The shifting dynamics of PBI, impacting agriculture and the seed sector

From Genetically Modified Organisms to Genome Edited Organisms

Alexandre Nepomuceno, *PhD*
General Head
Embrapa Soybean – Brazilian Soybean Research Center

GENETICS: How are Commercial Varieties being Generated?

Classical Breeding
Molecular Assisted Breeding

Germplasm Bank
Accessions
Introgression Lines
Recombinant Lines (MAS),
QTLs, SNPs, etc.

Genome Wide Seletion (GWS)

Germplasm

Biotechnology

Transgenics
Genome Edition
(Intragenics, Cisgenics, etc)

Phenoma
Exposure to treatments under different environmental conditions

Selection

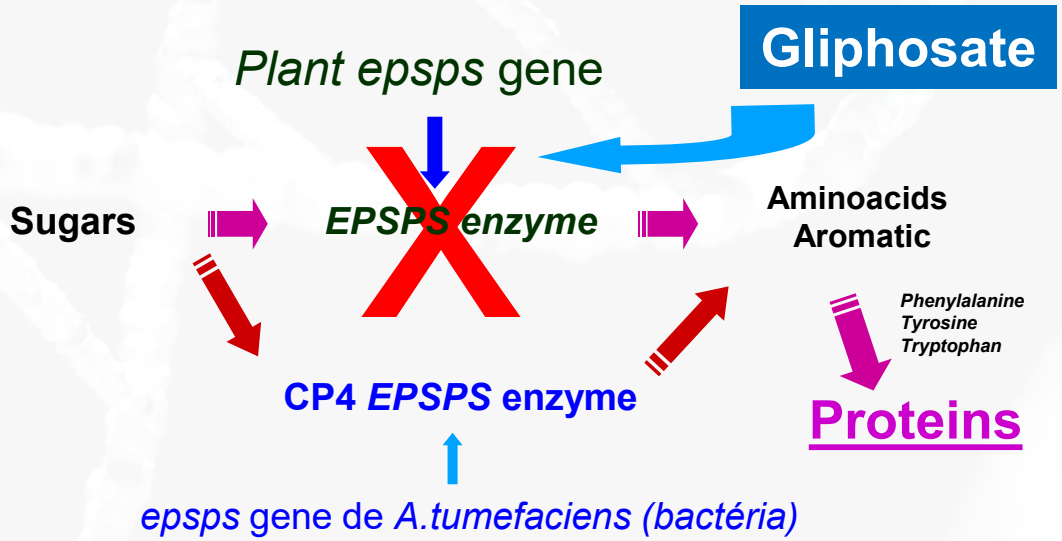
Combine the best specific gene arrangements in commercial species using the genetic base of the species, but also adding characteristics of tolerance to abiotic/biotic stresses generated in evolutionary lines of other species and/or related species.

"Begging" of Biotechnology in Agriculture

US 1996 – Argentina 1997 - Brazil 1998

Glifosate Resistance – *Roundup Ready Soybean* (RR)

GM First Transgenic plant used in large scale commercially

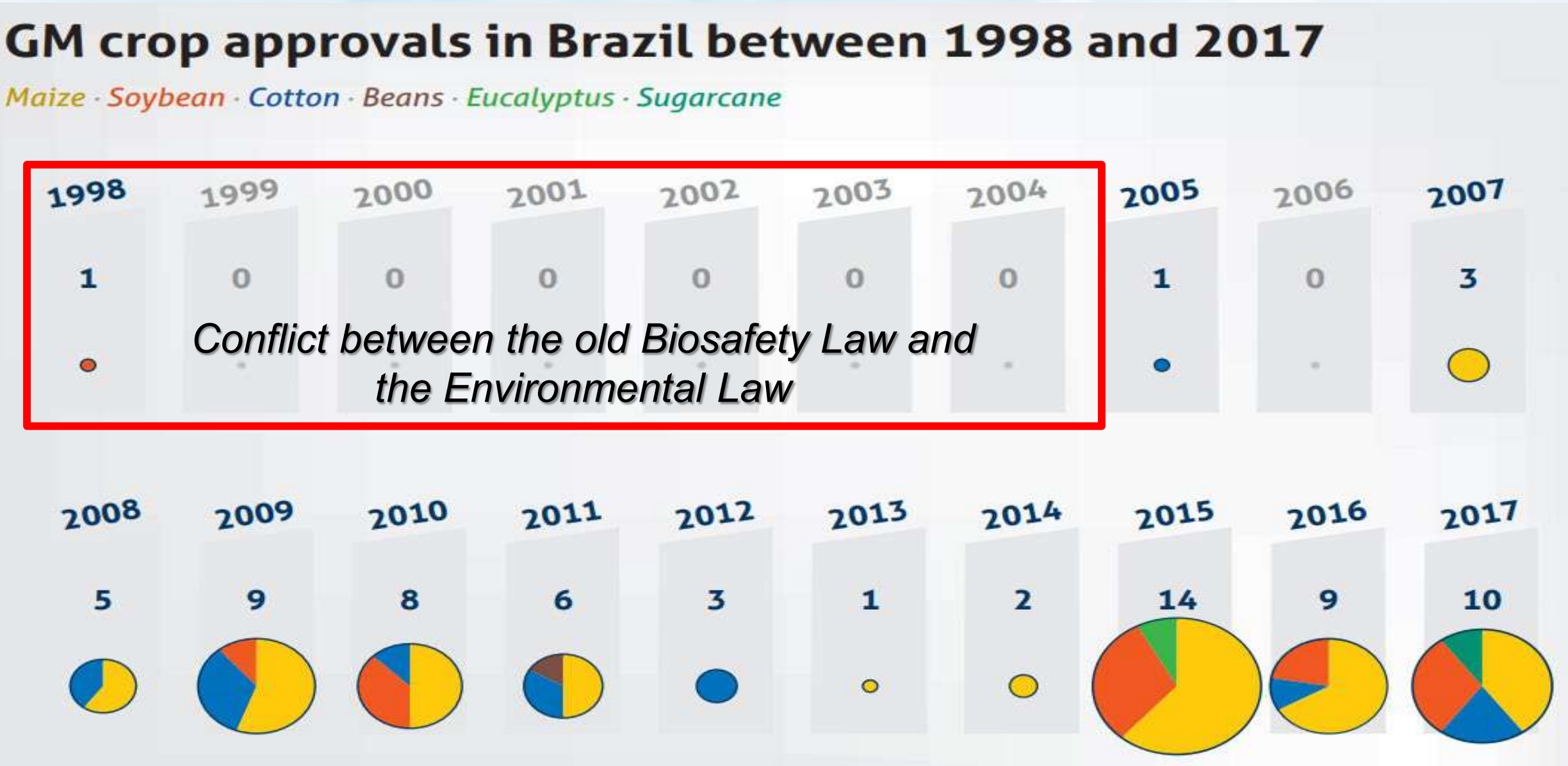


EPSPS : 5-enolpyruvylshikimate-3-phosphate synthase

Embrapa

Global “Paranoia” about GMOs/Transgenics in Agriculture

Brazil had an "unofficial moratorium" for 7 years on the use of GM Plants in Agriculture



Conflict between the old Biosafety Law and the Environmental Law

“NEW” Biosafety Law - 11.105/2005

Brazilian Biosafety Technical Commission - CTNBio

Full Members: 27 PhDs
Alternate Member: 27 PhDs

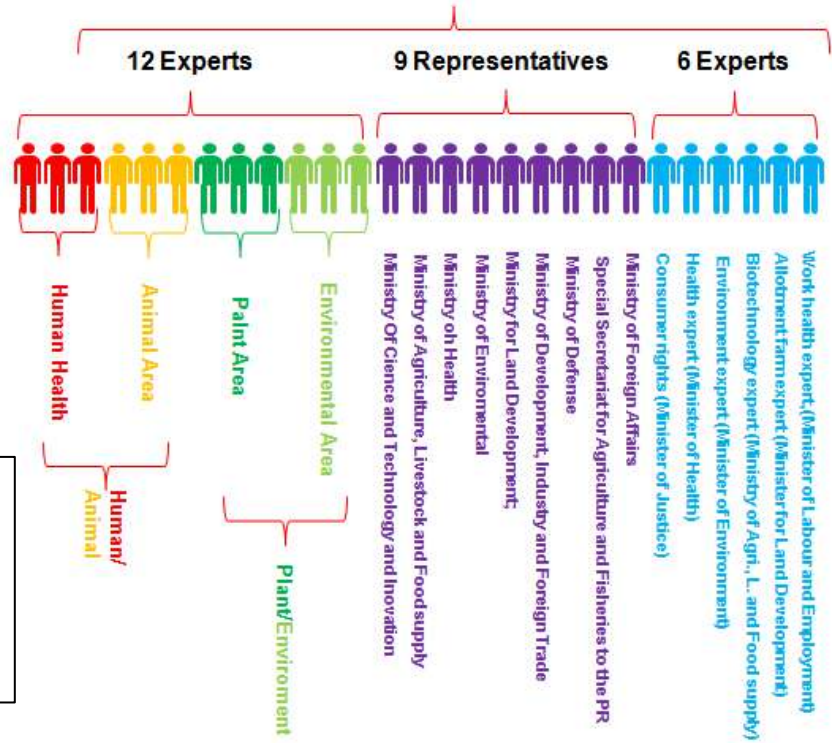
- National Biosafety Council
- National Biosafety Technical Commission
- Internal Biosafety Commissions
- Registration and Inspection Bodies

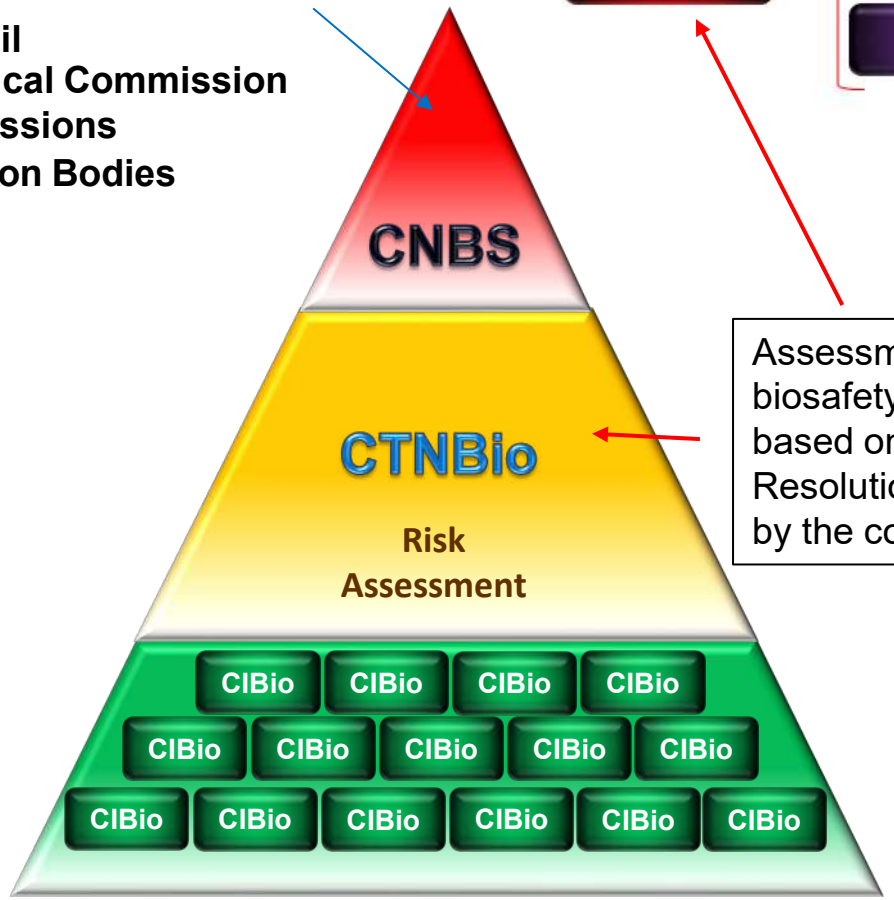
National interest and socioeconomic factors (not an obligation)

CTNBio

Secretariat

Members





Assessment of the biosafety of a product based on Normative Resolutions established by the commission

CIBio - Maintenance of biosafety

comissão técnica nacional
CTNBio
de biossegurança

Embrapa

MINISTÉRIO DA AGRICULTURA, PECUÁRIA E ABASTECIMENTO

COUNTRIES APPROVING GM CROP CULTIVATION

More than 30 countries have approved GM crop cultivation since 1996. See where GM crops are approved from 1996 to 2024.

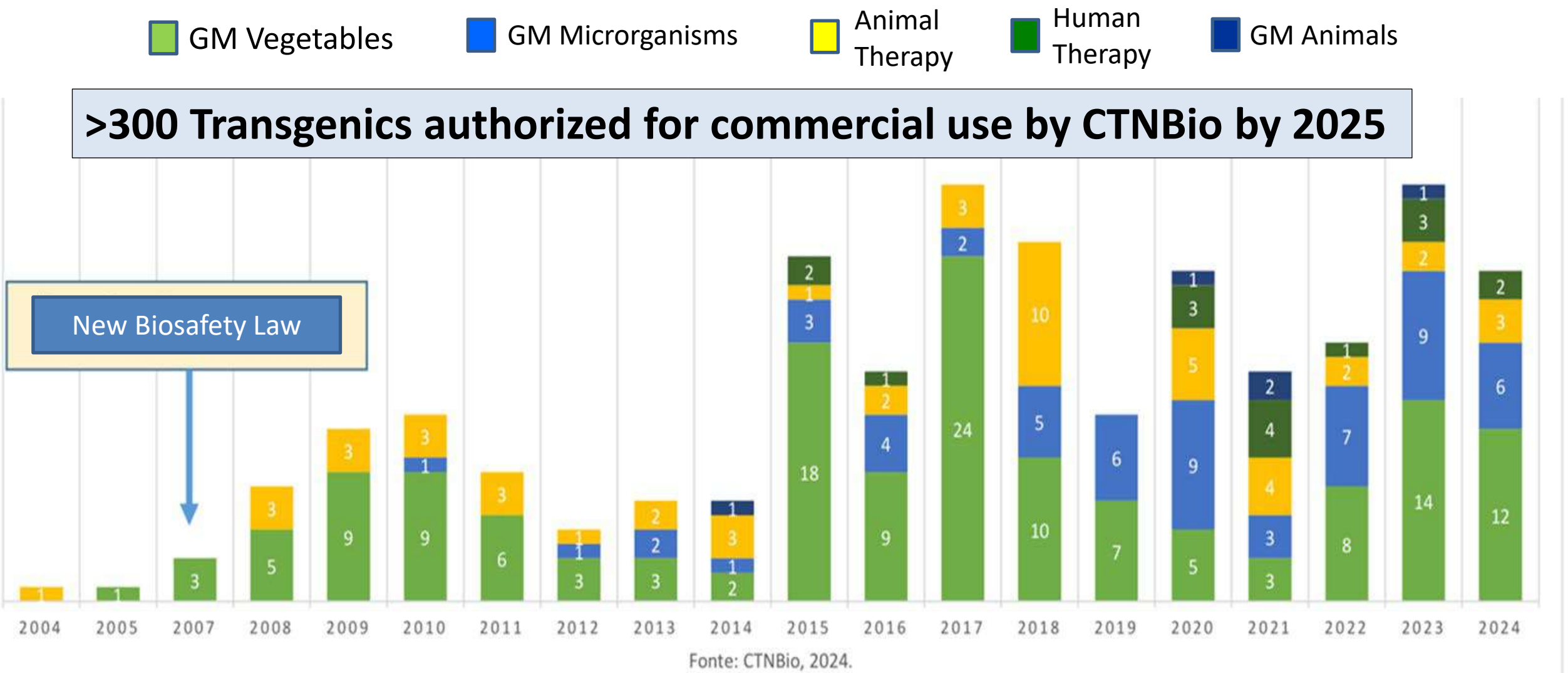
Today Brazil is the second largest producer of GM crops

Sources:
ISAAA Global Status of Commercialized Biotech/ GM Crops in 2019. ISAAA Brief No. 55.
ISAAA Biotech Updates. https://www.isaaa.org/kc/cropbiotechupdate/
USDA Economic Research Service. https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-u-s/recent-trends-in-ge-adoption/
Office of the Gene Technology Regulator. https://www.ogtr.gov.au/

FOR MORE INFORMATION ON BIOTECH CROPS, VISIT
www.isaaa.org
ISAAA Inc.

GMOs Commercially Released in Brazil from 1998-2024

CTNBio - Brazilian Biosafety Technical Commission



Embrapa

comissão técnica nacional CTNBio de biossegurança

Source: CTNBio, 2024

GMOs Commercially Released in Brazil from 1998-2025

Full Date in Table format can by downloaded at:

http://ctnbio.mctic.gov.br/documents/566529/1684467/Tabela+de+Plantas+Aprovadas+para+Comercializa%C3%A7%C3%A3o/e3087f9c-c719-476e-a9bd-bfe75def842f?version=1.27

"Unfortunately" more than 95% of the Commercial Liberations in Brazil (and in the World) are related only to Herbicide/Insect Resistance and in Commodities Crops

How biotechnology play an important role in the Brazilian agriculture (and Americas), economy and society

First Genetically Modified Organisms

and now also

Genetically Edited Organisms

Sustainability: GM Plants resistant to herbicides helped increase of No-Tillage systems in Brazil.

More sequestered Carbon, water and nutrient preservation, more plants/soil beneficial microorganisms, etc...

Non-Tillage in ~70% of the Brazilian production areas

Non-Tillage

Carbon Sequestration
~2,93 t ha^{-1} $year^{-1}$ of CO_2 eq.

↓

In 20 years

58 t CO_2 eq. ha^{-1}

20.000 L diesel/ha

In 40 million ha (Season 2021/22)

800 billion Liters of Diesel / 20 years

Embrapa

SOURCE: BABUJIA, L. C.; HUNGRIA, M.; FRANCHINI, J. C.; BROOKES, P. C. **Soil Biology & Biochemistry**, v. 42, p. 2174- 2181, 2010.

Sustainability: GM Insect resistant *Bt* plants

Neotropical Entomology (2025) 54:61
https://doi.org/10.1007/s13744-025-01275-5

FORUM

Check for updates

Over 10 Years of *Bt* Soybean in Brazil: Lessons, Benefits, and Challenges for Its Use in Integrated Pest Management (IPM)

Research Article

Received: 23 February 2022 Revised: 25 May 2022 Accepted article published: 9 June 2022 Published online in Wiley Online Library: 30 June 2022

(wileyonlinelibrary.com) DOI 10.1002/ps.7034

Regional pest suppression associated with adoption of Cry1Ac soybean benefits pest management in tropical agriculture

Embrapa

New GM Plants (transgenic) approved/in analysis in Brazil that soon might reach the market

Herbicide resistance
Insect resistance
Nematode resistance
Disease resistance

New GM strategies approved in Brazil..

Soybean

New GM strategies Approved to Brazil..

Gliphosate,

New GM strategies approved in Brazil...

