Practical aspects of Genetically Edited Organisms regulation: the Brazilian experience.

Maria L. Z. Dagli

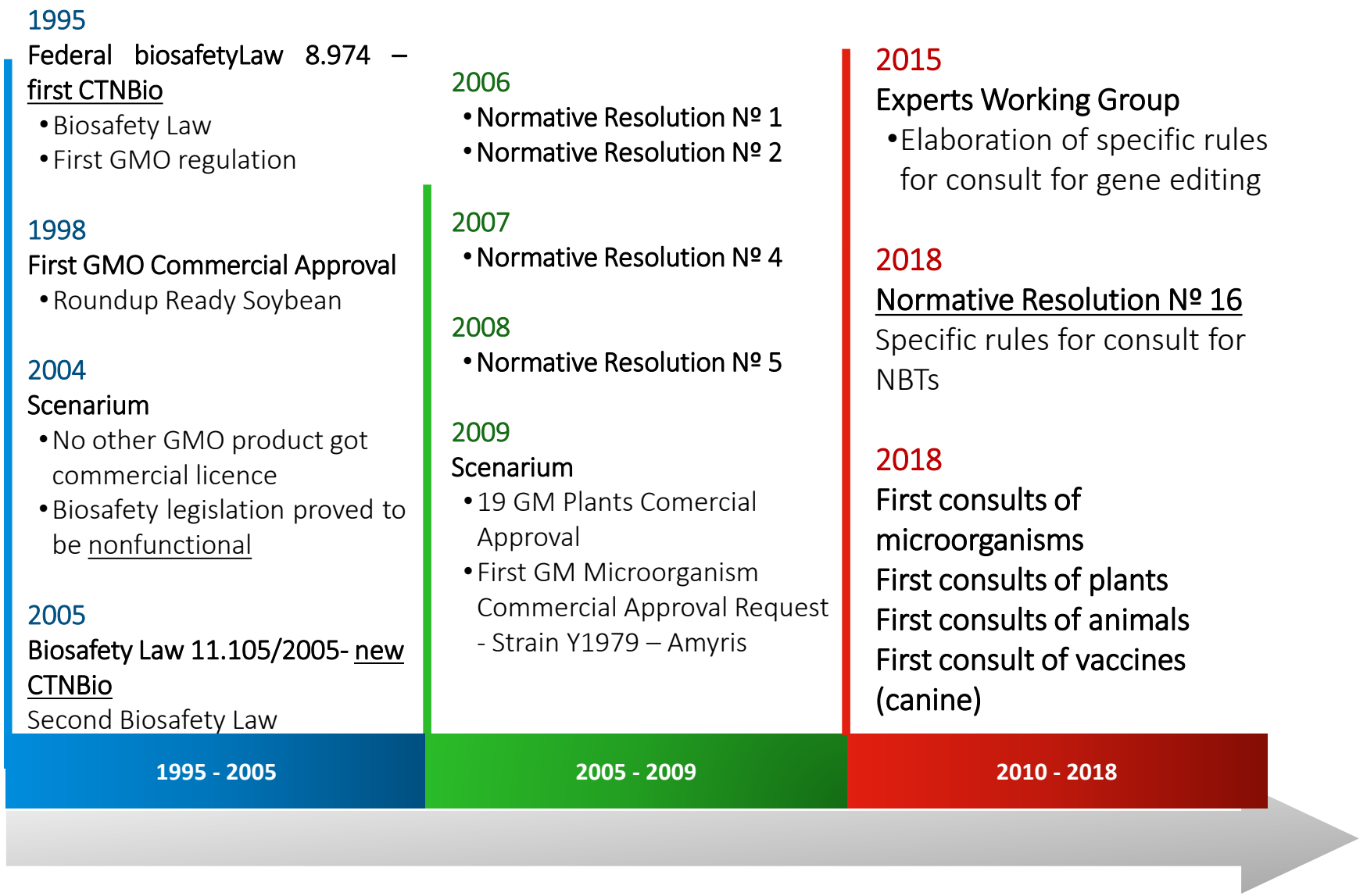
University of São Paulo, Brazil

Member of CTNBio

comissão técnica nacional
CTNBio
de biossegurança

Brazilian Biosafety Regulation

Historical context of GMO and Gene-editing Regulation in Brazil



CTNBio
National Technical Commission of Biosafety of Brazilian Ministry of Science, Technology and Innovation (MCTI).

- **Law 11.105 – March 24, 2005**
- 54 members (27 members and 27 alternates), all scientists holding a PhD title.
- All approvals need 14 votes

- Brazil signed the Cartagena Protocol in 2000.

Brazilian model of GMO regulation

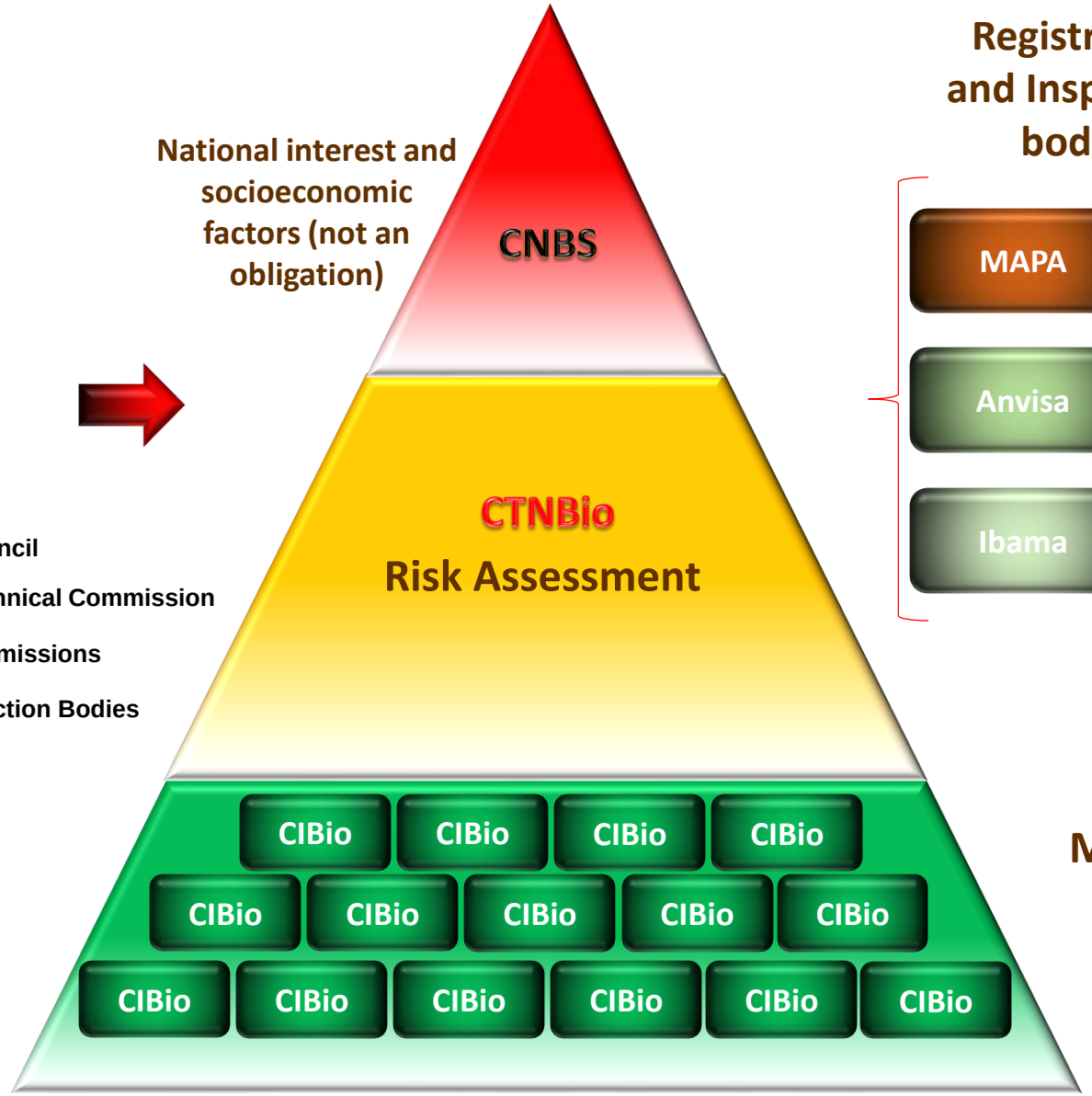
- Regulation of processes and products
- Science-based and case by case assessment
- The same biosafety law and rules for plants, microorganisms, vaccines, animals, insects, gene therapies.
- **Robust** and **transparent** technical assessment.

