PHILIPPINE BIOTECHNNOLOGY REGULATORY SYSTEM

Biotechnology and Regulation in the Philippines
29 April 2022

PRESENTATION OUTLINE

Philippine Biotechnology Regulatory System

DOST-DA-DENR-DOH-DILG JOINT DEPARTMENT CIRCULAR SERIES OF 2021

Rules and Regulations 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**

NCBP RESOLUTION NO. 001, SERIES OF 2020

The Regulation of Plant and Plant Products Derived from the Use of Plant Breeding Innovations (PBIs) or New Plant Breeding Techniques (NBTs)

DA MEMORANDUM CIRCULAR NO.___, SERIES OF 2022

Rules and Procedure to Evaluate and Determine When Products of Plant Breeding Innovations (PBIs) are Covered Under the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2021 Based on the NCBP Resolution No.1, Series of 2020

DOST-DA-DENR-DOH-DILG
JOINT DEPARTMENT CIRCULAR SERIES OF 2021

Rules and Regulations 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

Outline of Joint Department Circular No.1, Series of 2021

Preambulatory Clause

Article I. General Provisions

- Section 1. Applicability
- Section 2. Definition of Terms

Article II. Biosafety Decisions

- Section 3. Guidelines in Making Biosafety Decisions

Article III. Administrative Framework

- Section 4. Role of National Government Agencies
- Section 5. Biosafety Committees
- Section 6. Joint Assessment Group
- Section 7. Bureau of Plant Industry Biotechnology Unit
- Section 8. Institutional Biosafety Committee
- Section 9. External Technical Experts

Article IV. Contained Use of Regulated Articles

- Section 10. Policy on Contained Use of Regulated Articles

Article V. Field Trial of Regulated Articles

- Section 11. Policy on Field Trial of Regulated Articles
- Section 12. Procedural Requirements for Securing a Biosafety Permit for Field Trial
- Section 13. Public Participation for Field Trial

Article VI. Commercial Propagation of Regulated Articles

- Section 14. Policy on Commercial Propagation of Regulated Articles
- Section 15. Procedural Requirements for Securing a Biosafety Permit for Commercial Propagation
- Section 16. Public Participation for Commercial Propagation

Outline of Joint Department Circular No.1, Series of 2021

Article VII. Direct Use of Regulated Articles for Food and Feed, or for Processing

- Section 17. Policy on Direct Use of Regulated Articles for FFP
- Section 18. Procedural Requirements for Securing a Biosafety Permit for Direct use for FFP
- Section 19. Public Participation for Direct Use for FFP

Article VIII. Genetically Modified Plants and Plant Products with Stacked Events

- Section 20. Regulation of Stacked Events
- Section 21. Registration in the BPI Approval Registry for Propagation
- Section 22. Registration in the BPI Approval Registry for Direct Use
- Section 23. Registration under the Fertilizer and Pesticide Authority

Article IX. Importation of Regulated Articles

- Section 24. Policy on the Importation of Regulated Articles
- Section 25. Additional Documentary Requirements

