

Inter. Webinar Murdoch
University & ISAAA
“Crop from New Breeding
Technologies”
11 June 2021

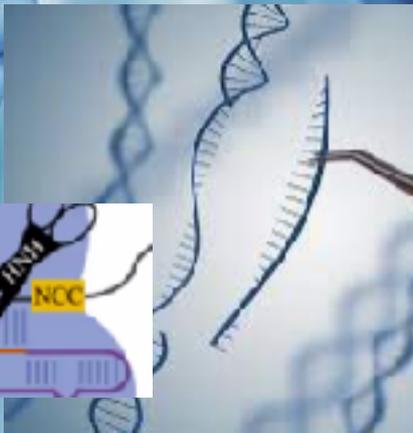


Status of Regulation dan Development of Products Derived from Genome Editing in Indonesia

Bambang Prasetya

*Indonesia Biosafety Committee of Genetically Engineered
Products (KKH-PRG)*

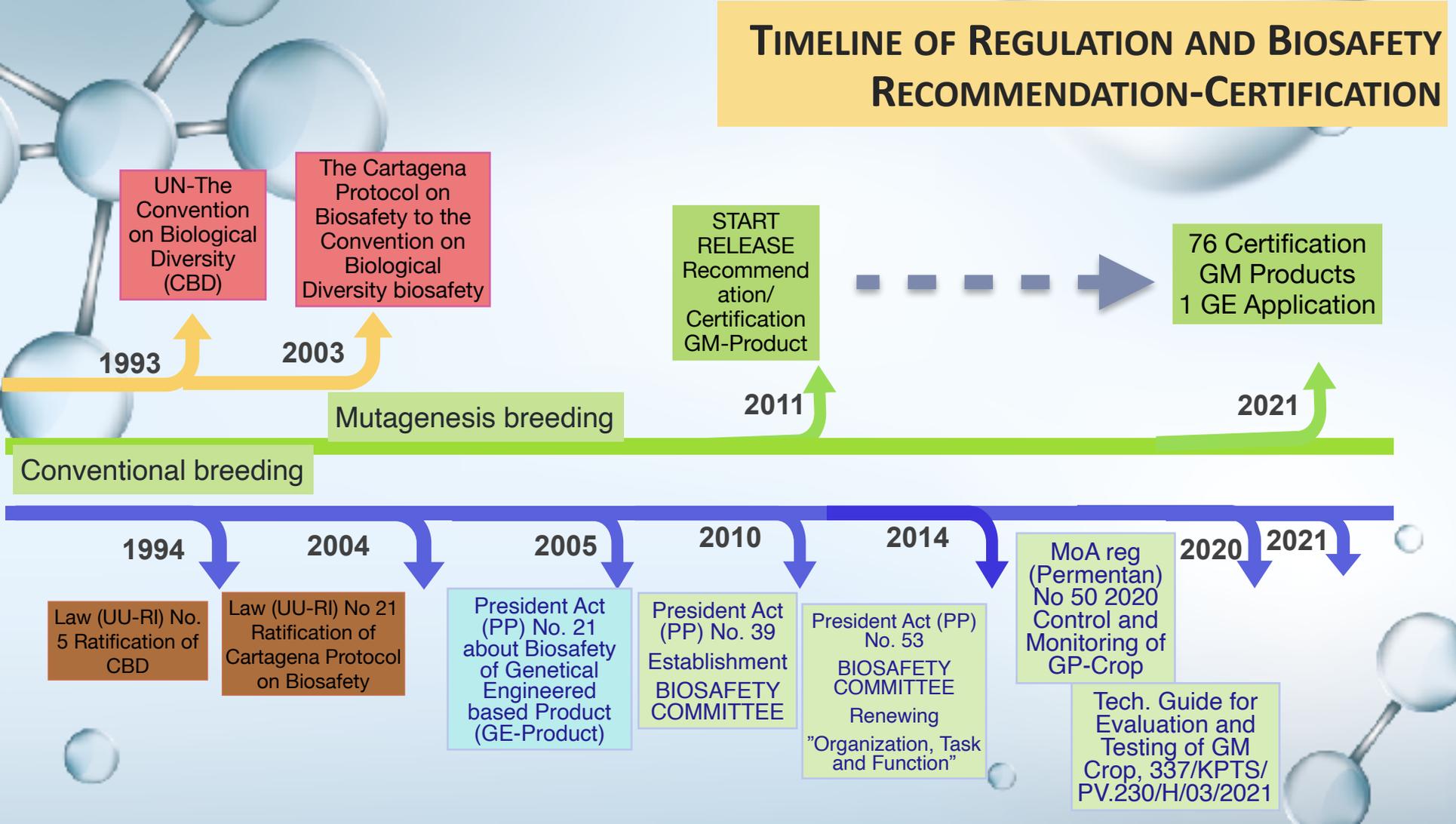




OUT LINE of Presentation

- 01 Introduction
- 02 Basic Regulation
- 03 Procedure and assessment system
- 04 Overview of Indonesia Production and Trade
- 05 Key strategies and potential collaboration

TIMELINE OF REGULATION AND BIOSAFETY RECOMMENDATION-CERTIFICATION



