

PHILIPPINES POLICY AND **REGULATION ON GENE EDITING TECHNOLOGY AND** PRODUCTS DERIVED FROM THE TECHNOLOGY

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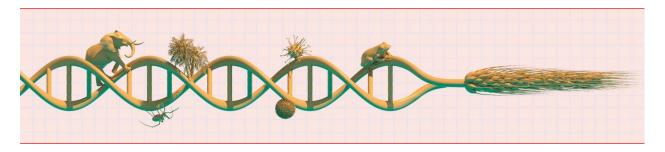
Presented at the "Gene Editing Technology: Application in Agriculture and Regulations on Food Derived from Gene Editing Technology" 20 – 21 October 2021, Bangkok, Thailand(Online Seminar) Organized by THASTA, ISF, CBIJ, CropLife, APSA



Recent addition to the plant breeder's toolbox...

Genome editing is a fundamentally different way to engineer the genome:

The genome editor itself is ABSENT from the resulting organism. Only the desired edit is present.



Genome editing redefines the meaning of the word "natural"

it allows you to move a natural form of a gene from one living organism to another - without adding an extra gene to the recipient (solely by changing the recipients' own natural gene to a different equally natural form)



Policy on gene editing

NCBP Resolution on Plant **Breeding Innovations/New Breeding Techniques**



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 Connectite on Biosafety of the Philippines (NCBP) shall be the lead body to coordinate and harmonize interagency 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 book into NBTs and help in developing guidelines or amending existing biosafety

WHEREAS, the NCBP recommended that the DA take the lead in availating and monitoring plant and plant products derived from the use of modern biotechnology. including Plant Breeding Innovations,

WHEREAS, during its 17th meeting held on 28 February 2020, the NCSP unanimously approved the adoption of the foregoing findings and recommendation of the TWG.

RESOLVED, AS IT HEREBY RESOLVED, that products from Plant Breeding Innovations may be classified either as: (a) GMOs, if - as defined under E.O. 514 s. 2005 - they contain a novel combination of genetic material obtained through the use of modern biolectivology, which 'novel combination' the NCBP defines as a resultant penetic combination in a living organism that is not possible through conventional breading; or (b) non-GMOs or conventional products, if they do not contain a novel combination of genetic material. A decision tree is attached to this resolution as Annex.

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 PSII-derived GM plants and plant products would be regulated under the JDC1. Consequently, PSI-derived non-GM plants and plant products would not be regulated under the said Circular.



DIL EUFENSO T. HASCO, JR.

DR. MA. CRISTINA D. PADOLINA

Physical Scientist Member male that MS. MA. LOURDES S. FLORENDO Industry Representative

ATTY, ANTONIO F. JAMON, JR.

RET, GEN, MARCELO C. BLANDO

LEGAL BASIS



Executive Order 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"



DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, Series of 2016:

"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"



SCOPE

This regulation shall cover plant and plant products derived from New Plant Breeding Techniques or Plant Breeding Innovations to determine whether or not they should be regulated as Genetically Modified Organisms (GMOs)

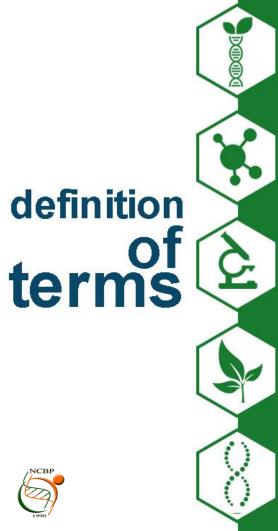




Definitions



- Since 2005, NBTs have been subject of global regulatory discussion, because organisms developed with NBTs can have genetic changes that could have been achieved through traditional breeding or which could occur naturally.
- This raised regulatory concerns, e.g.:
 - Do those organisms fall under the regulatory definitions (e.g. GMO, GEO, LMO)?
 - Enforcement detection and identification?
- Whether and which genome edited organisms fall under regulations depends on the regulatory definitions. :
 - Whether and which genome edited organisms are LMOs in the sense of the Cartagena Protocol on Biosafety (CPB) depends on whether they fall under the LMO definitions of the CPB