Article X. Miscellaneous Provisions

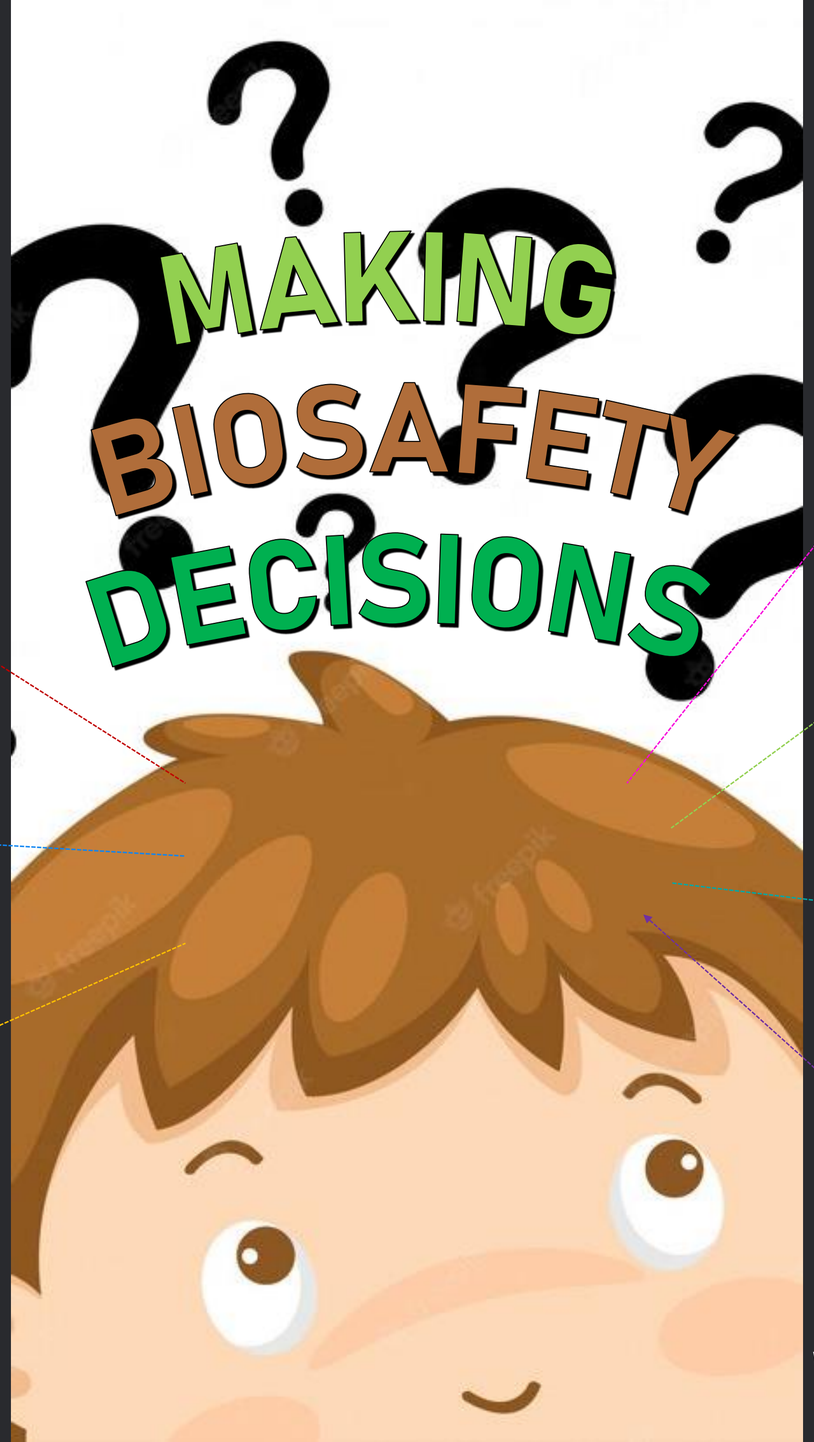
- Section 26. Monitoring for Compliance with Permit Conditions
- Section 27. Approval Registry for Regulated Articles
- Section 28. Application File
- Section 29. Reportorial Requirements
- Section 30. Management of Regulated Article
- Section 31. Confidential Information
- Section 32. Outside Experts and Accredited Laboratories
- Section 33. Fees
- Section 34. Petition for Reconsideration
- Section 35. Funding
- Section 36. Remedies
- Section 37. Issuances of Implementing Orders
- Section 38. Transitory Provisions
- Section 39. Repealing Clause
- Section 40. Separability
- Section 41. Effectivity

Legal Basis of JDC No.1, Series of 2021

- Philippine Constitution
- Cartagena Protocol on Biosafety
- Executive Order No. 514: National Biosafety Framework
- Executive Order No. 292: Administrative Code of 1987
- Presidential Decree 1433: Plant Quarantine Law of 1978
- Executive Order No. 192: Reorganization Act of the Department of Environment and Natural Resources
- Republic Act No. 7160: Local Government Code of 1991
- Republic Act No. 10611: Food Safety Act of 2013
- Republic Act No. 7394: Consumer Act of the Philippines
- Republic Act No. 11032: Ease of Doing Business and Efficient Government Service Delivery

SALIENT FEATURES OF JDC No.1, Series of 2021

Biotechnology and Regulation in the Philippines
29 April 2022



Standard of Precaution

Risk Assessment

Environmental and Health Risk Assessment

Social, Economic, Ethical, and Cultural Considerations

Access to Information

Transparency and Public Participation

Prompt and Efficient Action

Role of National Government Agencies

Department of Agriculture

Lead in addressing biosafety issues related to the country's agricultural productivity and food security.

