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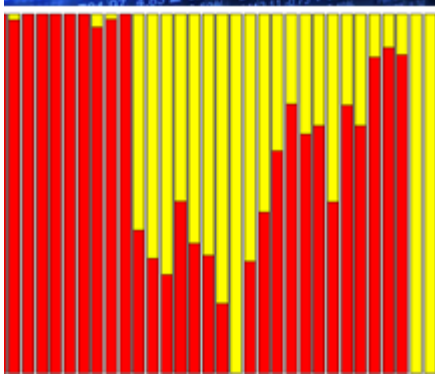

Virtual Workshop Series on Regulatory Approaches for Agricultural Applications of Animal Biotechnology

Session III: Environmental safety aspects of regulations for genetically engineered/modified animals

October 7th 2020

José Fernando Garcia
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Universidade Estadual Paulista - UNESP – BRASIL
IAEA Collaborating Centre on Animal Genomics and Bioinformatics

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ZGC Zebu Genome Consortium

Background in the Evolution of Science

- Scientific innovations are daily incorporated to technological repertoire
- Laws do not follow scientific progress
- It is impossible to “de-invent” something!
- Unlimited innovative capacity: science main feature!

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CTNBio motivation in 2016

- Need to evaluate the *"Precision Breeding Innovation"* (PBI)
- Involving the *"New Breeding Technologies*" – NBTs
- Framed on the legal definitions of Law 11.105/2005 (Biosecurity Act)

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Normative Resolution Nº 16
Técnicas Inovadoras de Melhoramento Genético - TIMP (PBI)

Resolução Normativa Nº 16, de 15 de janeiro de 2018

Imprimir

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 recombinante no produto final;

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TIMP/PBI

- TIMP/PBI encloses a group o new methodologies and approaches which differ from transgenic genetic engineering, **by resulting in the absence of recombinant DNA/RNA in the final product;**
- Legal definition of GMO is at the Article 3rd of the Biosecurity Act (2005)

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Biotechnological Novelties

Early flowering
Seed Production Technology
Reverse Breeding
RNA-dependent DNA methylation
Site-Directed Mutagenesis
Oligonucleotide Directed Mutagenesis
Agroinfiltration / agroinfection
Topical/systemic use RNAi
Viral vector
Other

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Normative Resolution Nº 16

Consultation Letter:

Asking if the PRODUCT generated by TIMP/PBI is framed in the legal definition of GMO (or derivatives) or not

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1. With regard to the original organism (Parentals), inform:

1.1 The identification of the **genetic technology**, purpose and intended use of the resulting organism and its derivatives;
1.2 The **taxonomic classification**, from family to the most detailed level of the organism to be released, including, when appropriate, subspecies, cultivar, patovar, strain and serotype;
1.3 The **risk classification** of the genetically modified organism in accordance with Normative Resolution No. 2 of November 27 2006
1.4 The **gene** (s) and / or **genetic element** (s) **handled**, the organism (s) of origin and their specific functions, where applicable
1.5 The **genetic strategy** (s) used to produce the desired modification (s); the genetic map (s) construction (s) used in the process indicating, with all genetic elements present;
1.6 The **molecular characterization** of the result of manipulation in the recipient organism (parent and final product), where applicable, providing information related to: (1) number of manipulated copies (e.g. number of genomic sequences, number of copies alleles, etc.); (2) location in the genome of the manipulated region, when possible; (3) identify the presence of genetic modifications off-target, where applicable.
1.7 The **product of expression** of the manipulated genomic region (s), described in detail, where applicable.

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2 With regard to the product (offspring, lineage or final product) inform:

2.1 **Proof of the absence of recombinant DNA / RNA molecules**, through the use of molecular methods.
2.2 Whether the product containing DNA / RNA molecules for topical / systemic use has the **recombinant ability to enter into the target species** and / or non-target species.
2.3 Whether **the product** covered by the application **is commercially approved** in other countries.
2.4 If **the product uses the principle of gene drive** (gene drive) that may allow the phenotypic change has the potential to spread throughout the population of the recipient organism, to spell out the using at least two different strategies.
2.5 **How was evaluated the possibility of possible unintentional (off-target) effe**cts of the technology product.