- **Genetically Modified Organisms** also refers to "living modified organism" under the Cartagena Protocol on Biosafety and refers to any living organism that possesses a **novel combination of genetic material** obtained through the use of modern biotechnology;
- Living organism any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;
- Modern Biotechnology refers to application of: a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) or direct injection of nucleic acid into cells or organelles; or b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding selection;
- New Plant Breeding Techniques also refers to Plant Breeding Innovations, refers to a new set of
 molecular, genomic 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;
 - **Novel Combination of Genetic Material** a resultant DNA combination in a living organism that is not possible through conventional breeding

NEW BREEDING TECHNIQUES



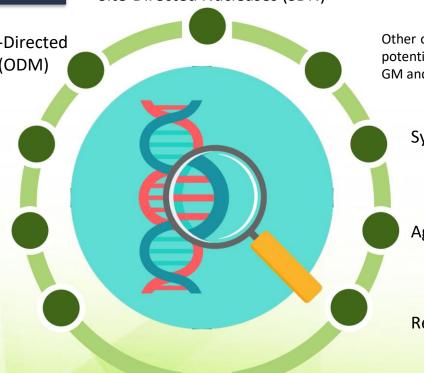
Site-Directed Nucleases (SDN)

Oligonucleotide-Directed Mutagenesis (ODM)

Cisgenesis and Intragenesis

RNA-dependent DNA Methylation (RdDM)

Grafting with GM material



Other or upcoming techniques that have the potential to produce non-GM or both non-GM and GM plants as final products

Synthetic Genomics

Agro-infiltration

Reverse Breeding

Resolution

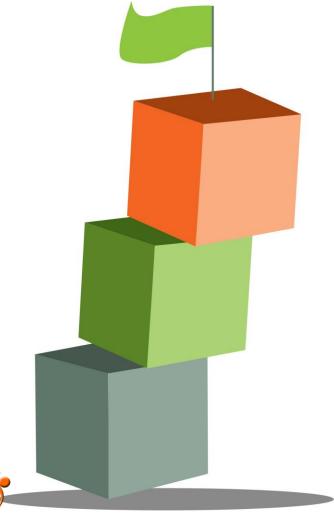


Products from NBTs or PBIs maybe classified as either:

- a) GMOs –if they contain a novel combination of genetic material obtained through the use of modern biotechnology, which "novel combination", this Resolution defines as a resultant genetic combination in a living organism that is not possible through conventional breeding, or
- b) non-GMOs or conventional products if they do not contain a novel combination of genetic material

NBT/PBI-derived GM plants and plant products will be regulated under the JDC#1, s2016;

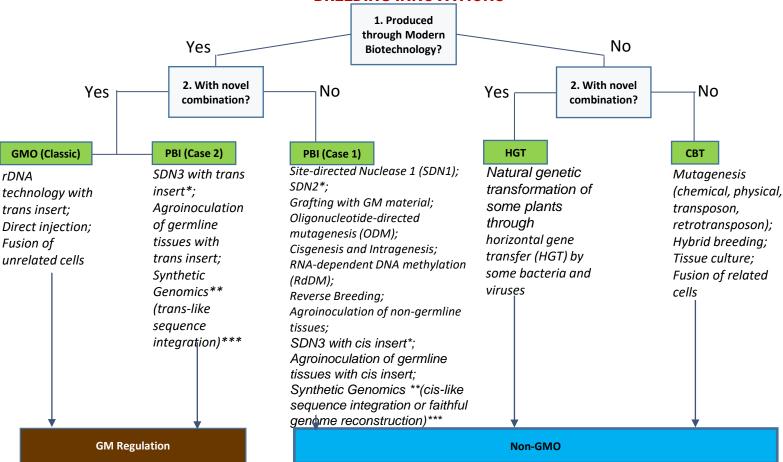
NBT/PBI-derived non-GM plants and plant products will not be regulated under this Circular