Lead in the evaluation and monitoring of regulated articles.

Department of Environment and Natural Resources

Ensure that the applicable environmental assessments are undertaken and potential impacts identified.

Lead in evaluating and monitoring bioremediation, improvement of genetic resources, and wildlife genetic resources.

Department of the Interior and Local Government

Oversee implementation of the activities undertaken in specific LGUs in relation to the conduct of public consultations as required by the Local Government Code.

Department of Science and Technology

Lead in ensuring that the best science is utilized and applied in adopting biosafety policies and in making biosafety decisions

Lead in evaluating and monitoring contained use of regulated articles

Department of Health

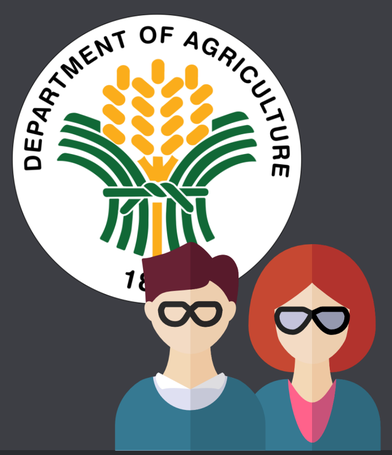
Formulate guidelines and review results of assessing the health impacts posed by modern biotechnology.

Lead in evaluating and monitoring processed food derived from or containing GMOs.

Joint Assessment Group

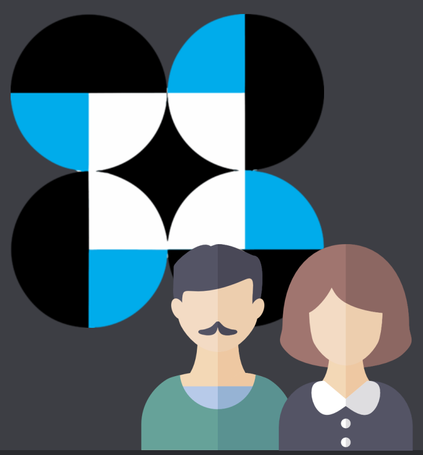
"The Department of Agriculture – Bureau of Plant Industry shall establish a Joint Assessment Group composed of qualified representatives or personnel from the concerned Departments' Biosafety Committees and external technical experts. The JAG shall evaluate applications for field trial, commercial propagation, and direct use to determine whether article does not pose greater risks to human health and the environment compared to its conventional counterpart and make its recommendations to the BPI Director." (Art. III, Section 7)

Joint Assessment Group Membership



Department of Agriculture Biosafety Committee

The DA-BC Chair or his/her appointee shall serve as the Chair of the JAG



Department of Science and Technology Biosafety Committee

Department of Environment and Natural Resources Biosafety

May make a determination of non-coverage for specific application for Direct Use

Department of Health Biosafety Committee

May make a determination of non-coverage for specific application for Field Trial

One external technical expert may be engaged to address specific issues in the application.