Lep4 (MON 95379): New Generation of Bt technology + Plant

CONVENCIONAL

Testing in the region of Santa Cruz
9 days after infe

New GM strategies approved in Brazil…

CORN

EMBRAPA AND
FULLY DEVELO
New technology is highly e
11/29/2022 - 05:18 PM

NEMA

New GM strategies approved in Brazil

"NEW WAVE" OF GM PLANTS FOR DISEASE RESISTANCE BEING EVALUATED BY CTNBIO IN BRAZIL

Soybean Rust and other Diseases

9.8. (Contém Informações Confidenciais) Syngenta Seeds Ltda; CQB 001/96; Processo: 01245.017854/2021-58; Liberação Planejada no Meio Ambiente de soja resistência a Doença e Tolerância a Herbicidas; Protocolado em 18/03/2024; Extrato Prévio nº 9420/2024; Relatoria definida em abril/2024: Dra. Janette Palma Fett; Assessoria: Orlando Cardoso;

9.5. (Contém Informações Confidenciais) Basf. S.A.; CQB 031/97; Processo: 01245.014646/2021-05; Relatório de liberação planejada no meio ambiente de Soja GM 2021/2022 e 2022/2022: Avaliação da Soja GM Resistente a Doença (2) Bio2-090"; Protocolado em 19/05/2023; Extrato Prévio nº 8897/2023; Relatoria definida em junho/2023: Dr. Antônio Costa de Oliveira (agosto/2023); Assessoria: Orlando Cardoso;

3.7. (URGENTE) (Contém Informações Confidenciais) Corteva Agriscience do Brasil Ltda.; CQB 013/97; Processo: 01245.022635/2023-52; Liberação planejada no meio ambiente e importação de sementes de soja geneticamente modificada. Os experimentos serão realizados na Unidades Operativas da

9.7. (Contém Informações Confidenciais) Monsanto do Brasil LTDA; CQB 003/96; Processo: 01245.014718/2021-14; Liberação Planejada no Meio Ambiente de soja geneticamente modificado tolerante à doenças; Protocolado em 07/03/2024; Extrato Prévio nº 9400/2024; Relatoria definida em abril/2024: Dra. Luciana Pimenta Ambrozevicius; Assessoria: Gutemberg Delfino;

Transgenic Animals also Commercially Released in Brazil

Aedes sp. First GM insect (Macho Stérile) released in Brazil in 2014

Mosquito Male Sterile

Brazil: First country to release GM animals for large-scale commercial use

GM Male Sterile
Spodoptera frugiperda

Authorized for commercial use in Brazil (March/2021)

New GM Insects coming
White fly
Fruits Fly
Embrapa

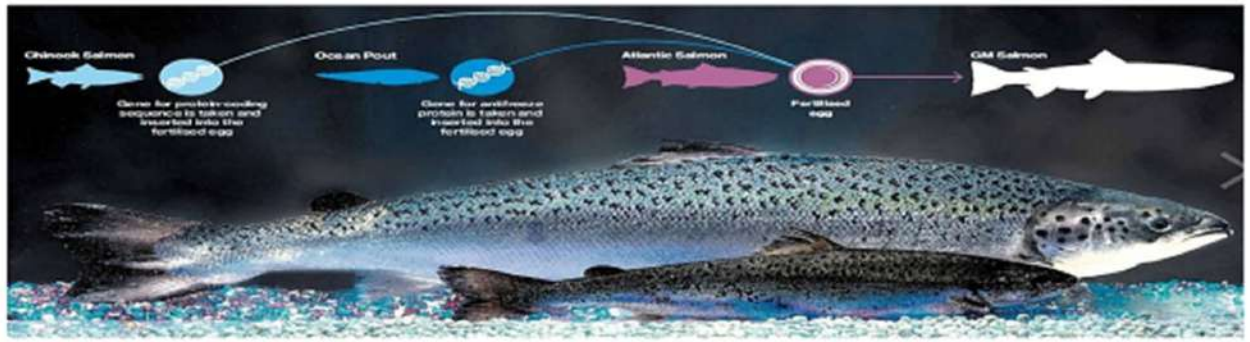
Male Sterile
Transgenic Mosquito (Aedes sp.)
&
Spodoptera frugiperda

Transgenic Salmon

GM Salmão

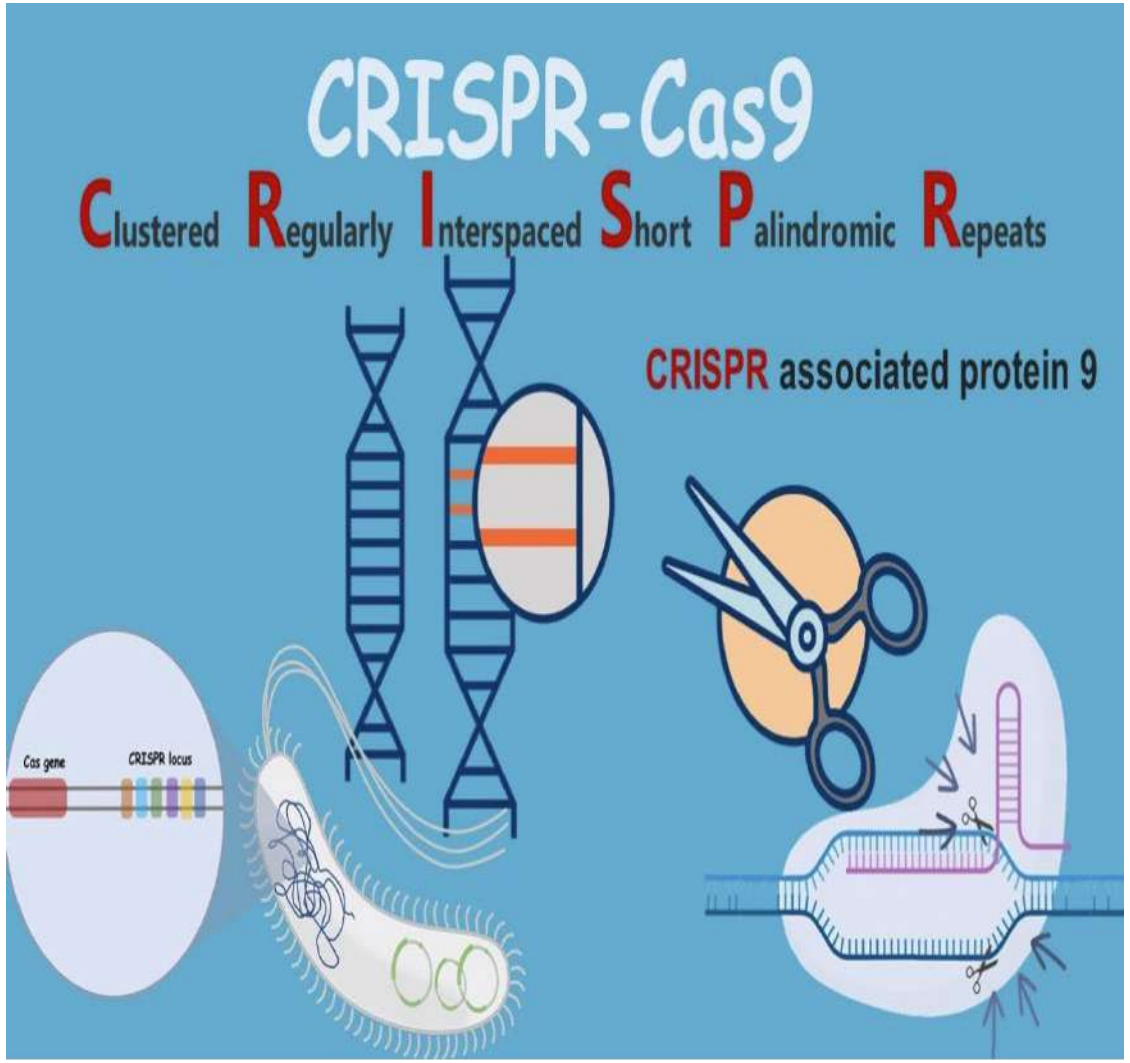
Liberado para consumo no BR em Maio/2021

"Sashimi GM" – 25 anos para ser liberado comercialmente no US/CA e 29 anos no BR

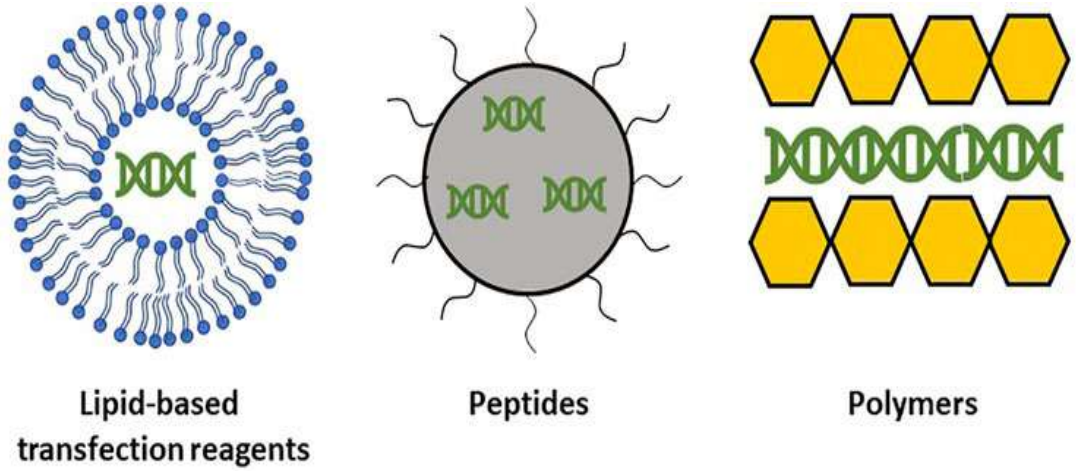


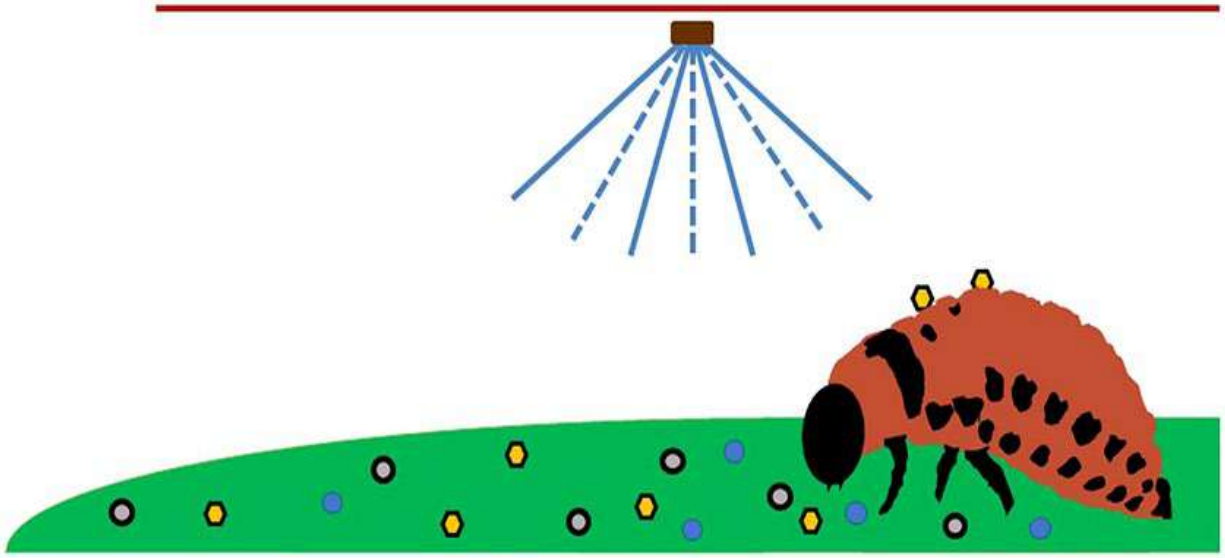
New important and sustainable technologies emerging in the word

Genome Edited Species (CRISPRs)



Topical use of RNAi – Sprayable RNAi to control





Clustered

Regularly

Interspaced

Short

Palindromic

Repeats

Earlier genome editing tools

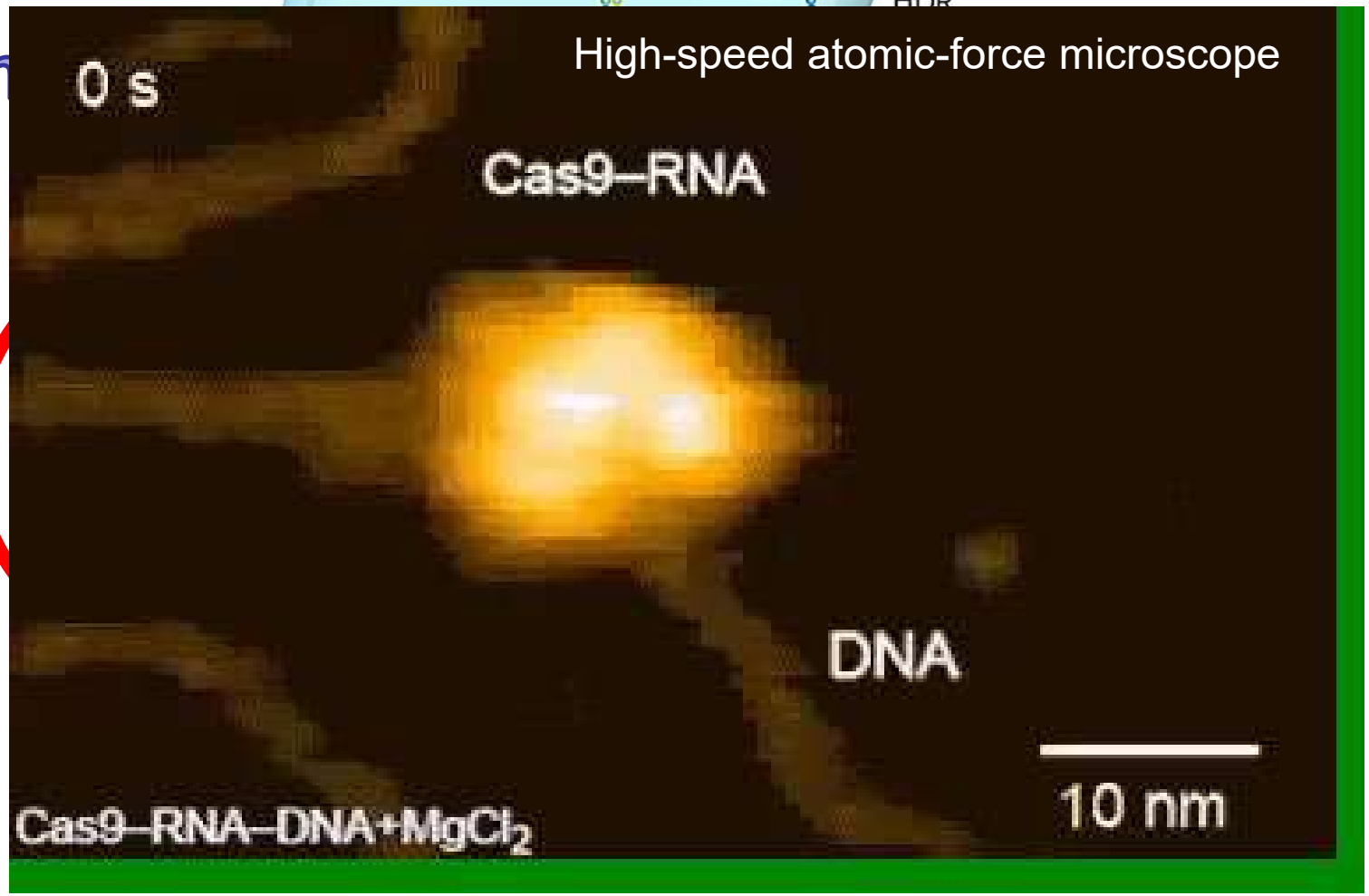
Meganucleases

Zinc Fingers

TALEs

Site Directed Nuclease:
SDN1/SDN2/SDN3

Non



Examples of *Genome Edited* products evaluated by the Brazilian Biosafety Commission (CTNBio) that were considered Non-GMO

comissão técnica nacional
CTNBio
de biossegurança

comissão técnica nacional
CTNBio
de biossegurança

FIRST PLANTS

Considered Non GM by CTNBio (2018)

Food DIVE — TOPICS — FEATURES

Inside CRISPR's gene editing technology — and how it could revolutionize the food industry

A new generation of genetically edited organisms has arrived and if early results are any indication, it has the potential to revolutionize the food manufacturing industry, as well as numerous industries.

On Monday, DuPont Pioneer announced the USDA will not subject a waxy corn hybrid created with CRISPR Cas9 gene-editing technology to regulations applied to traditional GMOs. The gene changes the functionality of starch. DuPont's officials believe the corn can be planted in fields in five years. The company is also growing CRISPR-edited wheat.

CORN (waxy corn)

Also authorized to be sowed as conventional variety in the US, Canada and Argentina

Usually Corn Starch has 75% Amylopectin and 25% Amylose

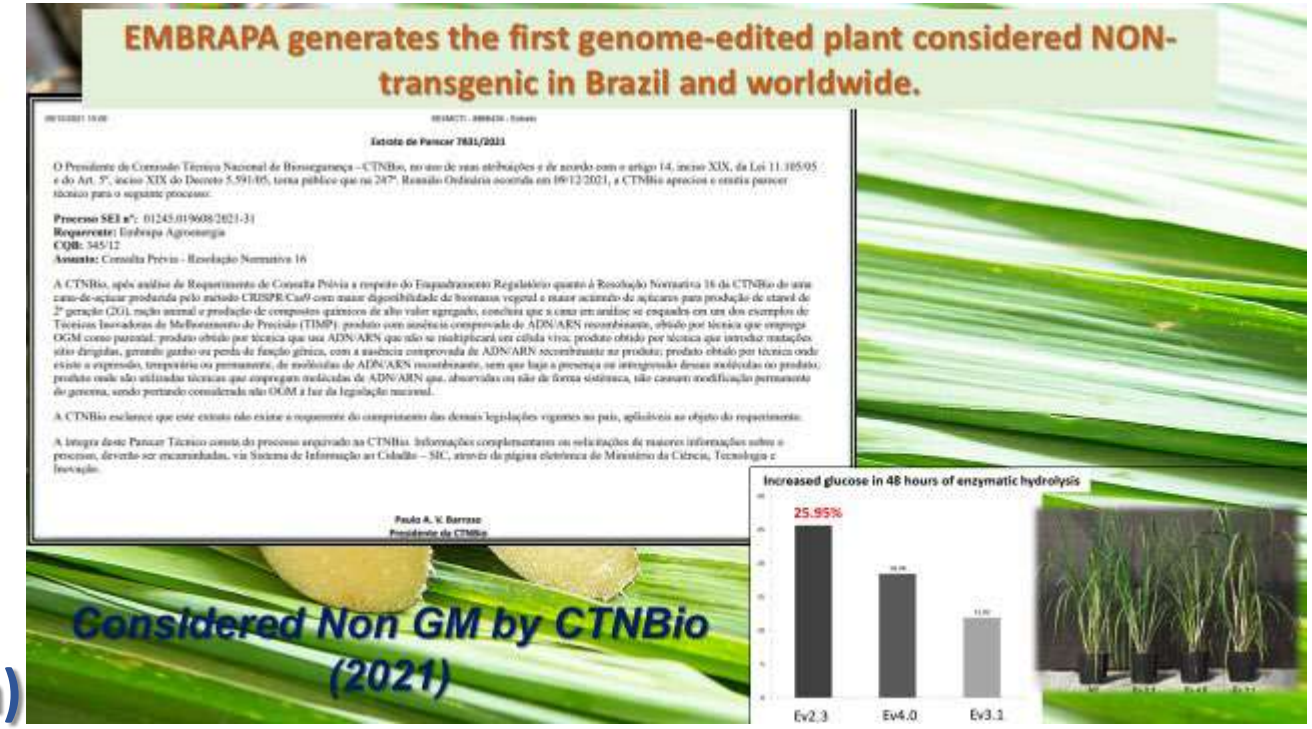
CRISPR

α-amylose KnockOut

100% Amilopectina
0% Amilose

CTNBio
Embrapa

EMBRAPA generates the first genome-edited plant considered NON-transgenic in Brazil and worldwide.



Extrato de Parecer 7031/2021

O Presidente da Comissão Técnica Nacional de Biossegurança – CTNBio, no uso de suas atribuições e de acordo com o artigo 14, inciso XIX, da Lei 11.105/05 e do Art. 5º, inciso XIX do Decreto 5.591/05, torna público que na 247ª Reunião Ordinária ocorrida em 09/12/2021, a CTNBio aprecion e emitiu parecer técnico para o seguinte processo:

Processo SEI nº: 01245.019608/2021-31
Requerente: Embrapa Agroenergia
CQB: 545/12
Assunto: Consulta Prévia - Resolução Normativa 16

A CTNBio, após análise de Requerimento de Consulta Prévia a respeito do Enquadramento Regulatório quanto à Resolução Normativa 16 da CTNBio de uma cana-de-açúcar produzida pelo método CRISPR/Cas9 com maior digestibilidade de biomassa vegetal e maior acúmulo de açúcares para produção de etanol de 2ª geração (2G), ração animal e produção de compostos químicos de alto valor agregado, conclui que a cana em análise se enquadra em um dos exemplos de Técnicas Inovadoras de Melhoramento de Precisão (TIMP): produto com ausência comprovada de ADN/ARN recombinante, obtido por técnica que emprega OGM como parental; produto obtido por técnica que usa ADN/ARN que não se multiplicará em célula viva; produto obtido por técnica que introduz mutações sítio-dirigidas, gerando: ganho ou perda de função gênica, com a ausência comprovada de ADN/ARN recombinante no produto; produto obtido por técnica onde existe a expressão, temporária ou permanente, de moléculas de ADN/ARN recombinante, sem que haja a presença ou integração destas moléculas no produto; produto onde não utilizadas técnicas que empregam moléculas de ADN/ARN que, observadas ou não de forma sistêmica, não causam modificação permanente do genoma, sendo portanto considerado não OGM à luz da legislação nacional.

