

Required Report: Required - Public Distribution

Date: November 24,2020

Report Number: ID2020-0037

Report Name: Agricultural Biotechnology Annual

Country: Indonesia

Post: Jakarta

Report Category: Biotechnology and Other New Production Technologies

Prepared By: Titi Rahayu

Approved By: Garrett Mcdonald

Report Highlights:

This report updates the 2019 Agricultural Biotechnology Annual Report. The U.S. exported over \$1.8 billion in genetically engineered (GE) products to Indonesia in 2019, including more than \$860 million of soybeans. Despite completing biosafety assessments for various GE products, Indonesia has yet to finalize monitoring guidelines for GE crops that would allow for full domestic commercial cultivation. A recently developed “Road Map for Genetically Engineered Products”, led by the Coordinating Ministry for Economic Affairs, has established research and production goals for GE varieties of several staple crops including corn, sugar cane, potato, soybean and rice.

EXECUTIVE SUMMARY

The United States exported over \$1.8 billion of genetically engineered (GE) products to Indonesia in 2019, including Bt cotton, herbicide tolerant soybeans and meal, Bt corn, and a variety of food products derived from GE crops and microbes, such as cheese and enzymes.

The Government of Indonesia's (GOI) overarching policy on agricultural biotechnology is to use science along with the "precautionary approach" on issues surrounding environmental safety, food safety, and/or feed safety. The stated policy is also to take into consideration religion, ethical, socio-cultural, and esthetic norms. As a result of all these considerations, the GOI has issued several regulations and technical guidelines, including regulations on food safety assessment (2018) and food crop variety release (2019).

To date, 18 GE corn varieties, 13 GE soybean varieties, three GE sugarcane varieties, one GE potato variety, and one GE canola variety have undergone risk assessment for either food, feed, or environmental safety. Of those, three GE corn varieties and one GE sugar cane variety has undergone all three. Additionally, the GE potato variety, having completed both food and environmental safety assessments, has essentially met all safety requirements as it does not require a feed safety assessment since the product is not for animal consumption. Despite receiving these safety approvals, the GE corn and potato products have yet to receive an official variety release pending GOI issuance of regulations related to the "monitoring and control" system for GE crops as required by Government Regulation 21/2005. Having previously received a variety release, the GE sugar cane developed by state-owned PT Perkebunan Nusantara XI (PTPN XI), now stands alone as the first GE crop to meet all existing regulatory requirements for public release. In addition to the above, the GOI has approved a GE structuring protein for human consumption, a GE livestock feed additive, and 11 GE animal vaccines for commercialization.

TABLE OF CONTENTS

CHAPTER 1: PLANT BIOTECHNOLOGY	4
PART A: Production and Trade	4
PART B: Policy	6
PART C: Marketing	32
CHAPTER 2: ANIMAL BIOTECHNOLOGY	33
PART D: Production and Trade	33
PART E: Policy	33
PART F: Marketing	34
CHAPTER 3: MICROBIAL BIOTECHNOLOGY	34
PART G: Production and Trade	34
PART H: Policy	35
PART I: Marketing	36

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:

Indonesia continues to develop GE crops, albeit at a moderate pace. For example, the Indonesian Institute of Science (LIPI) has completed confined field trials for stem borer-resistant rice in four locations and next will submit its environmental safety application to the Ministry of Environmental and Forestry (food and feed safety studies have already been conducted). Unfortunately, due to budget constraints, the submission of environmental safety and food safety applications may only occur in 2021. In addition, LIPI is also researching virus tungro resistant rice, drought tolerant rice, salinity tolerant rice, blast resistant rice, and shelf life extended cassava. Currently, these products are in the growth chamber for efficacy testing.

The Ministry of Agriculture's (MOA) Indonesia Center for Agricultural Biotechnology and Genetic Resources (ICABIOGRAD) has conducted confined field trials for virus resistant tomato in four locations. Currently, they continue to prepare the application for an environmental safety assessment and to finish the food safety study. In addition, they are conducting study on late blight resistant potato for variety registration purposes and continuing to conduct trials for their GE nitrogen use efficiency rice in their growth chamber. The status of their stem borer resistant sugar cane is also in trial in the growth chamber. ICABIOGRAD has also continued researching Bt rice and genome editing for gemini virus resistant chili, greening disease resistant citrus, and low cadmium absorbent rice. In addition, ICABIOGRAD has collaborated with the Ministry of Health to research genome editing for high-yield *Artemisia annua*.

The University of Jember, in collaboration with a state-owned company, is developing a GE, high glucose content sugarcane. The university has studied environmental safety and food safety of the GE sugarcane, and is currently conducting confined field trials in four locations. The University of Jember is also conducting research on golden rice (IR36) and will extend this research to include IR64 rice, with the expectation that these crops will be ready for risk assessment in two years. Research on mosaic virus resistant sugarcane at the University of Jember has completed and is pending further assessment for possible commercialization. In addition, the University of Jember is researching mosaic virus resistant sorghum, high yield rice, and mosaic virus resistant tomato. Meanwhile, the IPB University has successfully assembled bacterial wilt resistant potato.

USAID is funding the development of a GE late blight resistant potato. The potato project is being carried out in a partnership with Michigan State University, the University of Minnesota, University of Idaho, the JR Simplot Company and ICABIOGRAD, and organized under the Feed the Future Biotechnology Partnership Project. Under the regulated materials transfer agreement between Michigan State University and ICABIOGRAD, the research uses GE Diamant (the variant is originally from Bangladesh) and Granola potato varieties inserted with three virus-resistant genes from wild potato species. The stacked-gene Diamant variety

was harvested from confined field trials in June 2020 and the Granola variety that was planted for confined field trials in July 2020 had been harvested in November 2020.

Finally, Arcadia Biosciences Inc. which collaborated with MOA, completed their research on evaluating GE nitrogen use efficiency rice. Unfortunately, Arcadia didn't want to continue the project and all of the genetic materials have been destroyed. This project was funded under a USAID grant.

b) **COMMERCIAL PRODUCTION:**

The Ministry of Agriculture issued the feed safety certificate for GE drought-tolerant sugar cane on August 20, 2018 making it the first GE crop to be eligible for commercial cultivation. However, this eligibility is particular only to this specific crop, as it had previously obtained variety release and therefore was not required to wait for the establishment of "monitoring guidelines". Nor is the sugar cane truly a commercial release, in the sense of seeds being distributed or sold to farmers who can freely plant, harvest, and sell the crops. PTPN XI's sugar cane is currently only grown on lands owned by PTPN XI and the company itself is restricted from selling or distributing the seeds as they lack the proper registration to do so. It is also unlikely they will apply for such registration in the future, as the demand may be relatively limited to specific areas that frequently suffer from drought conditions. All other GE crops, including herbicide tolerant corn NK603 and GA21, as well as insect resistant BT 11 (which have received food, feed, and environment safety approvals), are awaiting MOA's issuance of monitoring guidelines.

c) **EXPORTS:**

Indonesia does not export any GE crops to the United States or any other country.

d) **IMPORTS:**

According to Trade Data Monitor, in 2019, Indonesian imported nearly 2.7 million metric tons (MMT) of soybeans. U.S. soybeans account for approximately 95 percent of all soybean imports and are mostly GE varieties. Soybean consumption in Indonesia is predominantly for human food, with most imported soybeans going to tempeh and tofu production.

As one of the world's largest cotton importers, Indonesia imported over 623,000 tons of cotton in 2019, including over 243,000 tons of cotton from the United States. The majority off all cotton imports are Bt cotton, which feeds Indonesia's major textile and garment industries.

Indonesia's livestock industry relies on imported soybean meal, corn and corn related products for feed. In 2019, Indonesia imported nearly 4.4 MMT of soybean meal, primarily from Argentina and Brazil. Corn imports increased to over 1 MMT in 2019 as the GOI was forced to allow imports for feed use to stabilize prices and because of higher levels of imports for Indonesia's growing corn wet milling industry. In 2019 local poultry producers imported over 287,000 tons of corn gluten meal and nearly 858,000 tons of distiller's dried grain and solubles (DDGS) originating primarily from the United States, primarily from GE corn.

Please see GAIN Reports [ID2020-0004](#), [ID2020-0006](#) and [ID2020-0007](#) for more information regarding the trade of soybeans, soybean meal, corn, and cotton.

- e) **FOOD AID:**
Indonesia is not a recipient or donor of food aid.
- f) **TRADE BARRIERS:**
Indonesia's regulatory framework continues to stifle the domestic commercialization of GE crops, despite importing large quantities of GE foods.

PART B: POLICY

a) **REGULATORY FRAMEWORK:**

The GOI's policy on biotechnology is "accept with a precautionary approach" and use science to assess environmental safety, food safety, and/or feed safety. In addition, the GOI's policy is to consider religion, ethical, socio-cultural, and esthetical norms. Indonesia's regulatory framework to evaluate and approve GE crops was incomplete until August 4, 2016, when MOA issued regulation 36/2016. Regulation 36/2016 established risk assessment guidelines for feed safety, completing the risk assessment framework, and environmental and food safety guidelines. Despite completing the risk assessment framework, Indonesia's approvals of GE products remain on hold due to MOA's invocation of Government Regulation 21/2005 on the Biosafety of Genetically Engineered Products. This regulation requires that a "monitoring and control" system be implemented in order to regulate approved GE products.

