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Plant Breeding Innovation

Regulatory Aspects

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The Brazilian Biosafety Law

- Law nº 11.105, dated March 24th, 2005
- **Provides for safety norms and inspection mechanisms for activities with GMOs and their by-products**
- National Technical Biosafety Commission – CTNBio
- MAPA: Registration and Inspection

CTNBio

CHAPTER III

The National Biosafety Technical Commission (CTNBio)

Article 10. CTNBio, which is part of the Ministry of Science and Technology, is a consulting and deliberating multidisciplinary collegiate, that provides technical and assistance support to the Federal Government to formulate, update and implement the National Biosafety Policy for GMOs and their by-products, as well as establishes safety technical norms regarding the authorization of research-related activities and the commercial use of GMOs and their by-products, based on the evaluation of their zoo-phytosanitary, human health and environmental risk.

Sole paragraph. CTNBio shall monitor the development and technical-scientific progress attained by the biosafety, biotechnology, bioethics and related areas, with aims at increasing their capacity of protecting human, animal and plant health and the environment.

It is under CTNBio mandate evaluate how the PBI/NBT will impact Biosafety for the Environment and Human/Animal Health

CTNBio - Working Group to Study PBI under the Brazilian Legislation scope

STRATEGY:

Plant improvement based on new scientific knowledge

Legal framework that can allow scientific advances, and also assure environment and Human/Animal Health security.

Other countries experiences

Concepts clarity and a legal base that can allow juridical security in research and product development by the use of NBTs

CTNBio - Working Group PBI: Conclusion

- Focus on the Product not in the Process

- **Organisms without the presence (in the progeny) of recombinant AND/ARN or with the presence of genetic elements that can be obtained by conventional breeding.**

Technical and Scientific Criteria

- Modification Origin/Nature and inheritance;
- Possibility that the modifications made by NBTs could occur throughout conventional breeding or naturaly;
- Possible “off target” effects;
- Availability of detection/identification methods for the techniques used.

CTNBio - Working Group PBI: Suggestion of Procedures for Evaluation

Research remains following Brazilian Biosafety Regulation (Biosafety Law and CTNBio Normatives);

Previous consultation mechanism with the molecular characterization to demonstrate if the final product is a GMO or not based on the WG conclusions;

Basic Concepts maintained: case by case and risk assessment.

NBT technique	Progeny obtained by NBT is considered GMO acording to Brazilian Biosafety Law?
SDN-1 (ZFN, TALEN, CRISPR, MN)	Previous Consultation
SDN-2 (ZFN, TALEN, CRISPR, MN)	Previous Consultation
SDN-3 (ZFN, TALEN, CRISPR, MN)	Yes
ODM	Previous Consultation
RdDM	Previous Consultation
Reverse Breeding	Previous Consultation
SPT	Previous Consultation
EF	Previous Consultation
GM Rootstock Grafting	Yes
Cisgenic	Yes
Intragenic	Yes
Agro-infiltration/infection	Previous Consultation
Floral Dip	Yes
RNAi topic use	Previous Consultation
RNAi expressed	Yes
Synthetic Biology	Previous Consultation
Viral Vector	Previous Consultation

CTNBio – Working Group PBI: Previous Consultation Mechanism

Applicant has the information about which techniques would generate organisms/ products non GM according to the legislation;

Submission of Information for a “simplified” Risk Assessment Evaluation;

The information to be submitted is based in the description of the product, methods used to generate it, molecular data of parental and progeny proving absence of DNA/RNA recombinant fragments in the progeny, etc.

PROPOSAL UNDER ANALYSIS BY CTNBIO

Thank you for your attention!