A CTNBio esclarece que este extrato não exime o requerente do cumprimento das demais legislações vigentes no país, aplicáveis ao objeto do requerimento.

A íntegra deste Parecer Técnico consta do processo arquivado na CTNBio. Informações complementares ou solicitações de maiores informações sobre o processo, deverão ser encaminhadas, via Sistema de Informação ao Cidadão – SIC, através da página eletrônica do Ministério da Ciência, Tecnologia e Inovação.

Paulo A. V. Barroso
Presidente da CTNBio

Increased glucose in 48 hours of enzymatic hydrolysis

Considered Non GM by CTNBio (2021)

SUGARCANE (increased sugar production)

Genome Edited Soybeans developed by **EMBRAPA SOJA**

CTNBio final decision considered both genotypes as conventional, Non-GM.

Embrapa Soja

ISSN 1677-7042

EXTRATO DE

A Presidência da Comiss
de suas atribuições e de acordo co
inciso XIX do Decreto 5.591/05, to
realizada em 01 de setembro de 2
seguinte processo:

Processo: 01245.009925
Requerente: Embrapa S
CQB: 002/96
Assunto: Carta Consulta

A CTNBio, após aná
geneticamente editada pela tecno
lectina (LE1), utilizando técnicas i
Resolução Normativa 16 da CTN
tecnologia CRISPR/Cas visando o s
como um novo OGM nas definiçõe

No âmbito das comp
5.591/05, a CTNBio concluiu que
pertinentes que visam garantir a
humana e animal.

A CTNBio esclarece que
das demais legislações vigentes no

Este é um extrato do Parecer Técnico da CTNBio. Sua íntegra, assim como todos os documentos referentes à solicitação, constam do processo armazenado na CTNBio. Informações complementares poderão ser solicitadas por meio do Serviço de Informação ao Cidadão - SIC ou pelo sistema FALABR, pelo sítio eletrônico https://esic.cgu.gov.br/.

PAULO AUGUSTO VIANNA BARROSO
Presidente da CTNBio

Embrapa | comissão técnica nacional CTNBio de biossegurança

A autenticidade deste documento pode ser conferida no site https://sei.mctl.gov.br/verifica.html, informando o código verificador **10871069** e o código CRC **9B4C7A8D**.

EMBRAPA SOYBEAN GENOME EDITION TEAM

Pesquisadores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João Kafer


Daniel Marin


Suellen Polizeli


João Vitor da Silva


Julia Sebben

Graduação


Giovana Zanella


Maria Eduarda Osco

Genome Edited Soybean for Above Ground Plant Arquitecture

NON GM In Brazil – March 2024

269ª REUNIÃO ORDINÁRIA DA COMISSÃO TÉCNICA NACIONAL DE BIOSSEGURANÇA – CTNBio

Data: 07 de março de 2024
Horário: 8h30 às 14h00
Local: Sala dos Conselhos, 1º andar – Setor Policial, Área 5, Quadra 3, Bloco E. **(transm. remota pela RNP)**

11.2. (Contém Informações Confidenciais) Monsanto do Brasil LTDA; CQB 003/96; Processo: 01245.022145/2023-56; A requerente apresenta Consulta sobre o enquadramento regulatório de produto hipotético para soja editada EB3335 com base na Resolução Normativa n°16/2018; rotocolado em 03/11/2023; Extrato Prévio nº 9205/2023; Relatoria definida em dezembro/2023: Dr. Eder Victor Braganti Toppa;

11.3. (Contém Informações Confidenciais) Monsanto do Brasil Ltda; Processo: 01245.024502/2023-11; A requerente submete consulta sobre o enquadramento regulatório de produto hipotético para soja editada EB3011 com base na Resolução Normativa n°16/2018; Protocolado em 19/12/2023; Extrato Prévio nº 9295/2024; Relatoria definida em janeiro/2023: Dr. Galdino Andrade Filho; Assessoria: Gutemberg Delfino.

USDA

NON GM in US April 2025

United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road
Riverdale, MD
20737

Tomasz Paciorek, Ph.D.
Bayer Crop Science
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Re: Confirmation of the regulatory status of improved architecture soybean

Dear Tomasz Paciorek:

Thank you for your letter dated April 4, 2025 (25-097-01air), inquiring whether the soybean (*Glycine max*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes the use of CRISPR-Cas based technology resulting in the desired improved above-ground architecture.

The Plant Protection Act of 2000 (PPA) provides USDA with broad authority to protect U.S. agriculture, the environment, and the economy by, among other things, regulating the introduction of plants and articles to prevent the dissemination or establishment of a plant pest within the United States. As such, USDA, through the Animal and Plant Health Inspection Service, regulates the "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe Are Plant Pests," as described in 7 CFR part 340. These regulations only apply to organisms that USDA deems regulated articles under § 340.1.

In your letter, you describe how you have generated or will generate soybean plants with edits in a target sequence claimed as confidential business information (CBI) to confer improved above-ground architecture. You use CRISPR-Cas technology to generate modifications in the target sequence resulting from cellular repair of targeted DNA break(s) in the absence of an externally provided template. You use *Agrobacterium*-mediated transformation to introduce a vector containing plant pest sequences and editing components into soybean plants and subsequently use conventional breeding methods to segregate away vector DNA sequences. You screen progeny using a CBI method to confirm the presence of the edit and absence of transformation vector DNA in soybean plants.

Sincerely,

Bernadette Juarez
APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Date: April 10, 2025

Genome Edited Corn for Insect and Disease Resistance

MAY 2023

comissão técnica nacional
CTNBio
de biossegurança

MINISTÉRIO DA CIÊNCIA, TECNOLOGIA E INOVAÇÃO

GOVERNO FEDERAL
BRASIL
UNIÃO E RECONSTRUÇÃO

261ª REUNIÃO ORDINÁRIA DA COMISSÃO TÉCNICA NACIONAL DE BIOSSEGURANÇA – CTNBio

Data: 10 de maio de 2023
Horário: 8h30 às 14h00
Local: Reunião Virtual e Presencial no MCTI

5.2. KWS Melhoramento e Sementes Ltda.; CQB 374/14; Processo: 01245.003181/2023-11; a Requerente encaminha Consulta Prévia a respeito do Enquadramento Regulatório do Produto milho tropical ZmLOX3_SDN-1 genótipos:: GEZM152-T012 a GEZM152-T013. Trata-se de milho convencional cv. L57021 alterado por mutagênese sítio-dirigida para obtenção de mutações de perda de função em ZmLOX3 (Lipoxigenase 3).; Protocolado em 02/02/2023; Extrato Prévio nº 8709/2023; Relatoria definida em março/2023: Dr. Fernando Hercos Valicente; Assessoria: Gutemberg Delfino.

Insect Resistance

5.3. (Contém Informações Confidenciais) Corteva Agriscience Brasil Ltda.; CQB 013/97; Processo: 01245.004586/2023-76; A requerente solicita parecer para a consulta sobre o status regulatório do Milho NLB18-R CRISPR-CAS9 protocolado em 24/02/2023; Extrato Prévio nº 8758/2023; Relatoria definida em abril/2023: Almy Junior Cordeiro de Carvalho.; Assessoria: Orlando Cardoso;

Disease Resistance

SDN1

SDN2

Considered Non GM Corn

May 2023

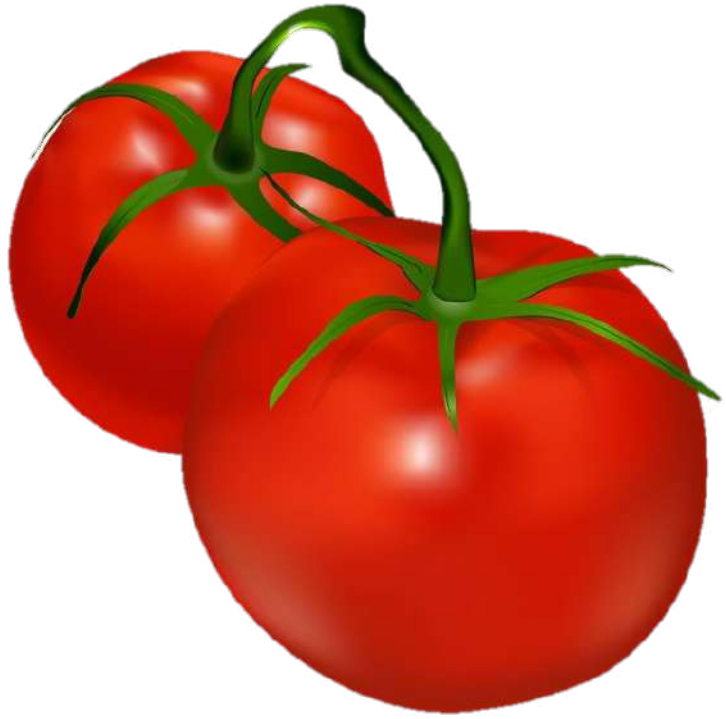
(Corn DNA in Corn DNA)

01 August 2024 – First Tomato with Genome Edited considered **Non-GM** in Brazil

comissão técnica nacional CTNBio de biossegurança

MINISTÉRIO DA CIÊNCIA, TECNOLOGIA E INOVAÇÃO

GOVERNO FEDERAL BRASIL UNIÃO E RECONSTRUÇÃO



273ª REUNIÃO ORDINÁRIA DA COMISSÃO TÉCNICA NACIONAL DE BIOSSEGURANÇA – CTNBio

Data: 1º de agosto de 2024

Horário: 8h30min às 14h00min

Local: Portal de Conferência RNP (virtual)

5.4. **(Contém Informações Confidenciais)** Syngenta Seeds Ltda.; CQB 001/96; Processo: 01245.003393/2024-89; Consulta sobre o Produto Tomate E001TMFM obtido por Técnicas Inovadoras de Melhoramento de Precisão - TIMP; Protocolado em 12/03/2024; Extrato Prévio nº 9430/2024; Relatoria definida em abril/2024: Dr. Emanuel Maltempi de Souza; Assessoria: Orlando Cardoso.

Embrapa

Greater Shelf life

Up to Aug 2025, CTNBio consultations also in Cotton, Rice, Sorghum and Blackberry.

First Genome-Edited Organism in Brazil for comercial use

June 2018

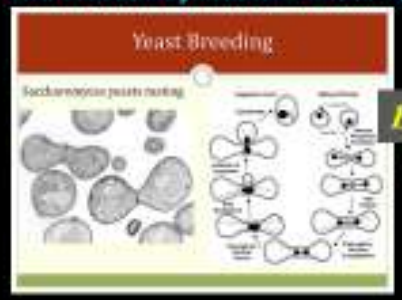
globalyeast
Belgian-Brazilian biotechnology startup

Saccharomyces cerevisiae

Development Procedures

Yeast Germplasm Bank: 80 Strains tested for high alcohol and low glycerol production

Three S. cerevisiae strains chosen and crossed by classical breeding



Excellomol

Excellomol 4.0 Next

All four mutations were introduced by CRISPR/Cas9 into the Excellomol strain

A Forth strain with very high alcohol production was identified. Mutation in 4 genes are responsible for this high efficiency.

Embrapa

comissão técnica nacional
CTNBio
de biossegurança

Embrapa

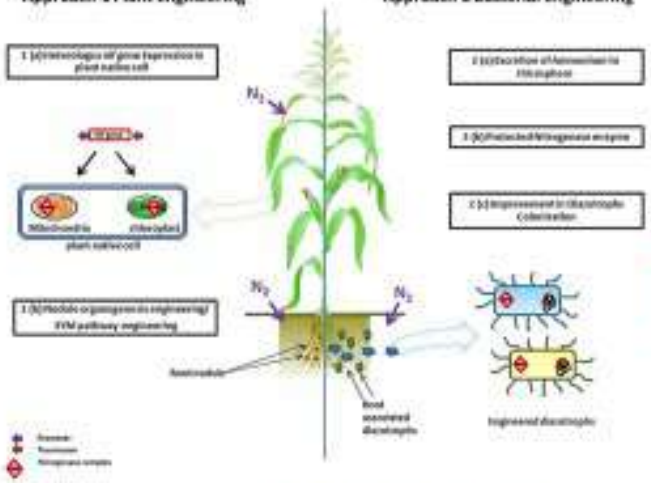
MICRORGANISMS

~50% of CTNBio consultations are on microorganisms (Bioinputs)

Genome Edition on Diazotrophs organisms

Considered Non GM by CTNBio (2021)

Nitrogen fixing cereal: A rising hero towards meeting food security



Nitrogen Fixation Bacteria
Klebisiela varicola

Table 1
Selected examples of Associative and/or endophytic diazotrophs and their associated plant hosts.

Associative and/or endophytic diazotrophs	Plant hosts	References
Azospirillum spp.	wheat, maize, rice, *Digitaria decumbens*, millet grass, rice	Kendrick et al., (1987); Khammas et al., (1989)
Gluconacetobacter diazotrophicus	sugarcane, sugar beet, coffee, maize, sweet potato, sorghum, tomato, pineapple, wetland rice, wheat, oilseed rape, grass, finger-millet, radish, barnyard, tea, cameroon grass	Erbs et al. (2014)
Herbaspirillum seropedicae	maize, sorghum, wheat, rice, sugarcane, forage grass	Baldani et al., (1986); Jaenes et al., (2002)
Marinella sp., *Burkholderia* sp. and non-cultivated cyanobacterium	peach palm	de Almeida et al. (2004)
Burkholderia spp.	maize, coffee, rice, sugarcane, tomato, wheat, grapes, peas, *Quercus* sp., *Banda* sp., cocoa	Compant et al., (2008); Mckinny et al., (1995)
Klebsiella spp.	maize, rice, sugarcane	Dobereiner et al., (1995); Palus et al., (1996); Kenyon Rivera et al., (2014)
Pseudomonas spp.	maize, rice	Palus et al., (1992); Jaenes et al., (2002)
Enterobacter spp.	rice, maize	Palus et al., (1992); Jaenes et al., (2002)
Nostoc	cycads, hornworts, and liverworts	Rai et al. (2000)
Anabaena	azolla	Yatabampaya et al. (2001)
Azoarcus spp.	millet grass, wild rice	Engelhard et al. (2000)

FIRST ANIMALS

AGFeed NEGÓCIOS ECONOMIA AGTECH FINANÇAS

Home Negócios

Brazilian Fish coloca
no cardápio, com mai

Companhia paulista de piscicultura desen
deve chegar em breve ao mercado. Iniciat
100 milhões aportado nos últimos dois an

Gustavo Lustosa

Ramon Amaral, CEO da Brazilian Fish

5m The Fish Site

Find species, diseases, articles... Breeding & genetics Farm management Health & welfare Nutrition Environment Post-harvest

Gene edited tilapia secure GMO exemption

REGULATIONS · POLITICS · GENETICS & BREEDING · BIOTECHNOLOGY

by The Fish Site
18 December 2018, at 2:06p.m.

DEC2018

A line of tilapia that has been gene edited will not be classified as a genetically modified organisms (GMOs) in Argentina, according to a government advisory commission.

The line, known as FLT 01, has been developed by Intrexon and its subsidiary AquaBounty Technologies., the biotechnology company best known for its AquaAdvantage salmon strain. The tilapia were developed using gene editing

ta) e o animal controle não editado (esquerda)

- Non GMO

Considered Non-GM by CTNBio (Mar2021)

FIRST ANIMALS

NELORE breed GE to met production increase

Nellore Cattle Semen with Genome Edited for Myostatin

Increase of ~20% in meat production

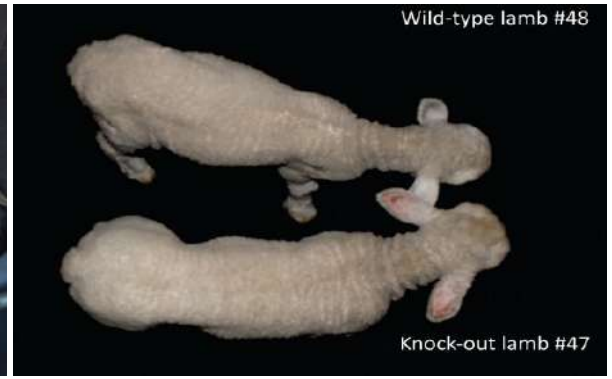
Other species being developed in China, Uruguay, Argentine, etc

Transgenic Res (2015) 24:147–153
DOI 10.1007/s11248-014-9832-x

ORIGINAL PAPER

Genome edited sheep and cattle

Chris Proudfoot · Daniel F. Carlson · Rachel Huddart · Charles R. Long · Jane H. Pryor · Tim J. King · Simon G. Lillico · Alan J. Mileham · David G. McLaren · C. Bruce A. Whitelaw · Scott C. Fahrenkrug



PIGS resistant to the Porcine Respiratory and Reproductive Syndrome virus (PRRSv),

FIRST ANIMALS

Alteration of the CD163 receptor by gene editing to prevent penetration of

PIC®

PIC PRRS-Resistant Pig Products Services Resources In the Ne

In the News

Colombia is First Country to Issue Positive Regulatory Determination for PIC's PRRS-Resistant Pig

October 5, 2023

Determination marks a critical milestone in the battle against the PRRS virus

HENDERSONVILLE, Tenn. (Oct. 5, 2023) – Genus plc (LSE: GNS), the parent company of PIC (Pig Improvement Company), announced today that Colombia's government issued a favorable regulatory determination for gene-edited pigs resistant to the Porcine Reproductive and Respiratory Syndrome (PRRS) virus. This means Colombia will treat the PRRS-resistant pigs the same as conventionally bred pigs.

PORK

News Product

PORK BUSINESS / NEWS / HOG PRODUCTION / TOP STORY

FDA Grants PIC Approval for PRRS-Resistant Pig Gene-Editing Technology

FDA's approval of PIC's gene-editing technology marks a major milestone for consumers, farmers and the entire pork industry who have desperately hoped for a solution to PRRS, says PIC COO Matt Culbertson.

JENNIFER SHIKE · April 30, 2025 07:23 AM

Animal Cell

Embrapa

FIRST ANIMALS

ANGUS Breed with Greater Heat Tolerance through Gene Editing

Genome Edition in Beef Cattle (slick gene)

Considered Non-GM by CTNBio ***Feb 2025***

Caracu breed

slick gene

Angus breed

The slick gene in cattle is a mutation in the prolactin receptor (PRLR) gene that results in a short, sleek coat. This mutation is beneficial for cattle because it helps them regulate their body temperature.