The Ministers of Environment, Agriculture, Forestry, Marine Affairs and Fisheries, and the Head of BPOM (National Food and Drug Agency) are the authorities responsible for approving and releasing GE products (See Table 1). The Indonesian Council of Ulama (MUI) in 2013, declared that GE food, pharmaceutical, and cosmetic products are halal.

The issuance of Presidential Regulation No. 11/2016 on suspension of nine non-structural institutions, including the National Seed Agency (BBN), caused an obstacle to commercialization of GE food crop and estate crop varieties. This is because BBN had previously authorized the release of all of food and estate crops varieties, including the GE products. However, with the issuance of a new regulation on crop variety release (Ministry of Agriculture's regulation No. 38/2019), the authority for releasing all crop varieties is with the Center for Plant Variety Protection and Agricultural Licensing, MOA.

For their part, BPOM has revoked three different regulations governing GE food (No. HK.03.1.23.03.12.1563/2012, No. HK.03.1.23.03.12.1564/2012, and No. 19/2016) and compiled them into regulation No. 6/2018 on Supervision of GE Food Products.

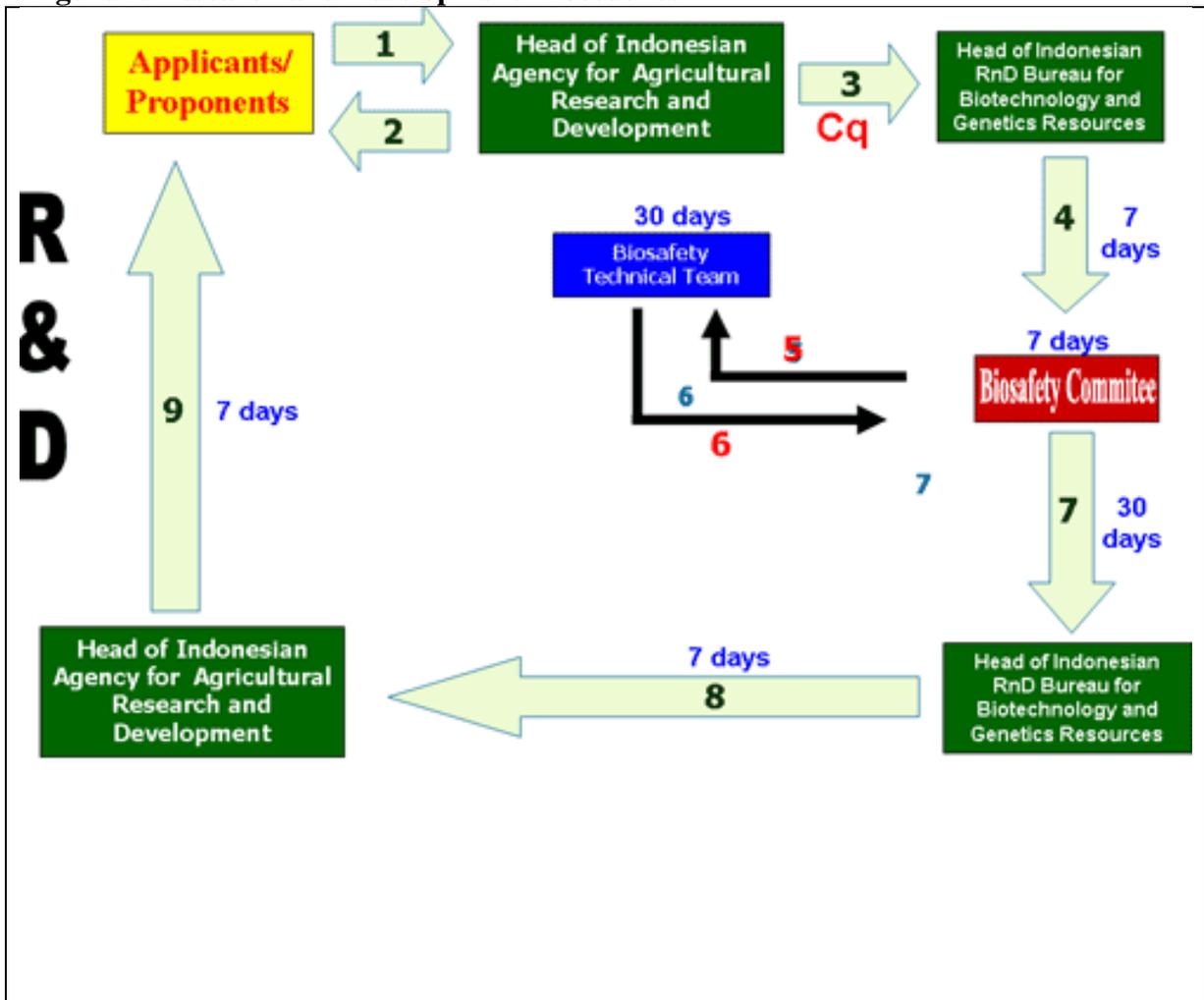
Additionally, the Ministry of Environment and Forestry published regulation 69/2016 on procedures for environmental safety testing of GE crops during confined field trials. Other Indonesian laws and regulations related to biotechnology can be seen at [the Indonesian Biosafety Clearing House \(BCH\)'s website](#).

Table 1. The National Competent Authority for GE Products

No.	National Competent Authorities		Area of authority
	Ministry/Agency	The Authorized Office	
1.	Ministry of Environment and Forestry	Directorate General for Conservation of Natural Resources and Ecosystem	Environmental safety
2.	Ministry of Agriculture	Indonesian Agency for Agriculture Research and Development	Feed safety
3.	Ministry of Agriculture	Center for Plant Variety Protection and Agricultural Licensing	Seed imports permit and crop variety release
4.	Ministry of Agriculture	Indonesian Agency for Agriculture Research and Development	Research permit
5.	Ministry of Agriculture	Indonesian Agency for Agriculture Quarantine	Plant and animal imports
6.	National Agency of Drug and Food Control (BPOM)	Deputy for Processed Food Control	Food safety
7.	Ministry of Marine Affairs and Fisheries	Research Center for Marine and Fisheries Product Processing and Biotechnology	Fisheries products and fish feed
8.	Ministry of Environment and Forestry	Agency of Research, Development, and Innovation	Forestry plants

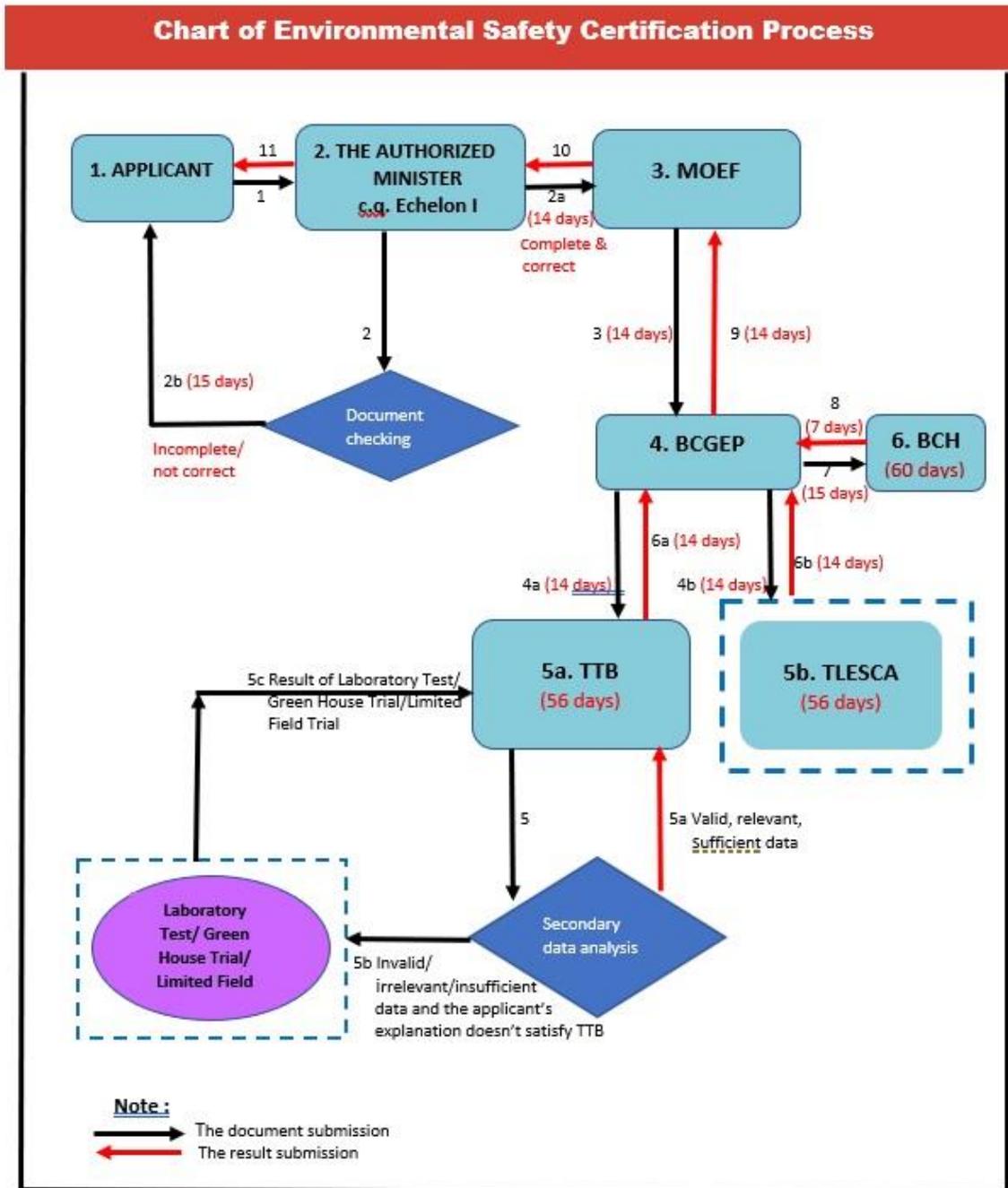
The procedures for the approval of food, feed, processing, and environmental releases are described in the diagrams below, as per government regulation No. 21, 2005.

