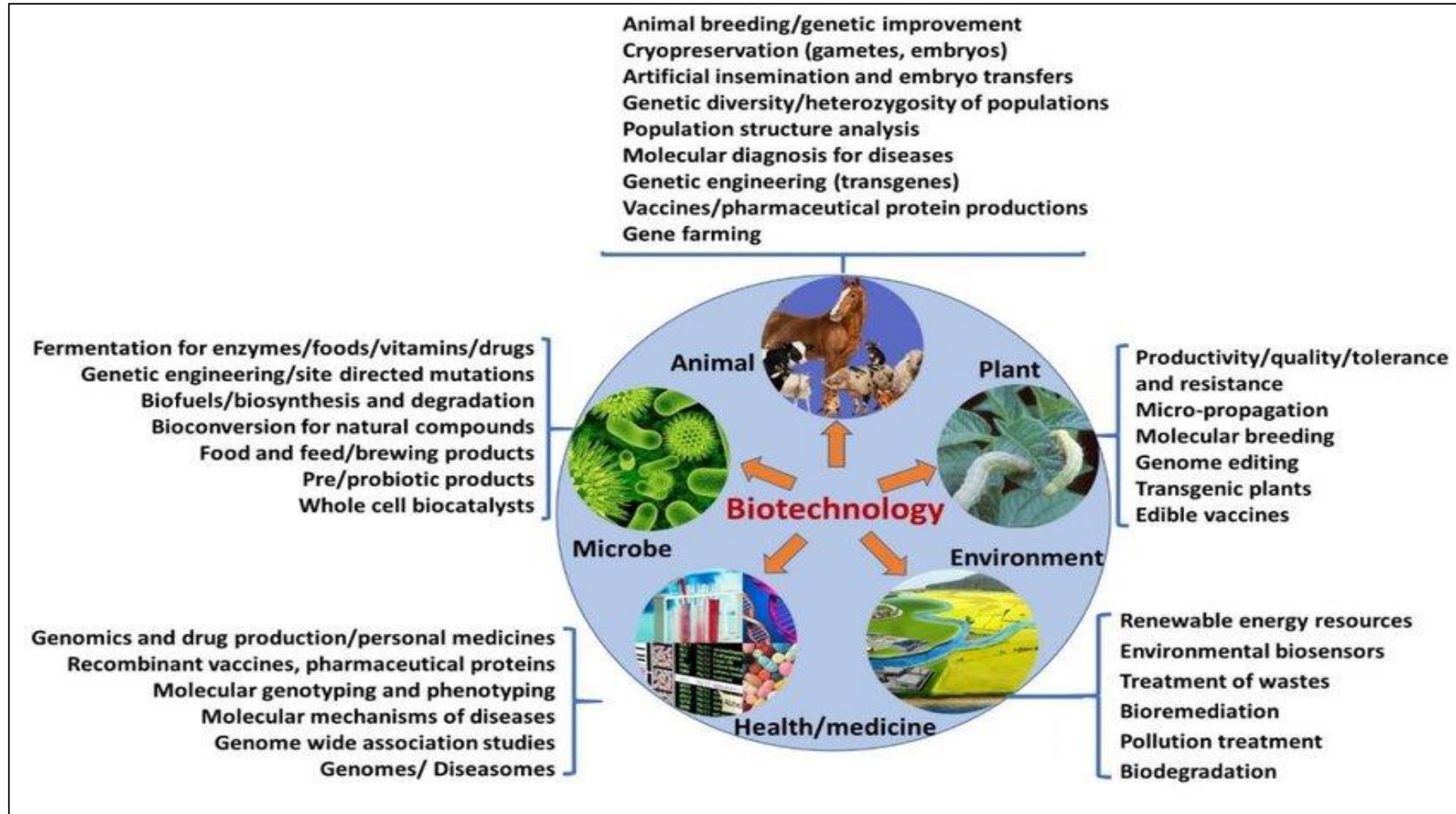


Figure 2. Biotechnology applications.