How the slick gene works

The slick gene truncates the PRLR protein, which is involved in prolactin signaling

The mutation acts as a dominant allele, so animals with one or two copies of the gene have similar body temperatures and liver gene expression

The slick gene is naturally present in some Caribbean Creole cattle breeds

Benefits of the slick gene

The slick gene helps cattle better control heat, which can reduce heat stress

The slick gene can also reduce the depression in milk yield that occurs during the summer

Genome Edition in Brazil – Submissions at CTNBio

Comissão Técnica Nacional de Biossegurança
CTNBio
Ministério da Ciência, Tecnologia e Inovações - MCTI
Comissão Técnica Nacional de Biossegurança - CTNBio
Atualizado:13/02/2025

PRODUTOS AVALIADOS - Técnicas Inovadoras de Melhoramento de Precisão - TIMPs

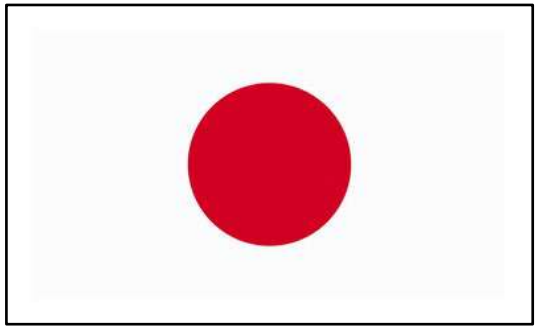
SEMPRE AGRITECH	01245.021105/2023-97	8913/2024	A requerente solicita consulta sobre o enquadramento do produto “SEMPRE – 005” que envolve a tecnologia do RNAi
Elemental Enzymes do Brasil Ltda	01245.018069/2023-84	8981/2024	A requerente solicita manifestação da Comissão sobre o status regulatório do produto à base de Bacillus thuringiensis E80B
Bioheuris S.A	01245.015460/2023-27	8982/2024	Requerimento de Carta Consulta Prévia sobre enquadramento regulatório do arroz que contêm substituições de bases no gene que codifica a acetolactato sintase (ALS) que confere tolerância a herbicidas do grupo ALS.
Elemental Enzymes do Brasil Ltda.	01245.023043/2023-58	9121/2024	Enquadramento regulatório do produto obtido através de Técnica Inovadora de Melhoramento de Precisão (TIMP) á base de Bacillus thuringiensis E95A.
Genus plc	01245.013694/2023-30	9035/2024	Uma edição genômica específica, aqui denominada como edição do gene CD163, em porcos domésticos (Sus scrofa domesticus) para conferir resistência à síndrome reprodutiva e respiratória dos suínos (PRRS).
Sempore AgTech	01245.001962/2024-51	9094/2024	formulado à base de RNA de dupla fita (dsRNA) objetivando o silenciamento do gene de S. frugiperda.
Bio He			Sorgo (Sorghum bicolor) geneticamente editado, utilizando-se da tecnologia "Base Editing" para a substituição de base no gene que
Setor			
Synge			
BioCo			a
Cerlev			
Cerlev - Inovação em Fermentação	01245.010330/2024-89	9304/2024	Classificação de organismo original SM584 e do produto SM584-NY3-NFF (S. cerevisiae)
Cerlev - Inovação em Fermentação	01245.010332/2024-78	9305/2024	Classificação de organismo original SM584 e do produto SM584-NY2-NFF (S. cerevisiae)
Cerlev - Inovação em Fermentação	01245.010325/2024-76	9306/2024	Classificação de organismo original SM584 e do produto SM584-NFF (S. cerevisiae)
SEMPRE AgTech	01245.007750/2024-88	9286/2024	Classificação de do produto SEMPRE-004-V2.0 encapsulado; composto à base de moléculas de RNA de dupla fita (dsRNA)
Sempre AgTech Ltda	01245.007734/2024-95	9560/2024	Requerimento de consulta prévia do enquadramento regulatório do produto SEMPRE-004-V2.0 para controle dos percevejos verde e marrom.
CERLEV - Projetos e Inovação na Biotecnologia da Fermentação Ltda	01245.015320/2024-30	9394/2024	Cepa de S. cerevisiae denominada CB2330, produto CB2330-NFF, foi desenvolvida para ser utilizada em um processo de produção de bioetanol de primeira geração.
CERLEV - Projetos e Inovação na Biotecnologia da Fermentação Ltda	01245.015322/2024-29	9.395/2024	Cepa de S. cerevisiae denominada CB2848, produto CB2848.2-NFF, foi desenvolvida para ser utilizada em um processo de produção de bioetanol de primeira geração.
CERLEV - Projetos e Inovação na Biotecnologia da Fermentação Ltda	01245.015245/2024-15	9396/2024	Cepa de S. cerevisiae denominada UOL19-NFF, foi desenvolvida para ser utilizada em um processo de produção de bioetanol de primeira geração.
BioConsortia, Inc.	01245.009921/2024-11	9398/2024	Microrganismos editados geneticamente denominados BEC180, BEC242, BEC243, BEC244, BEC245, BEC246, BEC247, BEC248, BEC249, BEC250, BEC251, BEC252, BEC254, BEC255 e BEC256 obtidos por Técnicas Inovadoras de Melhoramento de Precisão (TIMPs)
Bioheuris S.A	01245.009837/2024-90	9403/2024	Edição gênica para resistência a herbicidas do grupo ALS em arroz. O gene do arroz editado codifica a enzima acetolactato sintase (ALS)
Elemental Enzymes	01245.013824/2024-15	9404/2024	Cepas de Bacillus subtilis utilizadas na produção das enzimas, baseadas na cepa hospedeira B. subtilis WB800N que é derivada da B. subtilis 168
Sempre Agtech	01245.014966/2024-08	9409/2024	Produtos Sf_3g_600 e Sf_3g_564 à base de moléculas de RNA de dupla fita (dsRNA), naturalmente não tóxicos, não alergênicos e não virulentos.
Acceligen do Brasil Biotecnologia e Pesquisa Cientifica Ltda.	01245.018996/2024-85	9449/2025	Animais bovinos da raça Angus. “Angus editados para SLICK" (SLCK005, SLCK007, SLCK012, SLCK013, SLCK019 e SLCK020) gerados com a aplicação de Tecnologias Inovadoras de Melhoramento de Precisão (TIMP)

> 80 Processes Evaluated by Aug2025

Other Examples Worldwide

JAPAN: Commercial tomato

The GABA Tomato has had its genome edited to express higher levels of Gamma-Aminobutyric Acid (GABA), an amino acid involved in relaxation processes and blood pressure reduction.



Source: Ministry of Agriculture, Forestry and Fisheries, 2023.

BIOTECH UPDATES
A weekly summary of world developments in biotechnology, produced by the ISAAA Global Knowledge Center on Biotechnology direct to your inbox.
ISAAA Inc.

Japan Starts Sale of Genome-Edited High-GABA Tomato

September 22, 2021

Photo Source: Sanatech Seed

Sanatech Seed Co., Ltd., together with its partner for sales Pioneer EcoScience Co, Ltd., has announced that the commercial sales of Sicilian Rouge High GABA, their genome-edited tomatoes with increased gamma-aminobutyric acid (GABA) will begin on September 15, 2021

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First successful gene editing of Cowpea - Israeli Genetics & Seeds Company 'BetterSeeds' redesigns architecture of Cowpea plant to enable its mechanized harvesting

NEWS PROVIDED BY
BetterSeeds →
25 Jan, 2023, 16:00 IST

The architecture of the cowpea stems/fruits is not suitable for mechanized harvesting;

It is an indeterminate plant that spreads along the ground with the gradual appearance of pods.

Cowpea Genome Edited to Enable Mechanical Harvesting

- BetterSeeds edited the cowpea genome, targeting genes that alter the plant's architecture;
- Transforming it into a plant with a more determined cycle, simultaneous appearance of pods, and a more upright posture for mechanized harvesting.

Philippines:

Bananas without browning (less oxidation) with longer shelf life (commercial) Apr 2023

AgNews

PR Alliance | Seed Industry | # Gene Editing #

Tropic's non-browning gene-edited banana cleared for production in the Philippines CN

Apr. 24, 2023

Tropic Biosciences

Tropic Biosciences

United Kingdom

Tropic's non-browning banana received a non-GMO exemption decision from Philippines Department of Agriculture-Bureau of Plant Industry. This is the first gene-edited product to go through the Philippine's newly defined gene editing regulatory determination process. With this determination the Tropic non-browning can be freely imported and propagated in the Philippines.

Embrapa

***EUA**: High Oleic Soybean (comercial)*

Março/2019

Healthier oil for human consumption and produce 70% less GHG emissions

First gene-edited food—Calyxt's high oleic soybean oil—now on sale

Calyxt | March 1, 2019

USA: *"Conscious Greens" – Mustard plant with genome edited to produce leaves with greater nutritional value and more flavor (commercial).*

https://www.pairwise.com/news/pairwise-introduces-conscious-greens-into-u.s.-restaurants

May 16, 2023 9:16:34 AM

PRODUCTS

Pairwise introduces first food made with CRISPR technology in the U.S. market

Pairwise says Conscious Greens — part of its Conscious Foods brand — are derived from mustard greens and are part of the same family of vegetables as Brussels sprouts, cauliflower and kale.
(Photo courtesy Pairwise)

By THE PACKER STAFF May 16, 2023

Durham, N.C.-based startup Pairwise has unveiled Conscious Greens, which it says is the first food introduced in the U.S. that was developed with CRISPR technology.

China: *High Oleic Soybeans (commercial) May 2023 and Jan 24*

Healthier oil for human consumption and produce 70% less GHG emissions

Embrapa

REUTERS® World Business Markets Sustainability Legal Breakingviews Technology Inve

Science

China approves safety of first gene-edited crop

Reuters

May 4, 2023 5:57 AM GMT-3 · Updated a month ago

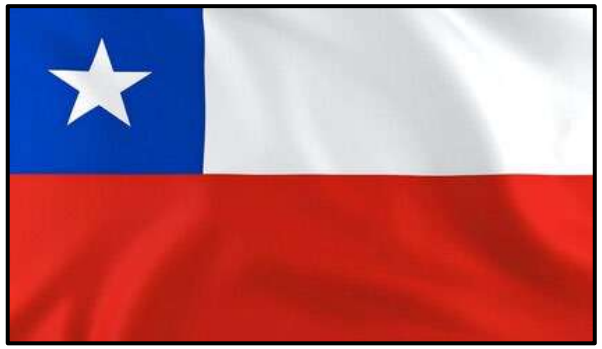
An employee picks out bad beans from a pile of soybeans at a supermarket in Wuhan, Hubei province April 14, 2014. REUTERS/Stringer

***Chile*: Wheat**

more dietary fibers

(commercial)

August 25



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Chile da luz Verde al Primer Trigo Genéticamente Editado en América

Seed World Staff August 8, 2025

Foto: Adobe

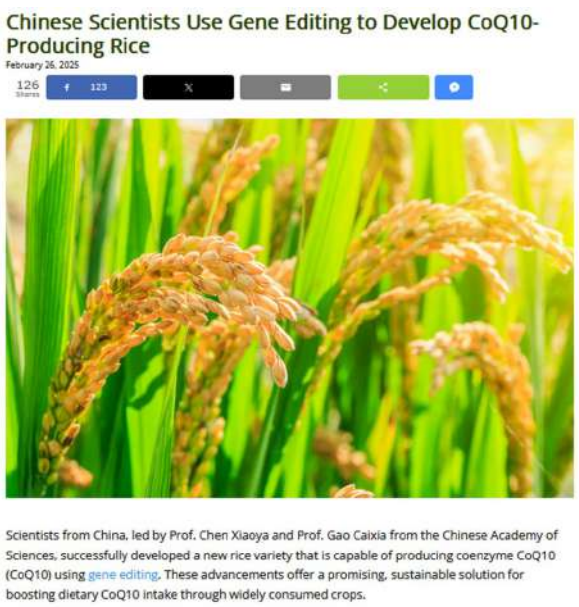
La startup chilena Neocrop Technologies, en colaboración con la empresa nacional de semillas Campex Baer y la argentina Buck Semillas, ha desarrollado una variedad de trigo genéticamente editado con un contenido de fibra dietética de cinco a diez veces mayor que el del trigo harinero convencional, sin comprometer el sabor, la textura ni la calidad de la harina blanca.

El 25 de julio de 2025, el Servicio Agrícola y Ganadero (SAG) de Chile confirmó oficialmente que estas nuevas líneas de trigo, desarrolladas mediante la tecnología de edición genética CRISPR, no están clasificadas como Organismos Genéticamente

Other Plant Characteristics introduced by genome edition

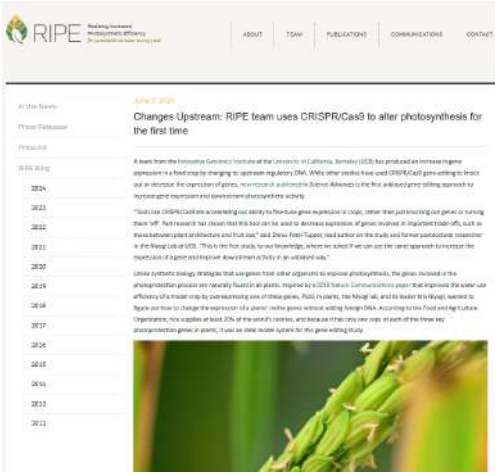
Shelf life (less browning)

Heart Health (CoQ10)



Nutritional Value (vit. D)

Rice Productivity (↑ Photosynthesis)



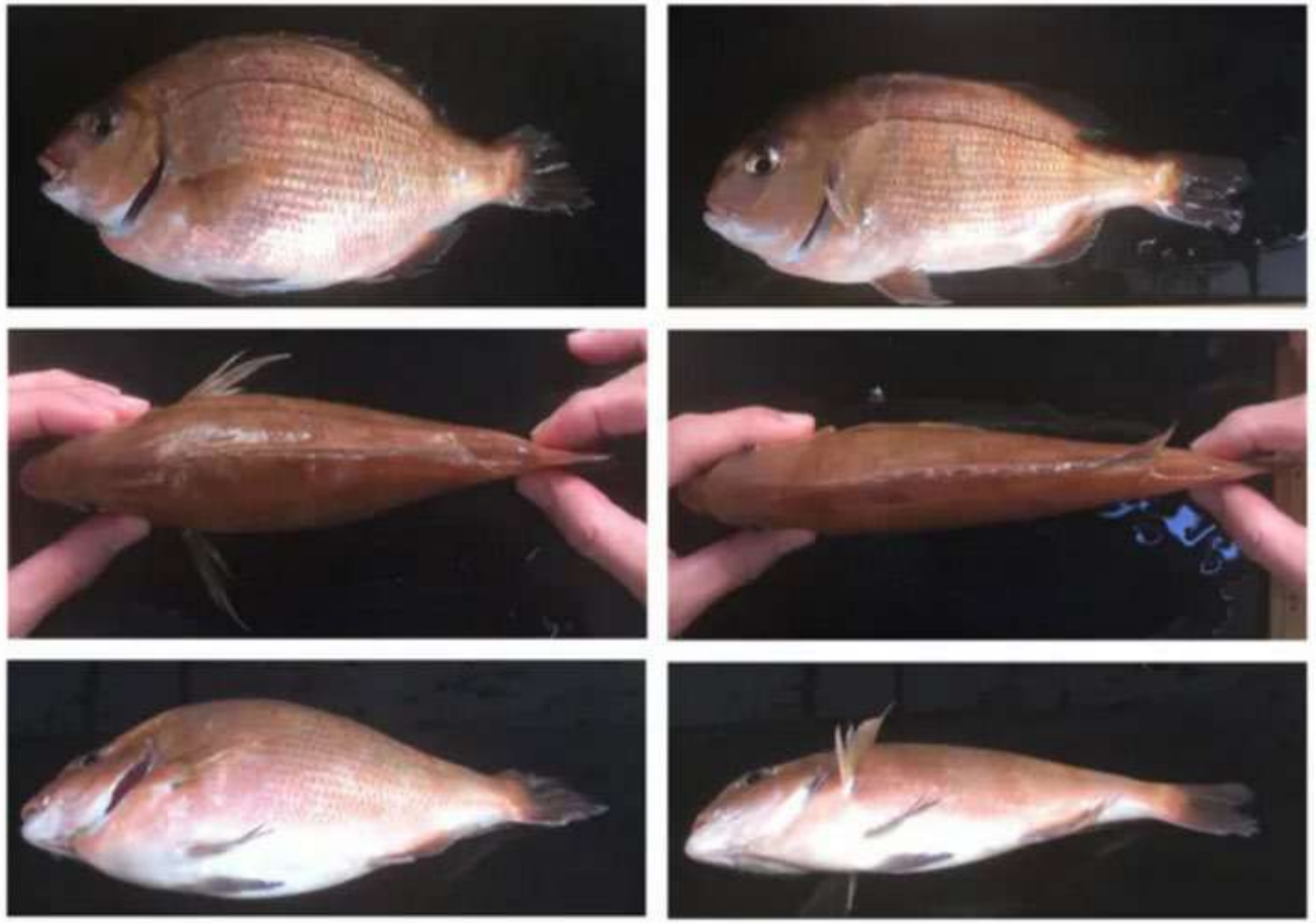
Commertial Value (no seeds)

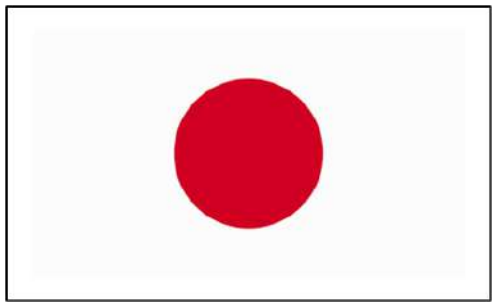
JAPAN: Edited fish, commercialized since Oct/21

The “Madai Red Sea Bream” with Genome Edited for the Myostatin gene has been commercialized since Oct/2021 in Japan.

In its natural form it corresponds to 10% of Japanese aquaculture.

The genome-edited “Madai” produces 20% to 60% more edible parts than its natural version.





Source: Regional Fish Co., Ltd., 2022; Ministry of Agriculture, Forestry and Fisheries, 2023.

In Research ARGENTINE

Reuters World ations More

Argentina breeds gene-edited polo super ponies

Myostatin gene: stronger muscles

By **Miguel Lo Bianco** and **Lucila Sigal**

February 4, 2025 12:00 PM GMT-3 · Updated 10 days ago

BUENOS AIRES, Feb 4 (Reuters) - Argentina's award-winning mare Polo Pureza will have her genes, or at least most of them, live on in five genetically edited horses designed to outrun the polo legend herself.

Scientists at Argentine biotech firm Kheiron have produced the world's first genetically edited horses using a technique called CRISPR-Cas9. The horses were born last October and November.

https://www.reuters.com/science/argentina-breeds-gene-edited-polo-super-ponies-2025-02-04/

"Myostatin gene genome editing" refers to the process of using genetic engineering techniques, like CRISPR-Cas9, to modify the "MSTN" gene (which codes for myostatin protein), allowing for deliberate changes in muscle growth by manipulating the protein's function, typically leading to increased muscle mass when the gene is edited to produce less myostatin protein; this is often studied in livestock animals to improve meat production. Key points about myostatin gene editing:

Function of Myostatin:

Myostatin is a naturally occurring protein that acts as a brake on muscle growth, so by editing the MSTN gene to reduce its production, muscle mass can increase significantly.