IMPORTANT FEATURES

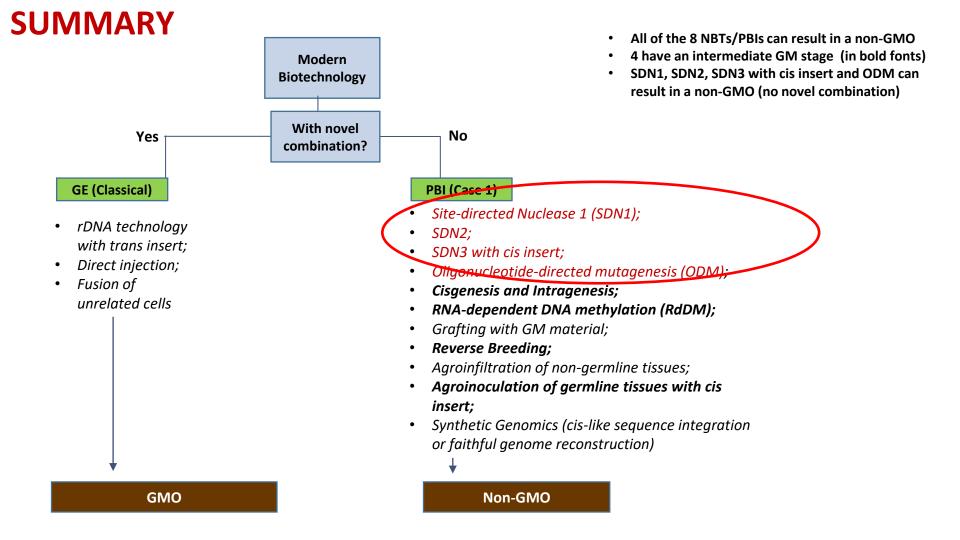
- Evidence-based policy informed by the advancing scientific evidence and experience worldwide and that the processes for deciding on regulatory oversight are transparent;
- Certainty confirms that products of NBTs, when they do not contain a novel combination of genetic material, do not fall within the scope of GMO regulation;
- Regulating trait/product- risk assessment should be based primarily on the specific, science-based characterization of new plant cultivars, by whatever method, not on the processes by which they are generated;
- Department of Agriculture issue guidelines and take the lead in evaluating and monitoring plants and plant products derived from the use of modern biotechnology, including Plant Breeding Innovations (PBIs) or New Plant Breeding Techniques (NBTs)

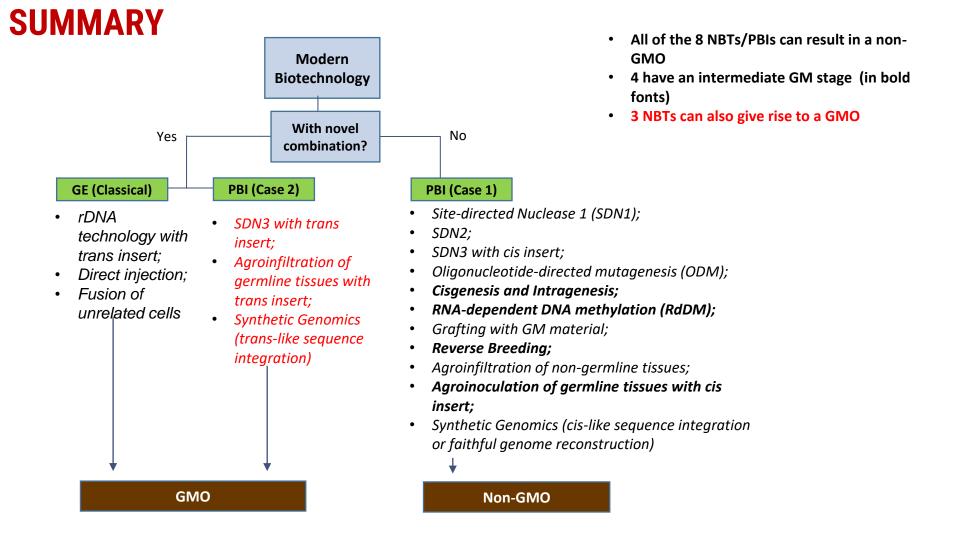
DECISION TREE ON THE TREATMENT OF PLANT AND PLANT PRODUCTS DERIVED FROM THE USE OF PLANT BREEDING INNOVATIONS