Brazilian model of GMO regulation

- All institutions that work with GMOs need to obtain a CQB (Certificate of Quality in Biosafety) and create a CIBio (Internal Commission of Biosafety) with approapriate members.
- **Projects** - CTNBio evaluates the laboratories, their researchers, technicians and students, level of biosafety.
- **Planned releases** to the environment
- **Commercial releases**

Brazilian Biosafety Law 11.105

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



comissão técnica nacional
CTNBio
de biossegurança

ctnbio.mctic.gov.br/inicio

Comissão Técnica Nacional de

Biossegurança

MINISTÉRIO DA CIÊNCIA, TECNOLOGIA, INOVAÇÕES E COMUNICAÇÕES

INSTITUCIONAL

A CTNBio

Secretaria Executiva

Processo de OGM

Reuniões

Atas

Pautas

Deliberações

Calendários das Reuniões

Relatórios Anuais

Audiência Pública

Contato

CIBIO

Instituições Cadastradas

Comunicados das CIBios

SERVIÇOS DA CTNBIO

Avisos

Livro CTNBio 25 Anos

No link abaixo, acesse o Livro "CTNBio 25 anos - Comissão Técnica Nacional de Biossegurança sob o olhar de seus presidentes". Livro CTNBio 25 Anos

Visualizar »

Sessão Solene em Comemoração à 250ª Reunião Ordinária da CTNBio

Acesse https://youtu.be/YbpMCGdDpb4

Visualizar »

Suporte ao SIB - Sistema de Informações em Biossegurança

Em caso de dúvidas, informações e qualquer necessidade de suporte em relação ao SIB, entre em contato pelo e-mail sib@mcti.gov.br

Visualizar »

Convite para o lançamento do livro "CTNBio 25 anos - Comissão Técnica Nacional de Biossegurança sob o olhar de seus presidentes"

A Comissão Técnica Nacional de Biossegurança - CTNBio e o Ministério da Ciência, Tecnologia e Inovações convidam para a sessão solene em comemoração da 250ª

Sistema De Informações Em Biossegurança - SIB

Clique AQUI para acessar o SIB .

Suporte ao SIB: sib@mcti.gov.br

Destaques

O Presidente da CTNBio, Paulo Augusto Viana Barroso, recebe título de "Cidadão Honorário do Município de Catuti".

/documents/566540/0/Homenagem+CTNBio.pdf/eae53878-e8ab-412e-a8a0-6b5178d2221a

Ler mais »

Walter Colli recebe o título de Professor Emérito da

CTNBio 25 anos

Comissão Técnica Nacional de Biossegurança sob o olhar de seus presidentes

Organizadores:
Paulo Augusto Vianna Barroso, Flávio Finardi e Isabela Sbampato


CTNBio 25
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Walter Colli
Ricardo Tostes Gazzinelli
Sergio Paulo Rudiowski
Ernesto Goulart
Fábio Lavorando
CTNBio
PÁTRIA AMADA BRASIL


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PAINEL 3
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CTNBio 25
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AGRICULTURA: IMPACTOS E PERSPECTIVAS
Adilson Paiva
Luiz Antonio Barreto de Castro
Marcos Fava
Francisco Aragão
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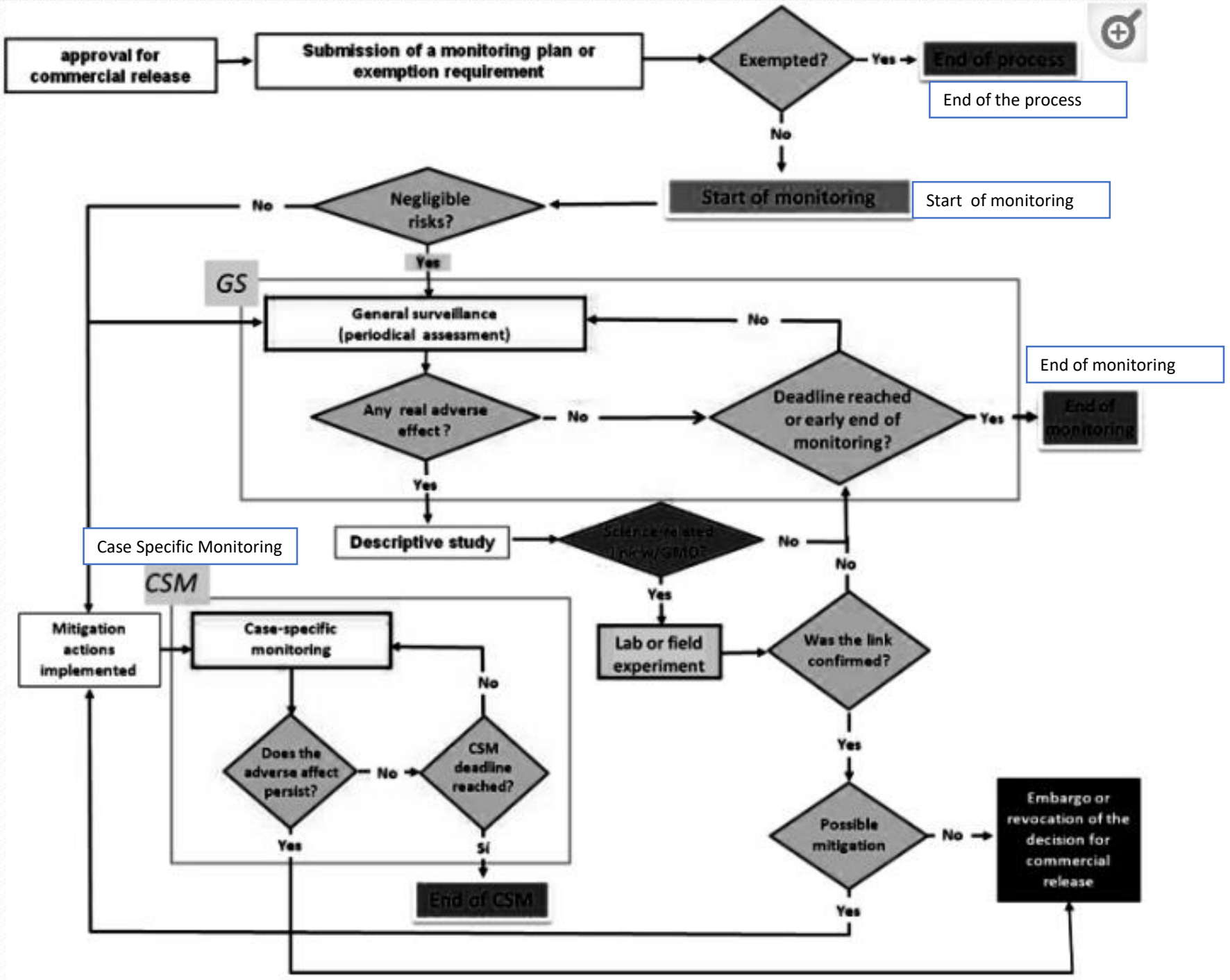
CTNBio
PÁTRIA AMADA BRASIL

