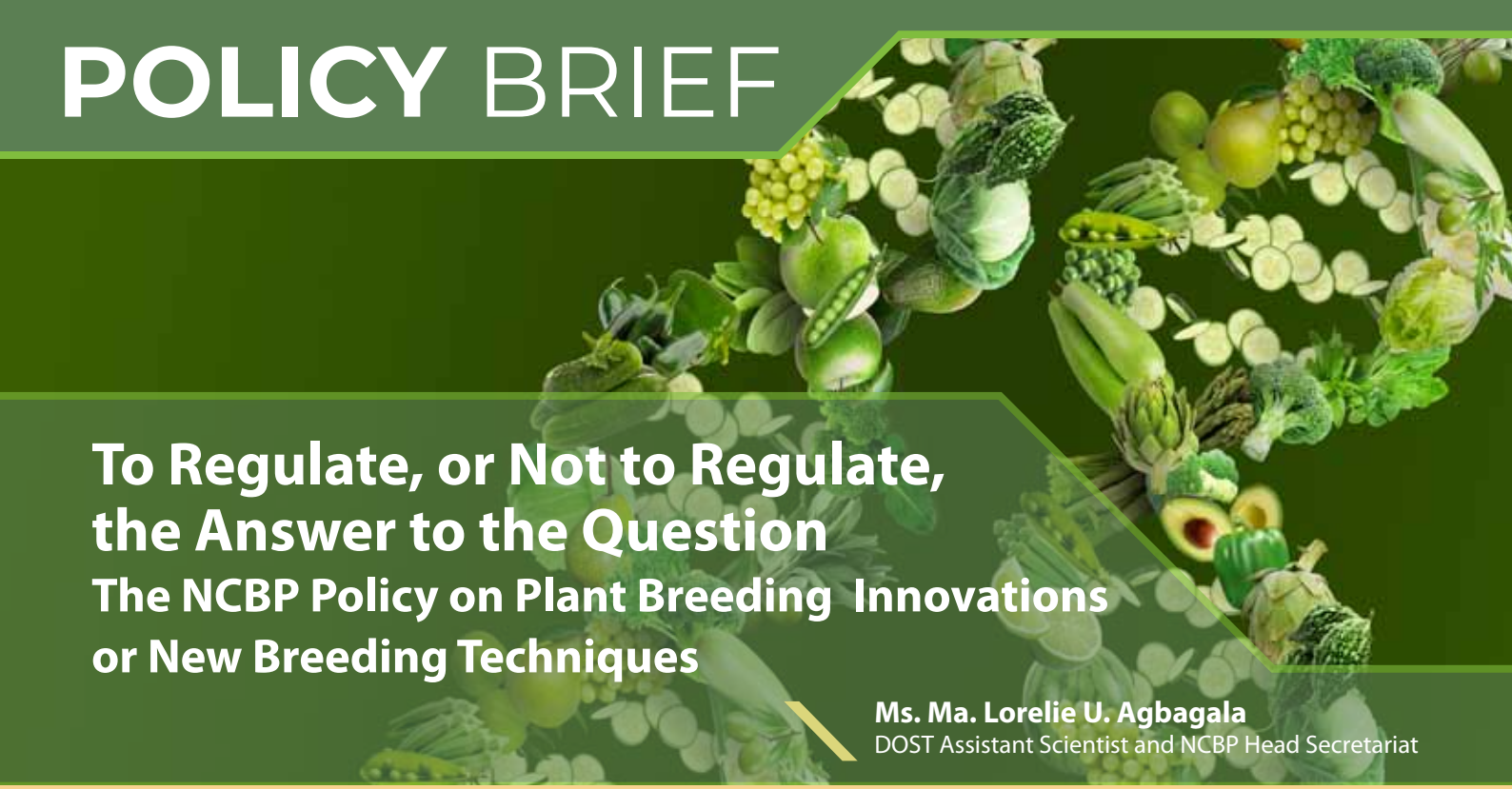
POLICY BRIEF



To Regulate, or Not to Regulate, the Answer to the Question

The NCBP Policy on Plant Breeding Innovations or New Breeding Techniques

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Policy Implications

The Philippines' policy on Plant Breeding Innovations (PBIs) or New Breeding Techniques (NBTs) is based on the country's approach to the regulation of Genetically Modified Plant and Plant Products—the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2021.

The National Committee on Biosafety of the Philippines (NCBP) Resolution No.1, Series of 2020: *The Regulation of Plant and Plant Products Derived from the Use of PBIs or NBTs* recommends a product-based approach in determining whether a product will be exempted from the existing GM plant and plant products regulation.