Regulatory Framework for Biotechnology in plants, microorganism and animals in Colombia

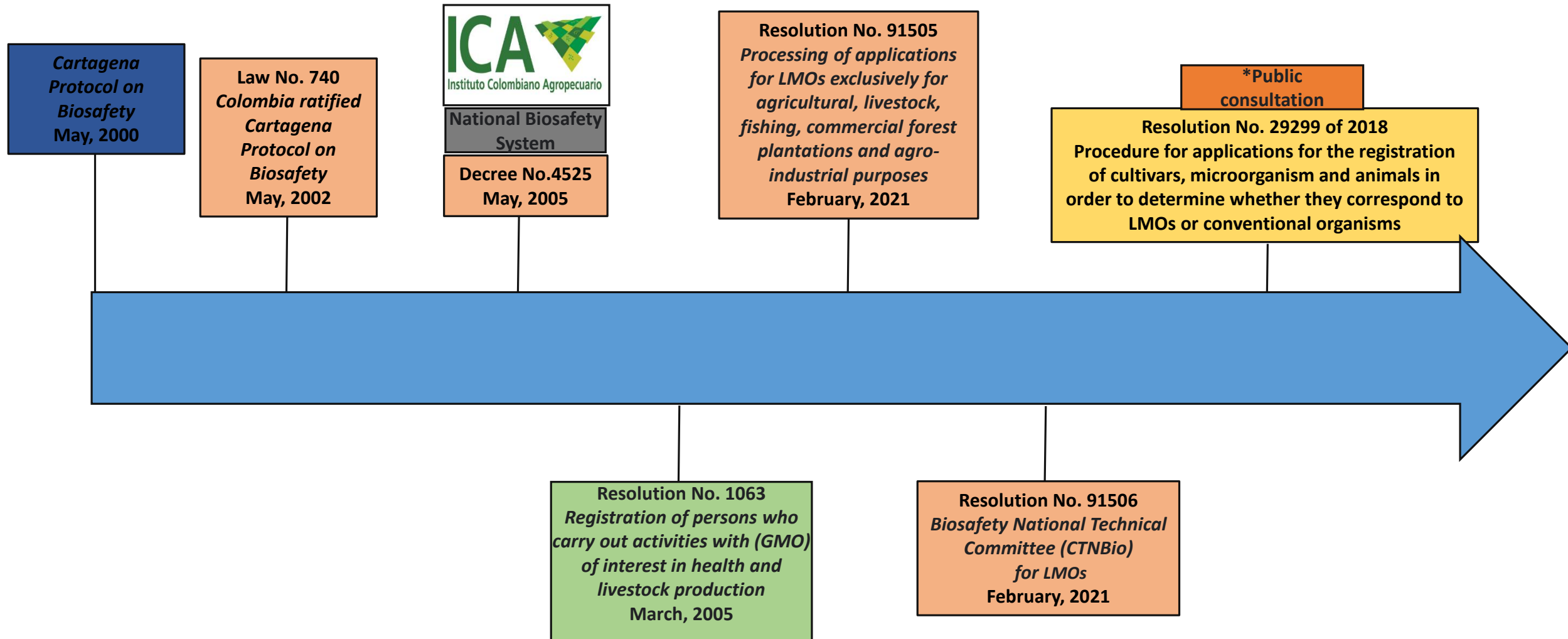


Figure 3. Regulatory Framework for Biotechnology in plants, microorganism and animals in Colombia.

Regulatory approach for products of Animal and Plant Biotechnology in Colombia



Colombia ratified Cartagena Protocol on Biosafety, as a supplementary agreement to the Convention on Biological Diversity, to ensure the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology




Source: <https://quizizz.com/>

National Biosafety System in Colombia



Autorization of LMOs in case of exclusively for agricultural, livestock, fishing, commercial forest plantations and agro-industrial use, which may have adverse effects on the conservation and sustainable use of biological diversity

REPUBLICA DE COLOMBIA



MINISTERIO DE AGRICULTURA Y DESARROLLO RURAL
DECRETO NÚMERO 4525 DE 2005
06 DIC 2005
Por el cual se reglamenta la Ley 740 de 2002
EL PRESIDENTE DE LA REPÚBLICA DE COLOMBIA

En ejercicio de sus facultades constitucionales y legales, en especial de las conferidas en el numeral 11 del artículo 189 de la Constitución Política, el artículo 8º literal g) de la Ley 165 de 1994, y el artículo 2º de la Ley 740 de 2002, y