In Research

In CHINA and BRAZIL: exclusion of a commercial undesirable characteristic. Presence of "small bones" in Carp and Tambaqui for consumption

Tambaqui native from South AmericaBrazil

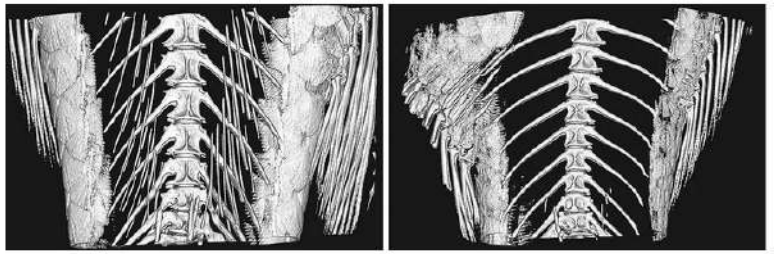
Carp native from Asia

GENETICS | GENOMICS | BIOSECURITY +9 more 13 March 2023, at 12:56pm

Embrapa

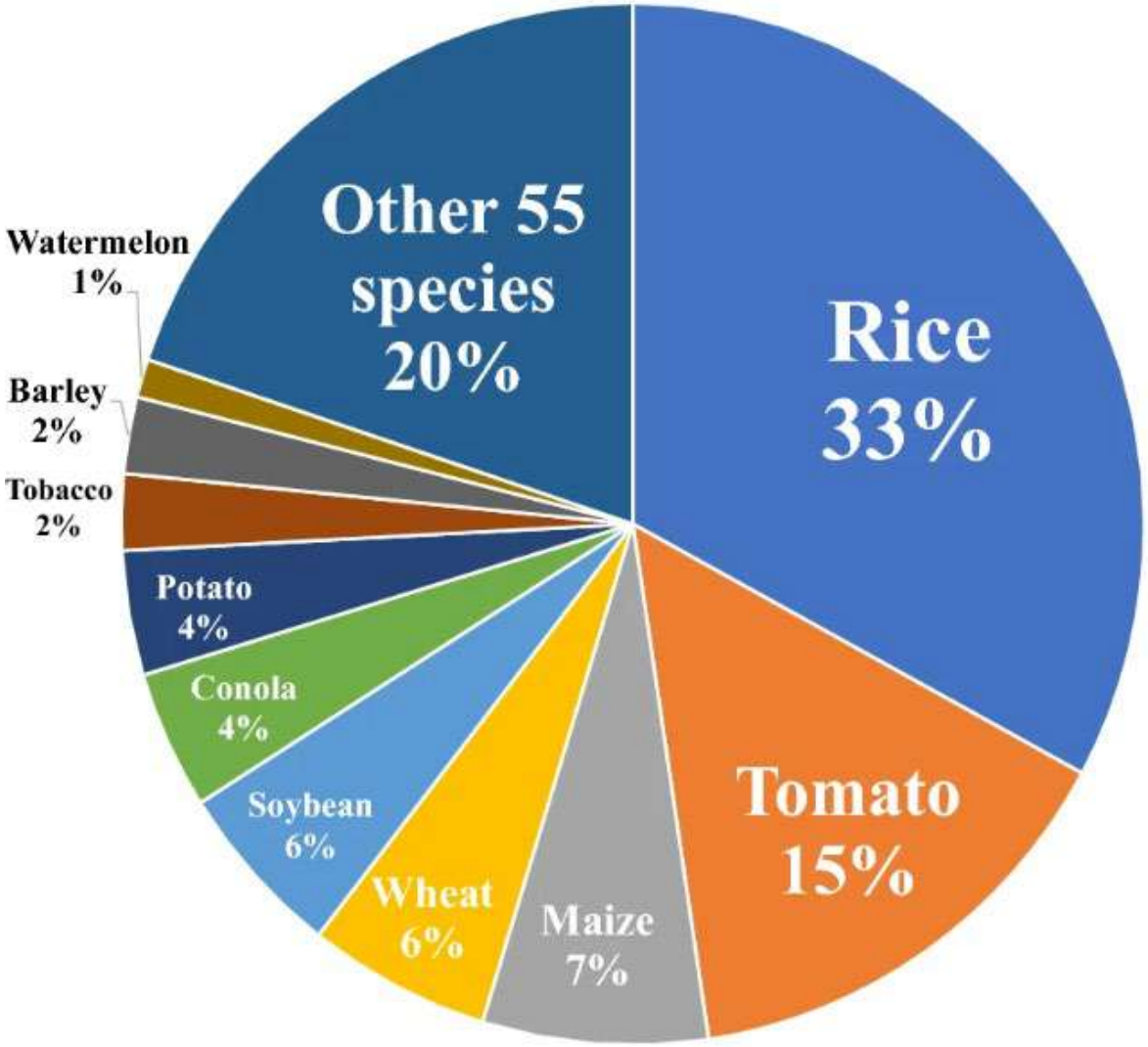
Chinese researchers use gene editing to remove small bones from crucian carp

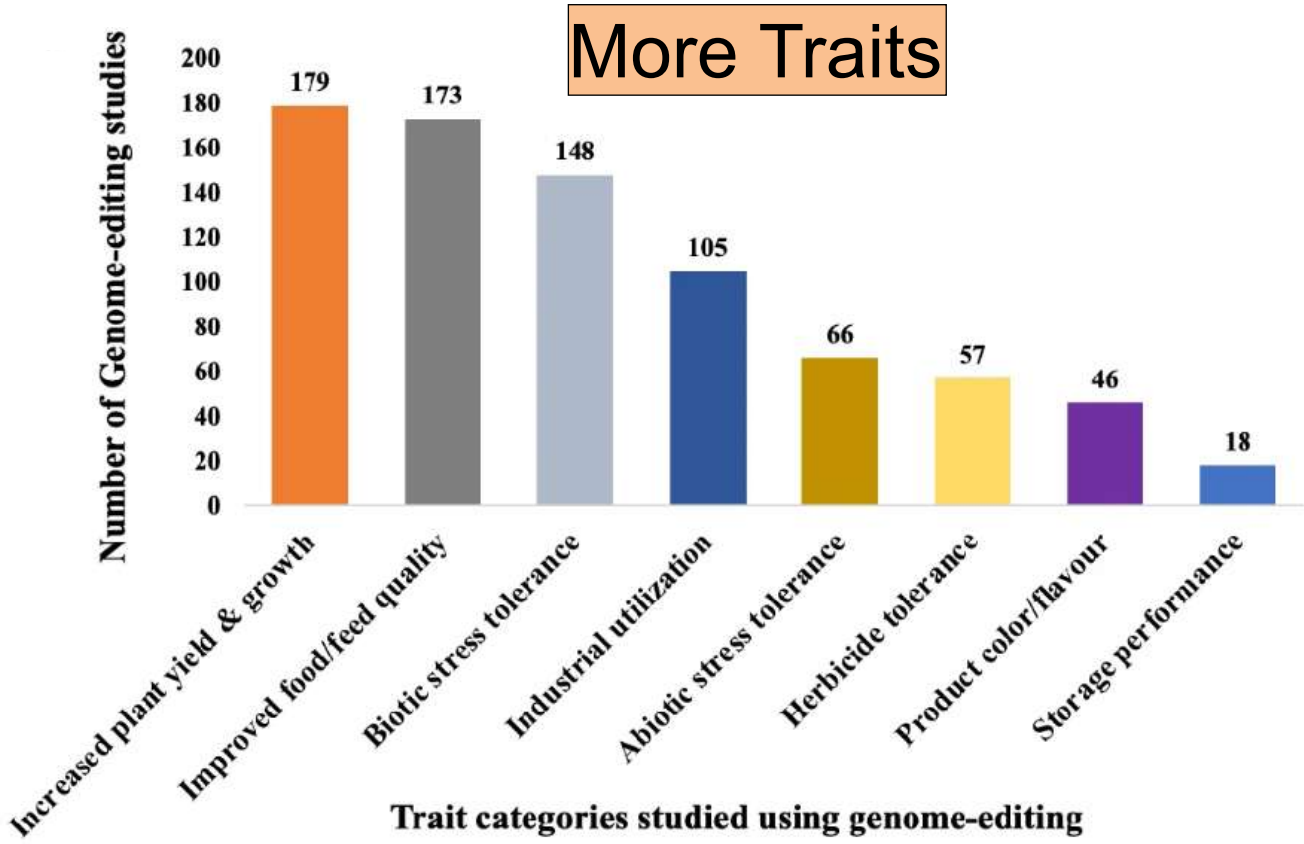
Scientists from the Chinese Academy of Fishery Sciences and Heilongjiang Fishery Research Institute are celebrating a key theoretical and technical breeding breakthrough after creating the world's first crucian carp without intermuscular bones.



Comparison of skeletal micro-CT scans of a wild crucian carp and one without intermuscular bones

Crop (species) Diversification and Traits of Interest

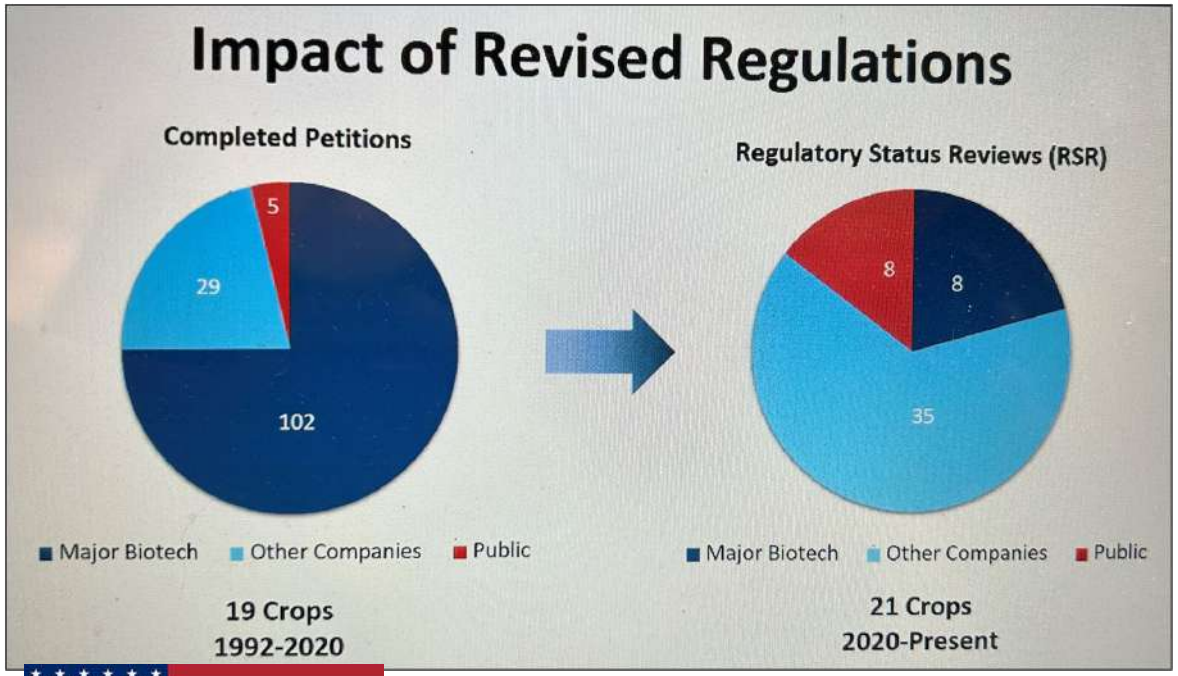




Embrapa

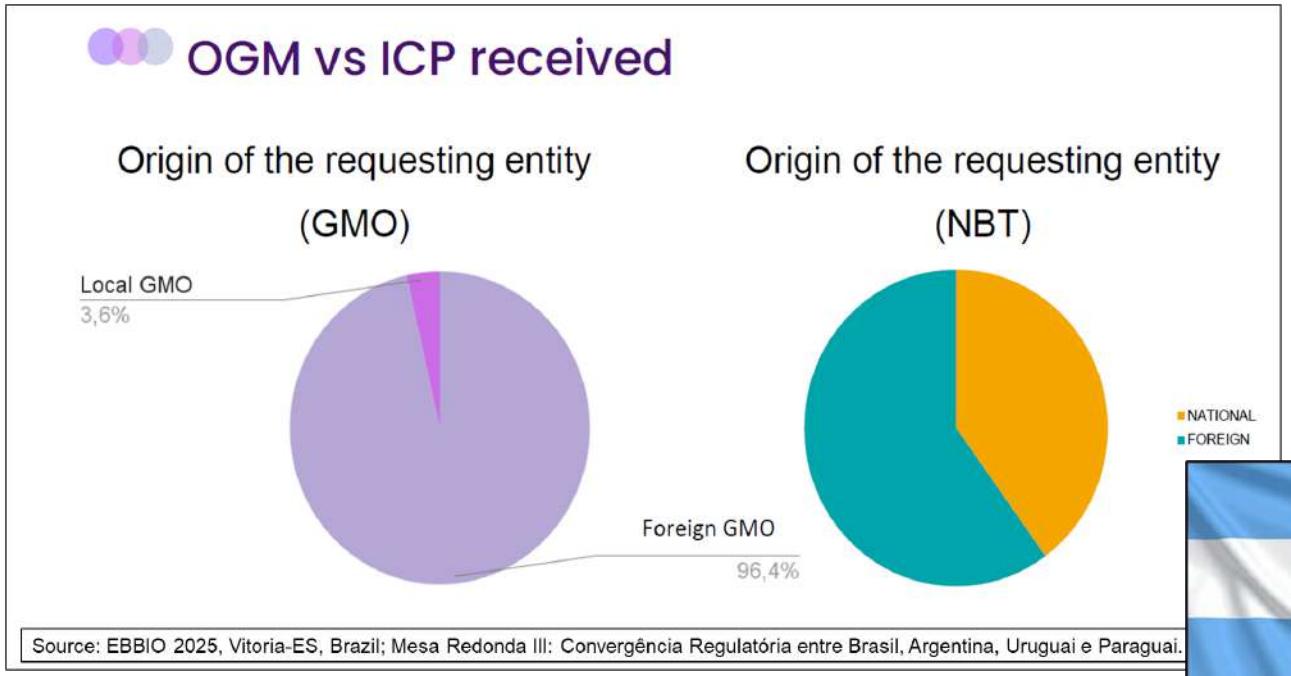
Source: Journal of Plant Biochemistry and Biotechnology (October–December 2023) 32(4):831–845 https://doi.org/10.1007/s13562-023-00863-z

Greater diversification of institutions and companies



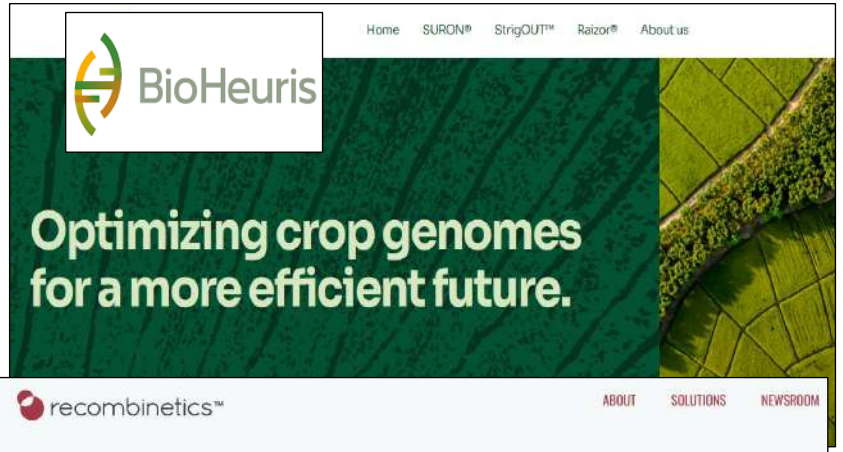
Source: US Delegation. OECD Meeting 2023

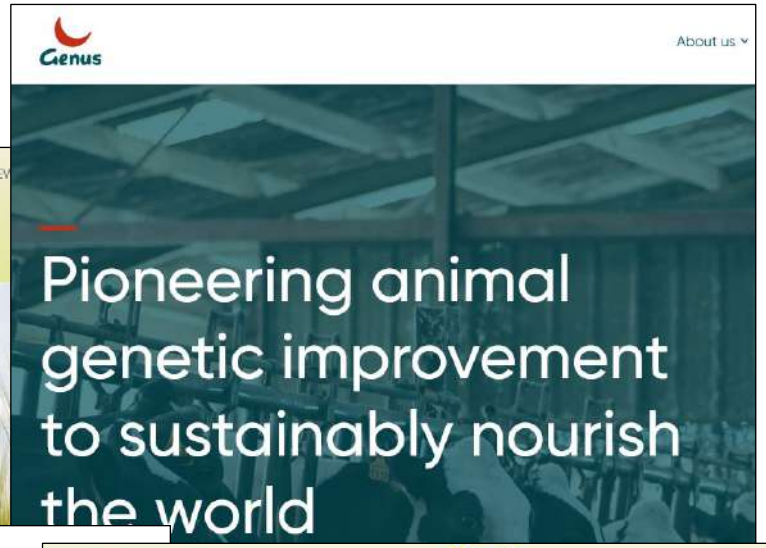
USA

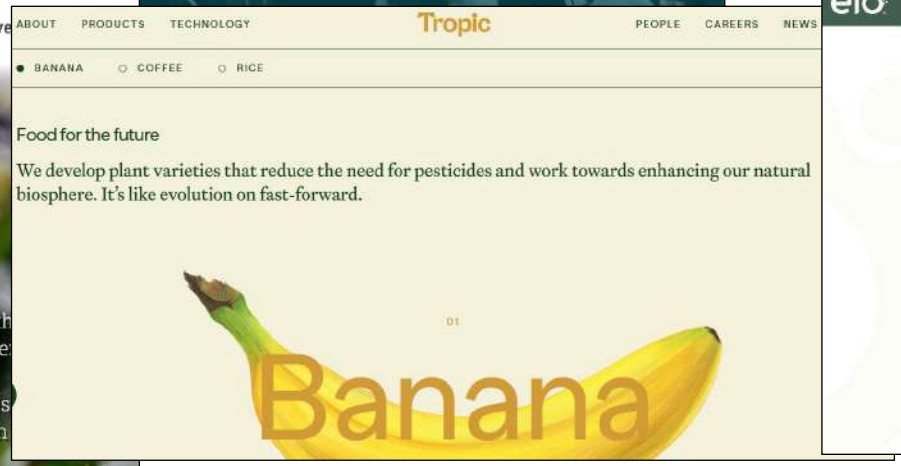


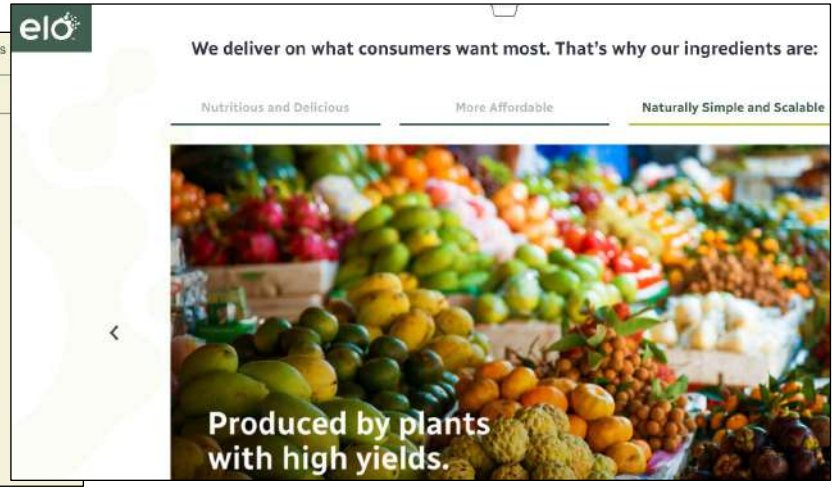
Argentine

Many emerging firms are forming partnerships with research institutions, agribusinesses, and governments to accelerate innovation and market access.









The tangled web of legal disputes over CRISPR

UC Berkeley (U of Vienna) x MIT/Harvard (Broad Institute)

...Last developments May 2025

Sections | UC Berkeley News

Campus news, Mind & body, Research

Federal appeals court sends CRISPR-Cas9 patent case back to patent office for reconsideration

Court of Appeals rules that Patent Trial and Appeal Board applied wrong legal standards

By Robert Sanders

May 2025

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NEWS

Crispr Nobel laureates get another chance to claim ownership in long-running patent dispute

MIT Technology Review

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BIOTECHNOLOGY AND HEALTH

A US court just put ownership of CRISPR back in play

At stake in the ongoing patent dispute over the gene-editing tool are rights to the most important new biotechnology of the age and credit for inventing it.

By Antonio Regalado

May 13, 2025

JDSUPRA

News & Insights | Trending [7] | Find Author | Subscribe | For Reporters

July 3, 2025

CRISPR Dispute Heats Up With Recent Federal Court Decision

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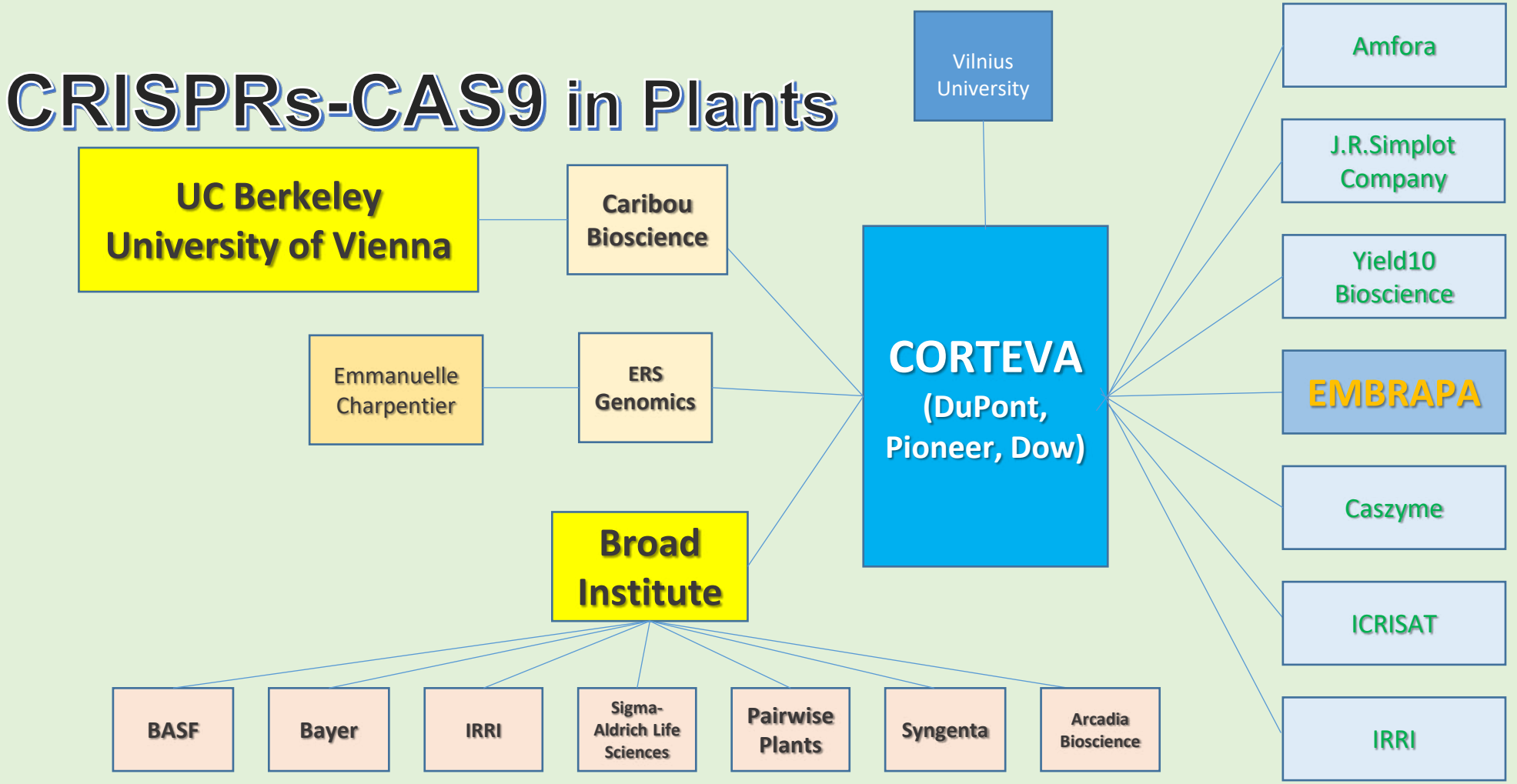
What do you want from legal thought leadership?

