

Regulatory approach for products of NBTs in the Philippines

ISAAA Webinar: *International Trade in Crops with New Breeding Technologies: The Australian Perspective*

June 11, 2021

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Modern Biotechnology

- rDNA technology
- Direct injection
- Fusion of unrelated cells

With novel combination

GMO



**DOST-DA-DENR-DOH-DILG
Joint Department Circular¹
No. 1, series of 2016**

**Effective:
April 15, 2016**

Subject: 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

WHEREAS, the Constitution protects the rights of the people to life, to health and to a balanced and healthful environment;

WHEREAS, the Philippines is a party to the *United Nations Convention on Biological Diversity* and its *Cartagena Protocol on Biosafety*;

WHEREAS, the President issued Executive Order (E.O.) No. 514, series of 2006, "*Establishing the National Biosafety Framework, Prescribing Guidelines for Its Implementation, Strengthening the National Committee on Biosafety of the Philippines, and for other Purposes,*" to guide the development, adoption, and implementation of all biosafety policies, measures, and decisions concerning the research, development, handling, transboundary movement, release into the environment and use of genetically modified organisms;

WHEREAS, the Department of Science and Technology (DOST) is the lead agency to provide central direction, leadership, and coordination of scientific and technological efforts, including modern biotechnology, in areas that are geared and utilized in areas that yield significant benefits for the people;

WHEREAS, under the National Biosafety Framework, the Department of Science and Technology (DOST) take the lead in evaluating and monitoring research and development, handling and use;

WHEREAS, the Department of Agriculture (DA), through the Bureau of Plant Industry (BPI), is the lead agency in the research and development, handling and use of genetically modified plant and plant products;

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Secretary
Department of Science and Technology
DSEC-16-00395

PROCESO J. ALCALA
Secretary
Department of Agriculture

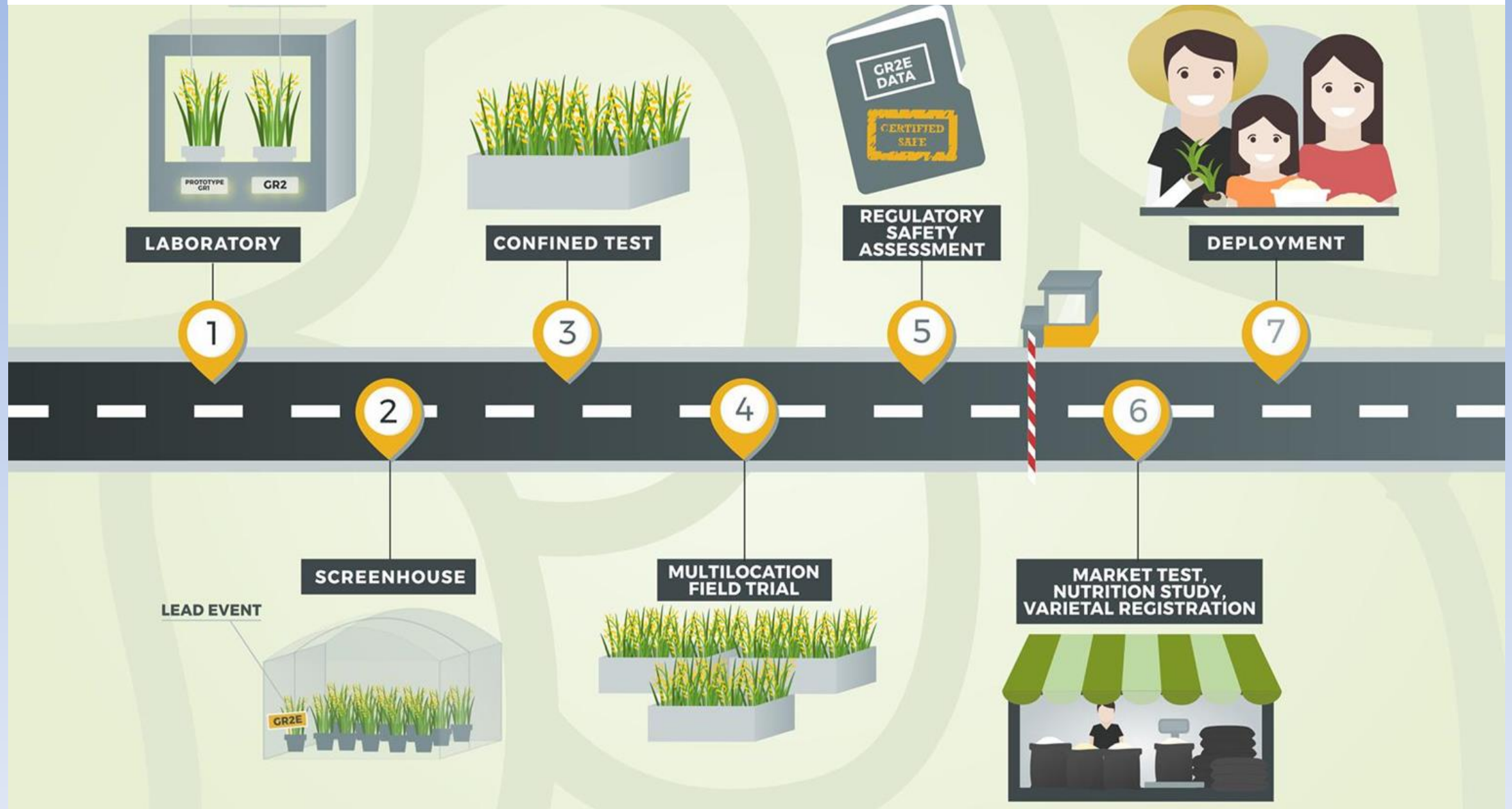
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DILG