Figure 1. Research and Development Procedures



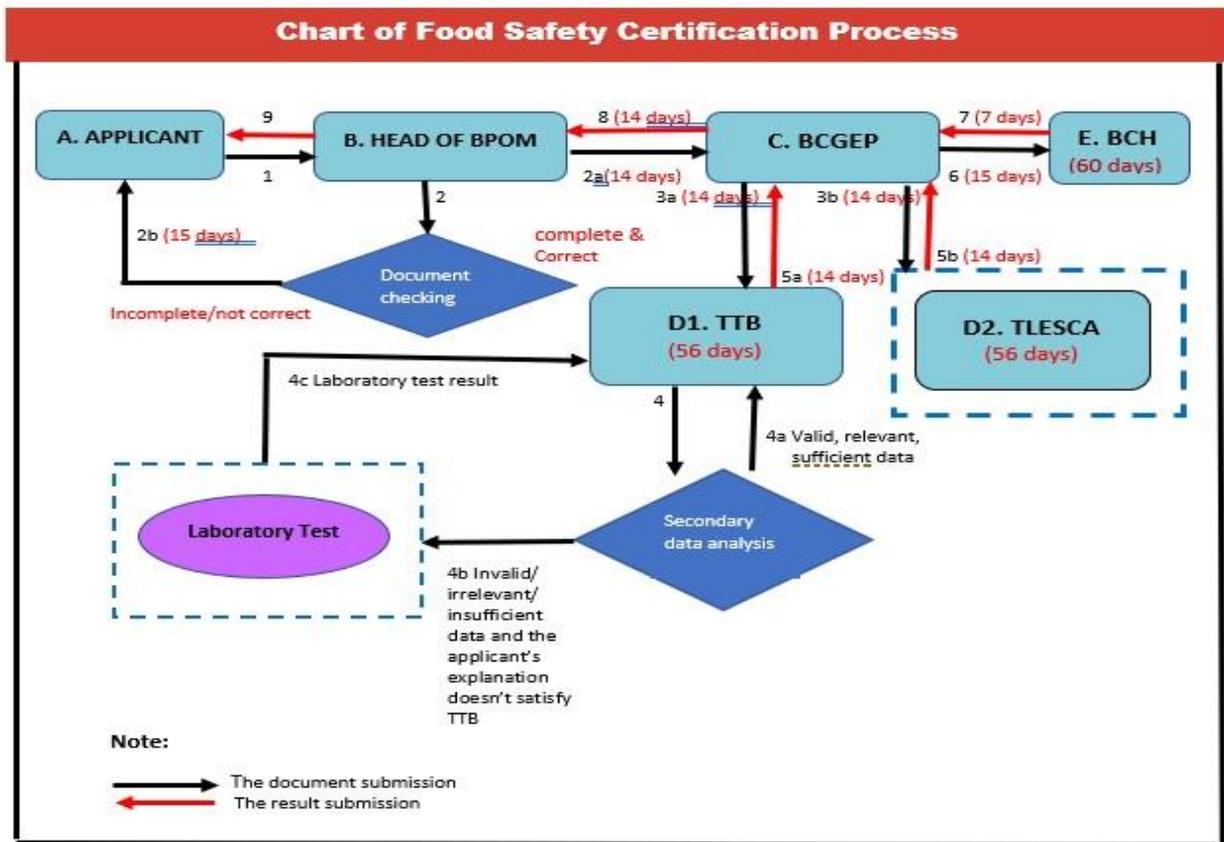
(Source: Indonesia Bio-safety Clearing House (BCH), 2010)

Figure 2. The Procedure for Obtaining Environmental Safety Certificate



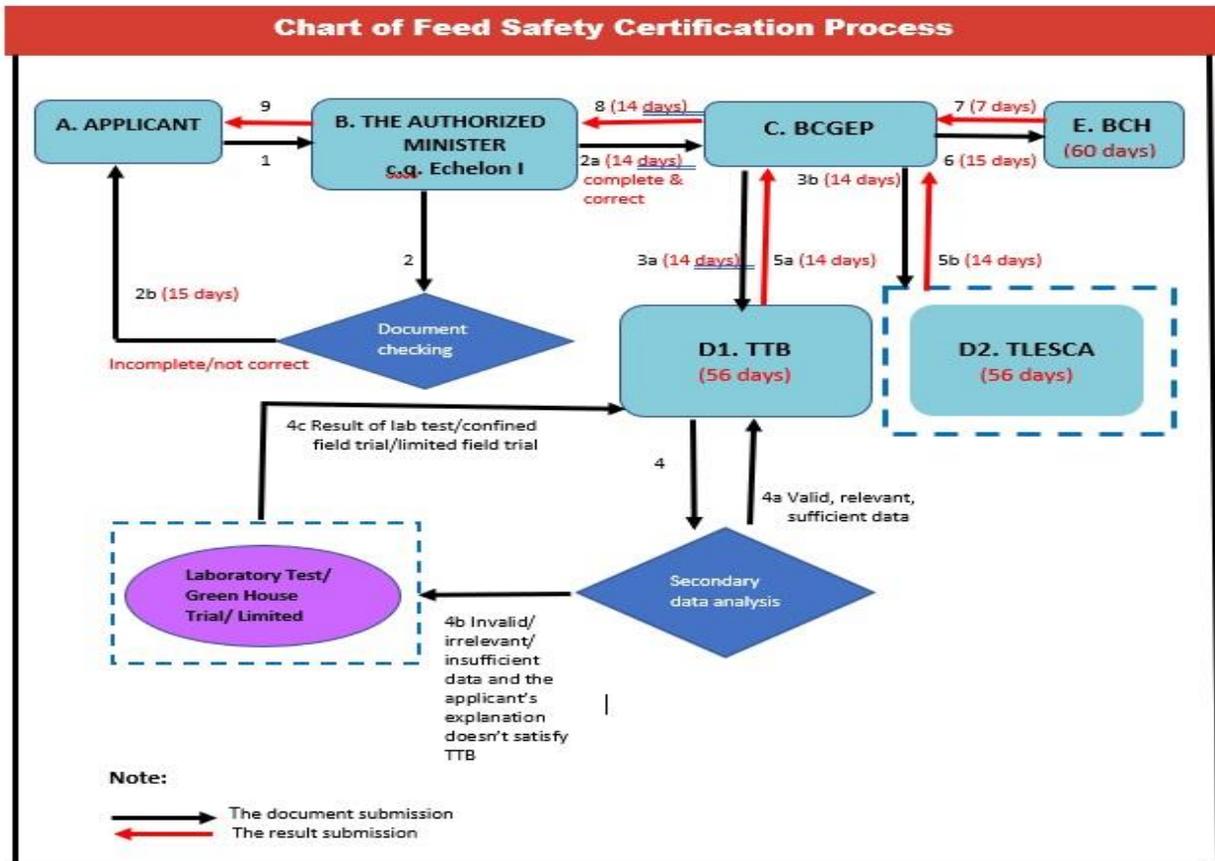
(Source: Indonesia Bio-safety Clearing House (BCH), 2019)

Figure 3. The Procedure for Obtaining Food Safety Certificate



(Source: Indonesia Bio-safety Clearing House (BCH)2019)

Figure 4. The Procedure for Obtaining Feed Safety Certificate



(Source: Indonesia Bio-safety Clearing House (BCH), 2019)

The National Biosafety Commission on Genetically Engineered Products (BCGEP) is responsible for providing biosafety recommendations, suggestions, and considerations of GE products to the authorized ministries. The first BCGEP, established in 2010 and based on Presidential Regulation 39/2010, was inactive until June 2, 2014, when it was reauthorized through [Presidential Regulation 53](#). The current BCGEP members were selected through the Presidential Regulation No. 50/2018 on September 27, 2018. The BCGEP consists of 19 members from the government, the community, and academia. In June 2020, the BCGEP was initially included on a list of non-structural institutions for suspension or restructuring as part of the GOI's attempt to streamline bureaucracy, however it was not included on the final announcement issued July 20, 2020, allowing the commission to continue its work.