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







Proposed Rules and Procedure to Implement NCBP Resolution on the Regulation of Products of Plant Breeding Innovations or New Plant Breeding Techniques

RESOLVED: "that products from Plant Breeding Innovations may be classified either as: (a) GMOs, if – as defined under E.O. 514 s. 2006 - they contain a novel combination of genetic material obtained through the use of modern biotechnology, which "novel combination" the NCBP defines as a resultant genetic combination in a living organism that is not possible through conventional breeding; or (b) non-GMOs or conventional products, if they do not contain a novel combination of genetic material. A decision tree is attached to this resolution as Annex A"

RESOLVED: "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"

RESOLVED: "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"

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 P
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

SECRETARY JEODORO L. LOCSIN, JR.

SECRETARY RAMON M. LOPEZ

Department of Trade and Industry

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

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MS. MA. LOURDES'S. FLORENDO Industry Representative ON LEAVE

RET. GEN. MARCELO C. BLANDO Community Representative





Republic of the Philippines **DEPARTMENT OF AGRICULTURE**Elliptical Road, Diliman, Quezon City

Tel: (632) 928-8741 to 65

MEMORANDUM CIRCULAR

No. ____ Series of 2021

Subject: RULES AND PROCEDURE TO EVALUATE AND DETERMINE WHEN PRODUCTS OF PLANT BREEDING INNOVATIONS (PBIs) OR NEW PLANT BREEDING TECHNIQUES (NBTs) ARE COVERED UNDER THE DOST-DADENR-DOH-DILG JOINT DEPARTMENT CIRCULAR NO. 1, SERIES OF 2016 (IDC1) BASED ON THE NCBP RESOLUTION NO. 1, SERIES OF 2020

Procedure for the Conduct of Technical Consultation for Evaluation and Determination (TCED)

Procedural requirements for the conduct of a TCED:

- 1. TCED Request Form
- 2. Accomplished Prior Evaluation Form (PEF)
 - type of organism and species involved
 - description of breeding technique used
 - novel trait introduced and evidence of desired genetic change
 - proof of absence of inserted genetic material
 - Certification from DOST-BC (if locally developed)
 - scientific studies, experimental evidence, and other documento support claims in the PEF



Mutual Recognition Agreements





Decision

If GMO: will undergo regulation If non-GMO: Certificate of Non-Coverage

BPI-Biotechnology Regulatory Team

Responsible for the conduct of TCED. Discuss and review the submission, particularly the Prior Evaluation Form (PEF) and other supporting documents.

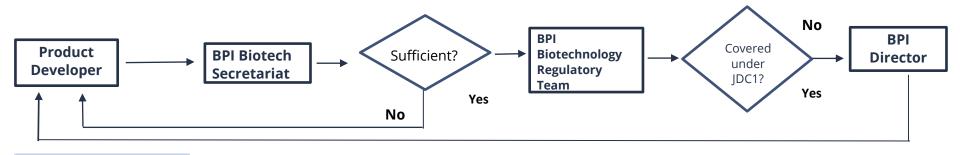
Technical Consultation for Evaluation and Determination (TCED)

Request for technical evaluation to determine whether or not the PBI/NBT product contain a novel combination of genetic material.