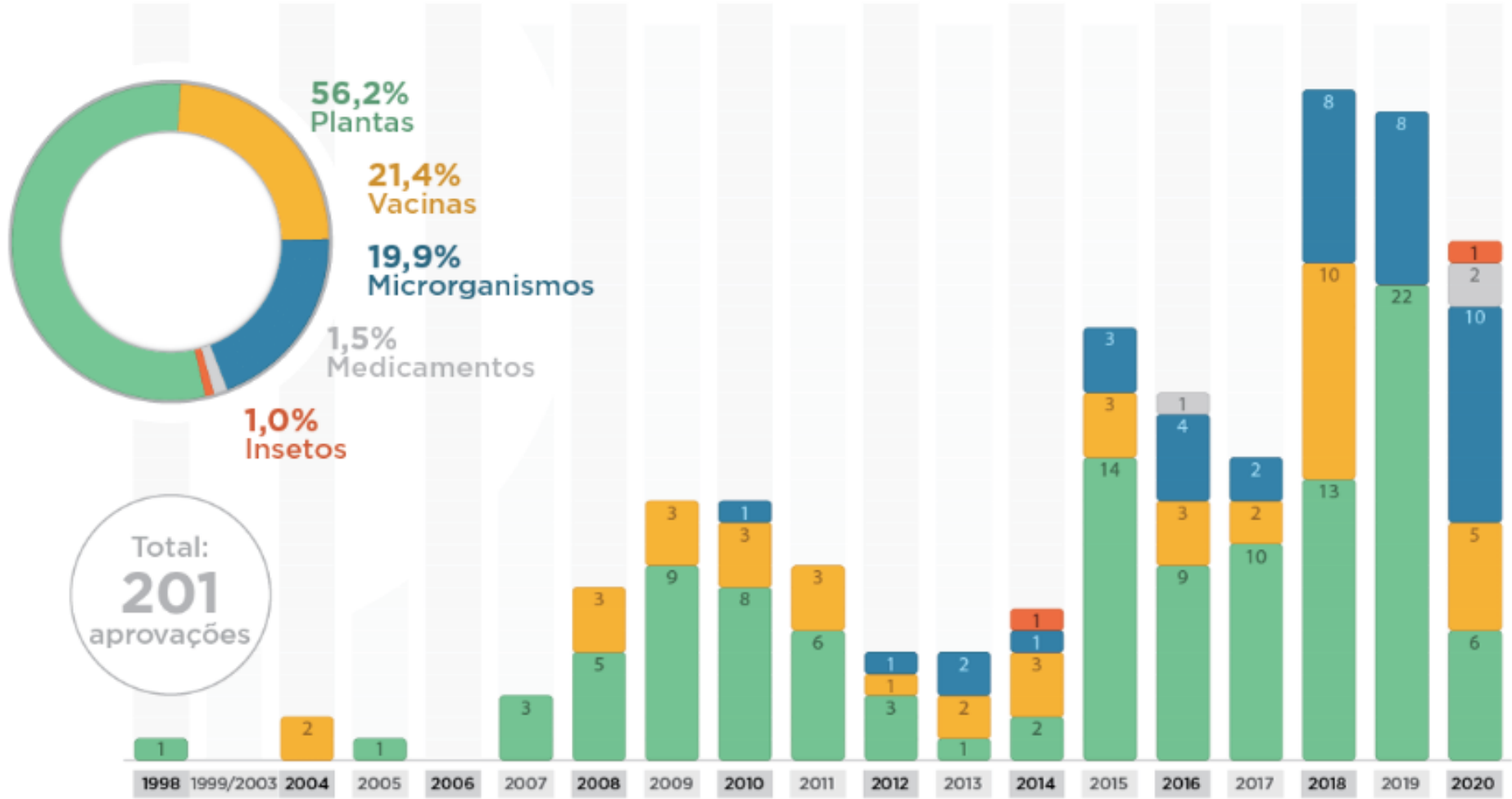


Andrade et al.,Transgenic Res. 2014

TOTAL GMO APPROVALS IN BRAZIL

- **104 genetically modified plants** (54 corn, 23 cotton, 18 soybeans, 6 sugar cane, 2 eucalyptus and 1 common bean),
- **50 recombinant vaccines** for dogs, cats, poultry, pigs, equines, tilapias
- **2 genetically modified mosquitos**
- **1 moth** (genetically modified *Spodoptera frugiperda*)
- **1 atlantic salmon (AquaBounty)**
- **42 genetically modified microorganisms**.
- All information can be accessed at CTNBio's website http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo

APROVAÇÕES CTNBIO



Fonte: CTNBio, 2020

CropLife BRASIL

Transgenic mosquitos

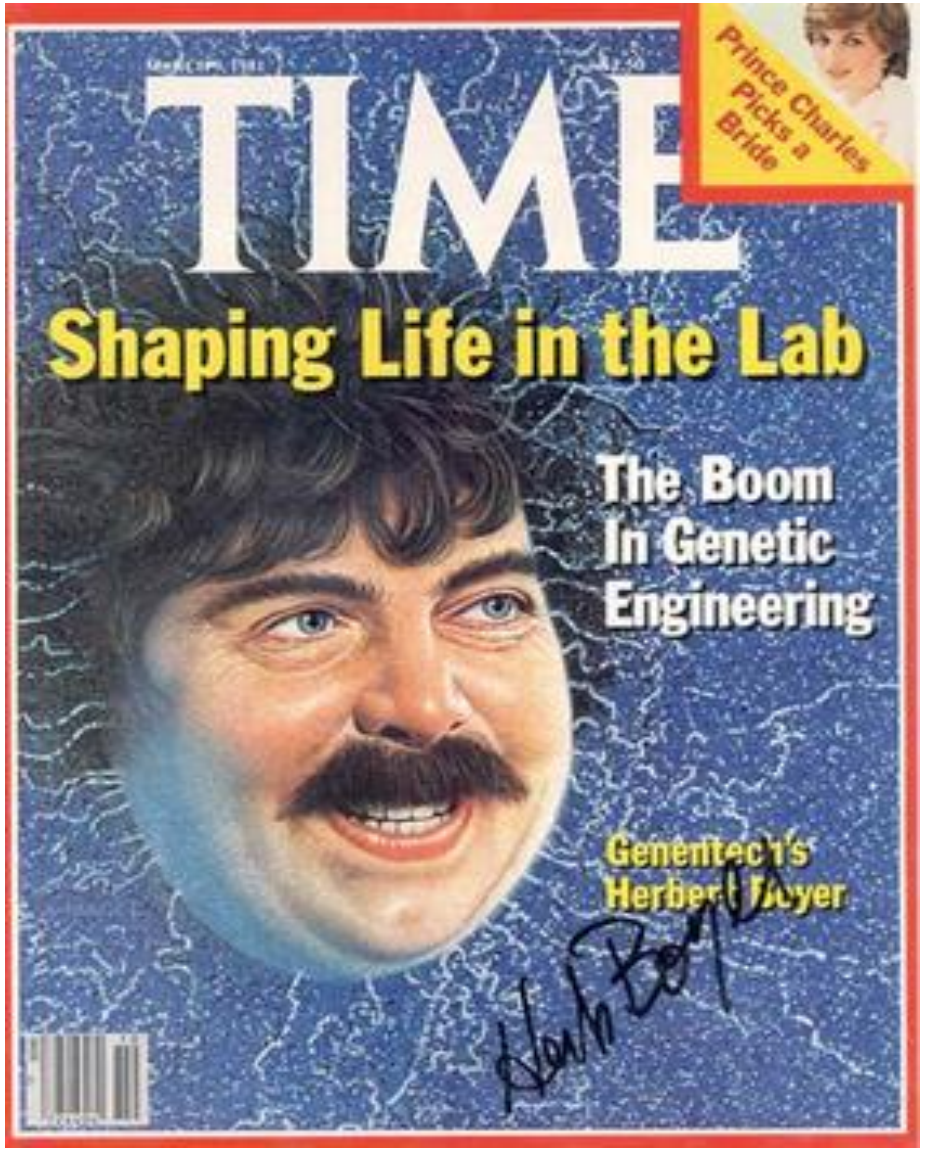
- **2014 -** OX513A de Aedes aegypti
- **2020 –** Oxitec OX5034 Aedes aegypti , linhagem de 2nd generation