Three Technical Teams for Biosafety (TTB) assist the BCGEP in conducting technical assessments and reviews for food, feed, and environmental biosafety. The technical team for environmental safety is divided into four groups: plant, animal, fish, and microorganisms. In addition to this team, BCGEP also established the Team of Legal, Economic, Social, and Culture Assessment (TLESCA) in 2012.

b) APPROVALS:

Several GE plants have received food, feed, and/or environmental safety certificates from the GOI. However, no imported or locally developed GE plants have yet been commercialized for cultivation.

Since the [2019 Biotechnology Annual Report](#), progress has been made on several approvals. Under a new leadership, BCGEP, assisted by TTB, has actively conducted technical biosafety assessments and provided biosafety recommendations for several GE products. Currently, GE canola events RF3 and MS8 are on the biosafety clearing house for receiving comments on their food safety. Meanwhile, GE stacked event Bt11xGA21 is awaiting an environmental safety recommendation from BCGEP. In addition, BCGEP is still in discussion for providing food safety recommendations of GE corn events 59122, DAS-40278-9, T25 and stacked event Bt11xGA21.

Herbicide tolerant corn events NK603 and GA21, as well as insect resistant corn event BT 11 have completed all three risk assessments, but are still waiting for MOA's varietal release approvals, which are dependent on the issuance of monitoring guidelines.

Please see the below table of approved GE products from each category.

Table 3. GE Plants with Environmental, Feed and/or Food Safety Approvals

For Food Safety		
No.	Product	Applicant
1.	Insect resistant corn event MON 89034	PT. Branita Sandhini
2.	Herbicide tolerant corn event NK 603	PT. Branita Sandhini
3.	Herbicide tolerant soybean event GTS 40-3-2	PT. Branita Sandhini
4.	Herbicide tolerant soybean event MON 89788	PT. Branita Sandhini
5.	Herbicide tolerant corn event GA21	PT. Syngenta Indonesia
6.	Insect resistant corn event MIR 162	PT. Syngenta Indonesia
7.	Insect resistant corn event BT 11	PT. Syngenta Indonesia
8.	Insect resistant corn event MIR 604	PT. Syngenta Indonesia
9.	Corn event 3272 (contained optimal alpha amylase enzyme for ethanol production)	PT. Syngenta Indonesia
10.	Drought tolerant sugarcane event NXI-1T	PT. Perkebunan Nusantara XI
11.	Drought tolerant sugarcane event NXI-4T	PT. Perkebunan Nusantara XI
12.	Drought tolerant sugarcane event NXI-6T	PT. Perkebunan Nusantara XI
13.	Insect resistant soybean event MON 87701	PT. Branita Sandhini
14.	Herbicide tolerant and fatty acid change soybean event MON 87705	PT. Branita Sandhini
15.	Herbicide tolerant and insect resistant corn event TC 1507	PT. DuPont Indonesia
16.	Herbicide tolerant soybean event MON 87708	PT. Branita Sandhini

17.	Higher nutritional value soybean event MON 87769	PT. Branita Sandhini
18.	Herbicide tolerant corn event MON 87427	PT. Branita Sandhini
19.	Drought tolerant corn event MON 87460	PT. Branita Sandhini
20.	Late blight resistant potato Katahdin event SP951	ICABIOGRAD, Ministry of Agriculture
21.	High oleic acid and herbicide tolerant soybean event 305423	PT. DuPont Indonesia
22.	Herbicide tolerant soybean event SYHT02H2	PT. Syngenta Seed Indonesia
23.	Insect resistant corn event MON 810	PT. Branita Sandhini
24.	Herbicide tolerant and insect resistant corn event MON 87411	PT. Branita Sandhini
25.	Insect resistant soybean event MON 87751	PT. Branita Sandhini
26.	Herbicide tolerant and insect resistant corn event MON 88017	PT. Branita Sandhini
27.	Herbicide tolerant and insect resistant corn event MZIR098	PT. Syngenta Seed Indonesia
28.	Herbicide tolerant corn event MZHG0JG	PT. Syngenta Seed Indonesia
29.	Herbicide tolerant canola event DP73496	PT. DuPont Indonesia
30.	Insect resistant corn event 5307	PT. Syngenta Seed Indonesia
31.	Herbicides tolerant corn event DAS-402789	PT. Dow Agro Sciences Indonesia
32.	Herbicide tolerant and insect resistant corn event 59122	PT. DuPont Indonesia
33.	Herbicide tolerant soybean event A55547-127	PT BASF Indonesia
34.	Herbicide tolerant soybean event A2704-12	PT. BASF Indonesia
35.	Herbicides tolerant soybean event DAS-44406-6	PT. Dow Agro Sciences Indonesia
36.	Herbicide resistant soybean FG72	PT BASF Indonesia
For Feed Safety		
1.	Herbicide tolerant corn event NK 603	PT. Branita Sandhini
2.	Insect resistant corn event MON 89034	PT. Branita Sandhini
3.	Drought tolerant sugar cane event NXI-4T	PT. Perkebunan Nusantara XI
4.	Insect resistant corn event BT 11	PT. Syngenta Seed Indonesia
5.	Herbicide tolerant corn event GA21	PT. Syngenta Seed Indonesia
6.	Insects resistant corn event MIR 162	PT. Syngenta Indonesia
7.	Insect resistant corn event MIR 604	PT. Syngenta Indonesia
8.	Insect resistant soybean event MON 87701	PT. Branita Sandhini
9.	Herbicide tolerant and insect resistant corn event TC 1507	PT. DuPont Indonesia
10.	Corn event 3272 (contained optimal alpha amylase enzyme for ethanol production)	PT. Syngenta Indonesia
11.	Insect resistant corn event 5307	PT. Syngenta Seed Indonesia

For Environmental Safety		
1.	Herbicide tolerant cotton event MON 1445	PT. Monsanto Indonesia
2.	Insect resistant cotton event MON 531	PT. Monsanto Indonesia
3.	Drought tolerant sugarcane event NXI-1T	PT. Perkebunan Nusantara XI
4.	Drought tolerant sugarcane event NXI-4T	PT. Perkebunan Nusantara XI
5.	Drought tolerant sugarcane event NXI-6T	PT. Perkebunan Nusantara XI
6.	Herbicide tolerant corn event NK 603	PT. BranitaSandhini
7.	Herbicide tolerant corn event GA21	PT. Syngenta Seed Indonesia
8.	Late blight resistant potato Katahdin event SP951	ICABIOGRAD, Ministry of Agriculture
9.	Insect resistant corn event BT 11	PT. Syngenta Seed Indonesia

Source: [Biosafety Clearing House, Secretary of BCGEP](#), and [the Directorate of Processed Food Standardization of NADFC](#) (2020)

Note: In 1999, BCGEP approved environmental safety for Roundup Ready (RR) cotton and Bt cotton. The Bt cotton received a limited variety release approval from MOA for planting in South Sulawesi province in 2001. The approval was extended on a yearly basis until 2003 when the company responsible for commercialization halted use.

The below table provides information on non-crop products that have received feed or environmental safety approvals:

Table 4. Non-Crop GE Products with Environmental or Feed Safety Approvals

No.	Product	Applicant
For Feed Safety		
1.	Ronozyme AX (CT)	PT. DSM Nutritional Product Indonesia
For Environmental Safety		
1.	GE vaccine Ingelvac Circoflex	Boehringer Ingelheim Indonesia
2.	GE vaccine Vectormune HV NDV + RIspens	PT. Ceva Animal Health Indonesia
3.	GE vaccine HimmvacDalguban N Plus Oil	PT. Blue Sky Biotech
4.	GE vaccine HimmvacDalguban BEN Plus Oil	PT. Blue Sky Biotech
5.	GE vaccine Vectormune HVT NDV	PT. Ceva Animal Health Indonesia
6.	GE vaccine Vaxxitek HVT + IBD	PT. RomindoPrimavetcom
7.	GE vaccine Nobilis rHVT-ND	PT. Intervet Indonesia

8.	GE vaccine Himmvac Dalguban BN Plus Oil	PT. Blue Sky Biotech
9.	GE vaccine Nobilis rHVT-ILT	PT. Intervet Indonesia
10.	GE vaccine Porcilis ®PCV M Hyo	PT. Intervet Indonesia
11.	<i>Corynebacterium glutamicum</i> CJM107 (KCCM-10227) (U.S. Patent No: U.S. 9,777,28282)	PT. Ajinex International

Source: [Biosafety Clearing House and Secretary of BCGEP](#) (2020)

c) STACKED or PYRAMIDED EVENT APPROVALS:

Environmental safety approval for stacked events is similar to single event approval. Such GE crops must undergo laboratory and biosafety containment tests, confined field trials, and an environmental risk analysis. GOI has decided that the existing food and feed safety approval process for single events can be used for stacked events. While no new regulation is expected for stacked gene approvals, additional guidelines may be added to the food and feed assessments addressing stacked genes.