National Consolidation and Formulation of Regulation of Genome Editing



2021

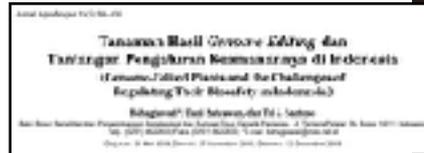
Policy recommendation to Ministry (MoA, MoEF, NADFC)
Setting of the cross-functional Technical Assessment from groups existing Technical Team.



2019-2020 : Experts Group Discussion (3 Times)
Research Center, University
Regulators
Association
Expert from Japan, Argentina, , USA, IRRI



2018-2020
Review the trend of
Genome Editing
Comparative Studies
Publications :
Bahagiawati et al, 2019
Prasetya & Nugroho 2020



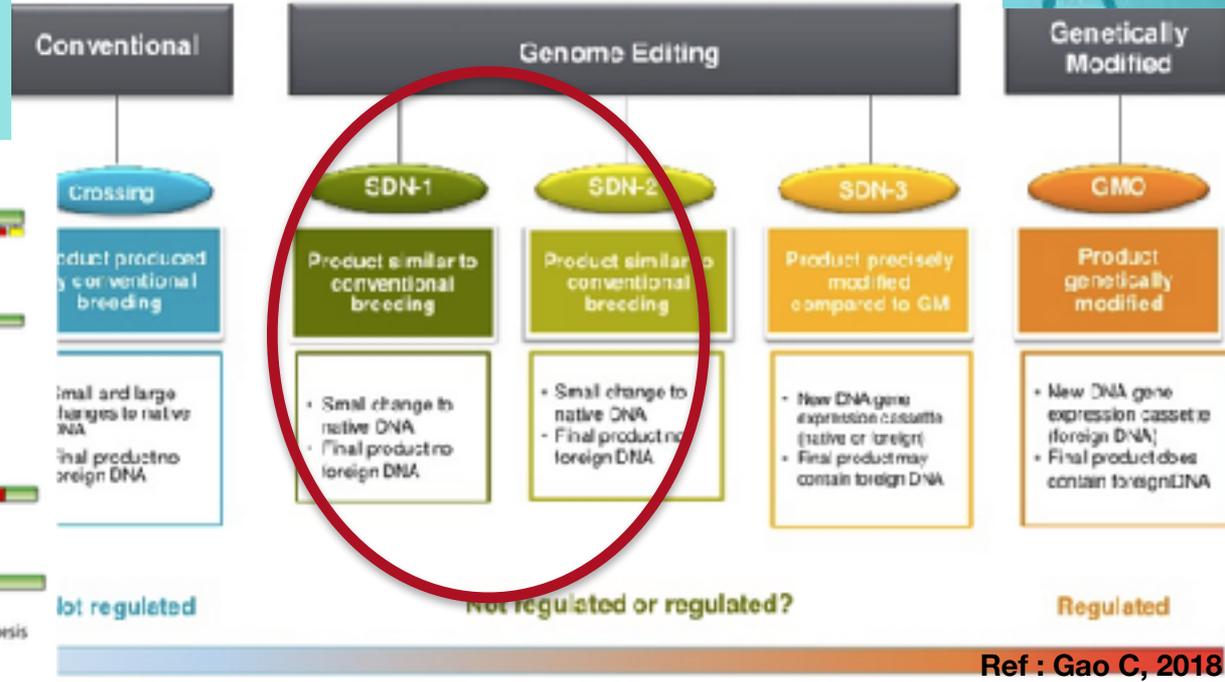
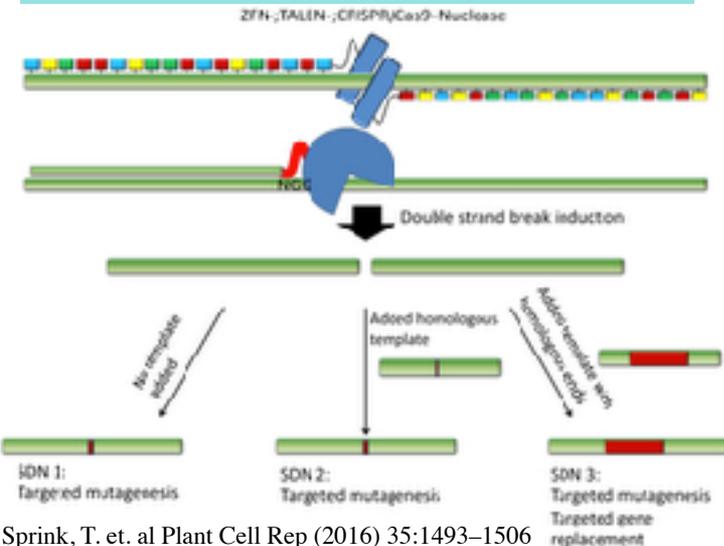
Basic Concept of GE and Position of Regulation