On May 12, 2025, the U.S. Court of Appeals for the Federal Circuit (CAFC) revived the Regents of the University of California's (Regents) challenge to the Broad Institute's CRISPR-Cas9 patents, overturning a 2022 decision by the Patent Trial and Appeal Board (PTAB)[1]. The main issue centers on inventions related to the CRISPR-Cas9 editing in eukaryotic cells. The Patent

PATENT Landscape

Intelectual Property??? Licencing?!



Source: Bagley, 2021 - Genome Editing in Latin America: CRISPR Patent and Licensing Policy

Patent filing for CRISPR technologies in agriculture (Global Overview)

Total de Invenções

Depositadas no MUNDO
4.322

Depositadas no BRASIL
345

Principais culturas associadas às invenções

ARROZ	MILHO	SOJA	TRIGO
1.263	786	577	527

ALGODÃO	CANA	CAFÉ	EUCALIPTO
325	220	64	49

Finalidade

Principais escritórios onde os pedidos foram depositados

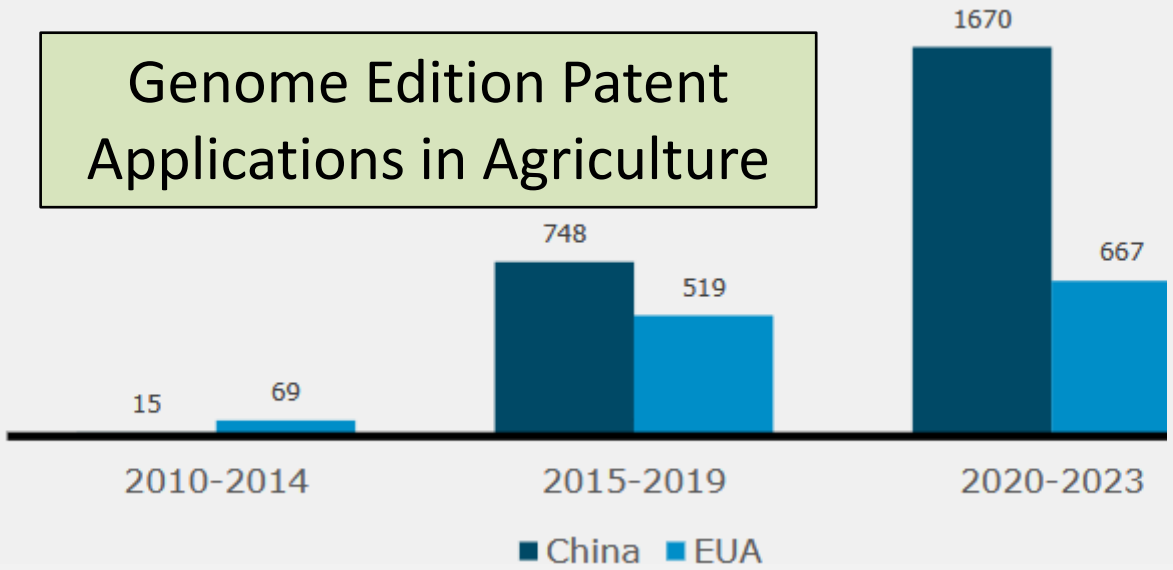
Quantas invenções foram depositadas por ano?

Quem gerou as invenções?

Depositante	Total de Famílias	Depósitos no Brasil	Tamanho médio da Família
CORTEVA/PIONEER/DOW AGROSCIENCES/ DUPONT	164	74	5,21
HUAZHONG AGRICULTURAL UNIVERSITY	135	2	1,07
INSTITUTE OF CROP SCIENCE OF CAAS	124	1	1,11
INSTITUTE OF GENETICS AND DEVELOPMENTAL BIOLOGY CHINESE ACADEMY OF SCIENCES	112	19	2,47

Quais países deram origem às invenções?

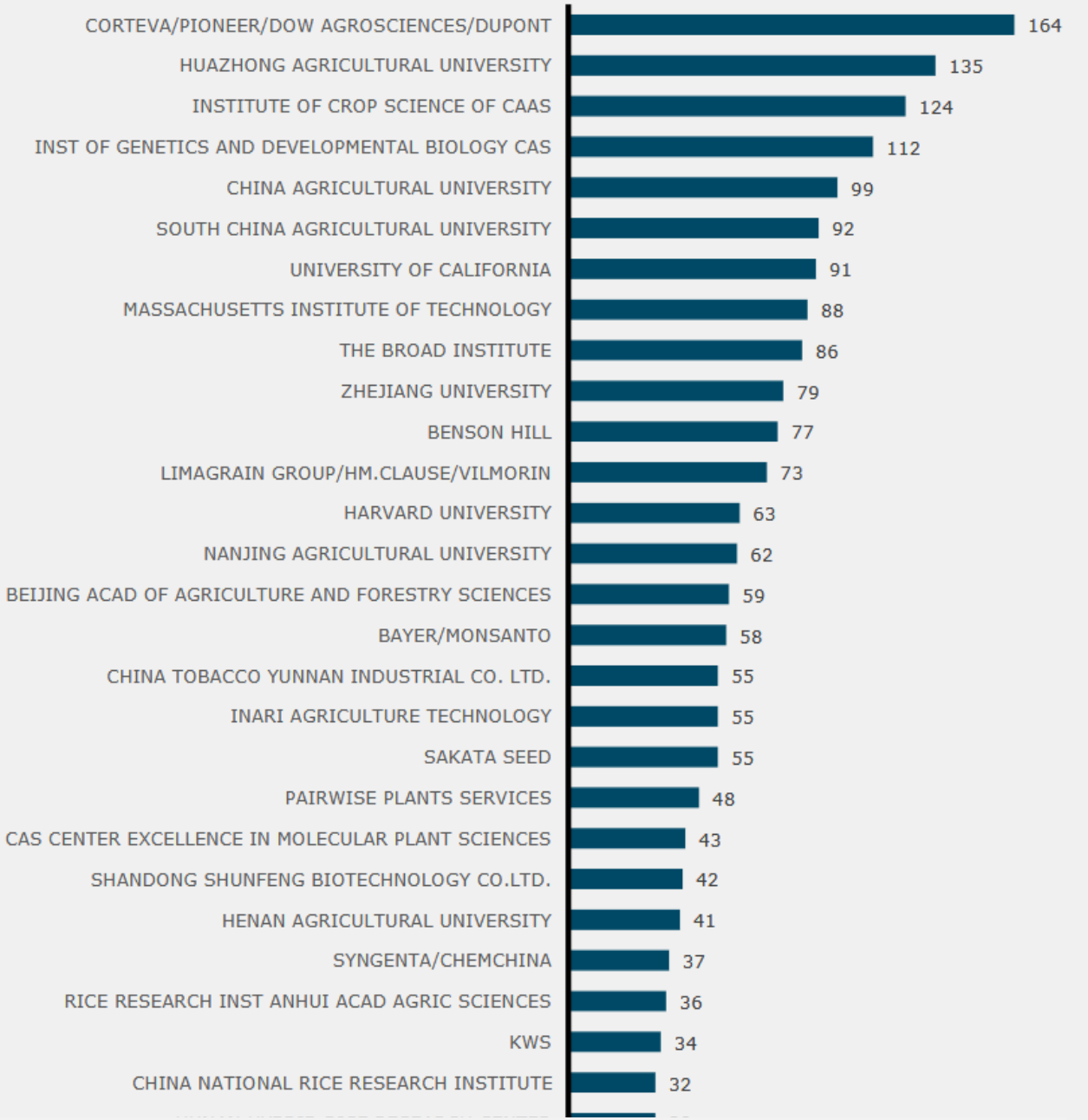
Genome Edition Patent Applications in Agriculture



Number of CRISPR patent application families in Agriculture in the world originating in China and the USA by filing period.

Number of patent application families related to gene editing technologies in the world by year of filing

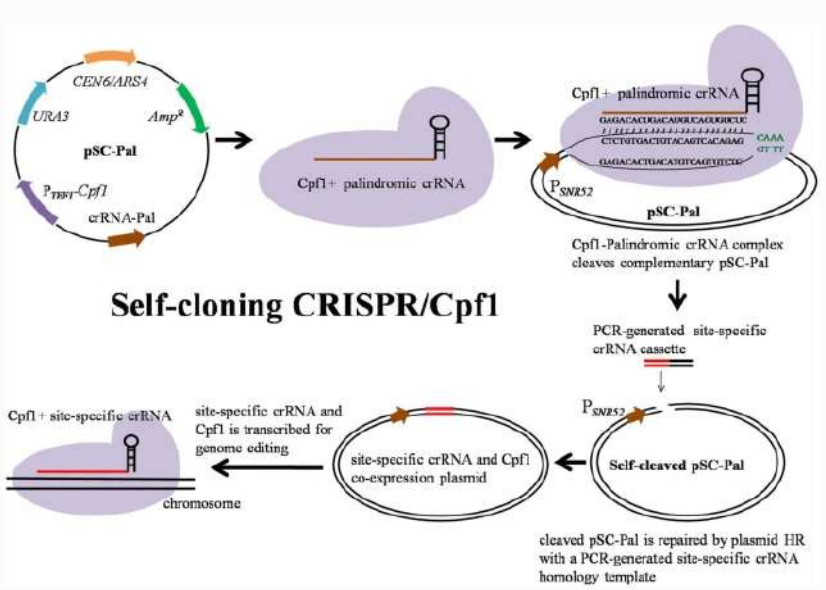
Source: Oliveira, S.S. INPI, Radar Tecnologico 2024

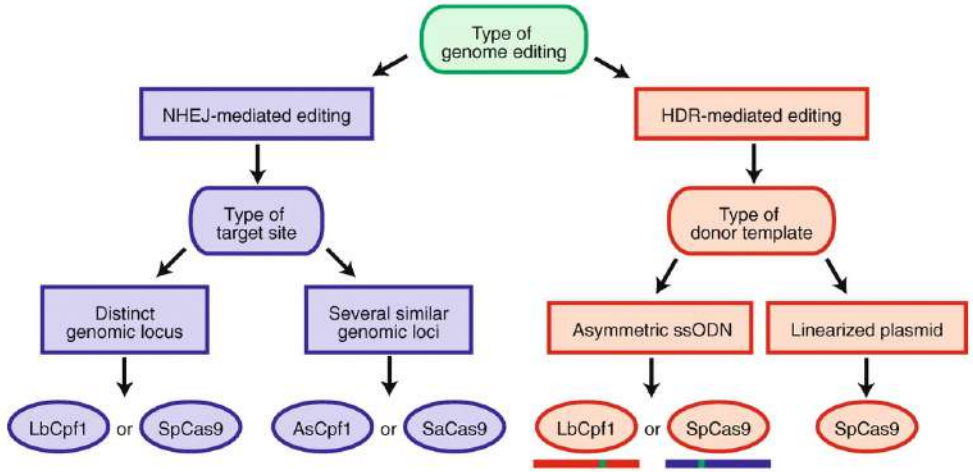


Top applicants in number of families of CRISPR patent applications in Agriculture in the world

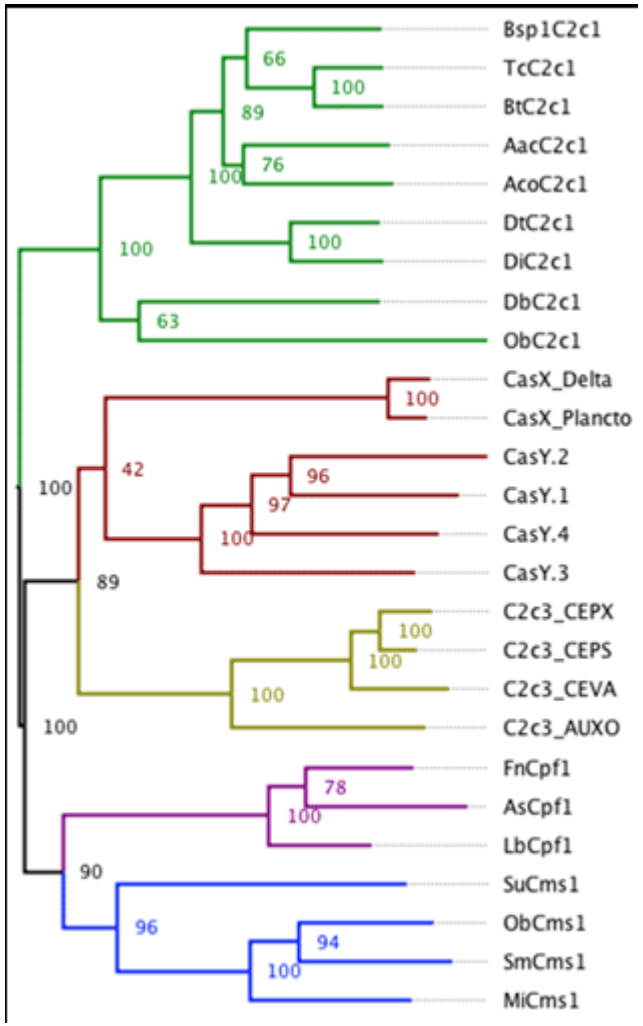
Multiple editing strategies, with dozens/hundreds of new enzymes being discovered/developed

Genome Edition will be like PCR???





Flowchart to guide CRISPR-Cas users in selecting the appropriate system for their experiments. The choice of Cas endonuclease depends on several considerations, such as the type of genome modification desired or the type of repair template to be utilized. For HDR-mediated editing with ssODNs, we recommend asymmetric donors that are complementary to either the target or non-target strand when used in combination with LbCpf1 or SpCas9, respectively



Journal of Genetics and Genomics xxx (xxxx) xxx

Contents lists available at ScienceDirect

Journal of Genetics and Genomics

Journal homepage: www.journals.elsevier.com/journal-of-genetics-and-genomics/

Original research

Genome editing in plants with MAD7 nuclease

Qiupeng Lin [a, b, 1], Zixu Zhu [a, b, 1], Guanwen Liu [c, d, 1], Chao Sun [a, b], Dexing Lin [a, b], Chenxiao Xue [a, b], Shengnan Li [c, d], Dandan Zhang [c, d], Caixia Gao [a, b], Yanpeng Wang [a, b, *], Jin-Long Qiu [c, d, *]

Conclusion of the European Commission Report on the detection of organisms with genome edited using CRISPRs

European Commission

JRC TECHNICAL REPORTS

Explanatory Note

Challenges for the detection of genetically modified food or feed originating from genome editing

EU Reference Laboratory

in consultation with the

Mutations made by humans using CRISPRs are indistinguishable from natural mutations produced by nature.

8 Conclusions

With respect to the challenges for GMO detection laboratories as framed in the scenario above the following can be concluded:

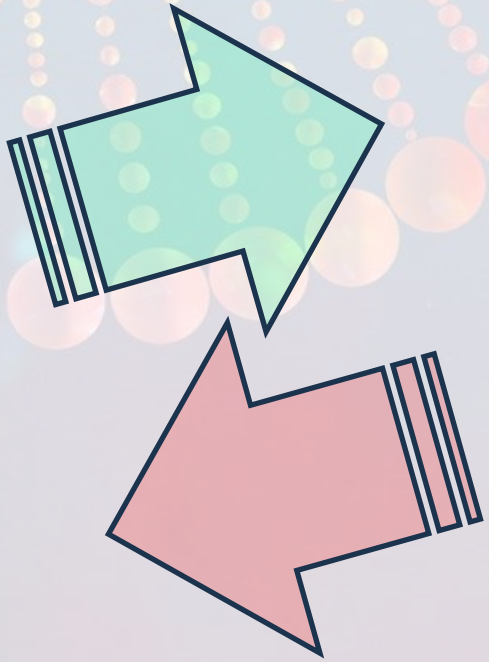
Most of the mutations induced by genome editing technologies cannot be unequivocally distinguished from natural mutations as they may also occur naturally. Plant genomes have inherently a considerable sequence variability which is at present not only insufficiently documented for any crop, but the genomes keep also changing over time.

Moreover, mutations obtained by new mutagenesis techniques can currently not be differentiated from those induced by conventional mutagenesis techniques, which have been incorporated in traditional breeding programs and are often not thoroughly documented.

Regulatory Systems (examples)