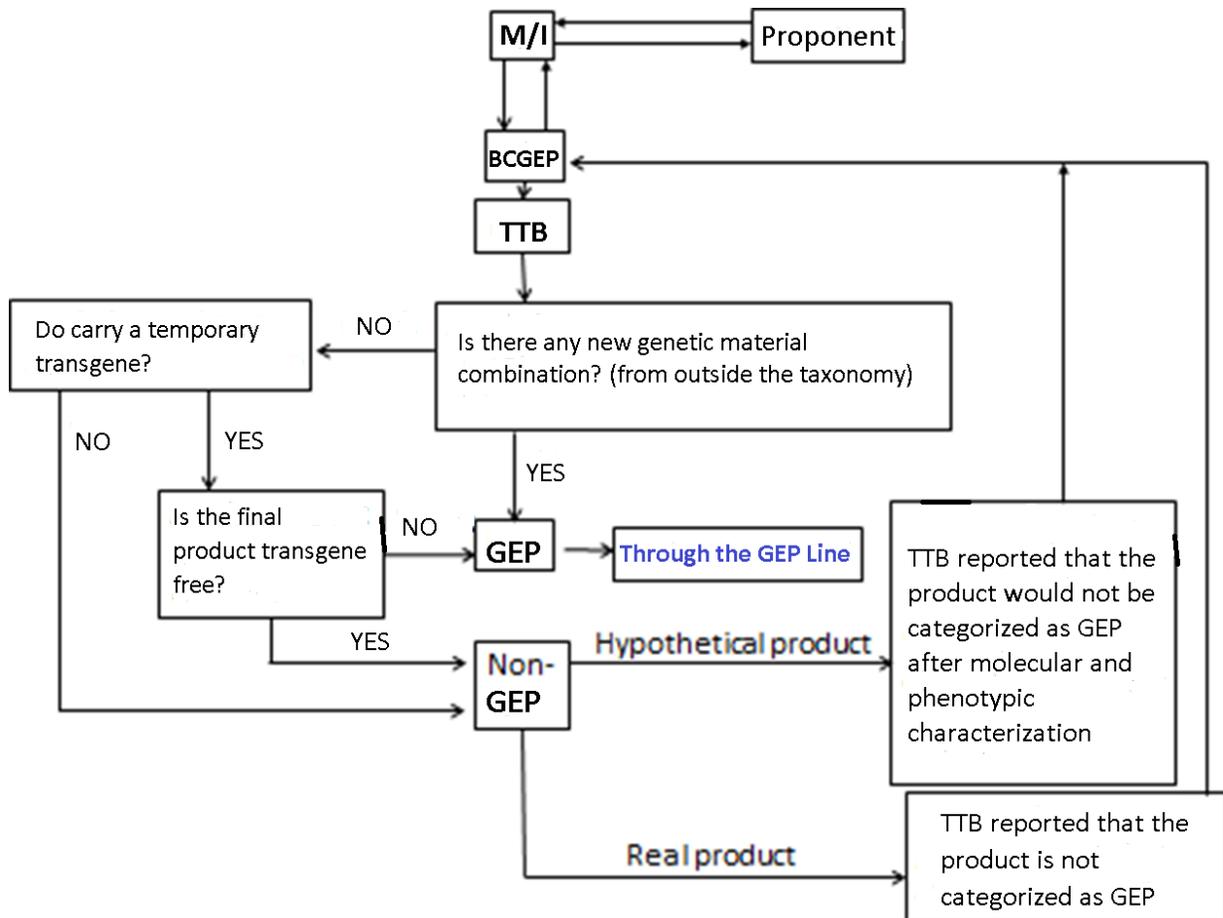
d) FIELD TESTING:

Limited field trials of GE plant are conducted under Government Regulation No. 21/2005 and the Guideline of Agricultural Biotechnology Products from Genetically Engineering, Series: Plant (2006). The recent [MOA regulation 38/2019](#) supersedes regulation No. 40/2017 and No. 61/2011, which provide procedures for testing, evaluating, releasing, and withdrawing food crops and estate crops varieties, including GE crops. This regulation also includes aspects of the environmental safety approval process and field trials. Under this regulation, limited field trials for the environmental safety assessment can be done in parallel with the adaptation trial for variety release. Furthermore, if the GE crop comes from approved conventional hybrids, the product will not require multi-location field trials and will only require a single location field trial from one planting period.

e) INNOVATIVE BIOTECHNOLOGIES:

In February 2020, biotech stakeholders including regulators, academia, researchers, and industry conducted a meeting to discuss a new draft regulation related to innovative biotechnologies, such as genome editing by using Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology and other techniques. The meeting was hosted by the Biotech Research Center (LIPI) and resulted in a draft regulation for innovative biotechnologies. According to the draft regulation, products created from innovative biotechnologies will follow the regulatory framework of GE products if there is a new genetic material combination or the final product contains a transgene. The following process flow was prepared to demonstrate the scheme for approving genome edited products:

Figure 5. Draft of Genome Editing Regulation.



f) **COEXISTENCE:**

Indonesia has no national policy on co-existence.

g) **LABELING AND TRACEABILITY:**

The BPOM issued a regulation on food labeling controls for GE products in March 2012, implementing a 1999 regulation that requires labels and special logos for food containing GE ingredients. According to this regulation, packaged food that contains at least 5 percent GE products must be labeled with the statement “Food Containing Genetically Engineered Material.” The 5 percent threshold level is measured as the content percentage of Deoxyribo Nucleid Acid (DNA) of GE product against the DNA of non-GE products. This 2012 regulation has since been superseded by [regulation No. 6/2018](#) on Supervising of Genetically Engineered Products. However, there is no change on the procedures of GE product labeling.

- h) **MONITORING AND TESTING:**
Government Regulation No. 21/2005 on Biosafety of Genetically Engineered Products requires the establishment of a monitoring and control system for the cultivation of GE crops. The lack of such monitoring guidelines has created a bottleneck with regards to the establishment of commercial cultivation of GE crops in Indonesia. Various agricultural biotechnology stakeholders, including industry, academia, NGO's and GOI researchers have indicated that MOA has prepared the required guidelines and that a new regulation will be forthcoming. However, to date, Post has seen no information indicating a clear timeline for issuance. Accordingly, the future of commercial cultivation of GE crops in Indonesia remains uncertain.
- i) **LOW LEVEL PRESENCE POLICY:**
Indonesia is a member of the Global Low-Level Presence Initiative (GLI), a group of countries that have endorsed the International Statement on LLP and committed to working collaboratively to develop international approaches to manage LLP.
- j) **ADDITIONAL REGULATORY REQUIREMENTS:**
Post is unaware of any additional requirements of GE seeds registration.
- k) **INTELLECTUAL PROPERTY RIGHTS (IPR):**
Law No. 13/2016 on the Patent Act and Law No. 28/2014 on the Copyright Act addresses IPR, providing inventors with exclusive rights. Additionally, Law No. 29/2000 on Plant Variety Protection regulates intellectual property of new plant varieties. The breeder or the plant variety's right holder may use their own plant variety or license others to use it for a specified period. The MOA's Center of Plant Variety Protection and Agricultural License manages new plant variety registration.
- l) **CARTAGENA PROTOCOL RATIFICATION:**
In 2004 Indonesia ratified the Cartagena Protocol through Government Regulation No. 21/2004 concerning Biosafety to the Convention on Biological Diversity. As a Cartagena Protocol ratification country, Indonesia has:
- assigned the Ministry of Environment as the National Focal Point of the Cartagena Protocol;
 - appointed the Ministries/Agencies to be the National Competent Authority of the Cartagena Protocol;
 - published Government Regulation No. 21/2005 concerning the Biosafety of Genetically Engineered Products; and
 - established the Biosafety Clearing House (BCH)
- More details can be found at [the Indonesia BCH's website](#).
- m) **INTERNATIONAL TREATIES/FORUMS:**
Indonesia is a member of the International Plant Protection Convention (IPPC) and the Codex Alimentarius (Codex). However, Indonesia hasn't taken any significant positions pertaining to biotechnology in these forums. Indonesia actively participates in the APEC High Level Policy

Dialogue on Agricultural Biotechnology (HLPDAB) and hosted the 2013 APEC annual meeting, including the APEC HLPDAB. In addition, Indonesia has participated in the Global Low-Level Presence (LLP) Initiative forum. BPOM's National Food and Drug Testing Center is Indonesia focal point of ASEAN Genetically Modified Food and Feed (GMFF) Testing Network and is involved in its activities.

n) RELATED ISSUES:

In July 2019, the Deputy for Food and Agriculture Coordination, Coordinating Ministry for Economic Affairs, in collaboration with the DG of Agricultural Research and Development Center, Ministry of Agriculture, and BCGEP issued the 2020 – 2045 Roadmap of GE Seeds Development, which provides a reference to related government agencies and stakeholders in developing the production and the use of locally produced GE seeds to achieve food security and improve farmers' income. GE crops mentioned in the report and predicted to be commercialized and planted in Indonesia were rice, corn, sugar cane, and potato.