GM gene therapies

- **LUXTURNA** (voretigene neparvovec): gene therapy indicated for the treatment of adult and pediatric patients with vision loss due to hereditary retinal dystrophy by biallelic mutation of RPE65 gene (Novartis);
- **Zolgensma**: gene therapy for the treatment of pediatric patients with spinal muscular atrophy (Novartis);
- **Lamzede**: commercial name of the active component alphavelmanase, which is a human recombinant alpha-mannosidase, indicated for the treatment of adult and pediatric patients suffering from the deficiency of the lysosomal enzyme alpha-mannosidase (Chiesi Farmacêutica Ltda.);
- **Kymriah®**, tisagenleleucel (CTL019) leukemia treatment B-cell acute lymphoblastic (ALL) refractory and post-transplant recurrence, second relapse or relapse later. (Novartis)
- **ciltacabtagene autoleuce** (cilta-cel, JNJ-68284528), indicated for the treatment of multiple myeloma, CAR-T treatment, Janssen

2021 – VACCINES for COVID 19

- Pfizer
- Jenssen - Cilag
- Sputnik
- Astrazeneca/Oxford
- Biomanguinhos (Fiocruz, Brazil).



1972-1973 – first recombinant DNA techniques

- **Herbert Boyer ,**
- **Stanley Cohen and PAUL BERG**

2013 – CRISPR – CAS 9

‘‘clustered regularly interspaced short palindromic repeats’’ associated nuclease system (CRISPR/Cas9)

MICHELLE CHARPENTIER
JENIFFER DOUDNA

Legal definition of GMO according to the Brazilian biosafety Law 11.105/2005

Genetically modified organism

Genetically modified organism - GMO refers to an organism whose genetic material, DNA/RNA, has been altered by any **genetic engineering technique;**

Genetic engineering

Genetic engineering refers to the production and manipulation of **recombinant DNA/RNA molecules**;

Recombinant DNA/RNA

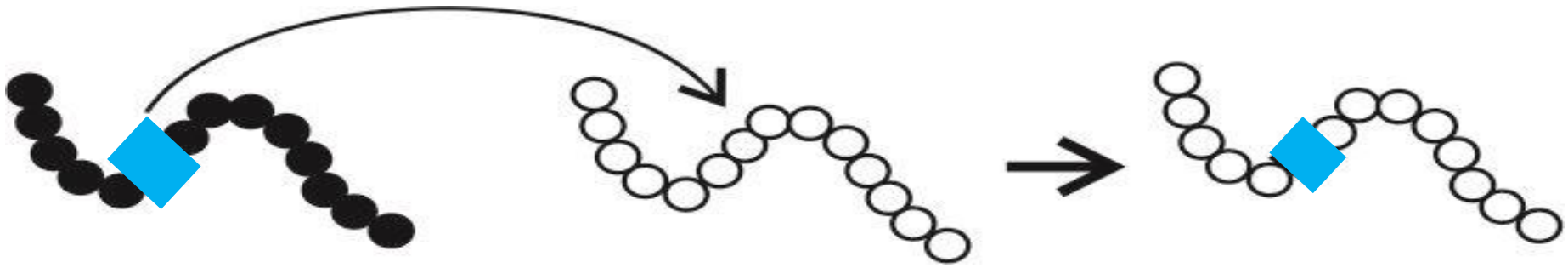
Molecules that are **manipulated outside living cells** by altering natural or synthetic DNA/RNA segments and that can **multiply themselves in a living cell,** or the DNA/RNA molecules resulting from this multiplication; they also refer to the synthetic DNA/RNA segments equivalent to natural DNA/RNA segments

“GMO ”

Modern biotechnology application

New combination of genetic material

Transgenesis



DNA 1

1 Donor organism **Desired feature**

DNA 2

2 Receiving organism

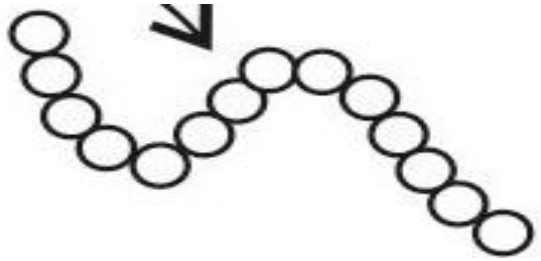
DNA 2 + gene DNA1

3 **product**

“**Genome** editing”

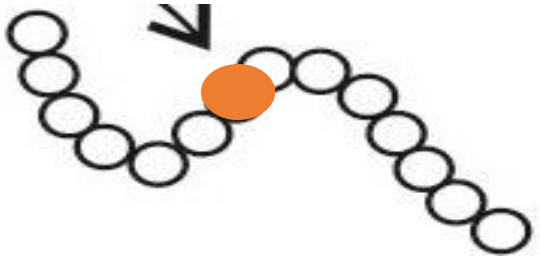
Modern biotechnology application

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



1 Organism ***receiver***

Gene editing techniques



2 Gene editing ***product***

Current policy for genome-edited organisms in Brazil – CTNBio and the Normative Resoution 16.

Normative Resolution 16, from January 2018.

Front. Agr. Sci. Eng. 2020, 7(2): 204–210
https://doi.org/10.15302/J-FASE-2019301

Available online at http://journal.hep.com.cn/fase

REVIEW

Brazilian biosafety law and the new breeding technologies

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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;

NORMATIVE RESOLUTION No. 16, OF JANUARY 15, 2018

Sets forth the technical requirements for submitting an inquiry to the CTNBio concerning Precision Breeding Innovation Techniques.

THE NATIONAL BIOSAFETY TECHNICAL COMMISSION (CTNBio), using its legal and regulatory powers and in observance of sections XV and XVI of article 14 of Law No. 11.105 of March 24, 2005;

Whereas there is a need to assess Precision Breeding Innovation (PBI) techniques, which also comprise the so-called New Breeding Technologies (NBTs) in the light of Law No. 11.105 of March 24, 2005;

Whereas Law No. 11.105, of 2005 defines recombinant DNA/RNA molecules, genetic engineering, and genetically modified organism (GMO) in Article 3, sections III, IV and V, respectively;

Whereas these PBI techniques are based on a set of new methodologies and approaches–that differ from the transgenic genetic engineering strategy that results in the absence of recombinant DNA/RNA in the final product;

Whereas the PBI techniques can introduce innovative uses of molecular biology tools, which can result in:

1. Precise edition of genomes, by the induction of specific mutations, generating or modifying wild and/or mutated alleles without insertion of transgene(s);

2. Genetic transformation and/or control of gene expression (activation/inactivation);

3. Epigenetic regulation of gene expression by natural mechanisms with no genetic modification in the individual;

4. Genetic transformation and/or control of gene expression with genes of sexually compatible species;

5. Temporary and non-inheritable genetic transformation of cells and tissues;

6. Permanent or non-host infection of genetically modified viral elements;

7. The creation of alleles with autonomous inheritance, and recombination potential with the possibility of altering a whole population (gene drive);

8. The construction of heterologous genes or new copies of homologous genes.

Paragraph 2. The cases to be classified are not restricted to the technologies described in Annex I, since the ongoing and fast progress of different technologies will lead to new products, to which the provisions of this Normative Resolution shall also apply.