Defined under Executive Order (EO) No. 514, Series of 2006, products from PBIs can be classified as a GMO if it contains a novel combination of genetic material obtained through modern biotechnology. The NCBP defines a novel combination as a resultant genetic combination in a living organism that is not possible through conventional breeding. Otherwise, a product is a non-GMO or conventional.

Further, the NCBP identified the Department of Agriculture (DA) as the primary agency for the evaluation and monitoring of products of PBIs or NBTs.

Introduction

Conventional breeding includes traditional agricultural breeding practices, such as selective breeding, hybridization, mutation breeding, marker-assisted selection, and genomic selection, that yield valuable agronomic characteristics.

In the 1980s, advances in molecular biology led to the development of techniques to introduce new specific traits into organisms: adding DNA sequences into their genomes. These genetic engineering (GE) techniques can change agricultural organisms in ways that would not be possible or could take decades to achieve through conventional breeding. Recent developments in GE have allowed for increasingly specific genetic manipulation that does not always require the introduction of a foreign DNA.

GE includes recombinant DNA technology, genome editing, and other NBTs. In each case, genetically engineering agricultural species to express traits of interest is a multistep process that can involve significant time and resources to achieve. GE may create changes that are heritable (i.e., changes that can be passed to offspring) or non-heritable (i.e., changes that affect only the GE organism and cannot be passed to the offspring).

With ***recombinant DNA technology***, scientists use certain techniques to combine DNA from two or more sources to achieve desired outcomes. Organisms bearing recombinant DNA from an individual of the same species are *cisgenic*, while organisms bearing recombinant DNA from an individual of a different species are *transgenic*. In this approach, scientists are generally unaware of where in the organism's genome was the recombinant DNA placed; only that it has been integrated into the genome.

Compared to recombinant DNA technology, ***genome editing*** is a more precise form of genetic engineering. In this approach, researchers can make specific changes to an organism's DNA by inserting, deleting, or modifying genes or gene sequences. Genome editing tools include ZFNs (zinc- finger nucleases) and TALENs (transcription activator-like effector nucleases), and the most adopted CRISPR (clustered regularly interspaced short palindromic repeats) combined with Cas9 (CRISPR-associated protein 9).

Discussion

PBIs or NBTs are a new set of molecular, genomics, and cellular tools that enable the targeted and efficient development of new varieties of crops with desired traits in a way that is faster and more precise than conventional plant breeding techniques.

However, there is a considerable debate on how these new techniques should be regulated, and whether some or all of them should fall within the scope of GMO regulation.

The Regulation of Plant and Plant Products Derived from the Use of PBIs or NBTs (NCBP Resolution No.1, Series of 2020)

Recent developments and advances in GE and related technologies led the Department of Agriculture Biotechnology Program Office (DA-BPO) to initiate a Study Group in early 2018 to look into the state of the art, regulatory landscape, applicable domestic laws and policies, and current capabilities of public R&D institutions on NBTs. The output of the said study group was submitted in May 2019 to the NCBP, which subsequently created an Ad Hoc Technical Working Group (AHTWG) in June 2019 to look into NBTs and assist in developing guidelines or amending existing biosafety guidelines to address issues unique to NBTs.

The group was tasked to draft a policy that will appropriately and adequately address biosafety requirements of these new techniques to ensure safe and sustainable research, development, and use of their products; and to ensure that the regulatory requirements are appropriate to the technologies and/or their products. The AHTWG has considered existing policies on NBTs developed in other countries in crafting its recommendations, which was submitted to NCBP in March 2020.

The policy was formulated based on the following existing biosafety policies in the country:

- The National Biosafety Framework (NBF), issued under EO 514, Series of 2006 - applies to the development, adoption and implementation of all biosafety policies, measures, and guidelines and in making biosafety decisions concerning the research, development, handling and use, transboundary movement, release into the environment, and management of regulated articles; and
- The DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, Series of 2021 (JDC No.1, s. 2021) - serves as guidelines for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically Modified Plant and Plant Products Derived from the Use of Modern Biotechnology.