40
Working Days*

3 Days
Pre-Assessment

27 Days
Assessment Period
And Public Participation

5 Days
Decision from BPI

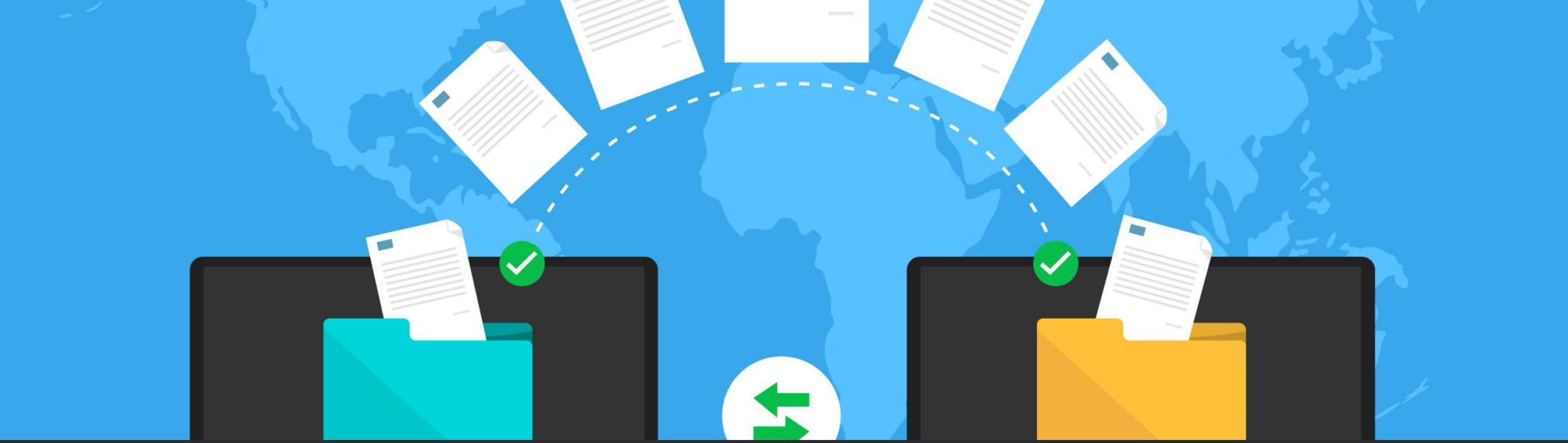
Timeline for Processing of Biosafety Applications

**Pursuant to the Ease of Doing Business Law for Highly Technical Applications*

GM Plants and Plant Products with Stacked Events

"Plants produced through conventional breeding of GM parental lines with approved individual events are not considered novel. The permit holder or an authorized licensee of registered events may request for the listing of their stacked events in the BPI Approval Registry for Commercial Propagation or BPI Approval Registry for Direct Use, as the case may be. (Art. VIII, Section 20)"

"The permit holder or an authorized licensee of registered events may also request the BPI for the listing of any sub-stacks or intermediate stacks. (Art. VIII, Sections 21 and 22)"



Data Transportability of Environmental Risk Assessment for Field Trials

"Applications for permits for regulated articles developed in other countries may be filed directly for a Biosafety Permit for Field Trial if the BPI determines that the data set generated in other countries is applicable to the local setting. (Art. V, Section 11)*"

**Consistent with the decision by the National Committee on Biosafety of the Philippines reached during its 21st meeting held on 26 March 2021.*

Petition for Reconsideration

"In case of the applications for field trial, commercial propagation, and direct use, an aggrieved party may file a request for the reconsideration of the decision with the DA Secretary within fifteen (15) working days from the announcement of the decision. (Art. X, Section 34)"

Transitory Provision

"All existing original and renewed Biosafety Permits for Commercial Propagation and Direct Use issued therein shall be valid unless otherwise revoked under conditions set in Section 15.J for Commercial Propagation and Section 18.J for Direct Use of this new Joint Department Circular. (Art. X, Section 38)"

PRESENTATION OUTLINE

Philippine Biotechnology Regulatory System

DOST-DA-DENR-DOH-DILG JOINT DEPARTMENT CIRCULAR SERIES OF 2021

Rules and Regulations 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**

NCBP RESOLUTION NO. 001, SERIES OF 2020

The Regulation of Plant and Plant Products Derived from the Use of Plant Breeding Innovations (PBIs) or New Plant Breeding Techniques (NBTs)

DA MEMORANDUM CIRCULAR NO.___, SERIES OF 2022

Rules and Procedure to Evaluate and Determine When Products of Plant Breeding Innovations (PBIs) are Covered Under the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2021 Based on the NCBP Resolution No.1, Series of 2020

NCBP RESOLUTION NO. 001, SERIES OF 2020

The Regulation of Plant and Plant Products Derived from the Use of Plant Breeding Innovations (PBIs) or New Plant Breeding Techniques (NBTs)