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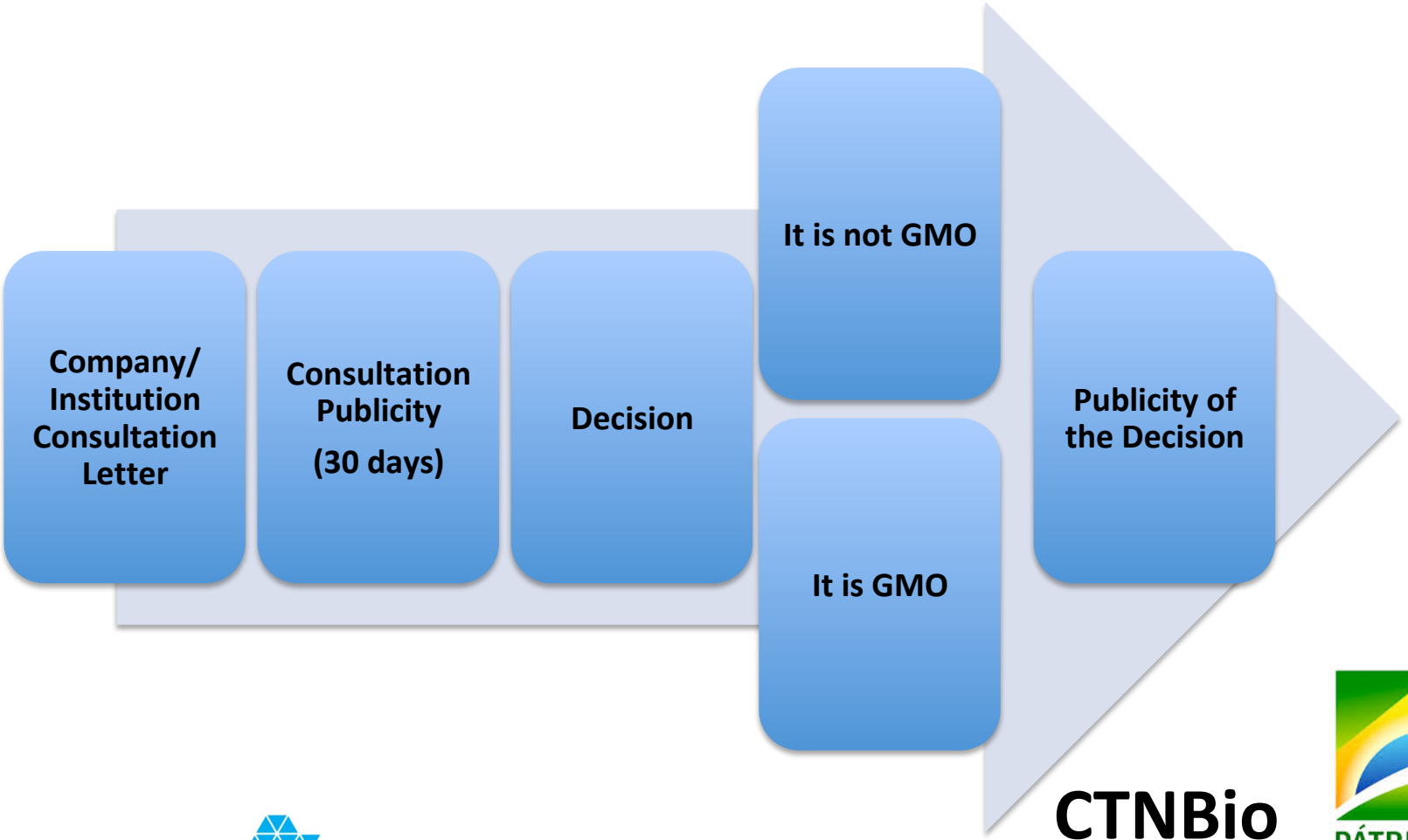
Procedures



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Normative Resolution Nº 16
CTNBio Decision