GENETIC ENGINEERING

GENETICALLY MODIFIED ORGANISM

ANIMAL TESTING OF MEDICINES

Source: <https://www.freepik.es/>

Registration of persons who carry out activities of import, commercialization, research, biological development and quality control of Genetically Modified Organisms (GMO) of interest in health and livestock production, their derivatives and products that contain them

Ministerio de Agricultura y Desarrollo Rural
ICA
INSTITUTO COLOMBIANO AGROPECUARIO

Hoja No. 1/7

RESOLUCIÓN No. 001063
(22 MAR 2005)

Por la cual se expiden normas para el registro de personas que realicen actividades de importación, comercialización, investigación, desarrollo biológico y control de calidad de Organismos Modificados Genéticamente (OMG) de interés en salud y producción pecuaria, sus derivados y productos que los contengan

EL GERENTE GENERAL DEL INSTITUTO COLOMBIANO AGROPECUARIO "ICA"

En ejercicio de sus atribuciones legales y estatutarias, en especial las conferidas por los Decretos 2141 de 1992, 1840 de 1994, la Resolución 2935 de 2001 y el Acuerdo 0004 de 2002 y

RESOLUCIÓN No. 91505
(15 FEB 2021)

"Por medio de la cual se establece el trámite de las solicitudes de los Organismos Vivos Modificados –OVM con fines exclusivamente agrícolas, pecuarios, pesqueros, plantaciones forestales comerciales y agroindustriales ante el ICA"

LA GERENTE GENERAL
DEL INSTITUTO COLOMBIANO AGROPECUARIO (ICA)

En ejercicio de sus atribuciones legales y en especial la conferidas por el artículo 12 del Decreto 4765 de 2008, el artículo 4 del Decreto 3761 de 2009, el artículo 2 del Decreto 4525 de 2005 y el artículo 2.13.1.1.2 del Decreto 1071 de 2015 y

CONSIDERANDO:

Resolution No.
29299 of 2018
and animal
register

Procedure for applications for the registration of cultivars, microorganism and animals of zootechnical interest with innovative breeding techniques using modern biotechnology, in order to determine whether they correspond to LMOs or conventional organisms

Processing of applications for LMOs exclusively for agricultural, livestock, fishing, commercial forest plantations and agro-industrial purposes



Source:https://www.pinterest.com.mx/



Source:Credit: Getty Images

*Public
consultation

July 29 - September 27, 2022

RESOLUCIÓN No.
()

"Por medio de la cual se establece el procedimiento para el trámite ante el ICA de las solicitudes de nuevos productos obtenidos por Innovación en Mejoramiento Genético, con el fin de determinar si corresponden a Organismos Vivos Modificados (OVM) o a Organismos Convencionales"

LA GERENTE GENERAL
DEL INSTITUTO COLOMBIANO AGROPECUARIO- ICA


En ejercicio de sus atribuciones legales y en especial de las conferidas por el artículo 65 de la Ley 101 de 1993, el artículo 4 del Decreto 3761 de 2009, el artículo 2.13.1.1.2 del Decreto 1071 de 2015 y

CONSIDERANDO

Competent National Authorities



MINISTERIO DE SALUD Y PROTECCIÓN SOCIAL



MINISTERIO DE AGRICULTURA Y DESARROLLO RURAL



MINISTERIO DE AMBIENTE Y DESARROLLO SOSTENIBLE



MINISTERIO DE CIENCIA, TECNOLOGÍA E INNOVACIÓN

Decree 4525 of 2005

Biosafety National Technical Committee for LMOs (CTNBio)



Source: www.prensajuridica.com

Risk Assessments



El campo es de todos **ICA** Instituto Colombiano Agropecuario

Página 1 de 8

RESOLUCIÓN No. 91506
(15 FEB 2021)

Por medio de la cual se establece el Reglamento Interno del Comité Técnico Nacional de Bioseguridad, CTNBio para Organismos Vivos Modificados OVM con fines exclusivamente agrícolas, pecuarios, pesqueros, plantaciones forestales comerciales y agroindustria, y se dictan otras disposiciones

LA GERENTE GENERAL DEL INSTITUTO COLOMBIANO AGROPECUARIO (ICA)