The scope of the roadmap includes a) the economic advantages, b) the strategic factors of GE seed development, c) the strategic analysis of GE seed development, d) the strategies of GE seed development, and e) the actions plan. The roadmap focuses on five strategic targets: (1) achieving self-sufficiency in rice, corn and soybeans, and increasing sugar production; (2) increasing food diversification; (3) increasing value added and competitiveness of commodities for export and import substitution; (4) supplying bio industry and bioenergy raw materials; and (5) increasing farmers' incomes. The targets for GE seed development are: 1) increasing availability of GE seeds, especially food crop seeds with traits adapted to conditions in Indonesia; 2) protecting and using national genetic resources to develop seed varieties; 3) guaranteeing environmental safety, food safety, and feed safety of GE seed varieties; 4) fulfilling private/industrial sector involvement in supplying GE seeds. In terms of specific actions, the roadmap specifies the following activities: 1) strengthening research on various characteristics of GE seeds; 2) providing financial support for the biosafety assessment submissions of government research institutes/universities; 3) maintaining and protecting genetic resources; 4) utilizing superior properties of genetic resources; 5) strengthening system and legislation in biosafety assessment of GE products; 6) strengthening the institutions of biosafety assessment and examination of GE products; 7) strengthening partnership cooperation between private and public sector GE seed research and development; 8) providing incentives and facilities for industry actively engaged in GE seed research and development.. Please see the tables below on the targets of GE seeds research and production, a priority research of GE seed development, a roadmap of GE seed development, and the action plan.

Table 5. GE Seed Production and Research Targets (2020 – 2045)

No.	GEP		Type of Program	Periods		
	Crop	Character		2020 - 2025	2026 - 2035	2036 - 2045
1.	Corn	TH	Seed Production	X	X	X
		TP	Research	X	X	X
			Assembly		X	X
			Production			X
		TSH	Seed Production	X	X	X
		TK	Seed Production		X	X
			Safety Testing	X	X	X
2.	Rice	TP	Research on resistance to plant diseases	X	X	
			Assembly		X	X
			Production			X
		TSH	Research on resistance to pest attacks	X	X	
			Assembly		X	X
			Production			X
		TCL	Research on tolerance to abiotic stress	X	X	
			Assembly		X	X
			Production			X
		FN	Research on fortification of pro-vitamin A, iron	X	X	X
	Assembly		X	X		
	Production			X		
3.	Soybean	TH	Research on herbicide tolerance	X	X	
			Assembly		X	X
			Production			X
		TSH	Research on resistance to pest attacks	X	X	
			Assembly		X	X
			Production			X
		TCL	Research on tolerance to abiotic stress	X	X	
			Assembly		X	X
	Production			X		
4	Potato	TP	Research on disease resistance	X	X	

			Assembly		X	X
			Production			X
		TSH	Research on resistance to pest attacks	X	X	
			Assembly		X	X
			Production			X
5.	Sugar cane	TCL	Research on tolerance to drought, low pH, heat, salinity	X	X	
			Assembly		X	X
			Production			X
		PR	Research on increasing sugar content	X	X	
			Assembly		X	X
			Production			X

Note: TH = herbicide tolerant; TP = disease resistant; TSH = insect pests resistant; TVP = pathogenic viruses resistant; TCL = environmental stress resistant; FN = Nutritional fortification; PP = increased productivity; PR = increase sugar content

Table 6. Roadmap of GE Seed Development

ROADMAP of GE SEEDS DEVELOPMENT				
OBJECT	2020 - 2025	2026 - 2035	2036 - 2045	SUBJECT
Market	Farmer, industry, export (Accelerated commercialization with the existing technology)			Farmer, Cooperative, Industry player, Association, Exporter, BULOG, Government
				
Product	<ul style="list-style-type: none"> HT corn seed (Period I) TSH paddy seed (Period I) TCL sugar cane seed (Period I) TP potato seed (Period I) 	<ul style="list-style-type: none"> TSH, TH, TCL soybean seed (Period II) TP, TN potato seed, (Period II) TSH, TVP, TH, TCL, EPUH paddy seed (Period II) 	<ul style="list-style-type: none"> Resistant to downy mildew corn seed (Period III) TSH, TVP, TH, TCL, EPUH paddy seed (Period III) 	Government, University, Research and Development Institution, Industry, State-owned Enterprises

		<ul style="list-style-type: none"> • TCL, RT sugar cane seed (Period II) 		
Technology	Assembly of GEP <ul style="list-style-type: none"> • New character exploration and integration • Genetic engineering • Reverse cross with popular varieties 	Seed Improvement <ul style="list-style-type: none"> • Genetic engineering • Reverse cross with popular varieties 	Seed Development <ul style="list-style-type: none"> • Genetic engineering • Reverse cross with popular varieties 	Government, University, Research and Development Institution, Industry, State-owned Enterprises
Research and Development	Applied Research, Development Research, Results Dissemination, and Continuous Improvement 			Government, University, Research and Development Institution, Industry, State-owned Enterprises
Resource	Genetic resources, existing technology, budget, facilities and infrastructure, human resources, science and technology, intellectual property rights, data and information			Government, University, Research and Development Institution, Industry, State-owned Enterprises

Note: TH = herbicide tolerant; TP = disease resistant; TSH = insect pests resistant; TVP = pathogenic viruses resistant; TCL = environmental stress resistant; FN = Nutritional fortification; PP = increased productivity; EPUH = efficient use of nutrients

Table 7. The Targets and Strategies of GE Seed Development

TARGET	STRATEGIES
1. The availability of GE crop seeds, specially food crop that has superiority over biotic and abiotic stresses and is in accordance with Indonesian conditions.	1. Strengthening of research on various superior characteristics of GE crop seeds. 2. Provision of financial support for superior GE seed product applications by government research institutes/universities.
2. Achieved maintenance, protection and utilization of national genetic resources for GE superior variety development.	1. Conservation and protection of genetic resources that have superiority for providing GE superior seeds.

	<ol style="list-style-type: none"> 2. Superiority characteristics utilization of the superior genetic resources for GE superior seed assembly. 3. Strengthening of regulations for guaranteed development and utilization of GE products.
3. Guaranteed biosafety for produced superior GE seeds	<ol style="list-style-type: none"> 1. Strengthening of systems and legislation in the GE biosafety assessment and examination. 2. Strengthening of GE biosafety assessment and examination institution. 3. Revitalization and strengthening of biotechnology institutions/organizations which promote and advocate GE products. 4. Strengthening of regulations for guaranteed development and utilization of GE products.
4. Fulfilment of private sector engagement in providing GE superior seeds.	<ol style="list-style-type: none"> 1. Strengthening of research and development GE seed partnership collaboration between government/ university research institutes with R&D industrial/private. 2. Provision of incentives and facilities for actively involved industries in the research and development of GE superior seeds. 3. Strengthening of regulations for the guaranteed development and utilization of GE products.
5. The utilization of GE seeds by farmers.	<ol style="list-style-type: none"> 1. The evidence that GE seeds are able to increase production and productivity of biotech crops. 2. Economic calculation socialization of the GE seeds utilization that is more profitable than other seeds.
6. The acceptance of GE food / feed by the community (consumers and industries).	<ol style="list-style-type: none"> 1. Outreach to the consumers about food safety and environmental safety of biotech crops. 2. The media utilization for explaining to the community that the biotech plants are environmentally friendly and have the similar of better food quality than the other products.