Basic Consideration/ Principles :

- End Product contains **no foreign gen**
- Based on classification of SDN (Site Directed Nuclease) : SDN-1 and SDN-2
- Assessment based on characterization of molecular and phenotype.

Exclude Genome Editing Technology from existing regulation for GM-Products

The decision whether product belong to GE or GM by Biosafety Committee based assessment from Technical Team of Biosafety



Supporting Team for Biosafety Assessment

Technical Team of
Biosafety for Food
(NADFC)

Technical Team of
Biosafety for Feed
(MoA)

Technical Team
Biosafety for
Environment
(MoEF)

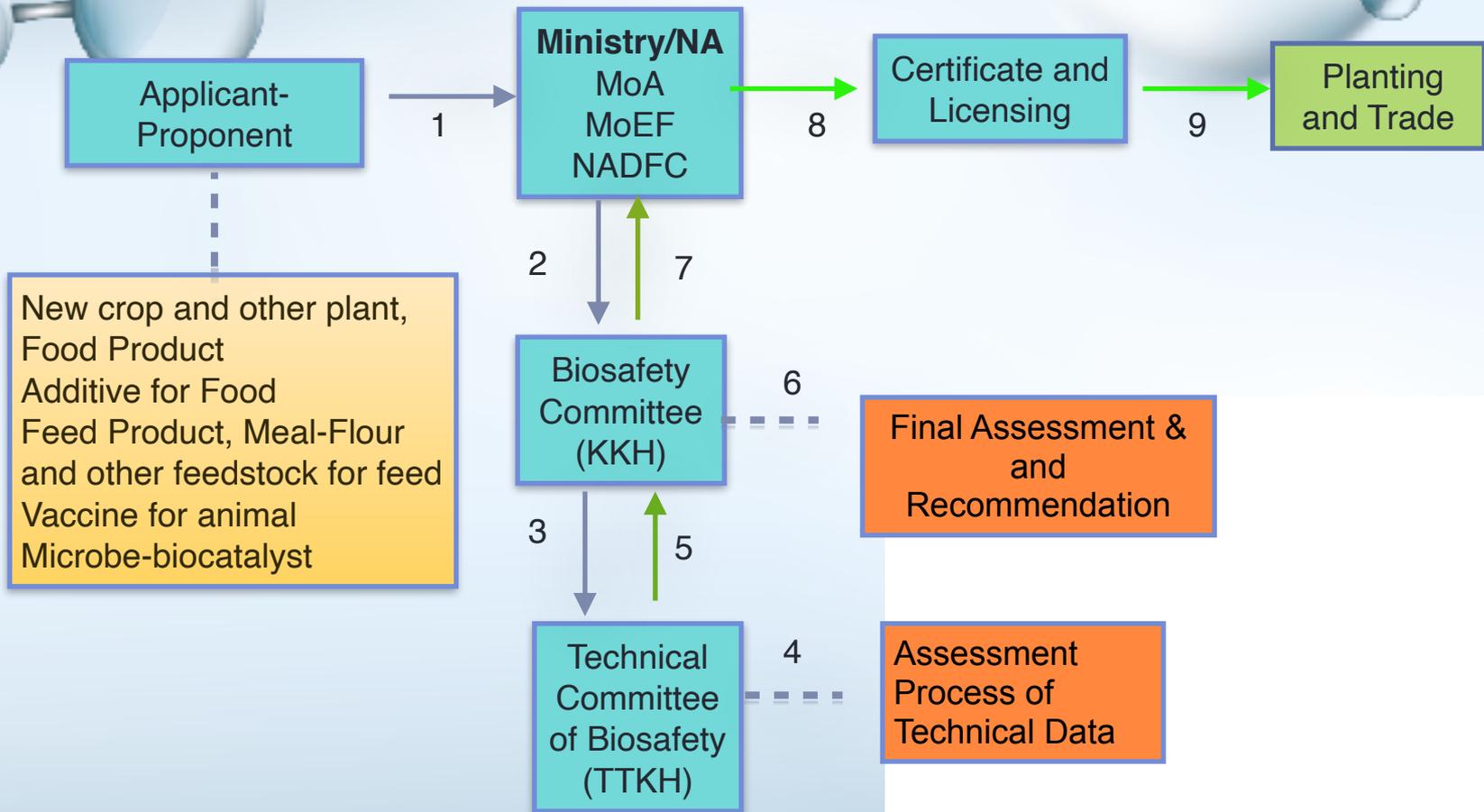
Team for Law, Socio-
Cultural and
Economic
Assessment