En ejercicio de sus atribuciones legales y en especial de las conferidas por el artículo 22 del Decreto 4525 de 2005, el artículo 12 del Decreto 4765 de 2008, el artículo 2.13.1.1.2 del Decreto 1071 de 2015 y

CONSIDERANDO:

Que mediante la Ley 740 de 2002, Colombia ratificó el Protocolo de Cartagena sobre

Roadmap for the regulatory LMOs and conventional products in Colombia

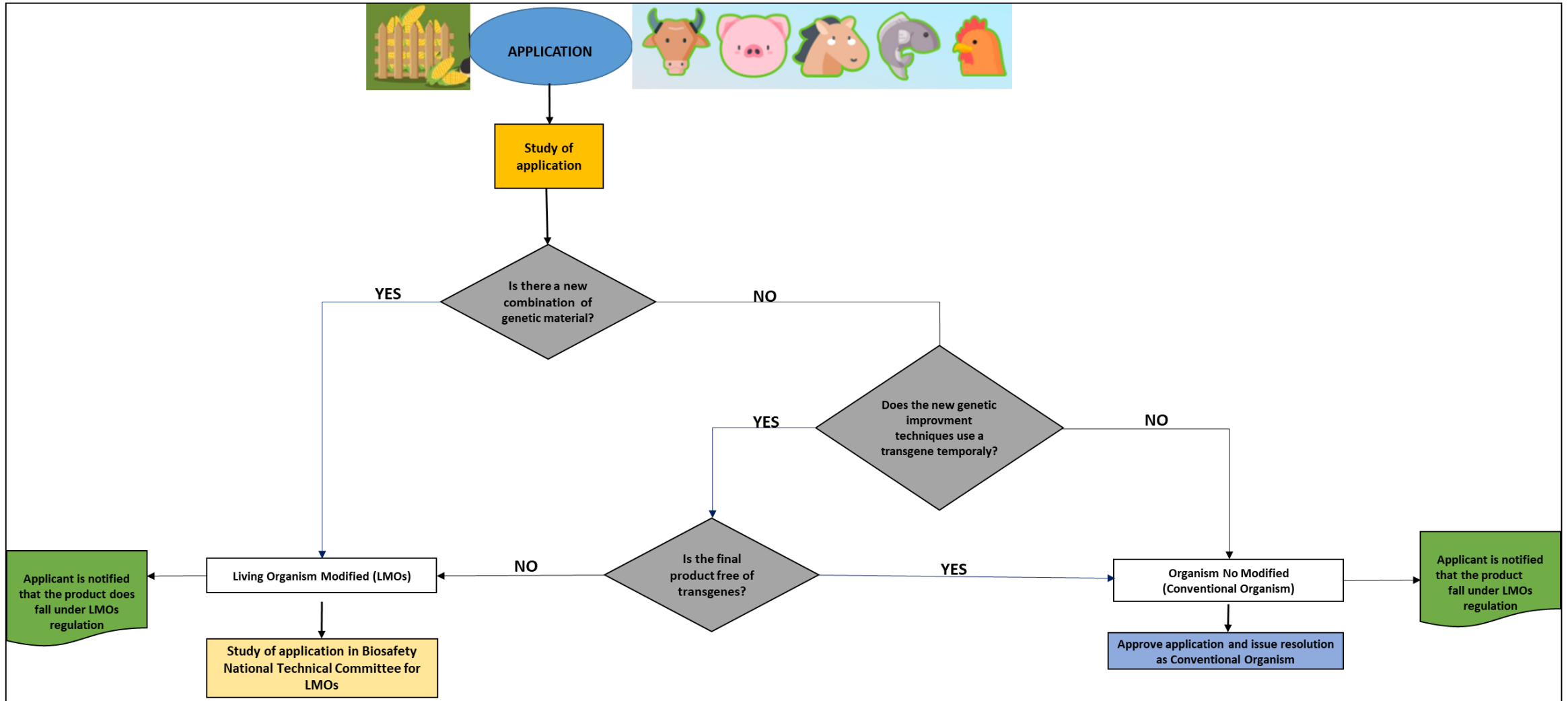
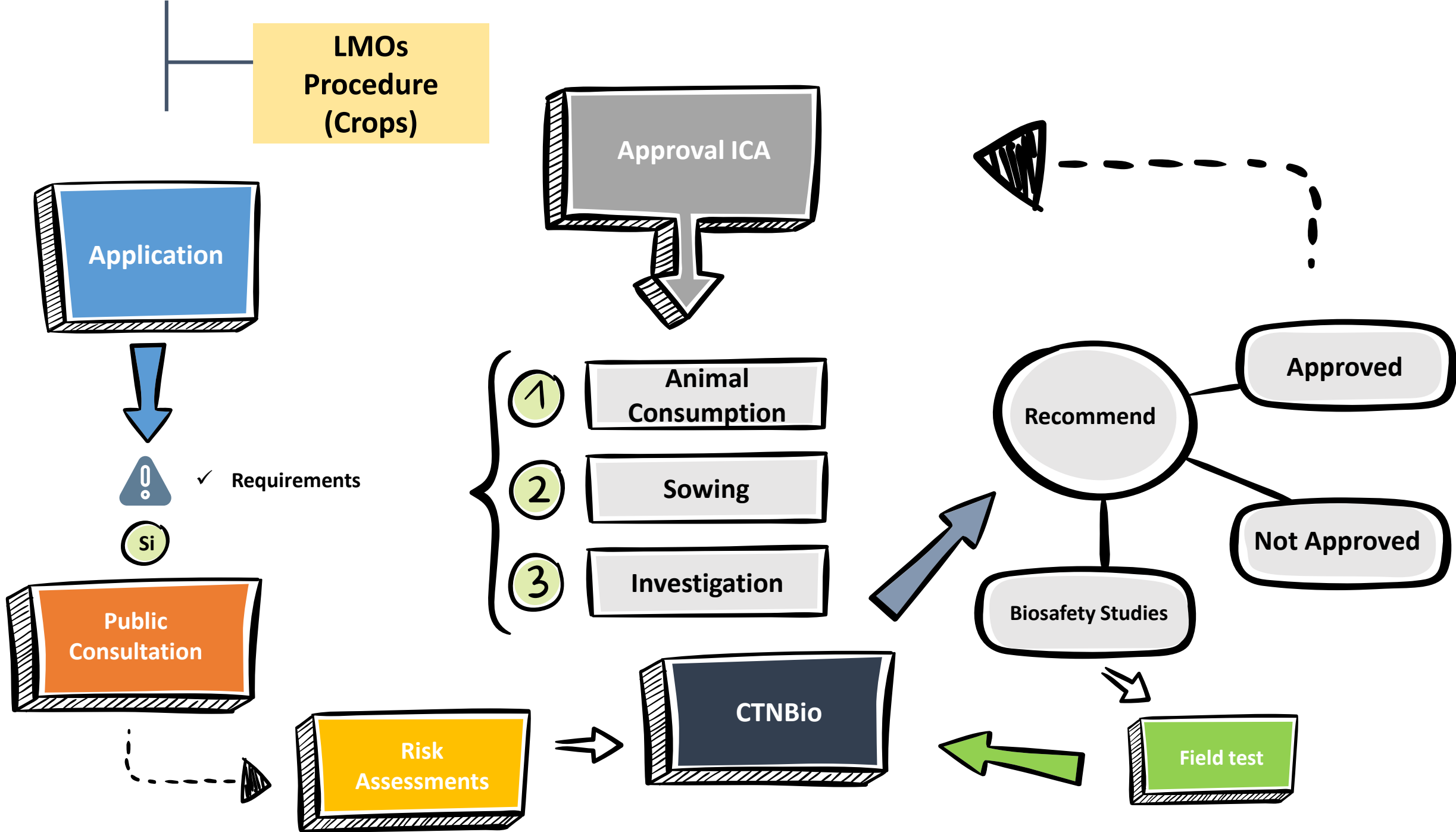