Table 8. The Strategies and Programs

STRATEGIES	PROGRAMS
1. Strengthening of research on various superiority characteristics of GE plant seeds.	<ol style="list-style-type: none"> 1. Basic research on plant superior characteristic identification to biotic and abiotic stress for GE plant development. 2. Basic research on plants superior characteristic identification in terms of productivity and nutritional prevalence for the GE plant development. 3. Research and development of superior characteristics integration in assembly GE plant superior seeds.
2. Providing of financial supports for GE superior seed product applications by the government research institutions/universities.	<ol style="list-style-type: none"> 1. The financing availability collateral for GE plant superior seed applications. 2. Incentives for GE plant superior seeds developers and inventors.
3. The conservation and protection of superiority genetic resources for providing GE superior seeds.	<ol style="list-style-type: none"> 1. Strengthening of conservation and protection of superior plant genetic resources through gene bank facility establishment. 2. Strengthening of conservation and protection of superior plant genetic resources through collection laboratory and nursery establishment. 3. The protections and incentives for breeders and developers of local genetic resource superior seeds.
4. The utilization of superior genetic resource superiority characteristics for GE superior seed assembly.	<ol style="list-style-type: none"> 1. The applied research to produce GE plant superior seeds. 2. The socio-economic assessment of GE plant superior seeds application for the farmers 'welfare.
5. Strengthening of regulations for guaranteed GE development and utilization.	<ol style="list-style-type: none"> 1. Review and anticipation of changes to the valid legislations, anticipating the biotech product utilization new development sharing. 2. Comparative studies of biotech legislations in several countries for regulators and the member of parliament and related ministries officials.
6. Strengthening of the system and the legislations in biosafety assessments and examinations of GE products.	<ol style="list-style-type: none"> 1. The existing legislations assessment; revision, enhancement and creation of new legislation.

	<ol style="list-style-type: none"> 2. Revising the existing framework so that it can function properly. 3. The issuance of new guidelines anticipates the science and technology development of GE seed production.
7. Strengthening of the biosafety examination and assessment institution of GE products.	<ol style="list-style-type: none"> 1. Revitalizing and strengthening of BCGEP and its supporting organization means. 2. Strengthening and capacity building of BCGEP and TTB members through knowledge and skills enhancement activities. 3. Streamlining of existing rules and mechanisms, so they are more efficient.
8. Strengthening of GE seeds research and development partnership collaboration between the government research institutes/universities with the research and development industries/privates.	<ol style="list-style-type: none"> 1. Identification and inventory of the universities and government institutions research results that have opportunities to be offered to the industries/R&D privates. 2. The cost and benefit sharing for developing of GE superior seeds that are cooperated between the government research institutes/universities with the industries.
9. The provision of incentives and facilities for the industries that actively involved in research and development of GE superior seeds.	<ol style="list-style-type: none"> 1. Tax relief (tax holiday/exemption) for industries/private institutions that are developing the R&D by themselves /collaboration with the government research institutions/universities.

Table 9. The action plan

NO.	ACTION PLAN	INDICATOR	TARGET YEARS			RESPONSIBLE AGENCIES	RELATED INSTITUTIONS
			2020 - 2025	2026 - 2035	2036 - 2045		
1.	Strengthening of researches on various superior characteristics of GE plant seeds.	<ul style="list-style-type: none"> The availability of GE food crop seeds that have superiority to stress biotic and abiotic as well as appropriate with the Indonesian conditions. 	X	X	X	<ul style="list-style-type: none"> MOA LIPI MORT HE 	<ul style="list-style-type: none"> CMEA NPA MOF MOH MOT BPOM Universities Business actors
		<ul style="list-style-type: none"> The achievement of basic research on plants superior characteristics identification to biotic and stress abiotic for GE plants development. 	X	X	X		
		<ul style="list-style-type: none"> The achievement of basic research on identification of plants superior characteristics in terms of productivity and nutritional prevalence for the GE plants development. 	X	X	X		
		<ul style="list-style-type: none"> The achievement of research and development of superior characteristics integration in assembly GE plant 	X	X	X		

		superior seeds.					
2.	Provision of financial support for applications of GE superior seed products by government research institutions/university.	<ul style="list-style-type: none"> The establishment of financing availability collateral for applications of GE plant superior seeds. 	X	X	X	<ul style="list-style-type: none"> MOA MOF 	<ul style="list-style-type: none"> CMEA NPA MOHA MOH MOT LIPI BPOM LG Universities Business actors
		<ul style="list-style-type: none"> The availability of incentives for GE plant superior seeds inventors and developers. 	X	X	X		
		<ul style="list-style-type: none"> The arrangement of a draft of Government Regulation on the financing availability collateral for GE plant superior seeds and the incentives for GE plant superior seeds inventors and developer. 	X	X	X		
3.	The conservation and protection of genetic resources that have advantages of providing GE superior seeds.	<ul style="list-style-type: none"> The arrangement of regulations on conservation, protection and utilization of national genetic for GE superior varieties development. 	X	X	X	<ul style="list-style-type: none"> MOA MOEF LIPI 	<ul style="list-style-type: none"> CMEA MOF MOH Universities Business actors
		<ul style="list-style-type: none"> The arrangement of regulations on strengthening of conservation and protection of superior 	X	X	X		

		plants genetic resources through the establishment of gene bank facilities.					
		<ul style="list-style-type: none"> The arrangement of regulations on strengthening of conservation and protection of superior plants genetic resources through collection laboratories and nurseries development. 	X	X	X		
		<ul style="list-style-type: none"> The availability of incentives for local genetic resources superior seeds breeders/developers. 	X	X	X		
4.	The superiority characteristics utilization of the superior genetic resources for GE superior seeds assembly.	<ul style="list-style-type: none"> The achievement of applied research for producing GE plants superior seeds 	X	X	X	<ul style="list-style-type: none"> MOA LIPI 	<ul style="list-style-type: none"> CMEA Universities
		<ul style="list-style-type: none"> The arrangement of socio-economic assessments of GE plants superior seeds application for farmers' welfare. 	X	X	X		
5.	Strengthening of the systems and the legislations in the biosafety assessment and	<ul style="list-style-type: none"> The arrangement of new guidelines for anticipating the science and technology development of GE 	X	X	X	<ul style="list-style-type: none"> BCGEP MOA MOEF BPOM 	<ul style="list-style-type: none"> CMEA LIPI Universities Business actors

	examination of GE products.	seeds production.					
		<ul style="list-style-type: none"> The arrangement of the revisions to the published regulations (BPOM, MOA, MOEF) that can hamper the GE products release. 	X	X	X		
6.	Strengthening of the biosafety assessment and examinations institution of GE products.	<ul style="list-style-type: none"> The establishment of revitalization and strengthening BCGEP and its supporting organization means. 	X	X	X	<ul style="list-style-type: none"> BCGEP MOA MOEF BPOM 	<ul style="list-style-type: none"> CMEA LIPI Universities
		<ul style="list-style-type: none"> The establishment of strengthening and capacity building of BCGEP and TTB members through knowledge and skills enhancement activities. 	X	X	X		
7.	Strengthening of GE seeds research and development partnership collaboration between the government research institutes/ universities with the research and development	<ul style="list-style-type: none"> The establishment of partnerships with the business actors/ privates in providing GE superior seeds. 	X	X	X	<ul style="list-style-type: none"> MOA NPA MORT HE MOF 	<ul style="list-style-type: none"> CMEA MOI LIPI BPOM Universities Business actors
		<ul style="list-style-type: none"> The arrangement of the identification and inventory of the government institutional and universities research results that have chances to be offered 	X	X	X		

	industries/private institutions.	to R&D industries/private institutions.					
		<ul style="list-style-type: none"> The arrangement of regulations on cost and benefit sharing for developing GE superior seeds that is collaborated between the government research institutes/universities with the industries. 	X	X	X		
8.	The provision of incentives and facilities for the national industries that are actively involved in the R&D of GE superior seeds.	<ul style="list-style-type: none"> The arrangement of regulations on tax relief (tax holiday/exemption) for industries/private sectors that developed R&D by themselves/in cooperation with government research institutes/universities. The arrangement of a draft of Government Regulation on provision of incentives and facilities for the industries that actively involved in the research and development of GE superior seeds. 	X	X	X	<ul style="list-style-type: none"> MOA MOF 	<ul style="list-style-type: none"> CMEA MOI The Cabinet Secretary The State Secretary LIPI Universities
			X	X	X		

9.	Strengthening the regulations to ensure the development and utilization of GE products.	<ul style="list-style-type: none"> The availability of legislations that are able to arrange GE products in accordance with the needs and developments of the latest science and technology. 	X	X	X	<ul style="list-style-type: none"> MOA 	<ul style="list-style-type: none"> CMEA MOEF LIPI BPPOM Universities Business actors
		<ul style="list-style-type: none"> The availability of an integrated system to speed up the process of GE assessments and examinations in order to shorten the waiting period of biosafety approval accomplishment. 	X	X	X		

Note: MOA = Ministry of Agriculture; LIPI = Indonesian Institute of Science; MORT HE = Ministry of Research & Technology Higher Education; CMEA = Coordinating Ministry for Economic Affairs; NPA = National Planning Agency; MOF = Ministry of Finance; MOH = Ministry of Health; MOT = Ministry of Trade; BPOM = National Agency of Drug and Food Control; MOHA = Ministry of Home Affairs; LG = Local Government; MOEF = Ministry of Environment & Forestry; BCGEP = Biosafety Commission for Genetically Engineered Product; MOI = Ministry of Industry

The GOI, through Presidential Regulation No. 18/2020 on the National Medium-Term Development Plan (RPJMN) for 2020 – 2024 issued in January 2020, has included biotechnology and GE products as efforts in supporting the national program of stunting eradication through bio-fortification. One of the strategies in improving the availability, access, and quality of food consumption is increasing the quality of consumption, safety, fortification, and bio-fortification of food. The implementation of this strategy includes the development of bio-fortified rice seeds and GE products, rice fortification, development of food nanotechnology, local food development, and food diversification at the community level, as well as providing and improving the quality of food for school-aged children.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS:

Several Indonesian non-governmental organizations (NGOs) occasionally oppose the production and use of GE plants, although their intended targets are usually multi-national companies behind the technology.