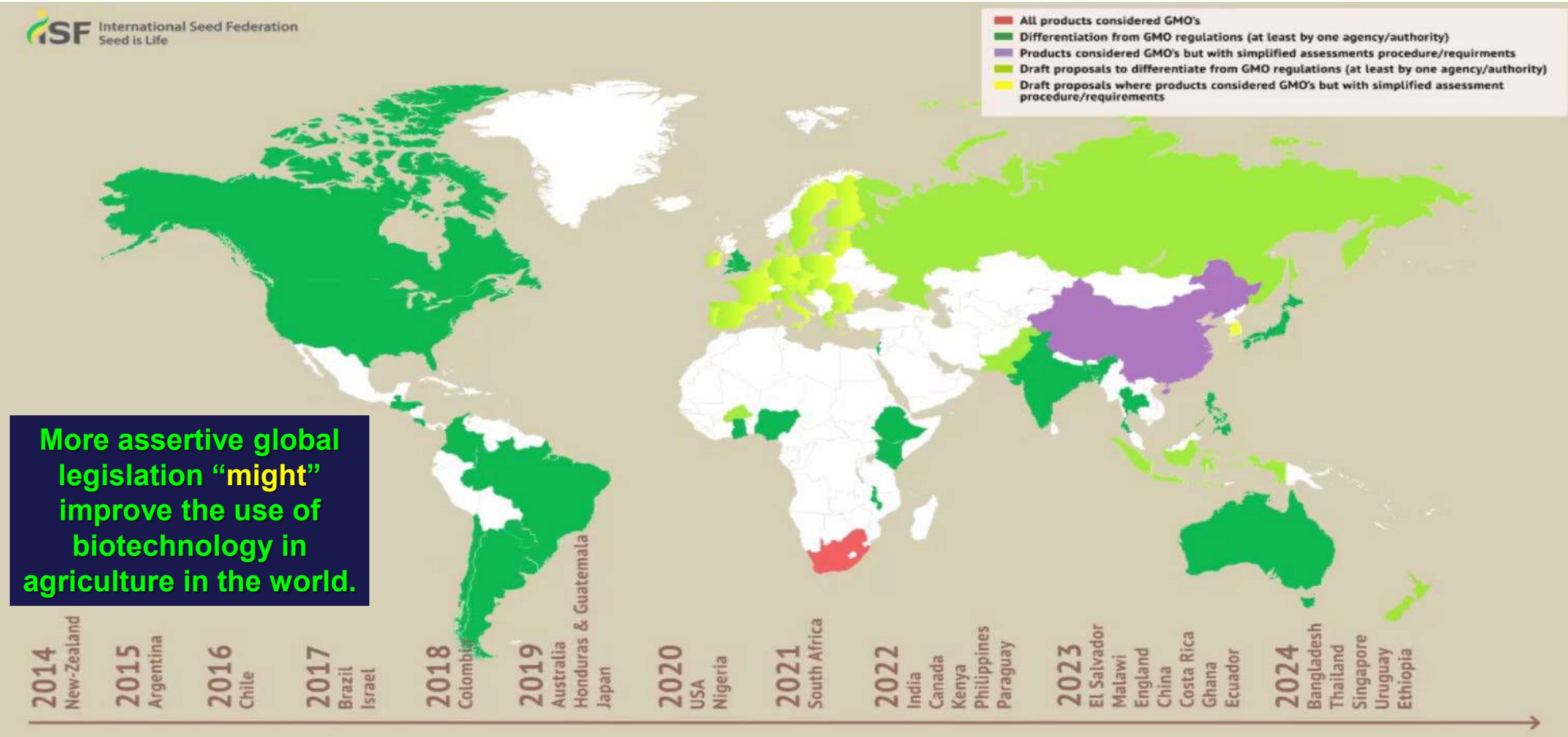
Biosafety

Innovation

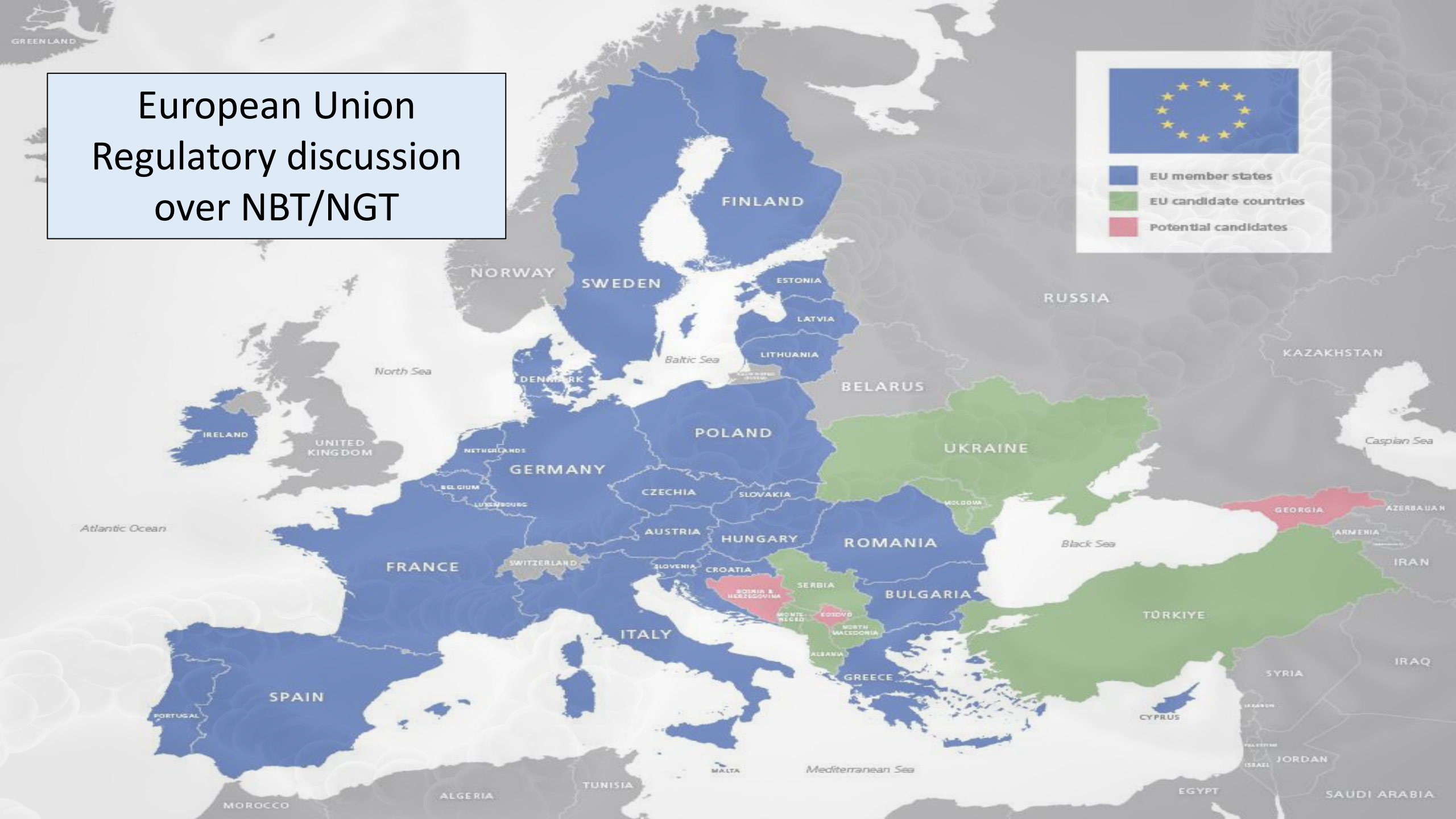


GLOBAL REGULATORY LANDSCAPE FOR GENE-EDITED CROPS

Established regulatory criteria for new breeding innovations in different world regions in the past decade



European Union Regulatory discussion over NBT/NGT



Summary of the last few months on developments related to the *New Genomic Techniques (NGT) Regulation* in the European Union.

The European Commission's Initial Proposal (July 2023)

EUROPEAN COMMISSION

Brussels, 5.7.2023
COM(2023) 411 final

2023/0226 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625

(Text with EEA relevance)

{SEC(2023) 411 final} - {SWD(2023) 411 final} - {SWD(2023) 412 final} - {SWD(2023) 413 final}

Proposal Summary

Under previous EU law, all NGT plants were subject to the same strict regulations as traditional GMOs, including extensive risk assessments and labeling requirements.

In July 2023, the European Commission proposed a new framework to NGT plants.

The key distinction is between:

Category 1 NGT plants: These are considered comparable to plants that could be developed through conventional breeding or that occur naturally. The Commission proposed that these plants be largely deregulated, meaning they would be exempt from the strict GMO rules, including a mandatory risk assessment and labeling on the final product.

Category 2 NGT plants: These are all other NGT plants that do not meet the criteria for Category 1. They would continue to be subject to most of the strict GMO regulations.

Summary of the EU Legislative Process

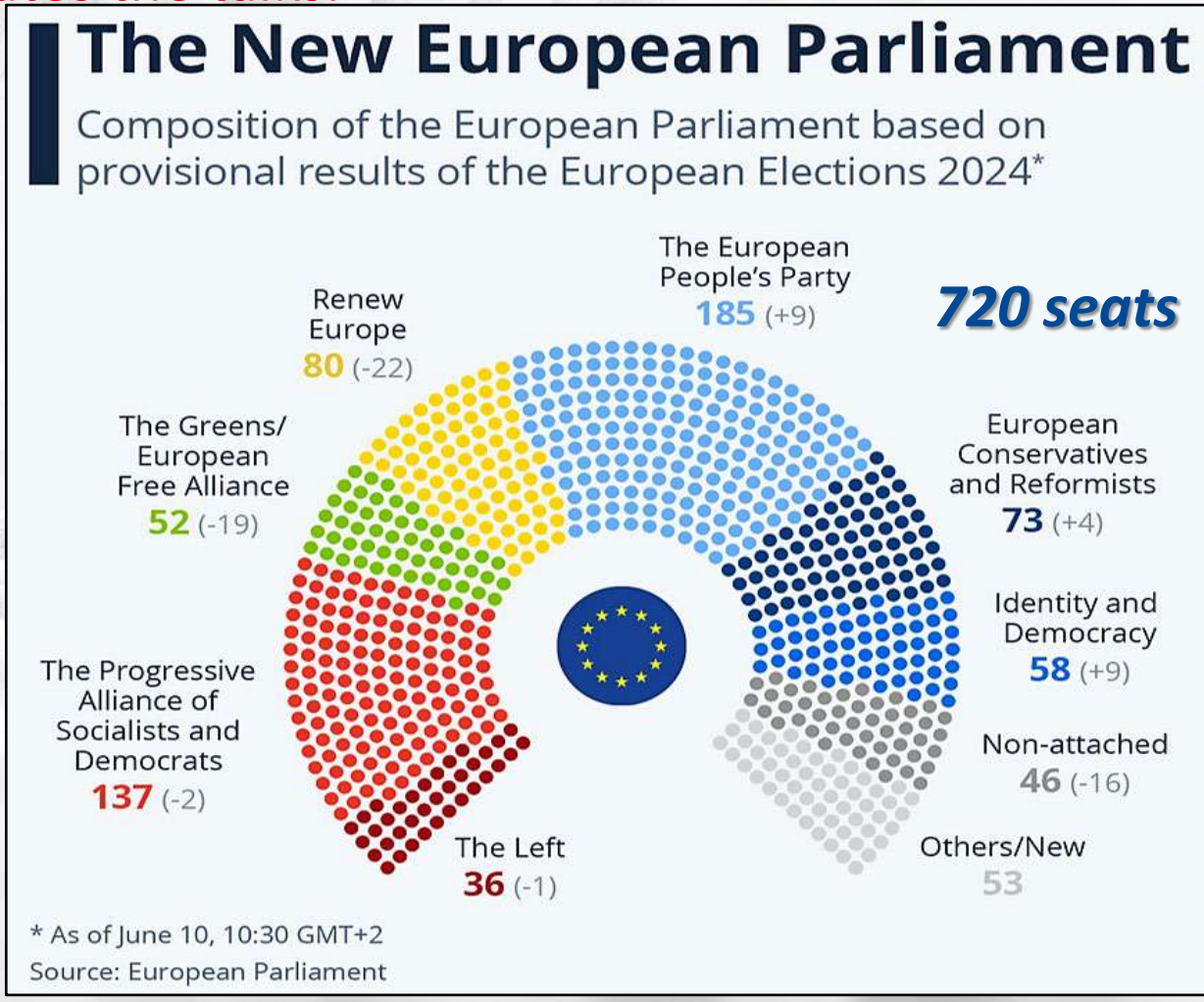
The EU's legislative process is a three-way negotiation, or "**trilogue**," among the:

European Commission: Proposes a law and mediates the talks.

Council of the EU: Representing member governments, Formulates its stance based on a compromise, often led by the rotating presidency

Poland (Jan-Jun/25)*(got consensus)*,
Denmark (Jul-Dec/25).

European Parliament: Represents EU citizens and establishes its own position through a vote.



During Poland’s presidency its was gained majority support in the Council by March 2025.

It allowed for the start of “Trilogue" negotiations with the European Parliament and the European Commission.

Trilogue negotiations that followed, focused on two primary issues:

Deregulation of Category 1 plants (NGT1 ≈ SDN1) _:

Poland's proposal was to deregulate these plants, as they are seen as comparable to conventionally bred plants. This approach faced criticism from groups concerned about the lack of safety checks, labeling, and transparency for consumers. Opponents argued that even NGT Category 1 plants could pose environmental risks and that the lack of labeling would make it difficult for farmers (especially organic ones) to prevent contamination.

Patents: (This was a particularly contentious issue).

The European Parliament's position was to push for a total ban on patents for all NGT plants and related genetic material. The goal was to prevent large corporations from gaining monopolies and to ensure that farmers and small breeders could access and use a diversity of plant material.

The Council's position, influenced by Poland's proposal, was different. Instead of a full ban, the Council's mandate aimed to address the issue with "targeted changes." This included proposals for greater transparency, such as requiring companies to disclose patent information for NGT Category 1 plants in a publicly available database. The goal was to strike a balance between protecting the legitimate interests of innovators and ensuring that farmers and breeders have freedom to operate.

China Regulatory System over NBT/NGT

中国农业大学
China Agricultural University

中国农业转基因生物安全评价管理要求

Regulation Requirements for Safety Evaluation of Agricultural GMOs in China

黄昆仑 教授

Professor Kunlun Huang

Member of the China National Biosafety Committee (NBC)

中国农业大学食品科学与营养工程学院

College of Food Science and Nutritional Engineering,China Agricultural University

农业农村部农业转基因生物安全评价（食用）重点实验室

Key Laboratory for food Safety Evaluation of Agricultural GMOs

Ministry of Agriculture and Rural Affairs

2024.11.12

GENOME EDITED PRODUCTS APPROVED IN CHINA FOR COMMERCIAL USE.

QH64112 soybean with a mutation in the Gml n gene for improved yield traits - Suzhou QiHe Shengke

in 2022)

Summary: GE products approved in China for commercial use:

Soybean (5): Productivity and Oil Quality
Corn (2): Productivity
Wheat (2): Herbicide Resistance and Disease Resistance
Rice (1): Starch quality (amylose content)

Source: Toppa, E.V.B., MAPA/SEBIO, Brazil 2025

(3) in vitro sir

(4) toxicologi

5.若上述数据

If the above

day feeding tr

Ltd. / Jiangsu Academy of Agricultural Sciences / Beijing QiHe Shengke Biotechnology Co., Ltd.

TaALS-4 wheat with a mutation in the TaALS gene for herbicide resistance - Suzhou QiHe Shengke Biotechnology Co., Ltd. / Institute of Genetics and Developmental Biology, Chinese Academy of Sciences

MLO-KNRNP wheat with mutations in the TaMLO-A1, TaMLO-B1, and TaMLO-D1 genes and TaMLOX for Disease Resistance - Suzhou QiHe Shengke Biotechnology Co., Ltd. / Institute of Genetics and Developmental Biology, Chinese Academy of Sciences

USDA Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Home | Travelers | Trade | Animals | Plants | Funding | About

Home > Plants > Biotechnology > Regulatory Status Review > Confirmation Letters

Confirmation Letters

Last Modified: February 27, 2025

Exemption Categories Table

USDA APHIS regulations at 7 CFR* §340

*Code of Federal Regulations

Table Key

(b)(1): A change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template

(b)(2): A targeted single base pair substitution

(b)(3): A gene known to occur in the plant's gene pool, or a change in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool

(AM1): An indel or contiguous deletion of any size, made at a targeted location, with or without insertion of DNA if generated without using a repair template, or without insertion of DNA if generated using a repair template

(AM2): A plant with up to twelve (12) modifications, made simultaneously or sequentially, if each modification individually qualifies for exemption and occurs in a different gene

(c): A plant-trait-mechanism of action combination that has been previously reviewed for risks to plant health and determined by APHIS not to be regulated under this part, either via the Regulatory Status Review process or a petition submitted pursuant to the legacy part 340 regulations.

37th Meeting of the OECD Working Party on the Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB)

OECD Conference Centre and via online conference system, 17-19 April 2023

Specifically, the regulations in 7 CFR part 340 do not apply to plants that have been modified such that they contain either a single modification of a type listed in paragraphs (b)(1) through (3) of § 340.1, or additional modifications as determined by the Administrator, and described in paragraph (b)(4) of § 340.1.

(1) The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template; or
(2) The genetic modification is a targeted single base pair substitution; or
(3) The genetic modification introduces a gene known to occur in the plant's gene pool, or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool.
(4) The Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding.

DEVELOPERS MAY VOLUNTARILY REQUEST CONFIRMATIOIN FROM USDA-APHIS THAT A MODIFIED PLANT QUALIFIES FOR AN EXEMPTION AND IS NOT SUBJECTED TO THE REGULATIONS

US reports at OECD Legislation Harmonization Group

38th Meeting of the OECD Working Party on the Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB)

OECD Conference Centre and via online conference system, 20-22 March 2024

- ***Confirming Products Exempt from Regulation.*** USDA-APHIS biotechnology regulations exempt certain modified plants that (1) are achievable through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants, or (2) have a plant-trait-mechanism of action combination that is the same as a plant that USDA-APHIS previously reviewed and determined to be unlikely to pose plant pest risk.

  Developers may voluntarily request USDA-APHIS confirm a modified plant qualifies for an exemption and is not subject to the regulations in 7 CFR part 340. USDA-APHIS will provide a written response ("confirmation letter") within 120 days of receiving a sufficiently detailed confirmation request. USDA-APHIS posts both the confirmation requests and the issued confirmation letters on its website, with redactions to protect Confidential Business Information and Personal Identifying Information, as appropriate. Since 2020, USDA-APHIS has issued 79 responses to confirmation request letters as of 02/29/2024 with an average timeframe of 54 days.

39th Meeting of the OECD Working Party on the Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB)

OECD Conference Centre and via online system, 24-26 March 2025

US Delegation did not participated

USDA APHIS regulations at 7 CFR §340

The table provides confirmation requests submitted to APHIS and APHIS' corresponding response.

Full Table at:

https://www.aphis.usda.gov/biotech-regulatory-status/confirmation-letters

Approximately 100 requests for non-regulatory status review by September 2025

	Requestor	Plant	Scientific Name	Trait	Exemption Category	Response Date	Confirmation Request
24-227-01cr	Phytoform Labs Ltd.	Tomato	Solanum lycopersicum	Altered Pedicel Structure	(b)(1)	9/27/2024	View Document
24-215-01cr	Donald Danforth Plant Science Center	Pennycress	Thlaspi arvense	Altered Plant Architecture	(b)(1)	9/27/2024	View Document
24-072-01cr	GFLAS Life Sciences, Inc	Tomato	Solanum lycopersicum	Altered Nutrient Composition	(b)(1)	7/3/2024	View Document
24-064-01cr	The New Zealand Institute for Plant and Food Research Limited	Thale cress	Arabidopsis thaliana	Altered Plant Architecture	(b)(1)	7/3/2024	View Document
24-095-01cr	CoverCress Inc.	Pennycress	Thlaspi arvense	Altered Plant Maturation Time	(b)(1)	5/10/2024	View Document
24-094-01cr	CoverCress Inc.	Pennycress	Thlaspi arvense	Altered Plant Maturation Time	(b)(1)	5/10/2024	View Document
24-087-01cr	CoverCress Inc.	Pennycress	Thlaspi arvense	Altered Flowering Window	(b)(1)	5/10/2024	View Document
24-060-01cr	Benson Hill, Inc.	Soybean	Glycine max	Altered Seed Composition	(b)(1)	4/8/2024	View Document
24-060-02cr	Benson Hill, Inc.	Soybean	Glycine max	Altered Seed Composition	(b)(1)	4/8/2024	View Document
24-060-03cr	Benson Hill, Inc.	Soybean	Glycine max	Altered Seed Composition	(b)(1)	4/8/2024	View Document

Showing 1 to 10 of 99 entries

Previous 1 2 3 4 5 ... 10 Next

CTNBio Normative Resolution 16

RN16

Técnicas
Inovadoras de
Melhoramento de
Precisão

DIÁRIO OFICIAL DA UNIÃO

comissão técnica nacional CTNBio de biossegurança

Publicado em: 22/01/2018 | Edição: 15 | Seção: 1 | Página: 2-8
Órgão: Ministério da Ciência, Tecnologia, Inovações e Comunicações / Comissão Técnica Nacional de Biossegurança

RESOLUÇÃO NORMATIVA Nº 16,.DE 15 DE JANEIRO DE 2018

ANEXO I

Estabelece os requisitos técnicos para apresentação de consulta à CTNBio sobre as Técnicas Inovadoras de Melhoramento de Precisão

A COMISSÃO TÉCNICA NACIONAL DE BIOSSEGURANÇA - CTNBio, no uso de suas atribuições legais e regulamentares e em observância às disposições contidas nos incisos XV e XVI do art. 14 da Lei nº 11.105, de 24 de março de 2005;

CONSIDERANDO a necessidade de avaliar as Técnicas Inovadoras de Melhoramento de Precisão (TIMP), do inglês Precision Breeding Innovation (PBI) e que também englobam as denominadas Novas Tecnologias de Melhoramento, do inglês New Breeding Technologies -NBTs, à luz dos preceitos previstos na Lei nº 11.105, de 24 de março de 2005;

Considerando que a Lei nº 11.105, de 2005, define moléculas de ADN/ARN recombinante, engenharia genética e organismo geneticamente modificado - OGM nos incisos III, IV e V de seu art. 3º, respectivamente;

Considerando que as TIMP abrangem um conjunto de novas metodologias e abordagens que diferem da estratégia de engenharia genética por transgenia, por resultar na ausência de ADN/ARN

Regulates the use of New Breeding Technologies (**NBTs**), also known as Precision Breeding Innovation (**PBI**) or New Genomic Techniques (**NGT**).

Argentina

Report at:

37th Meeting of the OECD Working Party on the Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB)

OECD Conference Centre and via online conference system, 17-19 April 2023

Arg
Edit
ma

New Breeding Techniques

39th Meeting WP-HROB - March 2025

A total of 28 Prior Consultation Instance (PCI) forms were submitted for the period April 2024 - March 2025. Thereof 2 (two) PCI forms were submitted for products in development stage, 18 (eighteen) for real products and the rest is under evaluation.

Hov
and

According to organisms, it can be said that out of the 28 PCI forms recieved, 17 PCI was submitted for a microorganism, 1 for animals and the rest for plants.

PCI
- pl
- m
- A

CONABIA considered that these products complied with characteristics established in the Policy Approach for NTBs (Resolution No. 21/21) and did not fall within the scope of the Regulatory Framework of Genetically Modified Organisms.