Figure 4. Roadmap for the regulatory LMOs and conventional products in Colombia



Approval of applications for LMOs and Conventional Organism in Colombia

Resolution No. 29299 of 2018*

| No. | Specie | Trait | Company | Concept | Comment | Year |
|-----|---------|-------------------------|-------------------------|--------------|---|------|
| 1 | Corn | Waxy | Dupont de Colombia S.A. | Conventional | | 2020 |
| 2 | Rice | Efficient use of P | AGROSAVIA | Pending | CTNBio approval – LMO Rice import for edition in Colombia | 2020 |
| 3 | Rice | Tolerance Xoo | CIAT - Bioversity | Conventional | | 2020 |
| 4 | Mustard | Improved flavor profile | Pairwise – Bayer S.A. | Conventional | | 2021 |

Resolution No. 91505 of 2021 – LMOs

| Specie | N° Events for Animal Consumption | N° Events for sowing |
|---------------|----------------------------------|----------------------|
| Cotton | 32 | 10 |
| Rice | 1 | 0 |
| Canola | 9 | 0 |
| Carnation | 0 | 4 |
| Chrysanthemum | 0 | 2 |
| Gypsophila | 0 | 2 |
| Corn | 90 | 20 |
| Rose | 0 | 2 |
| Beetroot | 1 | 0 |
| Soya bean | 35 | 1 |
| Wheat | 1 | 0 |
| Total | 169 | 41 |

***Public
consultation**

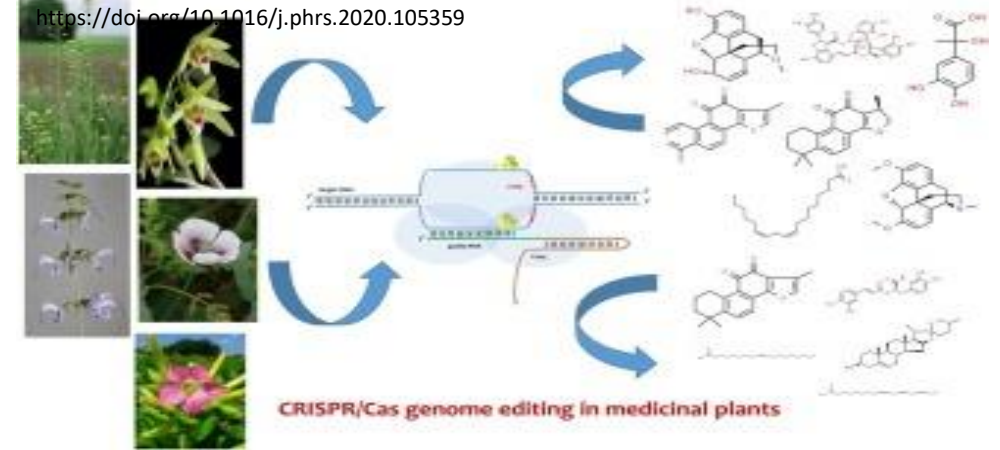
Importance of CRISPR/Cas9 Gene Editing Technique in Colombia



Gene editing constitutes a significant advance in genetic modification technologies with a consequent impact on increasing genetic variability



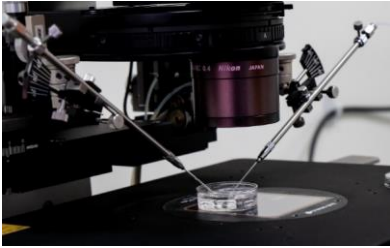
Animal population improvement can be accelerated with the use of gene editing by introducing or creating beneficial alleles, without the consequences of linkage drag associated with traditional introgression



Plant and animal genetic improvement throughout history has been accompanied by different vehicles represented by new technologies

Current Research in Biotechnology using CRISPR/Cas9 (Gene Editing Technique) in Colombia

Editing of the exón III of MSTN gene in Black Eared White (BON) criole cattle.



Production of bovine cell lines edited for the MSTN gene.

Somatic cell nuclear transfer for the purpose of producing gene-edited bovine embryos

Pending: perform same process of embryo production by nuclear transfer using edited cell lines.