The regulatory steps for GMOs in the Philippines



GMO Development Requiring Approvals/Permits

DOST-BC

DA



Contained use

Confined test

Field trial

Commercial propagation



Direct Use as Food and Feed, or for Processing

DOST Biosafety Committee (DOST-BC)

- formed in 2009 thru E.O. 514, s. 2006
- takes the lead in ensuring that the best available science is utilized and applied in adopting biosafety policies, measures and guidelines, and in making biosafety decisions.
- takes the lead in evaluating and monitoring regulated articles under contained use

National Committee on Biosafety of the Philippines (NCBP) Resolution on the assessment of NBT products



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)

WHEREAS, pursuant to Section 4.1 of Executive Order No. 514, Series of 2006, otherwise known as *“Establishing the National Biosafety Framework, Prescribing Guidelines for its Implementation, Strengthening the National Committee on Biosafety of the Philippines, and for Other Purposes”*, the National Committee on Biosafety of the Philippines (NCBP) shall be the lead body to coordinate and harmonize inter-agency and multi-sector efforts to develop biosafety policies in the Philippines;

WHEREAS, during the 13th meeting held on 19 March 2019, the NCBP accepted the technical study commissioned by the Department of Agriculture (DA) entitled *“A Review of the New Plant Breeding Techniques (NBTs) from the Viewpoint of Regulation”* which looked into the state of the art, regulatory landscape, applicable domestic laws and policies, and current capabilities of public R&D institutions on New Plant Breeding Techniques;

WHEREAS, DA recommended to create a Technical Working Group (TWG) that will look into NBTs and help in developing guidelines or amending existing biosafety guidelines to address issues unique to NBTs that do not fall under the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, Series of 2016 (JDC1), otherwise known as *“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”*;

RESOLVED, FURTHER, that 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.

RESOLVED, FINALLY, that only PBI-derived GM plants and plant products would be regulated under the JDC1. Consequently, PBI-derived non-GM plants and plant products would not be regulated under the said Circular.