PBI/NBT product for introduction into the environment

Completed contained use study under the DOST-Biosafety Committee (for locally-developed)

PROCESS FLOW FOR THE CONDUCT OF THE TECHNICAL CONSULTATION FOR EVALUATION AND DETERMINATION (TCED)



- Product Developer submits to BPI Biotech Secretariat Requests for TECD If its PBI product is covered by JDC1 based on the NCBP Resolution on PBI
- **Submission** includes:
 - a. Accomplished TECD Request Form
 - b. Accomplished Prior Evaluation Form (PEF)
 - c. Scientific studies, experimental evidences, other documents to support claims in PEF
 - d. 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
 - e. Proof of payment of processing fee

- BPI Biotech Secretariat
 examines submission in
 terms of sufficiency in form
 and substance
- If found sufficient, accepts submission and, within 3 days of acceptance, endorses to BPI Biotechnology Regulatory Team (BPI-BRT) for conduct of TECD
- If found insufficient, returns it to Product Developer

- Within 7 days upon receipt, **BPI-BRT** schedules its TECD meeting
- May seek technical advice from technical experts
- Invites Product Developer to be available during meeting (F-F or online) for possible presentation and clarification on PBI/NBT product
- Second consultation may be set within
 days after first, if there are additional concerns requiring further discussion
- During consultation/s , a) evaluates submission using PEF, scientific information, and Annex A of NCBP Resolution (decision tree), and b) determines regulatory status of PBI/NBT product if covered by JDC1, then c) drafts its Report on Official Determination (ROD)
- ROD is endorsed to the BPI Director within 7 days after conclusion of TCED

- Within 5 days upon receipt of ROD, **BPI Director:**
- a) If PBI/NBT product is determined as GMO, informs Product Developer in writing and advises that PBI/NBT product may be applied for biosafety permit under JDC1 for any of the activities and use of the regulated articles b) If PBI/NBT product is 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 and requires Product

Developer to submit report on annual

distribution of the PBI/NBT product

Comparison across Countries

Information Requirements	Argentina CONABIO	Brazil CTNBio	Chile SAG	Colombia ICA	Honduras SENASA	US USDA	Japan		Philippines
							MOE	MHLW	DA-BPI
Information: Voluntary vs. Required	R	R	R	R	R	V	R	R	R
(Breeding) Method used/Grouping of breeding method	✓	√	✓	✓	✓		✓	✓	✓
Alternative breeding method thru which the characteristic may have been obtained				√					
Description of intended new characteristic/ modification of existing characteristic/ equivalence to non-edited comparator	√	√	√	✓	√	√	√	✓	✓
Genetic map/construct used/delivery method		✓		✓	✓	✓			√
Molecular characterization/description of genetic change/sequence	√	√	✓	✓	✓	✓	✓	✓	✓
Information about methods used to discard foreign genetic material		√	✓		✓	✓		√	√
Information on authorization by other countries		√	✓	✓	√				√
Usage of the organism (cultivation vs. import for food/feed)						✓	✓		✓

Greetings!

This refers to the upcoming one (1) Intra-Department Consultation of DA and two (2) Stakeholder Consultations for the draft Memorandum Circular on the Rules and Procedure to Evaluate and Determine when Products of Plant Breeding Innovations (PBIs) or New Plant Breeding Techniques (NBTs) are Covered under the DOST-DA-DENR-DOH-DILG Joint Department Circular no. 1, series of 2016 (IDC1) based on the NCBP Resolution no. 1, series of 2021. The schedule of the abovementioned consultations are as follows:

Activity	Schedule	Meeting link			
Intra-Department	September 7, 2021 (Tuesday), 9:30	Zoom link: https://bit.ly/DA-			
Consultation of DA	- 11:30 AM	Consultation-on-PBIs			
		Meeting ID: 894 2784 9711			
		Passcode: 601948			
1st Stakeholder	September 23, 2021 (Thursday),	To be sent prior to the activity			
Consultation	9:30 - 11:30 AM				
2 nd Stakeholder	September 30, 2021 (Thursday),	To be sent prior to the activity			
Consultation	9:30 - 11:30 AM	-			

In line with this, we would like to invite a resource person from the NCBP to present the NCBP Resolution No.1 s 2020 The Regulation of Plant and Plant Products derived from the Use of Plant Breeding Innovations or New Plant Breeding Techniques on the said dates.

We have attached herewith a copy of the program, for your reference.