The salient features of the policy are:

- It is an evidence-based policy founded on scientific evidence and experiences worldwide;
- It provides legal certainty because it directs the regulators/ regulatory agencies to confirm that products of NBTs that do not contain novel combination of genetic material do not fall within the scope of GMO regulations;
- It adopts a product-based approach in determining the presence of novel combination of genetic materials to decide whether the plants are to be exempted from the existing GMO regulations or not. Thus, this policy aims to provide clarity as to which plants developed using genome editing techniques fall under current biosafety/GMO regulations; and
- It recognizes that the DA shall be the appropriate department to issue guidelines for its implementation and shall also take the lead in evaluating and monitoring plants and plant products derived from the use of modern biotechnology, including PBIs or NBTs.

The resolution identified eight different techniques that are currently being used globally.

A decision tree was provided to facilitate an understanding of what techniques are covered by the policy. This decision tree is based on the assessment of the different NBT final products in terms of the presence or absence of novel combinations (Figure 1).

Rules and Procedure to Evaluate and Determine when Products of PBIs are Covered under JDC No.1, s. 2021 (DA Memorandum Circular No. 8, Series of 2022)

Consistent with the NCBP Resolution No. 1, Series of 2020, products derived using such technologies that do not contain novel combinations of genetic materials obtained through the use of modern biotechnology are not covered by JDC No. 1, Series of 2021.

A developer who intends to introduce a PBI product into the country is required to submit a request to the Bureau of Plant Industry (BPI) Director for Technical Consultation for Evaluation and Determination (TCED). This determines whether the final product of the PBI contains a novel combination of genetic material obtained through the use of modern biotechnology.

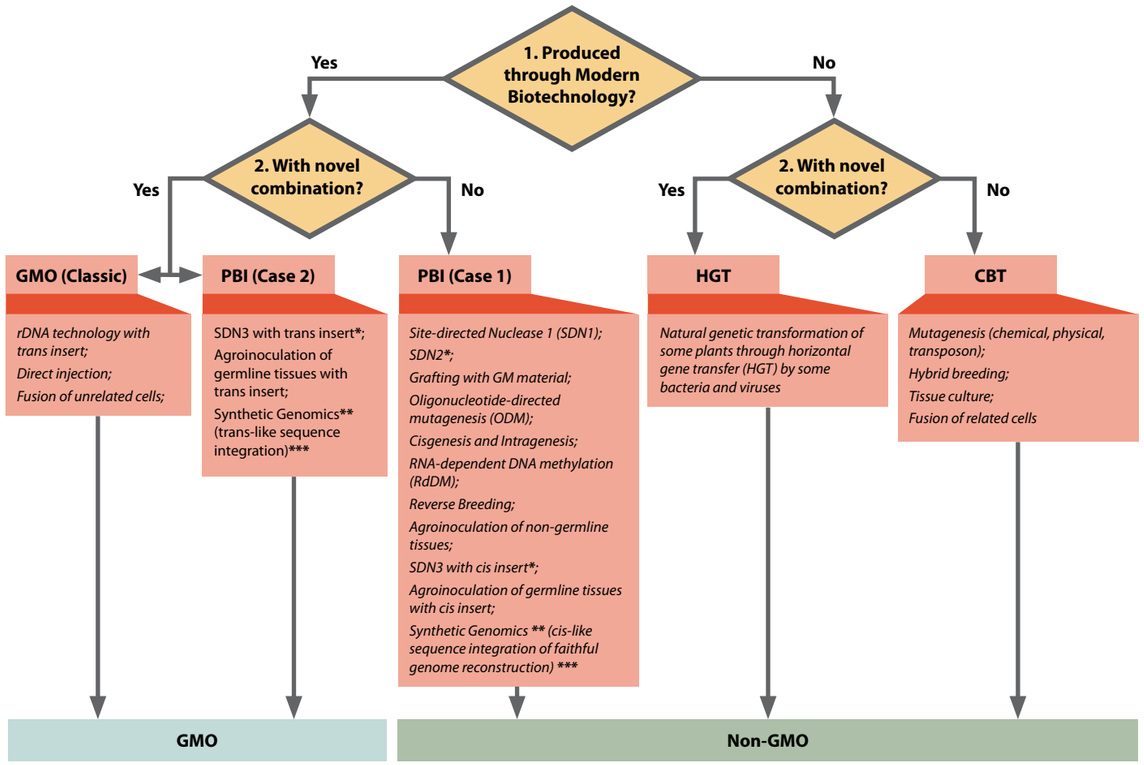
When the PBI product is officially determined as a GMO:

- The BPI will inform the product developer in writing that the GM PBI product is under the scope and coverage of the JDC No. 1, s. 2021; and will
- Advise the product developer to proceed with the application process under the JDC No. 1, s. 2021 should the developer desire to secure a biosafety permit for any of the activities and use for regulated articles.