Paragraph 3. The products referred to in the main section of this article show at least one of the following characteristics:

I – Product with proved lack of recombinant DNA/RNA, obtained with a technique using parental GMO;

II – Product obtained through a technique using DNA/RNA which will not multiply in a living cell;

III – Product obtained by a technique which introduces site-directed mutations producing genic function gain or loss, but proved absence of recombinant DNA/RNA in the product;

IV - Product obtained by a technique in which there is temporary or permanent expression of recombinant DNA/RNA molecules, but no presence or introgression of these molecules in the product; and

V - Product which uses techniques employing DNA/RNA molecules that do not modify permanently a plant's genome when in contact, or systemically or non-systemically absorbed by it.

ANNEX I

"New Precision Breeding Innovation (PBI) Techniques" - Examples

TECHNIQUE	SUMMARY
1. Precocious flowering	1.1 Silencing and / or super-expression of genes related to flowering by inserting genetic modification into the genome and subsequent separation or through transient expression by viral vector.
2. Seed Producing Technology	2.1 Inserting fertility-restoring genetic modification in naturally male-sterile lines in order to multiply these lines maintaining the male-sterile condition but not transmitting the genetic modification to descendants.
3. Reverse breeding	3.1 Inhibiting meiotic recombination in heterozygous plants selected for the trait of interest in order to produce homozygous parental lines.
4. RNA-dependent DNA methylation	4.1 Methylation driven by RNA interference ("RNAi") in RNAi homologous promoter regions in order to inhibit target gene transcription in live beings.
5. Site-Directed Mutagenesis	5.1. Protein or riboprotein complexes capable of causing site directed mutagenesis in microorganisms, plants, animals, and human cells.
6. Oligonucleotide Directed Mutagenesis	6.1 A synthesized oligonucleotide containing one or a few nucleotide alterations complementary to the targeted sequence, on being introduced into the cell, may cause substitution, insertion or deletion in the target sequence through the cellular repair mechanism (microorganisms, plants, animals, and human cells).
7. Agroinfiltration / agroinfection	7.1 Foliage (or other somatic tissue) infiltrated with Agrobacterium sp. or gene constructs containing the gene of interest to obtain a temporary expression at high levels located in the infiltrated area or with viral vector for systemic expression without the modification being transmitted to subsequent generations
8. Topical/systemic use RNAi	8.1 Use of double-stranded RNA ("dsRNA") with targeted-gene homologous sequence specifically silencing this gene or genes. Engineered dsRNA molecules may be introduced/absorbed into the cell from the environment.
9. Viral vector	9.1 Inoculation of live beings with recombinant viruses (DNA or RNA) expressing the genetic modification and amplification of the gene of interest through viral replication mechanisms without host genome modification.

Letter of inquiry (Normative Resolution 16)

In order to define if a product obtained by PBI would or not be considered a GMO and its derivatives, the applicant must submit a letter of inquiry to CTNBio (NR16), clarifying…….

In relation to original organism (Parentals), indicate:

- identification of the genetic technology, purpose and intended use of the resultant organism and its derivatives
- taxonomic classification, from family to the most detailed level of the organism to be released
- The risk classification of the parental
- the gene(s) and/or manipulated genetic element(s), organism(s) of origin and their specific functions, where applicable
- the genetic strategy(ies) used to produce the modification(ions) desired; the genetic map(s) of the constructs used in the process, indicating all the genetic elements present
- molecular characterization of the result in the recipient organism (parental and final product), where applicable, providing information related to: (a) number of copies manipulated; (b) location of the manipulated region in the genome, when possible; and (c) identification of the presence of off-target genetic modifications, if any
- the product of expression of the genomic region(s) manipulated, described in detail, when applicable

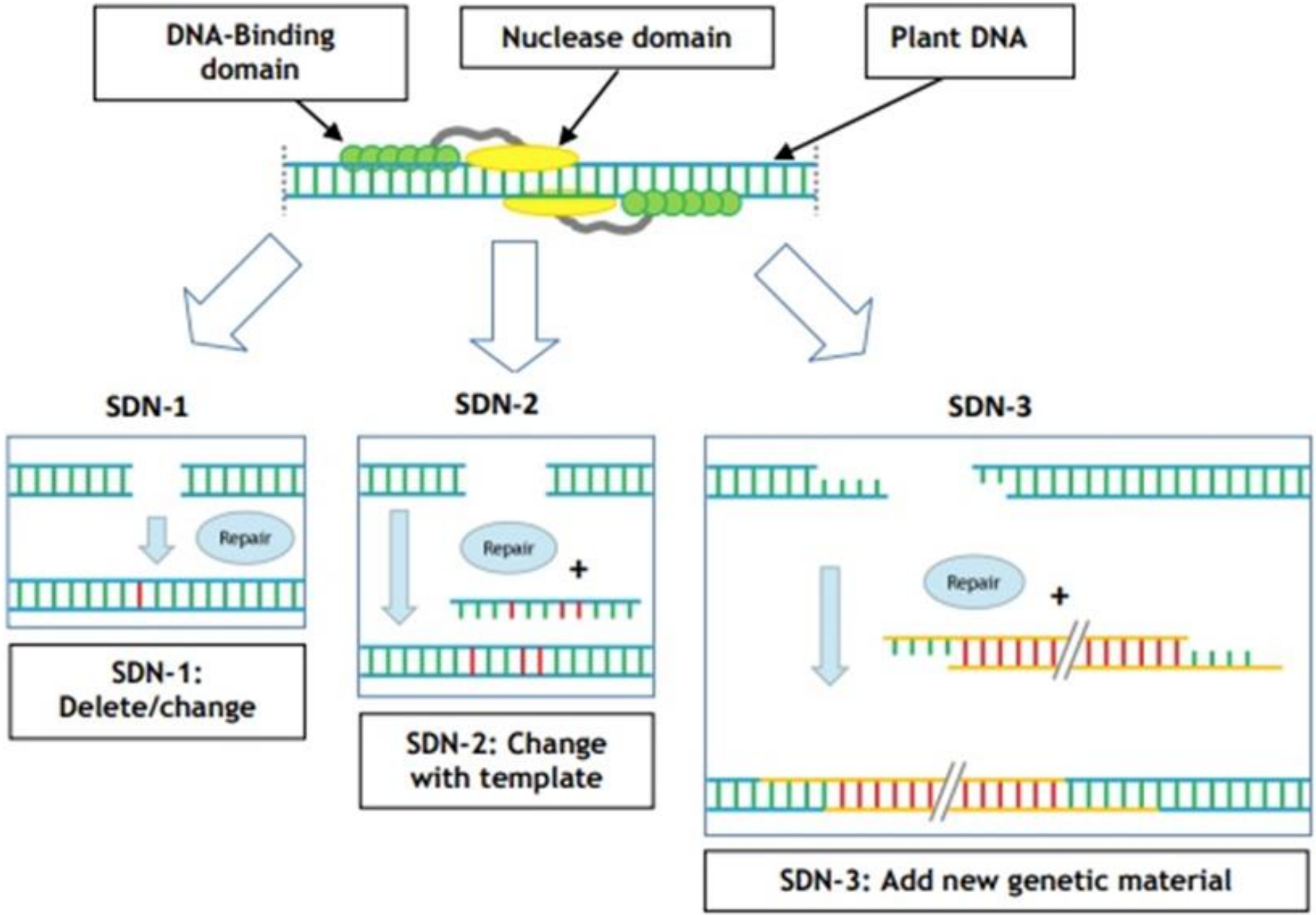
In relation to the product (descent, line or final product), indicate:

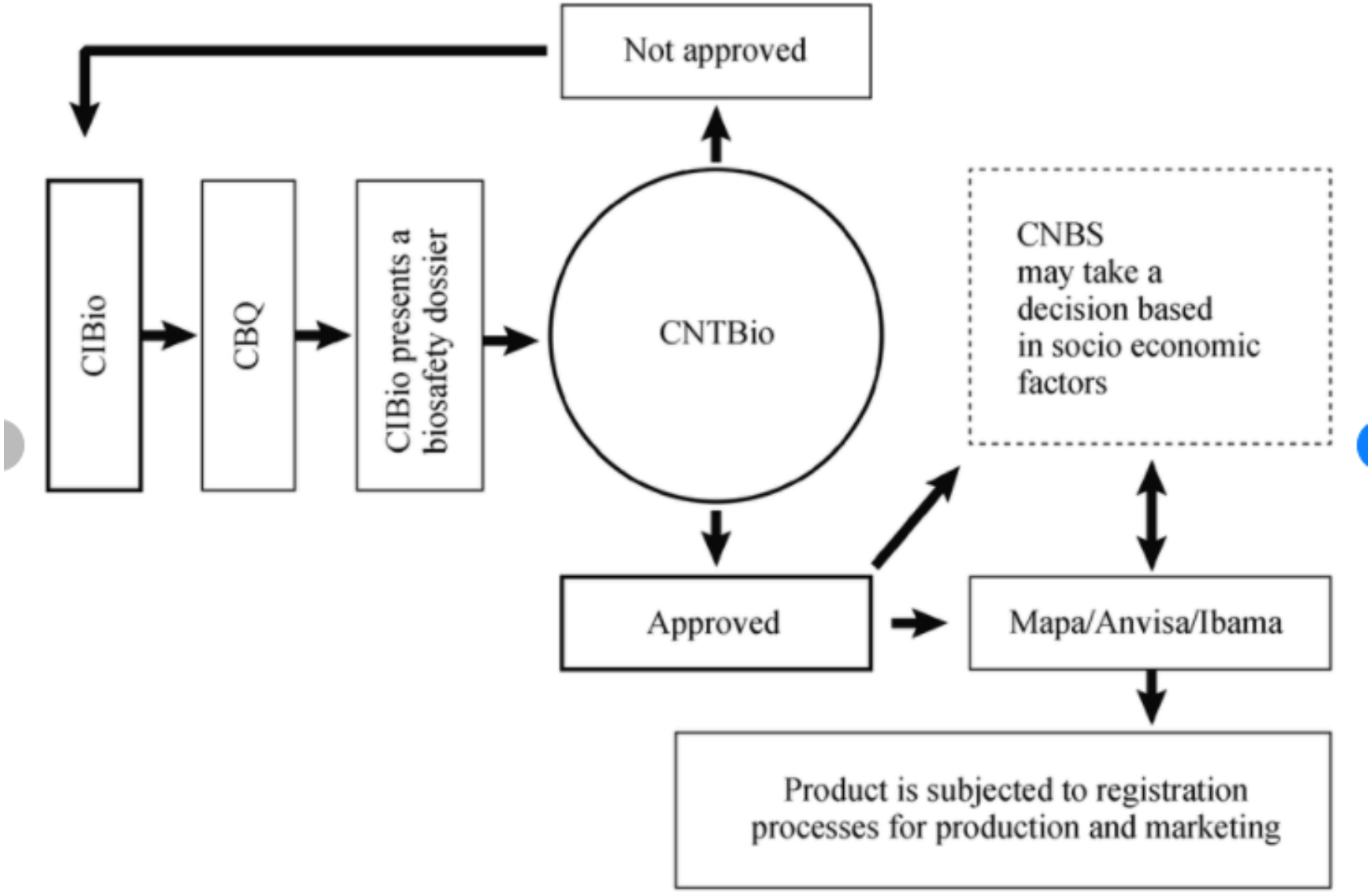
- evidence of the absence of recombinant DNA/RNA molecules through the use of molecular methods
- if the product containing DNA/RNA molecules for topical/systemic use has recombinant ability to insert into the target species and/or into non-target species
- whether the product referred to in the submission has been commercially approved in other countries
- if the product uses the principle of gene drive that may enable the phenotypic change conferred to be potentially disseminated throughout the recipient organism's population. In this case, explain the care to monitor the organism, using at least two different strategies;
- how the possibility of any off-target effects of the technology that may be present in the product was evaluated

Analysis of GMOs X Non-GMO organisms
Principles of Normative Resolution 16

- Letter of inquiry to CTNBio on the legal framework of the product
- Description of the Parental and Product
- Description of the technique employed
- **Precaution regarding** "Gene drive"
- **Precaution regarding** "off target" effects
- Principle of the case-by-case analysis

Conclusion of the inquire: whether product is a GMO or not according to the Brazilian Biosafety Law 11.105.