Thank you very much and we will be glad to follow up with the NCBP Secretariat regarding this

Intra-Department Consultation 7 September 2021

1st Stakeholder Consultation





Biotechnology Office

692 San Andres Street, Malate, Manila, Philippines Email Address: bpi.information@vahoo.com

Tel. No.: (02) 8525-7909, (02) 8525-2987 | Website: bpi.da.gov.ph

NOTICE OF STAKEHOLDER CONSULTATION

Stakeholder Consultation for the draft Memorandum Circular on the Rules and Procedure to Evaluate and Determine when Products of Plant Breeding Innovations (PBIs) or New Plant Breeding Techniques (NBTs) are Covered under the DOST-DA-DENR-DOH-DILG Joint Department Circular no. 1, series of 2016 (JDC1) based on the NCBP Resolution no. 1, series of 2021 on September 23, 2021 (Thursday), 9:30 - 11:30 AM via Zoom platform.

Volumey access the meeting



Department of Agriculture BUREAU OF PLANT INDUSTRY

Biotechnology Office 692 San Andres Street, Malate, Manila, Philippines Email Address: bpi.information@vahoo.com

Tel. No.: (02) 8525-7909, (02) 8525-2987 | Website: bpi.da.gov.ph

2nd Stakeholder Consultation 30 September 2021

NOTICE OF STAKEHOLDER CONSULTATION

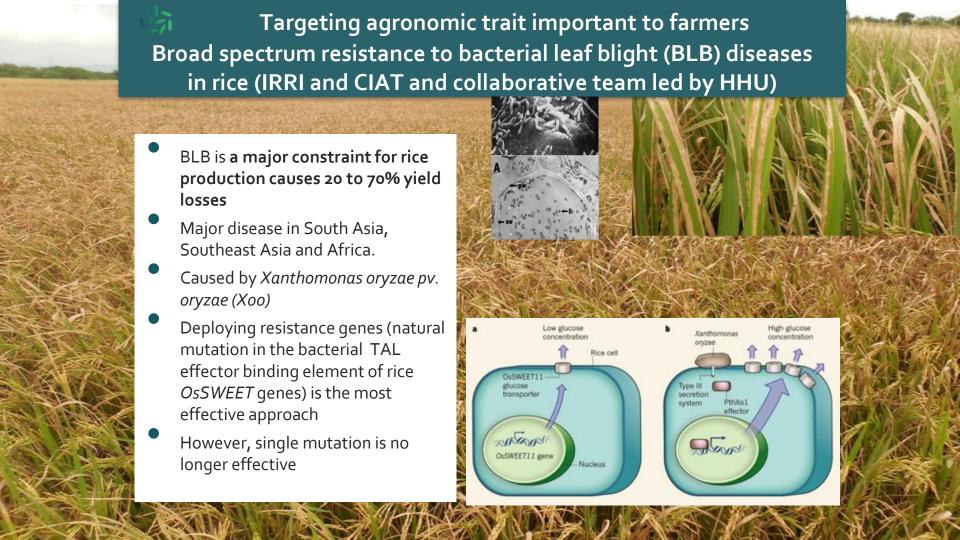
The Department of Agriculture will be conducting 2nd Stakeholder Consultation for the draft Memorandum Circular on the Rules and Procedure to Evaluate and Determine when Products of Plant Breeding Innovations (PBIs) or New Plant Breeding Techniques (NBTs) are Covered under the DOST-DA-DENR-DOH-DILG Joint Department Circular no. 1, series of 2016 (JDC1) based on the NCBP Resolution no. 1, series of 2021 on September 30, 2021 (Thursday), 9:30 – 11:30 AM via Zoom platform.