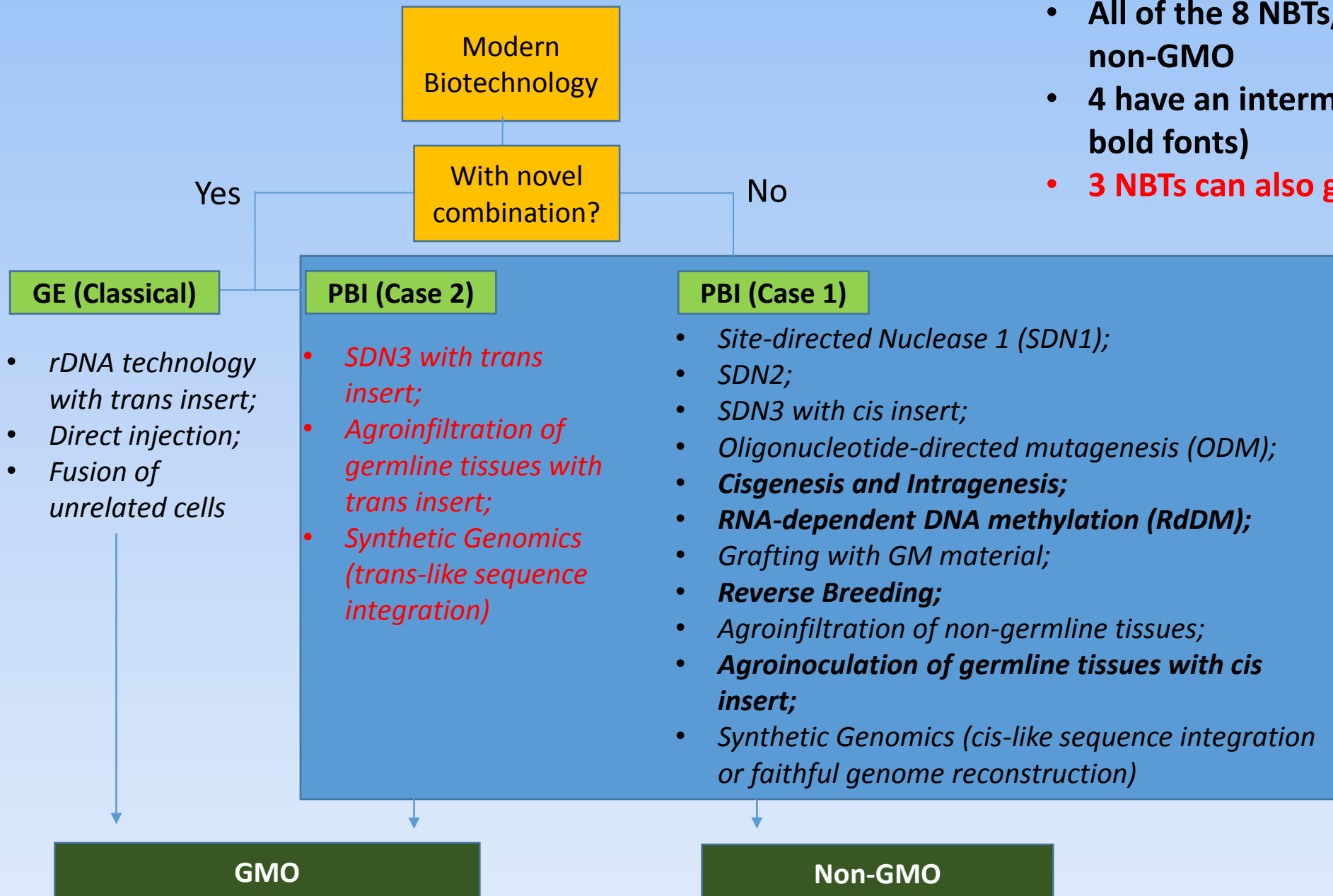
Done in the City of Taguig this 8th day of May 2020.

DEPARTMENT OF AGRICULTURE
In replying pls cite this code
For Signature: S-08-20-0121
Received: 08072020 07:50 AM

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REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES
SECRETARY ROY A. CIMATU





- All of the 8 NBTs/PBIs can result in a non-GMO
- 4 have an intermediate GM stage (in bold fonts)
- 3 NBTs can also give rise to a GMO

NCBP and DA-BC POSITION ON REGULATIONS OF PBI/NBTs

- **If products are GM**, it shall follow the rules and regulations of JDC 1
- **If products are non-GM**: It shall be regulated by one of the following:
 - BPI partnering with DA and Non-DA Experts
 - DA – Undersecretary for Regulations partnering with DA and Non-DA experts