RESOLUTION NO. 001
Series of 2020

THE REGULATION OF PLANT AND PLANT PRODUCTS DERIVED FROM THE USE OF PLANT BREEDING INNOVATIONS (PBIs) OR NEW PLANT BREEDING TECHNIQUES (NBTs)

SECRETARY FORTUNATO T. DE LA PEÑA
Department of Science and Technology
Chair, National Committee on Biosafety of the Philippines

SECRETARY WILLIAM D. DAR
Department of Agriculture

SECRETARY ROY A. CIMATU
Department of Environment and Natural Resources

SECRETARY FRANCISCO T. DUQUE III
Department of Health

UNDERSECRETARY BERNARDO C. FLORECE, JR.
Officer-In-Charge, Department of the Interior and Local Government

SECRETARY RAMON M. LOPEZ
Department of Trade and Industry

SECRETARY TEODORO L. LOCSIN, JR.
Department of Foreign Affairs

DR. RHODORA V. AZANZA
Environmental Scientist Member

DR. EUFEMIO T. RASCO, JR.
Biological Scientist Member

DR. MA. CRISTINA D. PADOLINA
Physical Scientist Member

ATTY. ANTONIO P. JAMON, JR.
Consumer Representative

MS. MA. LOURDES S. FLORENDO
Industry Representative

ON LEAVE
RET. GEN. MARCELO C. BLANDO
Community Representative

Key Decisions and Agreements made by the Resolution

GMO if they contain a novel combination of genetic material obtained using modern biotechnology

Non-GMO or Conventional Products if they do not contain a novel combination of a genetic material.

Only PBI-derived GM plants and plant products would be regulated under the JDC1

The DA shall issue guidelines and take the lead in evaluating and monitoring plant and plant products derived from the use of modern biotechnology, including Plant Breeding Innovations

PRESENTATION OUTLINE

Philippine Biotechnology Regulatory System

DOST-DA-DENR-DOH-DILG JOINT DEPARTMENT CIRCULAR SERIES OF 2021

Rules and Regulations 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**

NCBP RESOLUTION NO. 001, SERIES OF 2020

The Regulation of Plant and Plant Products Derived from the Use of Plant Breeding Innovations (PBIs) or New Plant Breeding Techniques (NBTs)

DA MEMORANDUM CIRCULAR NO. 8, SERIES OF 2022

Rules and Procedure to Evaluate and Determine When Products of Plant Breeding Innovations (PBIs) are Covered Under the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2021 Based on the NCBP Resolution No.1, Series of 2020

DA MEMORANDUM CIRCULAR NO. 8, SERIES OF 2022

Rules and Procedure to Evaluate and Determine When Products of Plant Breeding Innovations (PBIs) are Covered Under the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2021 Based on the NCBP Resolution No.1, Series of 2020

Republic of the Philippines
DEPARTMENT OF AGRICULTURE
Elliptical Road, Diliman, Quezon City
Tel: (632) 928-8741 to 65

MEMORANDUM CIRCULAR
No. 08
Series of 2022

Subject: **RULES AND PROCEDURE TO EVALUATE AND DETERMINE WHEN PRODUCTS OF PLANT BREEDING INNOVATIONS (PBIs) ARE COVERED UNDER THE DOST-DA-DENR-DOH-DILG JOINT DEPARTMENT CIRCULAR NO. 1, SERIES OF 2021 (JDC1, s2021) BASED ON THE NCBP RESOLUTION NO. 1, SERIES OF 2020**

Outline of DA Memorandum Circular No.8, Series of 2022

Preambulatory Clause

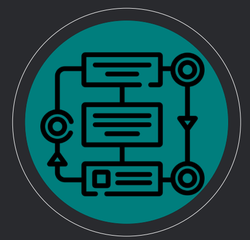
Section I. General Classification of Products of PBIs

Section II. PBI Products Falling under the Scope and Coverage of JDC1, s2021

Section III. Product Developer

Section IV. BPI Biotechnology Core Team-Plant Breeding Innovation

Section V. Technical Consultation for Evaluation and Determination (TCED)



Section VI. Procedural Requirements for the Conduct of a TCED.