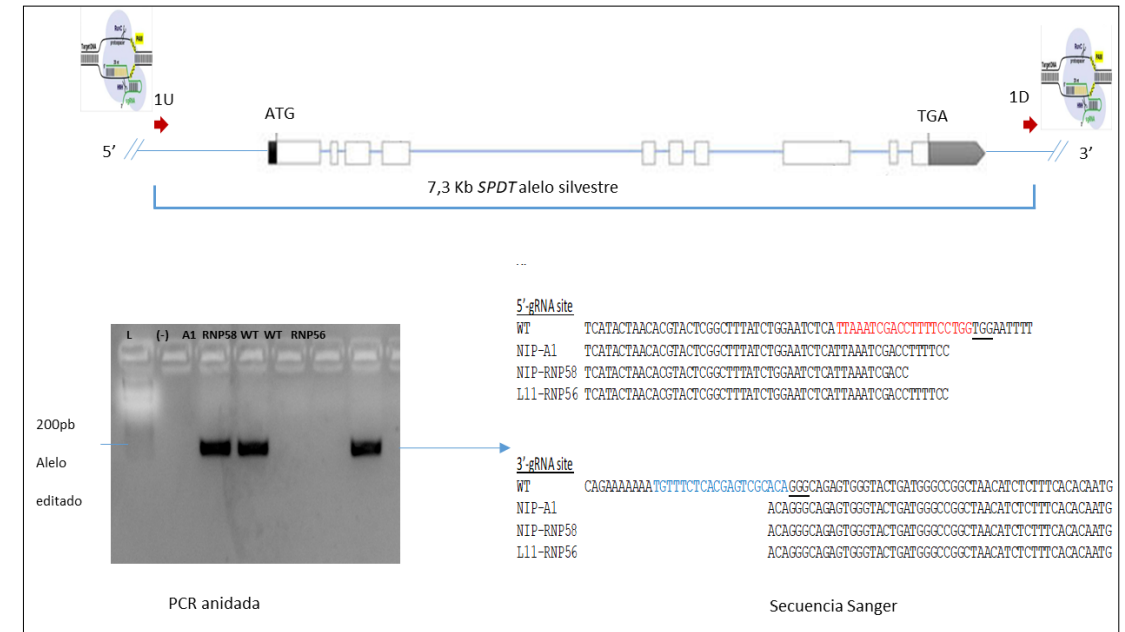
AGROSAVIA
Corporación colombiana de investigación agropecuaria

Group of Genetic Resources and Animal Biotechnology of Agrosavia

Tolerance to abiotic stress in a variety of rice for the Altilanura



AGROSAVIA
Corporación colombiana de investigación agropecuaria



ICA
Instituto Colombiano Agropecuario

El campo es de todos Minagricultura

RESOLUCIÓN No. 102584
(03 de agosto de 2021)

Por la cual se autoriza a la Corporación Colombiana de Investigación Agropecuaria AGROSAVIA la importación de semillas de plantas de arroz transformadas vía *Agrobacterium tumefaciens* usando el sistema de edición de genes CRISPR/cas9, para ensayos de investigación en medio confinado.

LA GERENTE GENERAL DEL INSTITUTO COLOMBIANO AGROPECUARIO, ICA

en uso de sus facultades legales y en especial por las conferidas por los Decretos 2141 de 1992, 4765 de 2008 y el 4525 de 2005 compilados en el 1071 de 2015.

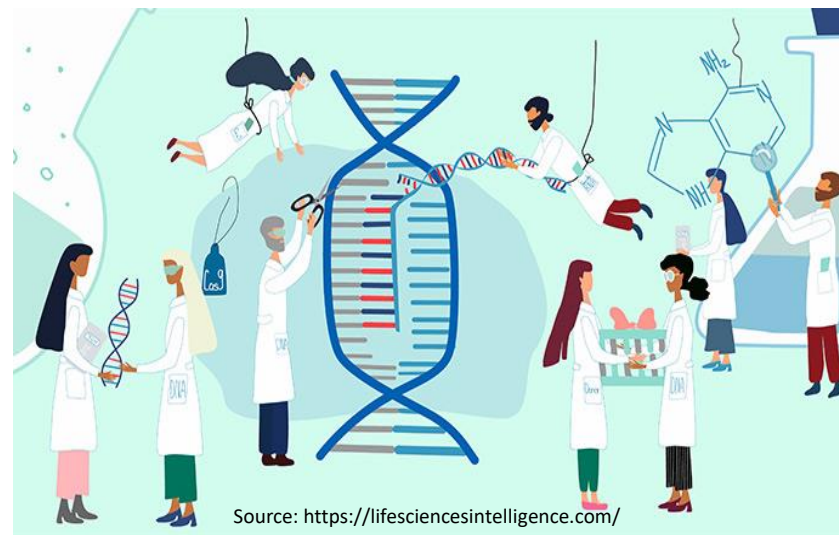
CONSIDERANDO:

Que el Gobierno Nacional, en desarrollo de la Ley 740 de 2002 expidió el Decreto 4525 de 2005, y designó al Ministerio de Agricultura y Desarrollo Rural, a través del Instituto Colombiano Agropecuario, ICA la competencia para la autorización de movimientos transfronterizos, el tránsito, la manipulación y la utilización de los Organismos Vivos Modificados - OVM con fines agrícolas pecuarios, pesqueros, plantaciones forestales comerciales y agroindustriales que puedan tener efectos adversos para la conservación y

- ❖ Rice varieties from Altilanura (Llanura 11 and Porvenir 12).
- ❖ SPTD gene deletion.
- ❖ Agreement with Cornell University in order to edit gene(s) with high phenotypic effect associated with tolerance to abiotic stress

Conclusions

- ✓ The first resolution to assess whether they are LMOs or conventional bodies (Currently in Public Consultation).
- ✓ The focus of regulatory research: Whether the products have a new combination of genetic material and/or have transgenes in the final product in relation to the definition of LMOs.
- ✓ The first research on the use of gene editing in animals in Colombia.



References

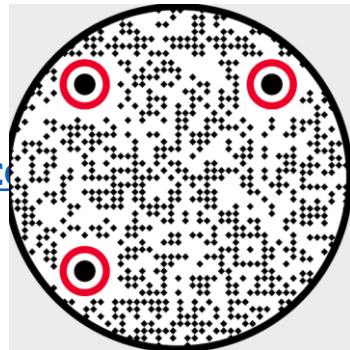
1. Bach, N., & Bich Thuy, L. (2019). Current Research, Challenges, and Perspectives of Biotechnology: An Overview. Vietnam Journal of Agricultural Sciences, 1(2), 187-199. <https://doi.org/10.31817/vjas.2018.1.2.09>
2. Dey, Abhijit (2021). CRISPR/Cas genome editing to optimize pharmacologically active plant natural products. Pharmacological Research
Volume 164, February 2021, 105359. <https://doi.org/10.1016/j.phrs.2020.105359>.
3. Nguyen, Bach & Duc, & Bach, Nguyen & Thi, Ly & Thuy, Bich & Vjas, Viet. (2019). Vietnam Journal of Agricultural Sciences Current Research, Challenges, and Perspectives of Biotechnology: An Overview. 10.13140/RG.2.2.11282.50881..
<https://doi.org/10.31817/vjas.2018.1.2.09>
4. Schmidt, Curtney, Swanson Lon. Wells Fargo. Food for Thought. Genetically modified vs. gene editing.
https://global.wf.com/hub_article/genetically-modified-vs-gene-editing/
5. <https://www.agrosavia.co/>.
6. <https://www.drugtargetreview.com/news/103749/an-effective-and-error-free-gene-editor/>
7. <https://www.freepik.es>
8. <https://www.gettyimages.com.mx/>
9. <https://www.ica.gov.co/home>
10. <https://lifesciencesintelligence.com/features/crispr-genome-editing-technology-the-future-of-gene-editing>
11. <https://mundoagropecuario.net/crispr-cas9-aclara-la-reduccion-de-la-destruccion-de-semillas-durante-la-domesticacion-del-arroz/>
12. www.pinterest.com.mx/



Thank you all for listening

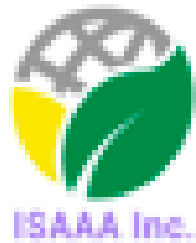
ckatepl@gmail.com
ycpinillal@unal.edu.co
yenny.pinilla@ica.gov.co

Phone: +573 108576443



Source: <https://www.drugtargetreview.com/>

Acknowledgments



Agriculture &
Food Systems
Institute



www.ica.gov.co



@icacolombia



ICAColombia



@ICACOLOMBIA



Instituto Colombiano Agropecuario -
ICA