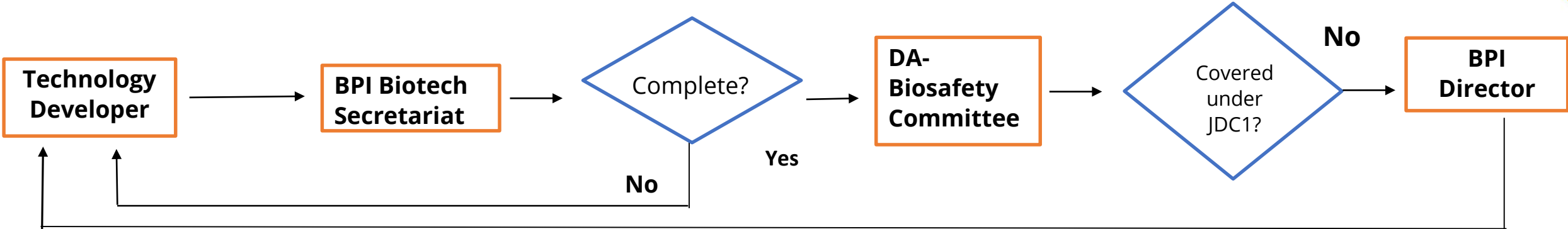
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DA-BC POSITION ON REGULATIONS OF PBI (Cont.)

1. Determination of the PBI product that if it contains a transgene by DA-BC;
2. If no transgene-**Food and Feed or only Food Safety assessments** not as rigorous as JDC 1 such as Proximate analysis by BPI and BAI or BPI only;
3. Or, outright issuance of Clearance that the product can be used as food, feed, food, and be propagated with no further regulations **if there are no biosafety issues;**
4. Environmental safety assessment if the product will be grown in the Philippines-BPI
5. Issuance of Clearance instead of Certificate of Safety issued by BPI or other competent office from DA

PROCESS FLOW FOR THE FORMAL DETERMINATION OF PBI PRODUCTS INTENDED FOR COMMERCIAL USE -Either for FFP or Propagation



- **Technology Developer** submits to BPI Biotech Secretariat **Requests for Formal Determination (RFD)** if its PBI product is covered by JDC1 based on the NCBP Resolution on PBI
- **Submission** includes:
 - a. Accomplished **RFD Form**, and
 - b. Technical dossier, if product is developed from abroad, or
 - c. DOST-BC Certificate of Non-Coverage, if product is locally developed and has undergone contained use in the Philippines under the supervision of DOST-BC
- Pays the processing fee (Find legal basis)

- Within 2 days upon receipt, **BPI Biotech Secretariat** shall process and evaluate the completeness of the Submission
- If incomplete, returns it to the Technology Developer
- If complete, endorses it to the DA-BC

- Within 30 days upon receipt, **DA-Biosafety Committee** convenes to evaluate the RFD Form and its attachments
- May get technical advice from external experts
- May schedule a meeting with the Technology Developer for questions and clarifications
- After its evaluation, makes a formal determination as to the nature of the PBI product based on the *NCBP Resolution on PBI: if covered under JDC1 or not based on the NCBP Resolution on PBI*;
- Endorses the Submission and the **Report on the DA-BC Formal Determination** to the BPI Director

- Within 5 days upon receipt, **BPI Director** issues **BPI Certificate of Non-Coverage** from the JDC1 but specifies in the certificate that said non-GM PBI product remains to be covered by other existing regulations depending on its application and use or outright issuance of clearance
- Causes the safety assessment of the Product for Food and Feed or Food only or propagation
- If found to be substantially safe, the product is listed in the Registry of **Non-GM PBI Products** for monitoring purposes and BPI issues Safety Clearance
- The Technology Developer is encouraged to register and or Protect the Variety under the existing Seed Laws of the Philippines

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Key Take-aways

- The Philippines now has a regulatory policy (NCBP resolution) on products of NBTs; fine details still to be developed by DA-BPI;
- For products of NBTs that do not possess foreign DNA insertions or novel combination of genetic materials, the existing GM regulation will not apply
- Any product coming from Australia would follow a determination step if it is going to be covered by the GM regulation (JDC) or not.
- Once, the NBT policy specific guidelines are formalized, a certificate of non-coverage can be obtained from DA-BPI for non-GM products of NBTs.