Section VII. Compliance with Other Regulations

Outline of DA Memorandum Circular No.8, Series of 2022

Section VIII. Target PBI Products

Section IX. Appeal

Section X. Confidential Information

Section XI. Mutual Recognition Agreements

Section XII. Funding

Section XIII. Repealing Clause

Section XIV. Separability

Section XV. Effectivity

SALIENT FEATURES OF DA MC No.8, Series of 2022

Biotechnology and Regulation in the Philippines
29 April 2022

Basis for the issuance of the DA Memorandum Circular No.8, Series of 2022

- DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2021, Rules and Regulations 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

- National Committee on Biosafety of the Philippines Resolution No.001, Series of 2020, The Regulation of Plant and Plant Products Derived from the Use of Plant Breeding Innovations (PBIs) or New Plant Breeding Techniques (NBTs).

General Classification of Products of PBIs

Genetically Modified Organisms (GMOs)*

"..as defined by Executive Order No.514, series of 2006, contain a novel combination of genetic material through the use of modern biotechnology, which novel combination, the NCBP defined as a resultant genetic combination in a living organism that is not possible through conventional breeding."

*Regulated under the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2021

Non-GMOs or Conventional Products

"...do not contain a novel combination of genetic material in the final product."

Product Developer

"…natural or juridical person who developed the PBI product submitted for the evaluation and determination of its regulatory status under JDC1, s2021. (a) any of the departments or agencies of the Philippine Government; (b) a university with research institutions in the Philippines; (c) an international research organization duly recognized by the Philippine Government; (d) a corporation registered with the Securities and Exchange Commission of the Philippines; or (e) a cooperative registered with the Cooperative Development Authority of the Philippines.

"A non-resident product developer shall appoint an agent who is a resident of the Philippines and shall be in-charge with all submissions to and official communications with the Department of Agriculture.."

BPI Biotechnology Core Team – Plant Breeding Innovation

- Composed of qualified technical staff from BPI and shall be chaired by the BPI Assistant Director for Regulatory Services.
- For every officially accepted request, it shall form a Technical Consultation for Evaluation and Determination (TCED) Group, composed of three (3) members, with at least two (2) members from the BCT-PBI selected based on availability and the other member appointed by the Chair of the BCT-PBI as an external expert, if deemed necessary…,
- TCED Group shall be responsible for the conduct of the technical evaluation and determination on the regulatory status of the PBI product under the JDC1, s2021.
- The BPI Director shall issue succeeding policy on the BCT-PBI on its composition, specific duties, and responsibilities in the implementation of this Circular.

Technical Consultation for Evaluation and Determination

A product developer who intends to introduce a PBI product into the country shall submit a request to the Director of BPI for Technical Consultation for Evaluation and Determination (TCED), which is a technical evaluation of the PBI product to determine whether or not the final product of the plant breeding process employed to produce the PBI product contain a novel combination of genetic material obtained through the use of modern biotechnology.

Timeline for Processing of Request under DA MC No.8, Series of 2022

32
Working Days*

10 Days
Pre-TCED and Public Participation

17 Days
TCED Proper

5 Days
Official Determination by the BPI Director

Action after Official Determination

In case when the PBI product is officially determined as a GMO:

a. Inform the product developer in writing that the GM PBI product is under the scope and coverage of the JDC1, s2021; and

b. Advise the product developer to proceed with the application process under the JDC1, s2021 should the developer desire to secure a biosafety permit for any of the activities and use for regulated articles.

In case when the PBI product is officially determined as a non-GMO:

a. Issue to the product developer a Certificate of Non-Coverage* from JDC1, s2021 for the non-GM PBI product which shall also be made public by its posting on the BPI website.

*The Certificate of Non-Coverage from the JDC1, s2021 granted to a PBI product shall refer 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.