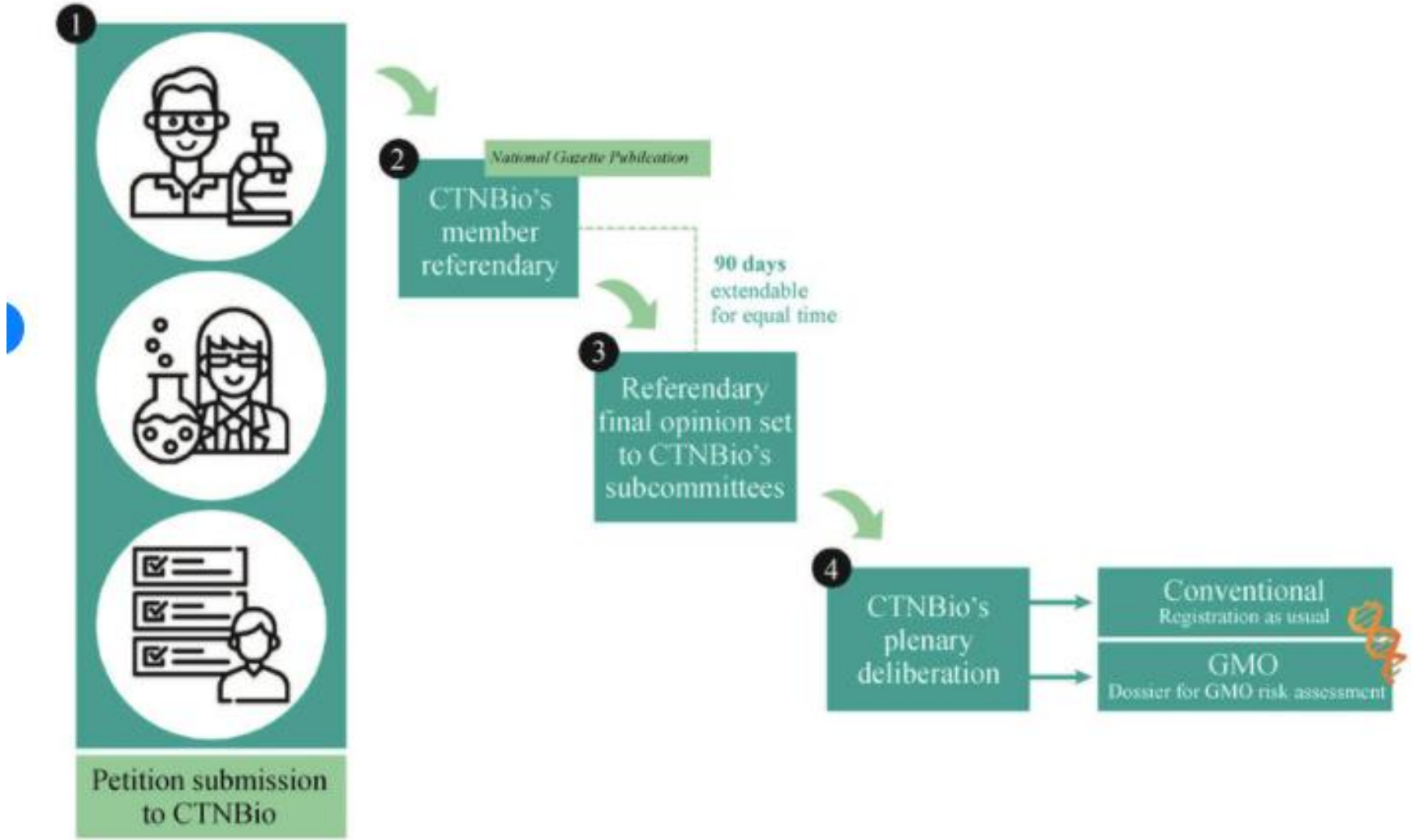

DNA-Binding domain
Nuclease domain
Plant DNA
SDN-1
SDN-2
SDN-3
Repair
Repair
Repair
+
+
SDN-1: Delete/change
SDN-2: Change with template
SDN-3: Add new genetic material



General procedure for a case-by-case consultation at CTNBio for a product generated by INIT, according to Normative Resolution No. 16. If the product is designated to be GM, the developer will have to go through all the biosafety requirements and will be approved only after the CTNBio risk assessment. If the product is designated as not GM (for the purposes of the legislation), it can be registered using the existing procedures.

Plant breeding innovation

CTNBio Normative Resolution No. 16 of January 15, 2018



Workflow representing the approval process of GMOs for commercial release according to the Brazilian Biosafety Law No. 11.105/2005 and its Normative Resolutions.

24 products considered as non-GMOs by CTNBio so far

- 10 yeasts for the production of etanol (*Saccharomyces cerevisae*)
- Waxy Corn - result of larger amounts of amylopectin
- Sugar cane (2 varieties, EMBRAPA)
- Low raffinose soy beans
- Canine parvovirus vaccine (Ourofino company, Brazil)
- 1 fish – **Acquabounty - tilapia**
- Sperm from a Nelore cattle – increased muscle – edited myostatin gene (Acceligen)
- **Hornless Cattle** – (Agropartners Consulting) - CANCELLED

Tilapia - Acquabounty

- *Oreochromis niloticus*
  - The Tilapia FLT-01 "Extra fillet" has an increase in fillet yield
  - It is obtained by knocking out an endogenous gene that causes the loss of the function of a negative regulator of muscle growth. 26 bp deletion in the gene of interest.
  - The edited tilapia shows an increase in muscle mass, showing a greater weight and yield of the fillet in comparison with its counterpart without editing.

Tilapia - Acquabounty

- *Oreochromis niloticus*
- Considered as Non-GMO by CTNBio

Hornless cattle

BURI
may 2018
Alison Van Eenennaam
University of California-Davis

Buri was developed by combining innovative precision breeding (TIMP) and targeted gene editing (HDR) techniques. The bull and his semen were bred by the Acceligen company (a subsidiary of the US-based company Recombinetics Inc.

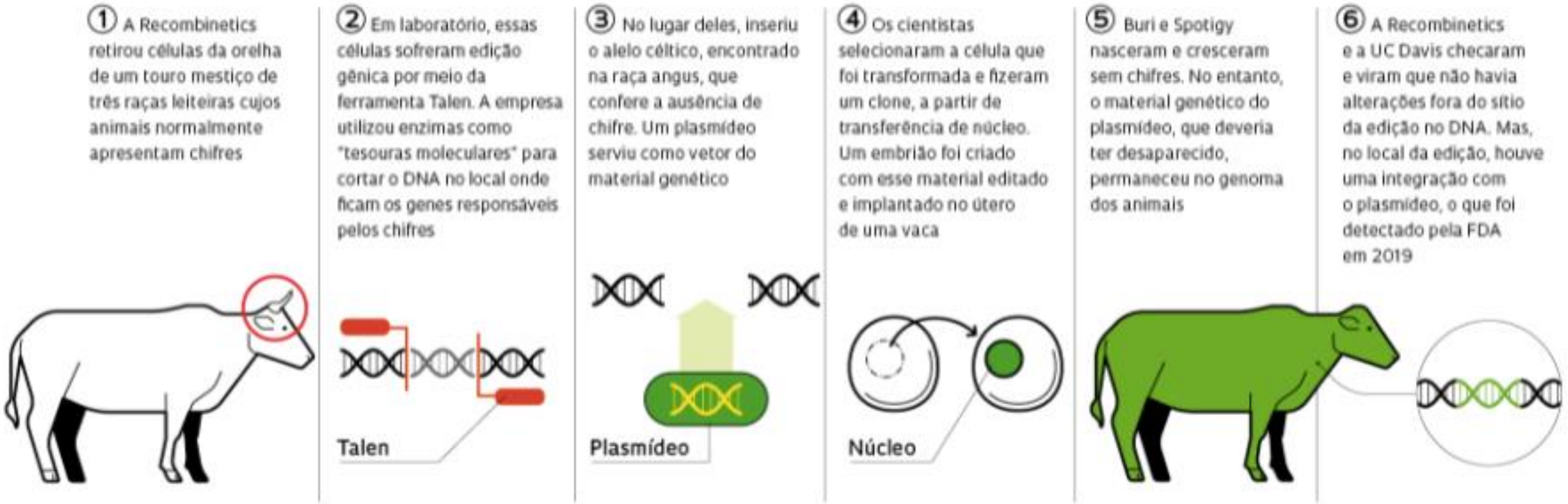
CARLSON, D. F. *et al*. Production of hornless dairy cattle from genome-edited cell lines. **Nature Biotechnology**. n. 5, p. 479-81. 2016.

CONTROL

PRINCESS

Princess, daughter of Buri at the University of California, Davis
Alison Van Eenennaam/University of California-Davis

A plasmid in the bull's genome



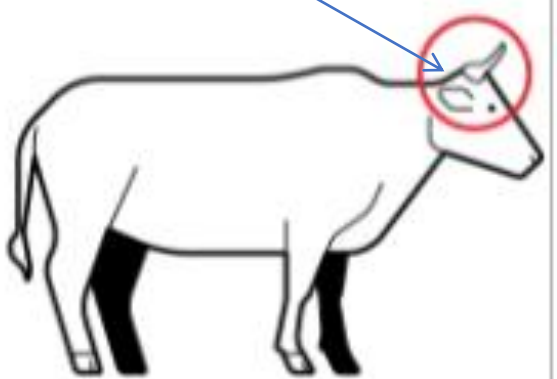
https://revistapesquisa.fapesp.br/um-engasgo-cientifico/#:~:text=O%20ano%20de%202019%20ainda,pesquisas%20no%20campo%20da%20biologia

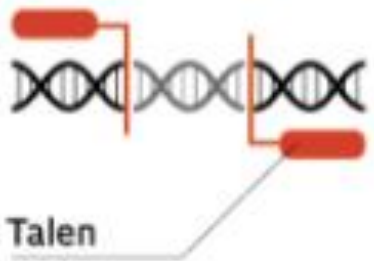
① A Recombinetics retirou células da orelha de um touro mestiço de três raças leiteiras cujos animais normalmente apresentam chifres