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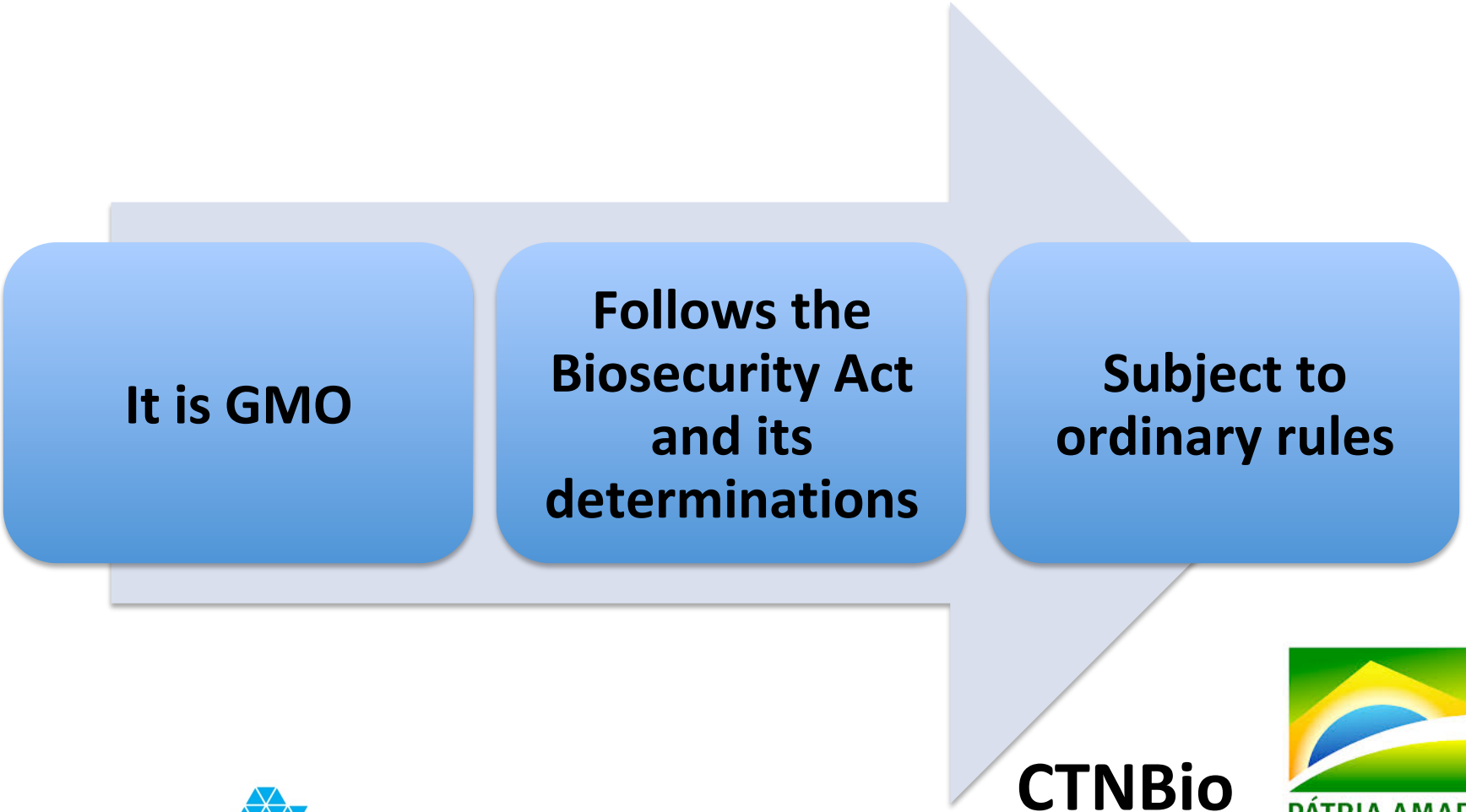
Normative Resolution Nº 16
CTNBio Decision: It is GMO