Target PBI Products

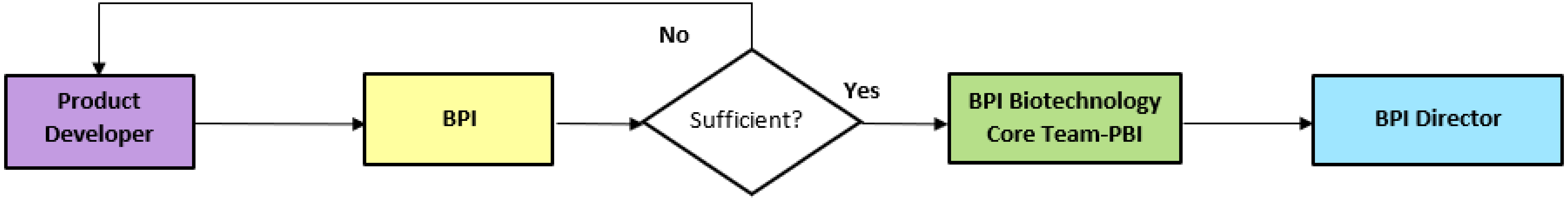
In the case of projects to develop or obtain PBI products that are still at the product concept or R&D phase, the product developer may file a request for TCED, following the same procedures as those specified in the foregoing sections, only for purposes of anticipating if the expected target product falls under the scope and coverage of the JDC1, s2021. In such a case, the TCED Group may perform a preliminary analysis and provide an indicative answer that will be communicated by BPI to the product developer. Upon the request of the product developer, portions of the submission may be treated as confidential information, subject to the provisions of Section 10 (Confidential Information) below. In the event that such PBI products are developed or obtained in the future, these shall be subject to the provisions of the foregoing sections, in order to confirm that such materialized PBI products contain the type of genetic change proposed in the preliminary consultation.

Appeal

An aggrieved party may file an appeal on the action taken by the BPI Director with the DA Secretary within fifteen (15) working days from (a) receipt by the product developer of the decision of the BPI Director, … or (b) posting on the BPI website of the Certificate of Non-Coverage, …

Mutual Recognition Agreements

The Department of Agriculture, upon the recommendation and facilitation by BPI, may enhance cooperation with counterpart competent authorities of other countries to establish mutual recognition agreements or arrangements on the determination of classification of PBI products under international agreements to which the Philippines is a party.



- **Product Developer** submits request for TCED at BPI addressed to BPI Director to evaluate and determine GM status of PBI product and its regulatory status under JDC1 based on *NCBP Resolution 1*
- ***Submission*** includes:
  a. Accomplished ***TCED Request Form***
  b. Accomplished ***Prior Evaluation Form*** (PEF),
  c. Scientific studies, experimental evidences, other documents to support claims in PEF, when applicable
  d. Proof of payment of processing fee