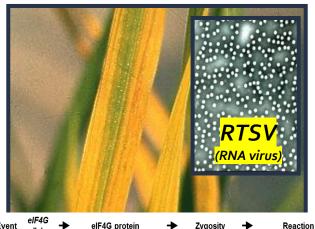
You may access the meeting room using the following credentials:





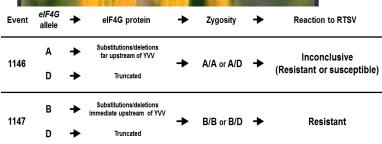
Status of R&D with the application of gene editing in the Philippines





Rice tungro spherical virus (RTSV)

- Rice Tungro Virus Disease is a serious constraint in rice production across tropical Asia. RTD is caused by the interaction between Rice tungro spherical virus (RTSV) and Rice tungro bacilliform virus (RTBV).
- Natural variation in 'Utri merah' resistant rice cultivar for RTSV Resistance is controlled by eIF4G in chr 7 (Lee et al., 2010).
- We developed novel variant by gene editing showing resistance to RTSV



Plant Biotechnol J. 2018 Nov;16(11):1918-1927. doi: 10.1111/pbi.12927. Epub 2018 Apr 30.

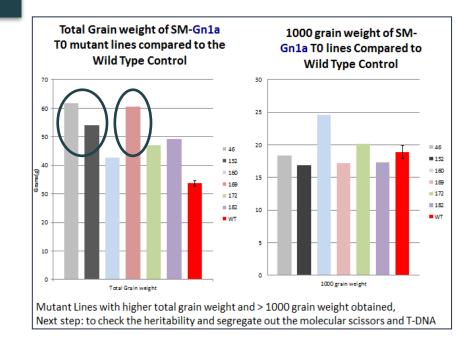
Novel alleles of rice eIF4G generated by CRISPR/Cas9-targeted mutagenesis confer resistance to Rice tungro spherical virus.

Yield trait

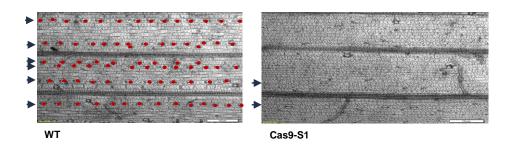


Knockout Yield Related Genes Using CRISPR-Cpf1 System in Samba Mahsuri and IR64

Gen : *Gn1a*



OsEPFL9 Knocked-out in Rice Using CRISPR to reduce the mature stomata number for Water Use Efficiency





Biofortification by Gene Editing approach in progress

?

VITAMIN A

Past 20 years, 10 billion capsules, (reduce preschool mortality by

Cost US\$10-15 billion

12-24%)



IRON (Fe)

- About 1.5 billion people suffer from Fe deficiency anemia
- Impairs cognitive function in children

ZINC

- Affects 1.2 billion people
- Results in weakened immune systems, higher mortality, and stunting
- 25% children (<5 years) are stunted
- Stunting results in poor brain development and

Source: Van Der Straetten, Slamet-Loedin et al, 2020 Nature comm.

Targeted Genome Editing using CRISPR-Cas9 Technology: Capacity Building and Proof-of-Concept in Rice, Corn, and Tomato

Dr. ANTONIO C. LAURENA

Project Leader

Implementing Agency: University of the Philippines Los Baños

Cooperating Agency: IRRI















Seminars, trainings and workshops on CRISPR-Cas9 for capacity-building of University faculty, staff and students and other SUC's

Tissue culture rice, corn and tomato plants as starting material for transformation

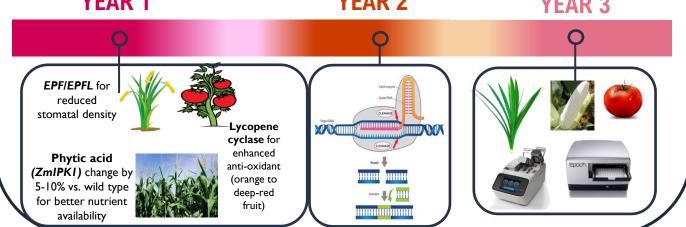
Gene Editing using CRISPR (Cas9 and Cpf1)

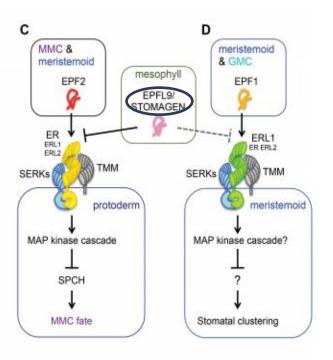
T1-T2 Generation: Phenotypic analysis and chemical characterization