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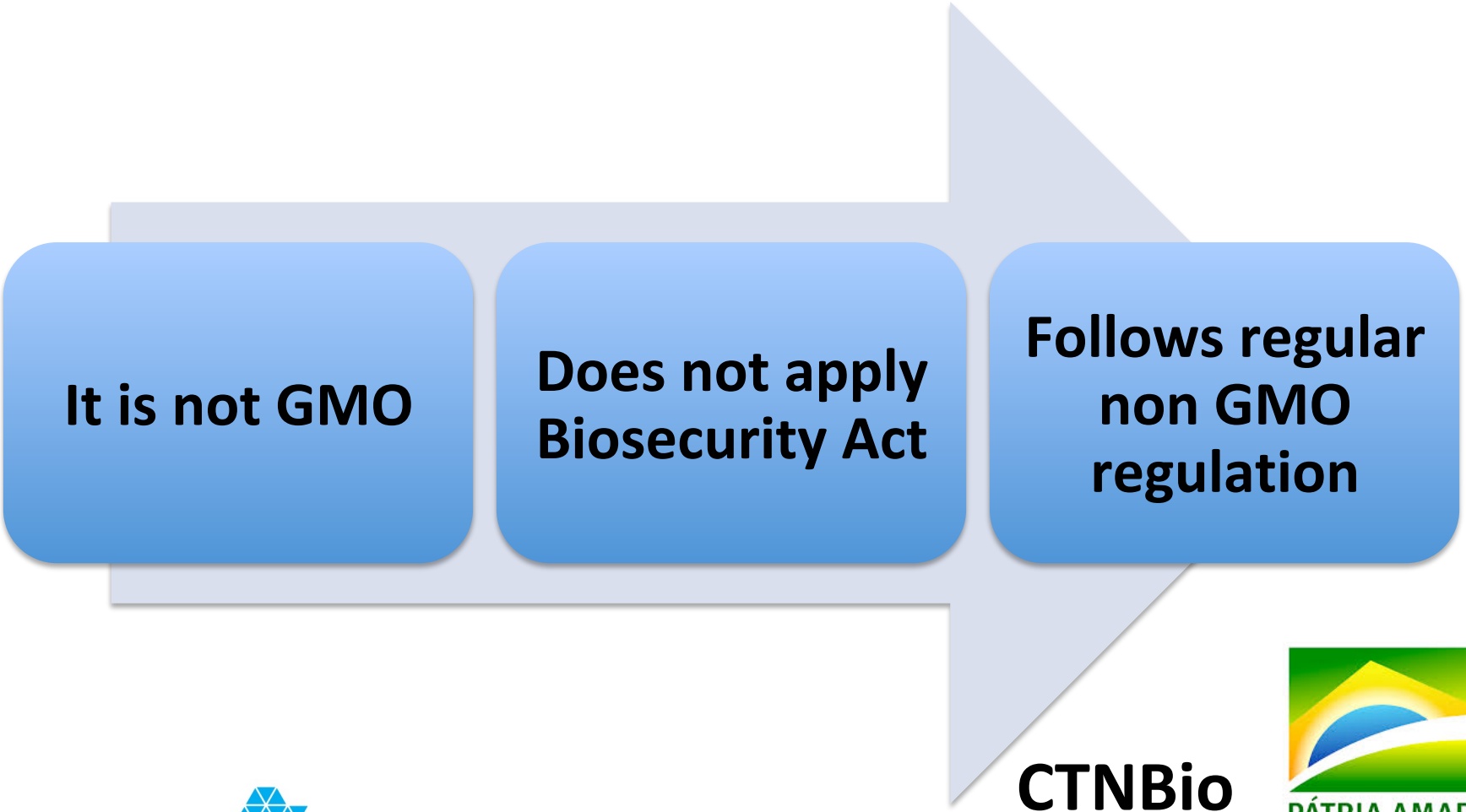
Normative Resolution Nº 16
CTNBio Decision: It is not GMO



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First Cases approved as Non GMO

Saccharomyces cerevisiae (bioethanol production)

E. coli for control of Salmonela infection in broiler birds (product added to wastewater)

Hornless Cattle (process canceled)

Tilapia fish (growth and yield)

Maize (starch)

Canine vaccine

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Normative Resolution Nº 16
CTNBio Principles

Prior inquire on the legal framework of the product

Parental and Product descriptions

Description of the technique (s) employed

Precaution with “Gene drive”

Attention to “off target” effects

Analysis “case-by-case”

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Thank You!

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