The logo for the Biosafety Clearing House is a circular emblem. It features a central stylized atom with three elliptical orbits and a central nucleus. Surrounding the atom is a circular border containing the letters 'C' and 'H' in a stylized font. The text 'Biosafety Clearing House' is written in blue across the center of the emblem.

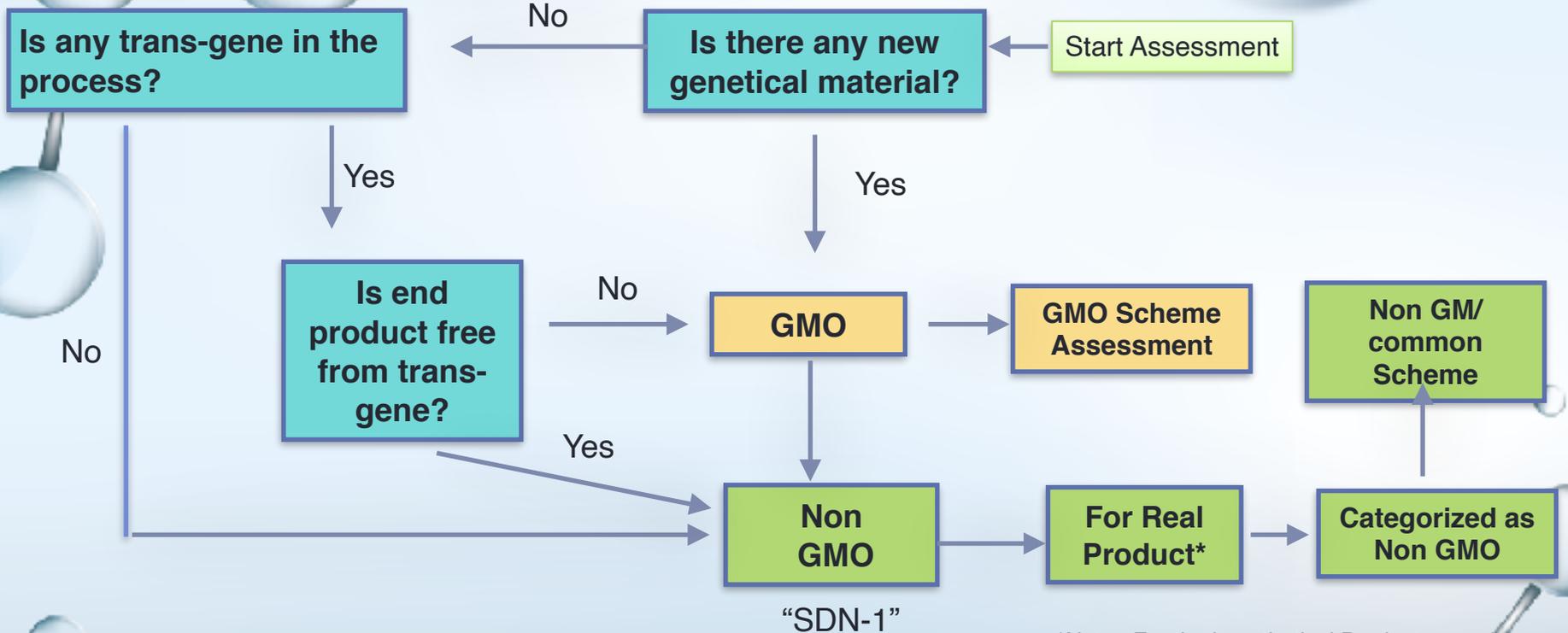
**Biosafety
Clearing
House**

Regulation of Genome Editing



Regulation of Genome Editing

“Flow of technical Assessment by Technical Team (TTKH)”



*Note : For the hypothetical Products, need support data of molecular analysis and phenotype

Biosafety Committee (KKH-PRG)

Pres Acts No. 53 2014

TASKs of Committee:

- A. Provide a recommendations of biosafety for GM Product the Minister of Environment and Forestry (MoEF), Minister of Agriculture (MoA), and Chair of National Agency for Drugs and Food Control (NADFC) as consideration for the issuance of a biosafety certificate.
- B. Provide certification of environmental safety, food and/or feed safety test results;
- C. Provide advice and consideration in establishing guidelines for monitoring impacts, managing risks and withdrawing PRGs from circulation.
- D. Providing advice and considerations as well as assisting the Minister of MoEF, MoA and chair of NCDFC who are authorized to carry out supervision over the importation and utilization of PRGs.

Total Recommendations (incl. on going process)

GM Product :

Food Biosafety : 40 products
(Soybean, Corn)

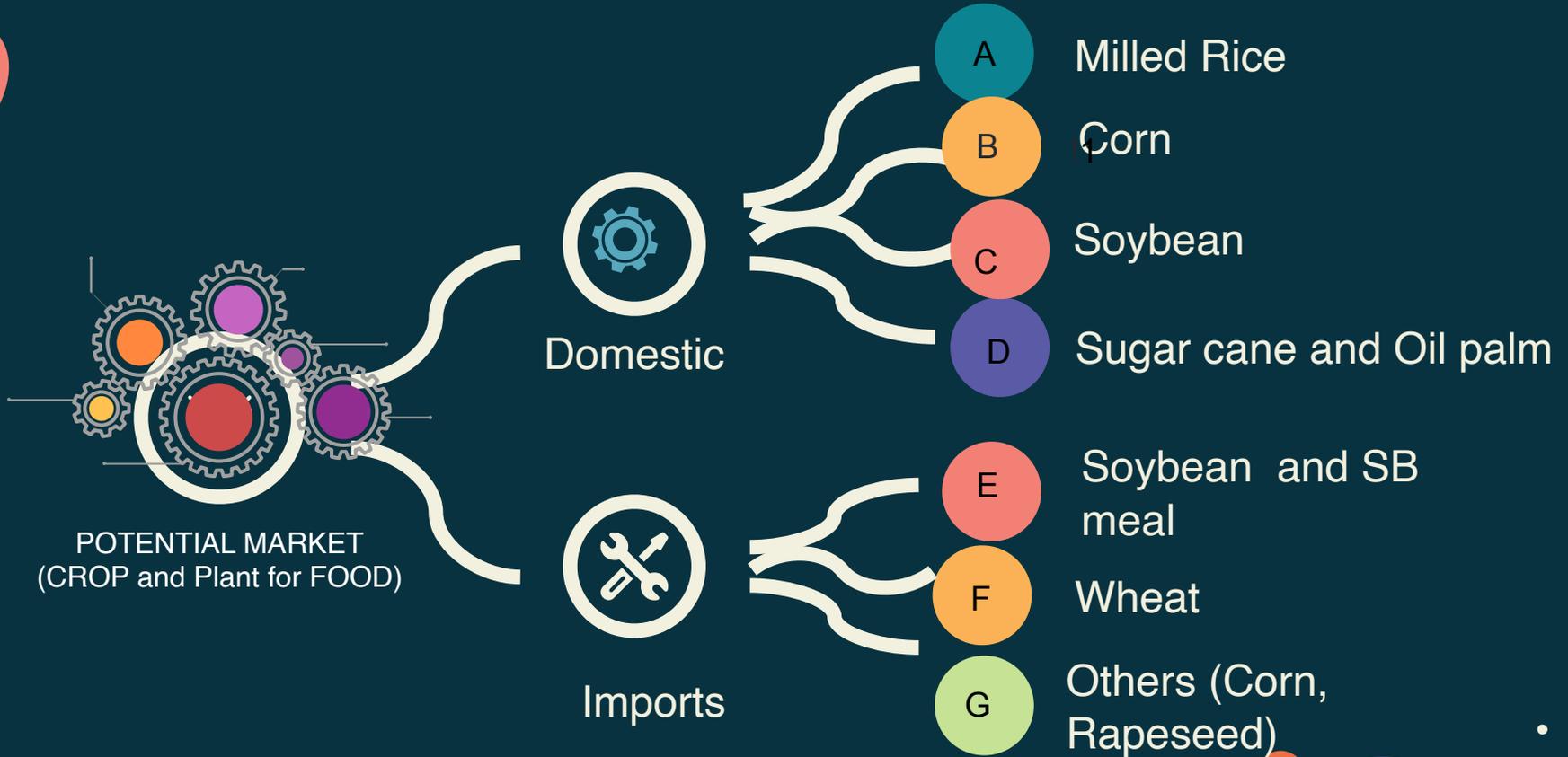
Feed Biosafety : 16 products (
Corn, Sugar Cane)