If the PBI product is officially determined as a non-GMO:

- BPI will issue a Certificate of Non-Coverage to the product developer, which shall also be made public by its posting on the BPI website.

*The Certificate of Non-Coverage from the JDC1, s. 2021 granted to a PBI product refers to the novel characteristic introduced in the current variety and the subsequent progenies. The certificate shall also apply to all germplasm or genetic backgrounds that will contain such characteristic produced by the product developer and/or its licensees in further breeding.



Techniques listed under PBI Case 1 and Case 2 may expand as new technologies emerge. Any PBI technique must potentially produce a non-GM or both non-GM and GM plant as a final product.

* Includes the new CRISPR-CAS with Prime Editing (Science. 2019)

** Different from Synthetic Biology which specializes on artificial organisms

*** Pertains to a largely synthetic assembled genome

Figure 1. Decision Tree on the Regulation of Plants and Plant Products Derived from the Use of Plant Breeding Innovations or New Plant Breeding Techniques. (NCBP, 2020)

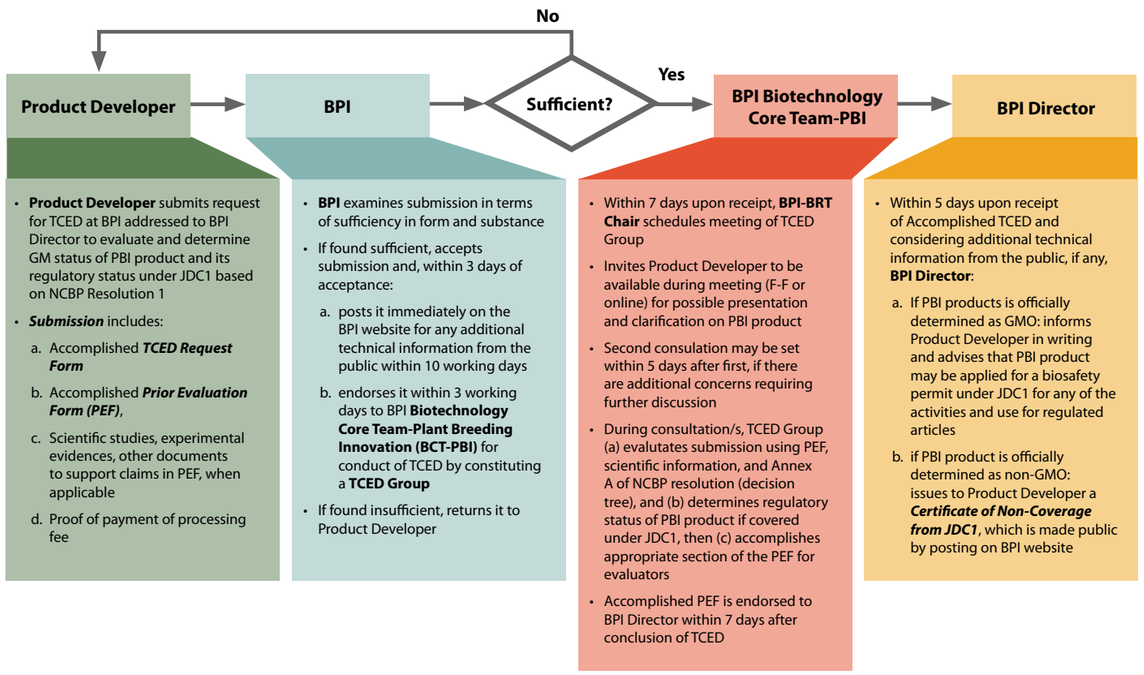


Figure 2. Process flow for the conduct of the Technical Consultation for Evaluation and Determination (DA, 2022)

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Conclusion

With the breakthroughs of new plant breeding innovations, regulations should be responsive to the changes and demands of the technology. Globally, there are different regulatory systems that range from overly restrictive to pragmatic. However, an ideal regulatory system should be science or evidence-based, predictable, and timebound to realize the benefits of PBI for both producers and consumers.

Guided by the experiences of other countries with more advanced regulatory systems, the Philippine regulations for NBTs or PBIs adopt a product-based approach for safety assessment and utilize sound science for decision-making.

Science develops new tools to better address the problems of today. Scientists should be able to predict the needs of tomorrow and work on them now. The latest breeding methods provide opportunities to target global challenges as well as local needs and can help achieve sustainable production and food security.

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