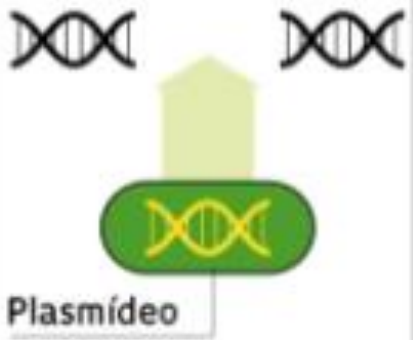
② Em laboratório, essas células sofreram edição gênica por meio da ferramenta Talen. A empresa utilizou enzimas como "tesouras moleculares" para cortar o DNA no local onde ficam os genes responsáveis pelos chifres

③ No lugar deles, inseriu o alelo céltico, encontrado na raça angus, que confere a ausência de chifre. Um plasmídeo serviu como vetor do material genético

fibroblasts





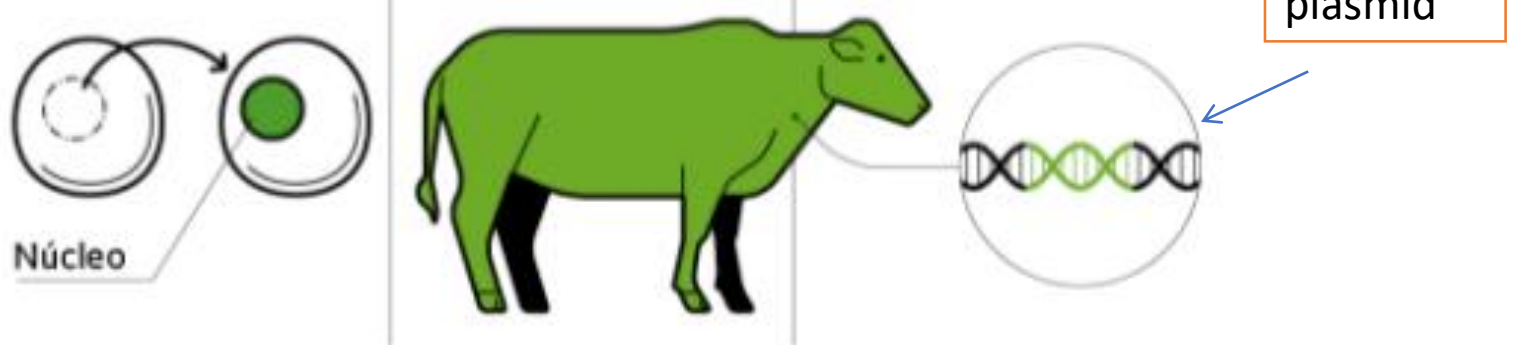


Celtic allele introgression
212 base pairs with 10 base pair deletion

④ Os cientistas selecionaram a célula que foi transformada e fizeram um clone, a partir de transferência de núcleo. Um embrião foi criado com esse material editado e implantado no útero de uma vaca

⑤ Buri e Spotigy nasceram e cresceram sem chifres. No entanto, o material genético do plasmídeo, que deveria ter desaparecido, permaneceu no genoma dos animais

⑥ A Recombinetics e a UC Davis checaram e viram que não havia alterações fora do sítio da edição no DNA. Mas, no local da edição, houve uma integração com o plasmídeo, o que foi detectado pela FDA em 2019



CTNBio analysed according to the RN16

- CTNBio concluded that Buri's semen is not a genetically modified organism (GMO), as described in article 3 of Law No. 11,105 of March 2005, Biosafety Law.
- The commission took into account the data available so far and pointed out that the inserted change, the silencing of the gene responsible for the appearance of the horns, occurs naturally in other cattle breeds.
- October 2018

FDA

FDA lab: Agency showed Buri's genome had plasmid genetic material
US Food and Drug Administration

Heather Lombardi: Apoio à edição gênica

Conclusion

- AgroPartners was preparing to import the semen when the discovery was announced by the US regulatory agency.
- "The São Paulo company learned of the FDA finding and informed CTNBio, requesting the cancellation of the process and informing that the bull's semen would not be imported."

YOUNG, A. E. *et al*. Genomic and phenotypic analyses of six offspring of a genome-edited hornless bull. **Nature Biotecnolgy**. Out. 2019.

NORRIS, A. L. *et al*. Template plasmid integration in germline genome-edited cattle. **bioRxiv**. On-line. 28 jul. 2019.

FDA NEWS RELEASE

FDA Makes Low-Risk Determination for Marketing of Products from Genome-Edited Beef Cattle After Safety Review

Decision Regarding Slick-Haired Cattle is Agency's First Enforcement Discretion Decision for an Intentional Genomic Alteration in an Animal for Food Use

For Immediate Release:

March 07, 2022

Today, the U.S. Food and Drug Administration announced it has made a low-risk determination for the marketing of products, including food, from two genome-edited beef cattle and their offspring after determining that the intentional genomic alteration (IGA) does not raise any safety concerns (low-risk determination). The IGA results in the equivalent genotype (genetic make-up) and short-hair coat trait seen in some conventionally bred cattle, known as a "slick" coat. This is the FDA's first low-risk determination for enforcement discretion for an IGA in an animal for food use.

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REVIEW

Towards progressive regulatory approaches for agricultural applications of animal biotechnology

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Abstract Traditional breeding techniques, applied incrementally over thousands of years, have yielded huge benefits in the characteristics of agricultural animals. This is a result of significant, measurable changes to the genomes of those animal species and breeds. Genome editing techniques may now be applied to achieve targeted DNA sequence alterations, with the potential to affect traits of interest to production of agricultural animals in just one generation. New opportunities arise to improve characteristics difficult to achieve or not amenable to traditional breeding, including disease resistance, and traits that can improve animal welfare, reduce environmental impact, or mitigate impacts of climate change. Countries and supranational institutions are in the process of defining regulatory approaches for genome edited animals and can benefit from sharing approaches and experiences to institute progressive policies in which regulatory oversight is scaled to the particular level of risk involved. To facilitate information sharing and discussion on animal biotechnology, an international community of researchers, developers, breeders, regulators, and communicators recently held a series of seven virtual workshop sessions on applications of biotechnology for animal agriculture, food and environmental safety assessment, regulatory approaches,

Table 1 Approaches to oversight of food safety of products of animal biotechnology in selected countries and supranational groups

Country/ Union	Regulatory agency	Regulatory policy for GM animals?	Consistent with Codex Alimentarius?	GM animal product approved for food?	Regulatory policy for GnEd animals?	Supporting presentation or reference
Argentina	SENASA[a]	Yes	Yes	No	Yes[b]	Maggi (2020) and Whelan (2020)
Australia/ New Zealand	Food Standards Australia New Zealand	Yes, Food Standards Australia New Zealand Act 1991	Yes	No	No; Code under review	Kelly (2020)
Brazil	CTNBio[c]	Yes, Biosafety Law 11,105, 2005; also see 28 Normative Resolutions	Yes	Yes	Yes	Finardi (2020)
Canada	Canadian Food Inspection Agency, Health Canada, othersd	Yes	Yes	Yes	NA[e]	Cianciarelli (2020)
Japan	Ministry of Health, Labor, and Welfare	Yes	Yes	No	Yes	Tsuda and Ohsawa (2020)
Philippines	Department of Agriculture, Bureau of Animal Industry	No	Yes	No	No	Mingala (2020)
South Africa	Department of Science and Innovation	Yes	Yes	No	No	Groenewald (2020)
United States	Department of Health and Human Services, Food and Drug Administration; others[f,g]	Yes	Yes	Yes	Yes	Kanelakis (2020)
African Union[h]	–	NA	NA	NA	NA	Nengomasha (2020)
European Union	European Food Safety Authority	Yes	Yes	No	No	EFSA (2012)

In conclusion

- CTNBio is a commission that, in Brazil, analyses both GMOs and genetically edited organisms.
- Transparent and robust, science-based.
- Ready to follow the innovations in biotechnology.

Thank you!

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CTNBio
Comissão Técnica Nacional de Biossegurança
25 Anos