Modeled on the success of the Biotechnology Coalition of the Philippines, a pro-biotech advocacy association, the Society of Indonesian Agricultural Biotechnology (previously named the Indonesian Coalition on Agricultural Biotechnology [ICAB] was formed in Lombok, West Nusa Tenggara on July 4, 2012, during the 5th Indonesia Biotechnology Conference for supporting the adoption of agricultural biotechnology in Indonesia. More information regarding ICAB can be seen at GAIN Report [ID1226](#). In addition, the Indonesian farmer association KTNA has stated their strong support for planting GE crops, as they believe the technology can greatly improve the livelihoods of their families.

b) MARKET ACCEPTANCE/STUDIES:

Indonesian farmers are open to using new technologies including biotechnology. There is broad support for the technology from farmer organizations.

Due to a lack of information and general knowledge about biotechnology, consumers are more hesitant if they know their food contains GE products. Nonetheless, Indonesians have widely consumed GE soybean derived tempeh and tofu for the last three decades. Post is collaborating with Michigan State University, CropLife Indonesia, and the Indonesia Biotechnology Information Center (IndoBIC) to conduct a consumer survey of public acceptance towards GE foods. The complete report on the study will be reported separately.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) **PRODUCT DEVELOPMENT:**

Some research institutions and local universities have reportedly conducted studies on molecular markers. This includes genetic research on local rhinos, cows, bulls, and chickens using gene markers, identification of animal characteristics to heat tolerance and feed utilization, poultry resistance to Newcastle disease, and characteristics of rapid growth and disease resistance in common carp and catfish. This research is far from commercial release. In addition, research on cloning using simple splitting techniques and somatic cell transfer methods has been done, though to date the results have yielded no significant reports or product development.

b) **COMMERCIAL PRODUCTION:**

There is no commercial production of GE animals or cloned animals in Indonesia.

c) **EXPORTS:**

Not applicable

d) **IMPORTS:**

Not applicable

e) **TRADE BARRIERS:**

Not applicable

PART E: POLICY

a) **REGULATORY FRAMEWORK:**

Regulatory framework of GE animals, including cloning, is similar to GE crops, although there are no specific guidelines for assessing and approving of GE animals. Please refer to regulatory framework of Part B: Policy section of Plant Biotechnology for more details.

b) **APPROVALS**

There are no approvals for the commercial or research use of GE animals.

c) **INNOVATIVE BIOTECHNOLOGIES:**

Not applicable

d) **LABELING AND TRACEABILITY:**

Not applicable

e) **INTELLECTUAL PROPERTY RIGHTS (IPR):**

Similar to crops, IPR for animal production will follow Law 13/2016 on the Patent Act and Law 28/2014 on the Copyright Act.

- f) **INTERNATIONAL TREATIES/FORUMS:**
Indonesia is a member of the Codex Alimentarius (Codex), World Organization of Animal Health (OIE), APEC High-Level Policy Dialog on Agricultural Biotechnology and frequently send their officials to the forums.
- g) **RELATED ISSUES:**
The Development Matrix of the National Medium Term Development Plan 2020 – 2024 (Appendix III of Presidential Regulation No. 18/2020 on the National Medium Term Development Plan (RPJMN) for 2020 – 2024), has included the research and innovation of modern biotechnology for superior beef cattle and superior local chicken starting from 2021 in West Java province with the Indonesia Institute of Science (LIPI) as an implementing agency.

PART F: MARKETING

- a) **PUBLIC/PRIVATE OPINIONS:**
Public and Private sentiment regarding GE or cloned animals is not well-established.
- b) **MARKET ACCEPTANCE/STUDIES:**
Currently there are no studies on market acceptance of cloned or GE animals. It can be expected that Indonesian consumers will demonstrate the same or stronger hesitancy towards GE or cloned animals as they currently do towards other GE products.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

- a) **COMMERCIAL PRODUCTION**
Post is not aware of any production of GE microbes in Indonesia.
- b) **EXPORTS**
Indonesia exports processed products, which may contain microbial biotech-derived food ingredients.
- c) **IMPORTS**
Indonesia imports significant volumes of products that often contain microbial biotech-derived food ingredients. In 2019, Indonesia imported over 530,000 tons of dairy products, nearly 489,000 tons of processed food products such as snack foods, prepared foods, condiments and breakfast cereals, and 6,700 metric tons of wine and beer. Additionally, Indonesia imported 5,467 metric tons of various enzymes, an increase of nearly 10 percent from 2018. Although Post is unable to discern the precise amount of products and products containing ingredients derived from microbial biotechnology within this volume, the global commonplace use of microbial biotechnology to produce food ingredients makes their inclusion highly likely.

d) **TRADE BARRIERS**

Post is unaware any trade disruption for microbial biotech-derived food ingredients or processed products containing microbial biotech-derived food ingredients, such as enzymes.

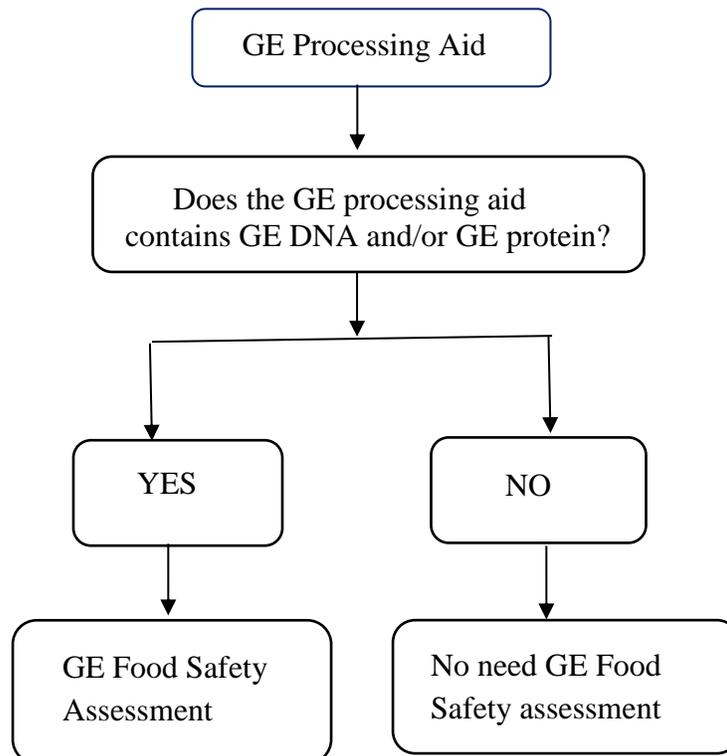
PART H: POLICY

a) **REGULATORY FRAMEWORK**

Regulations on GE microbes that contain DNA and/or protein follow the biosafety regulations for biotechnology products. GE microbes should undergo risk assessment for either food safety or environmental safety. For more details, please refer to part B section a. Since GE microbes are utilized for food production, they should also follow the regulation from BPOM, such as the regulation for food additives and/or food processing aid.

Please see below the scheme of the assessment of GE processing aid, based on BPOM's regulation No. 6/2018 on Supervision of GE Food Products.

Figure 6. The Assessment of GE Processing Aid



The documents required for the GE processing aid assessment are as follows:

1. The specification of processing aid product: name, stability (pH, temperature, time), and optimum conditions.
2. Production strains and host strains.
3. The source of the genes, the inserted genes (structure and sequence), and the plasmid used (structure and sequence).
4. The applied genetic engineering process.
5. Production and refining processes of GE processing aid.
6. Methods of proving the absence of DNA in the final product (such as: PCR, description of reproduced genes and size, as well as the primary sequence).
7. Application information for the use of GE processing aid in food products, including their processing.
8. Approval from the other countries that produce it and/or use it.

b) APPROVALS

Table 10. Microbial biotech-derived products that have Food Safety Approvals

No.	Product	Institution
1.	Ice Structuring Protein	PT. Unilever Indonesia
2.	2'-fucosyllactose (2-FL)	PT. Abbott Products Indonesia

c) LABELING and TRACEABILITY

Please refer to part B section g

d) MONITORING AND TESTING

Not applicable

e) ADDITIONAL REGULATORY REQUIREMENTS

Not applicable

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

Please refer to Part B Section k

g) RELATED ISSUES

Not applicable

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS

The general public in Indonesia does not have a strong positive or negative perception of GE microbes. This stems from a general lack of understanding about GE microbes and their use in food ingredients or other additives or consumed the food.

b) MARKET ACCEPTANCE/STUDIES
Not applicable

Attachments:

No Attachments