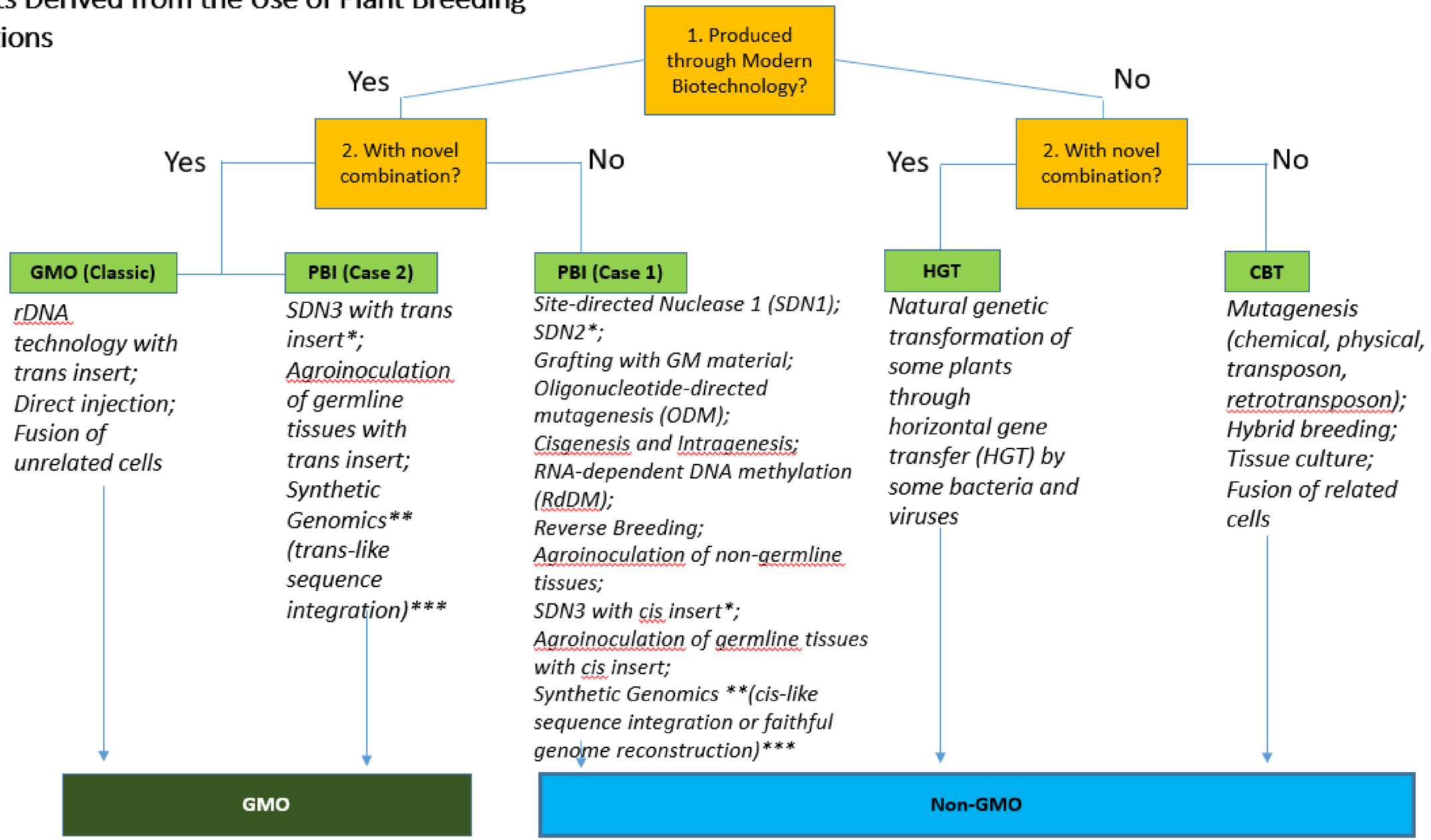
- **BPI** examines submission in terms of sufficiency in form and substance
- If found sufficient, accepts submission and, within 3 days of acceptance:
  a. posts it immediately on the BPI website for any additional technical information from the public within 10 working days
  b. endorses it within 3 working days to BPI **Biotechnology Core Team-Plant Breeding Innovation (BCT-PBI)** for conduct of TCED by constituting a **TCED Group**
- If found insufficient, returns it to Product Developer

- Within 7 days upon receipt, **BPI-BRT Chair** schedules meeting of TCED Group
- Invites Product Developer to be available during meeting (F-F or online) for possible presentation and clarification on PBI product
- Second consultation may be set within 5 days after first, if there are additional concerns requiring further discussion
- During consultation/s, TCED Group (a) evaluates submission using PEF, scientific information, and **Annex A** of NCBP resolution (decision tree), and (b) determines regulatory status of PBI product if covered under JDC1, then (c) accomplishes appropriate section of the PEF for evaluators
- Accomplished PEF is endorsed to BPI Director within 7 days after conclusion of TCED

- Within 5 days upon receipt of Accomplished TCED and considering additional technical information from the public, if any, **BPI Director:**
  a. If PBI product is officially determined as GMO: informs Product Developer in writing and advises that PBI product may be applied for a biosafety permit under JDC1 for any of the activities and use for regulated articles
  b. If PBI product is officially determined as non-GMO: issues to Product Developer a ***Certificate of Non-Coverage from the JDC1,*** which is made public by posting on BPI website

Process Flow for the Conduct of TCED

Decision Tree on the Regulation of Plants and Plant Products Derived from the Use of Plant Breeding Innovations



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

From DA Sec. William Dar, a slide in his presentation on “Enabling Policies for Genome Editing in Agriculture” during the international webinar on gene editing policies organized by APAARI on 18 August 2021.


Thank you.

NATIONAL COMMITTEE ON BIOSAFETY OF THE PHILIPPINES

Saliksik Building, Department of Science and Technology,
Gen. Santos Ave., Bicutan, Taguig City

secretariatncbp@gmail.com

+63 2 837-2071 local 2012