Tip
- R
- H

Since 2015 to date, 169 PCIs have been analysed for different organisms (plants, animals, and microorganisms).

Type of entity:
- Private: 47
- Public: 17
- Mixed: 3

approval requests?	• SSMA (comercial assessment)
Who makes the final decision?	Secretary of Agriculture, Livestock and Fisheries

South America Biosafety Agreements





Agreement between Argentina and Brazil on biosafety:

Memorandum of understanding between the regulatory agencies of Argentina (CONABIA) and Brazil (CTNBIO) for cooperation in biosafety of products derived from modern biotechnology. Signed on 20th October of 2022 by the Ministry of Science and Technology of Brazil and the Ministry of Economy of Argentina. Under this agreement Argentina and Brazil are committed to start working together and to build the necessary mechanisms and procedures for the joint evaluation and authorisations of products of agricultural biotechnology.

Having authorised the necessary internal procedures, both countries commit to begin joint evaluations and authorisations of modern biotechnology products. In 2024, the first 4 applications were submitted for joint evaluation.

Agreement between Argentina, Brazil, Paraguay and Uruguay on biosafety:

In terms of regional cooperation, on June 12, 2024, Argentina, Brazil, Paraguay and Uruguay signed a memorandum for the creation of the International Biosafety Network (ABRE-Bio, Biosafety Agencies Network for Biotechnology)

The main objective of the memorandum is to promote the exchange of scientific information and cooperation in the risk assessment and regulation of genetically modified organisms (GMOs) as well as products derived from new breeding techniques (NBT)

In addition, the countries are committed to working on common procedures for biosafety assessment, seeking to reduce costs and time, as well as harmonize regulations with the specific legislation of each country.The agreement also aims to promote innovation in the agriculture, livestock, fishing and agroindustry sectors through collaboration between public and private institutions.

Each country has designated institutions responsible for carrying out the activities derived from the agreement. In Argentina, the Coordination of Innovation and Biotechnology and the National Advisory Commission on Agricultural Biotechnology (CONABIA) will be in charge of these tasks.

BIOSAFETY: AGREEMENT BETWEEN ARGENTINA AND BRAZIL

Brazil and Argentina work together to accelerate the process, reduce costs, diversify developers, allow innovation to quickly reach the productive sector, while maintaining Biosafety.

AGRO-BIOTECHN PRODUCTS EVALUATED/UNDER EVALUATION:

- Potato M08001 Solanum tuberosum L. cv. Desiree (INTA)
- Yeast saccharomyces cerevisiae SCY010 (NOVOZYMES)
- Genetic Construction SEMPRE – 001 (SEMPRE AGTECH)
- Molecule ARNI based SEMPRE-004-V2.0 (SEMPRE AGTECH) for biopesticide

First POTATO with Genome Edited considered Non-GM in Brazil

comissão técnica nacional CTNBio de biossegurança

MINISTÉRIO DA CIÊNCIA, TECNOLOGIA E INOVAÇÃO

GOVERNO FEDERAL BRASIL UNIÃO E RECONSTRUÇÃO

03 October 2024
CTNBio meeting

275ª REUNIÃO ORDINÁRIA DA COMISSÃO TÉCNICA NACIONAL DE BIOSSEGURANÇA – CTNBio
Data: 3 de outubro de 2024
Horário: das 8h30 às 14h
Local: Setor Policial Sul, Quadra 3, Bloco E, 1º Andar, Auditório, Brasília-DF (presencial) e Portal de Conferência RNP (virtual).

Reduced PPO activity (reduced browning)

Developed by INTA
In ARGENTINE

INTA

CTNBio
Normative Resolution nº38

Ir para ESSIBILIDADE ALTO CONTRASTE MAPA DO SITE PORTUGUÊS ENGLISH

Biossegurança

MINISTÉRIO DA CIÊNCIA, TECNOLOGIA, INOVAÇÕES E COMUNICAÇÕES

Perguntas Frequentes | Contato | Serviços da CTNBio

INÍCIO > NORMAS E LEIS > RESOLUÇÕES NORMATIVAS > RESOLUÇÃO NORMATIVA Nº 38, DE 27 DE SETEMBRO DE 2023

INSTITUCIONAL

- A CTNBio
- Secretaria Executiva
- Processo de OGM
- Reuniões
  - Atas
  - Pautas
  - Deliberações

CTNBio

Resolução Normativa Nº 38, de 27 de Setembro de 2023

DOC PDF Imprimir

Estabelece os procedimentos para o trâmite de processos entre a Comissão Técnica Nacional de Biossegurança - CTNBio e instituições congêneres à CTNBio de outros países com as quais a CTNBio possui instrumentos de cooperação em biossegurança de produtos da biotecnologia moderna para fins de liberação comercial de organismos geneticamente modificados (OGM) e seus derivados e para a avaliação do enquadramento de produtos gerados por meio de Técnicas Inovadoras de Melhoramento de Precisão (TIMP).

A COMISSÃO TÉCNICA NACIONAL DE BIOSSEGURANÇA - CTNBio, no uso das competências conferidas pelo art. 14, incisos I, II, III, IV, VI, VII, XII e XVI, da Lei nº 11.105, de 24 de março de 2005, resolve:

Art. 1º Esta Resolução Normativa estabelece os procedimentos para o trâmite de processos entre a Comissão Técnica Nacional de Biossegurança - CTNBio e instituições congêneres à CTNBio de outros países com as quais a CTNBio possui instrumentos de cooperação em biossegurança de produtos da biotecnologia moderna para fins de liberação comercial de organismos geneticamente modificados (OGM) e seus derivados e para a avaliação do enquadramento de produtos gerados por meio de Técnicas Inovadoras de Melhoramento de Precisão (TIMP).

MOU among Argentina-Brazil-Paraguay-Uruguay's regulatory agencies to:

- Promote exchange of scientific information and collaboration;
- Develop common procedures for biosafety assessment;
- Foster innovation in Agriculture
- Reduce: asynchrony, costs, time.
- Etc…

2024
ABRE-Bio
Network of Biosafety Agencies for Biotechnology

MEMORANDO DE ENTENDIMIENTO MULTILATERAL ENTRE EL MINISTERIO DE ECONOMÍA DE LA REPÚBLICA ARGENTINA,

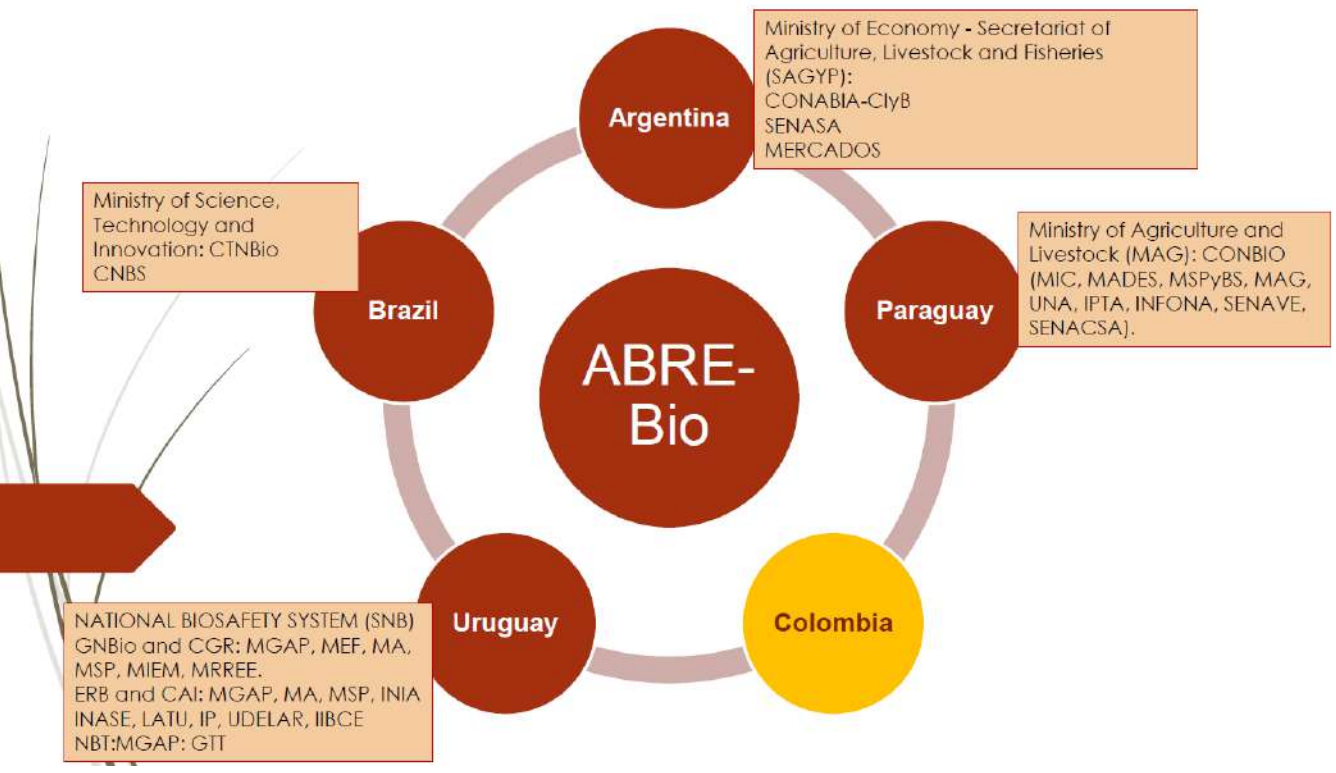
EL MINISTERIO DE CIENCIA, TECNOLOGÍA E INNOVACIÓN DE LA REPÚBLICA FEDERATIVA DE BRASIL,

EL MINISTERIO DE AGRICULTURA Y GANADERÍA DE LA REPÚBLICA DE PARAGUAY

Y

EL MINISTERIO DE GANADERÍA, AGRICULTURA Y PESCA DE LA REPÚBLICA ORIENTAL DEL URUGUAY

PARA LA CREACIÓN DE LA RED INTERNACIONAL DE BIOSEGURIDAD DE PRODUCTOS DERIVADOS DE LA BIOTECNOLOGÍA MODERNA



Level of (a)synchrony in the Region




82%		88%		57%	63%
98%		91%		60%	64%

Country	a	b	%	c	%
Argentina	108	88	82%	90	98%
Brasil	108	95	88%	105	91%
Paraguay	108	62	57%	103	60%
Uruguay	108	68	63%	107	64%

a. Total corn and soybean events approved in at least one MERCOSUR's country.
b. Number of approved events per country
c. Total applications submitted by country

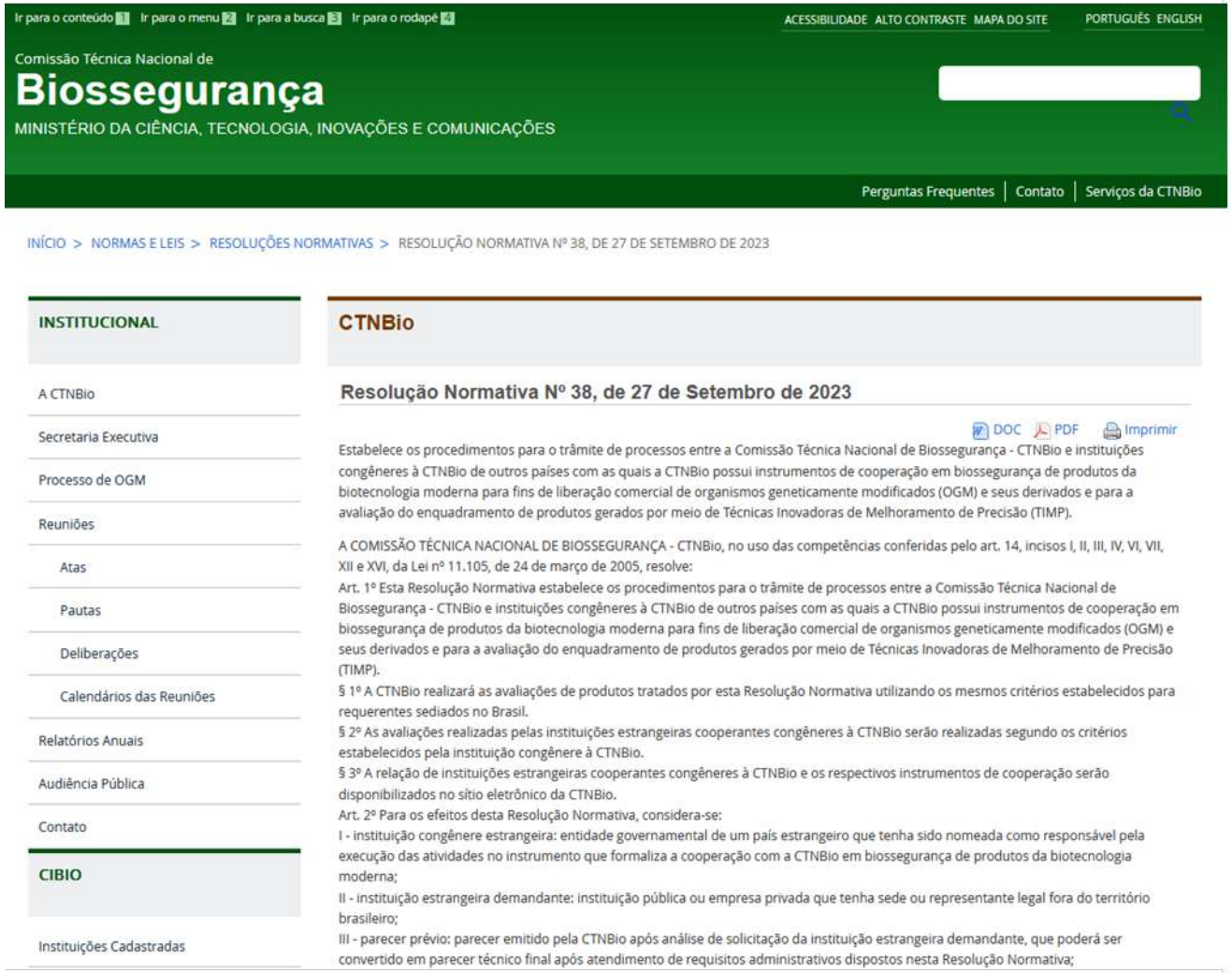
Current Field Events (Uruguay, 2022):
3 soybean events out of 12 approved
13 corn events out of 31 approved

Source: Ferenczi, A.; EBBIO 2025, Vitoria-ES, Brazil

Brazil proposed China a bilateral agreement on Biosafety analysis

(similar to the agreement made with Argentine and in the ABRE-Bio)

Based in the Normative Resolution 38



Ir para o conteúdo 1 Ir para o menu 2 Ir para a busca 3 Ir para o rodapé 4

ACESSIBILIDADE ALTO CONTRASTE MAPA DO SITE PORTUGUÊS ENGLISH

Comissão Técnica Nacional de

Biossegurança

MINISTÉRIO DA CIÊNCIA, TECNOLOGIA, INOVAÇÕES E COMUNICAÇÕES

Perguntas Frequentes | Contato | Serviços da CTNBio

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Resolução Normativa Nº 38, de 27 de Setembro de 2023

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Estabelece os procedimentos para o trâmite de processos entre a Comissão Técnica Nacional de Biossegurança - CTNBio e instituições congêneres à CTNBio de outros países com as quais a CTNBio possui instrumentos de cooperação em biossegurança de produtos da biotecnologia moderna para fins de liberação comercial de organismos geneticamente modificados (OGM) e seus derivados e para a avaliação do enquadramento de produtos gerados por meio de Técnicas Inovadoras de Melhoramento de Precisão (TIMP).

A COMISSÃO TÉCNICA NACIONAL DE BIOSSEGURANÇA - CTNBio, no uso das competências conferidas pelo art. 14, incisos I, II, III, IV, VI, VII, XII e XVI, da Lei nº 11.105, de 24 de março de 2005, resolve:

Art. 1º Esta Resolução Normativa estabelece os procedimentos para o trâmite de processos entre a Comissão Técnica Nacional de Biossegurança - CTNBio e instituições congêneres à CTNBio de outros países com as quais a CTNBio possui instrumentos de cooperação em biossegurança de produtos da biotecnologia moderna para fins de liberação comercial de organismos geneticamente modificados (OGM) e seus derivados e para a avaliação do enquadramento de produtos gerados por meio de Técnicas Inovadoras de Melhoramento de Precisão (TIMP).

§ 1º A CTNBio realizará as avaliações de produtos tratados por esta Resolução Normativa utilizando os mesmos critérios estabelecidos para requerentes sediados no Brasil.

§ 2º As avaliações realizadas pelas instituições estrangeiras cooperantes congêneres à CTNBio serão realizadas segundo os critérios estabelecidos pela instituição congênere à CTNBio.

§ 3º A relação de instituições estrangeiras cooperantes congêneres à CTNBio e os respectivos instrumentos de cooperação serão disponibilizados no sítio eletrônico da CTNBio.

Art. 2º Para os efeitos desta Resolução Normativa, considera-se:

I - instituição congênere estrangeira: entidade governamental de um país estrangeiro que tenha sido nomeada como responsável pela execução das atividades no instrumento que formaliza a cooperação com a CTNBio em biossegurança de produtos da biotecnologia moderna;

II - instituição estrangeira demandante: instituição pública ou empresa privada que tenha sede ou representante legal fora do território brasileiro;

III - parecer prévio: parecer emitido pela CTNBio após análise de solicitação da instituição estrangeira demandante, que poderá ser convertido em parecer técnico final após atendimento de requisitos administrativos dispostos nesta Resolução Normativa;

规范性决议文件 第 38 号（2023 年 9 月 27 日）

本文件明确了转基因生物（OGM）及其衍生产品在现代生物技术领域的商业化许可程序，并对精准改良技术（TIMP）产品的分类评估作出具体规定。同时，本文件规范了巴西国家生物安全技术委员会（CTNBio）与其他国家对等机构在该领域合作的操作流程。

巴西国家生物安全技术委员会（CTNBio）根据《2005 年 3 月 24 日第 11.105 号法》第 14 条赋予的权力，特做出如下决议：

第一条 本规范性决议规定了 CTNBio 与具备合作机制的外国对等机构之间的合作流程，确保在符合合作框架的基础上，推进现代生物技术领域内转基因生物（OGM）及其衍生产品的商业化许可，并进一步细化对创新改良技术（TIMP）产品的分类评估。

第1款 CTNBio 将按照对巴西境内申请人适用的标准，对本决议涵盖的产品进行评估。
第2款 与 CTNBio 合作的外国对等机构将按照其自身的标准进行评估。
第3款 CTNBio 将在官网上公布与外国对等机构的合作名单及相关合作文件。

第二条 本规范性决议中，相关定义如下：
第1款 外国对等机构：在现代生物技术产品生物安全领域，与 CTNBio 正式建立合作关系的外国政府机构；
第2款 外国申请机构：设立在巴西境外的公共机构、私人企业，或在巴西境外拥有合法代理的机构；
第3款 初步意见：CTNBio 在分析外国申请机构的申请后提出初步评估意见；在申请机构满足本规范性决议的行政要求后，该初步意见可转为正式的技术意见；
第4款 转基因生物（OGM）：指通过基因工程技术改造其基因组（DNA/RNA）的生物体；
第5款 转基因生物（OGM）衍生物：指从转基因生物（OGM）中提取，但不具备自我复制能力，或不含有活性 OGM 成分的产品；
第6款 **精准创新改良技术（TIMP）**：指 CTNBio 第 16 号规范性决议（2018 年 1 月 15 日）或其后续规定中涵盖的一系列现代育种方法和技术。

Questions whose answer is worth Billions (U$)

- **Will it be possible to protect intellectual rights for "mutations" made by gene editing (e.g. Brazil: INPI; EU parliament x EU Council?)**

- **What will happen to the use of CRISPR technique for commercial product development?**
  - CRISPR will be like PCR? “Just a tool” to reach the Final Product?

- **Will there be labeling?**
  - Countries like Argentina/United States/Brazil/etc... consider genome-edited varieties to be conventional !!!
  - Europe is currently discussing the creation of a third category, "conventional-like.“

- **If I can not detect, How will be the Value Capture?**
  - In the Final Product? Depending on each country’s legislation (e.g. Brazil: New Cultivars Protection Law ???).

- **In the edited plant market, will we have, as with Transgenic Plants, a few companies participating in the market? Or will we have more companies of all sizes?**

Thank You

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comissão técnica nacional
CTNBio
de biossegurança

Embrapa