YEAR 1

YEAR 2

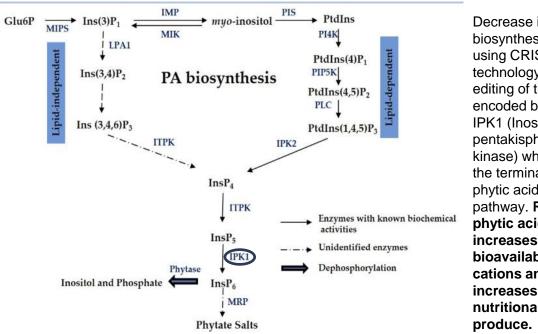
YEAR 3



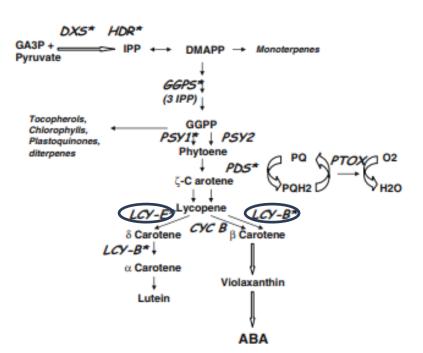


EPF1 and EPF2 have a negative role in rice leaf stomatal development while EPFL9/Stomagen acts as a positive regulator of leaf stomatal density. CRISPR-Cas9 and Cpf1 gene editing technology were applied to edit the EPF/EPFL genes to cause loss of function of the targeted genes. Knocking out the function of the positive regulator would reduce the stomatal density. This is desirable in the development of drought-resistant rice varieties to decrease the rate of transpiration, applicable in tropical countries like ours. Likewise, altering the expression of the negative regulator to produce the desired density of stomates will allow for efficient photosynthesis.

Tameshige, et al. 2016



Decrease in phytic acid biosynthesis in white corn using CRISPR/Cas9 technology by targeted editing of the enzyme encoded by the gene IPK1 (Inositol 1,3,4,5,6pentakisphosphate 2kinase) which catalyzes the terminal step of the phytic acid biosynthetic pathway. Reduction of phytic acid in corn increases bioavailability of many cations and thus increases the nutritional value of the



Tomato lycopene beta-cyclase (Lcy-b) and lycopene epsiloncyclase (Lcy-e) genes among the carotenoid genes in the carotenoid biosynthetic pathway are responsible for fruit color in tomato among other quality traits. Specifically, Lcy-b, which catalyzes several steps to convert relevant precursors to lycopene and carotene, while Lcy-e to further convert lycopene to carotene. By regulating this pathway, it is expected to produce a visible changes in fruit color, specifically favoring red fruit flesh due to the accumulation of lycopene carotenoid.

Te´lef, **et al. 2006**



Philippine Rice Research Institute





Improving popular released rice varieties through gene editing



Traits to be targeted

- Tungro resistance
- Bacterial leaf blight (BLB) resistance
- Optimized grain amylose content

■Ultimately, the outputs are expected to increase consumer preference, help secure farmers' incomes and reduce dependence on pesticides.









KEY TAKE-AWAY MESSAGE:



- The Philippines now has a regulatory policy (NCBP Resolution) on products of NBTs/PBIs, including genome editing;
- For products of genome editing that do not possess foreign DNA (SDN1, SDN2, ODM and SDN3 with cis insert), the existing GM regulation will not apply;
- SDN3 with trans insert (GMO) shall be covered by the GM regulation;
- The Department of Agriculture (DA) has already drafted the rules and procedure in evaluating products of NBTs and has conducted three consultations;
- Any genome-edited product is subject to a determination step if it is covered by the GM regulation (JDC#1 s2016) or not;
- A certificate of non-coverage from the JDC#1 is expected to be issued (by the DA-Bureau of Plant Industry) for non-GM products of NBTs.





THANK YOU!

References:

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