Environment Biosafety :
20 products

6 plants
and 14 Vaccine for Animal)

Genome Editing : 1 application (2021)

Main Production and Import in Indonesia



OVERVIEW OF PRODUCTION AND TRADE OF THE MAIN CROP IN INDONESIA 2015 vs 2020 (MILLION METRIC TON)

Commodities	Year	Production	Import	Export
Milled Rice	2015	36.2	1.05	0.002
	2020	35.0	0.7	0
Corn	2015	10.5	1.75	0.021
	2020	11.8	0.08	0.005
Soybean	2015	0.58	2.27	0.002
	2020	0.48	2.65	0.002
Soybean Meal	2015	0	4.2	0
	2020	0	5.0	0
Wheat	2015	0	10.04	0
	2020	0	10.00	0



STRATEGIC VALUES OF GENOME EDITING TECHNOLOGY AND POTENTIAL COOPERATION

1. GENOME EDITING BELONG PROMISING TECHNOLOGY DUE TO RELATIVE SIMPLER, CHEAPER, SHORTER TIME COMPARED TO GM TECHNOLOGY
2. GENOME EDITING HAVE A GOOD PROSPECTIVE TO BOOST OF FOOD SECURITY
3. REGULATION OF GE OPEN FLEXIBILITY IN RE-REGULATION ON EXISTING GM PRODUCT REGULATION
4. GW WILL BE OPEN POTENTIAL COLLABORATION G TO G OR I TO I FROM AT THE EARLY STAGE (ICL.R & D), TECHNOLOGY LICENSING, JOINT PRODUCTION AND MARKET
5. GENOME WILL BOOST FOR UTILIZATION OF POTENTIAL BIODIVERSITY TO VALUABLE PRODUCTS

RESEARCH CENTER DEVELOPING GE

- RC Biotechnology and Genetics Resources, Ministry of Agriculture
- RC Biotechnology -LIPI
- RC for Biotechnology fand Bioindustry Indonesia
- RC for Industrial and Beverage Plants, The Ministry of Agriculture
- State Univ Jember
- IPB University
- Gajahmada University

Research focus :

Rice, Orange, Chili, Sugar cane, Oil palm, *Artemisia sp*, *Amorphophallus sp*.



The background is a light green gradient. On the right side, there is a decorative pattern of squares in various shades of green, arranged in a grid-like fashion. The squares have a slight 3D effect with shadows.

THANK YOU

For your kind attention