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Report Highlights:

Following the approval of a GE potato variety in July 2021, the Government of Indonesia approved four GE corn events for domestic commercial cultivation in February 2022. The U.S. exported nearly \$2.2 billion in GE-derived products to Indonesia in 2021.

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EXECUTIVE SUMMARY

The United States exported nearly \$2.2 billion of genetically engineered (GE) products to Indonesia in 2021, including Bt cotton, soybeans, and soybean 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 accept it with a precautionary approach and use science to assess environmental, food, and/or feed safety. The stated policy is also to take into consideration religion, ethical, socio-cultural, and aesthetic norms. As a result of all these considerations, the GOI has completed regulations for GE products, including biosafety assessments of GE products, GE crops variety release, and monitoring guidelines.

To date, 21 GE corn, 16 GE soybean, three GE sugarcane, one GE potato, four GE canola, and five GE cotton varieties have undergone risk assessment for either "food, feed, or environmental safety". Of these, only a GE sugar cane variety has undergone all three assessments. The GE sugar cane developed by state-owned PT Perkebunan Nusantara XI (PTPN XI) is the first GE crop to meet all existing regulatory requirements for public release in Indonesia. Additionally, in July 2021, the Ministry of Agriculture (MOA) approved the release of the Bio Granola potato. This GE potato variety is a cross between a granola potato and GE Katahdin potato (event SP951). Bio Granola completed food and environmental safety assessments and met all necessary biosafety requirements; it does not require a feed safety assessment since the product is not for animal consumption. Later, in September 2021, the MOA approved the registration of four varieties of herbicide tolerant GE hybrid corn developed by multi-national companies, which were authorized for cultivation and commercialization in February 2022. The GOI has also approved a GE ice-structuring protein for human consumption, a GE livestock feed additive, and 10 GE animal vaccines for commercialization.

It is expected that more GE and gene edited products will be approved for commercialization in the upcoming years. Other information regarding the biotechnology situation in Indonesia can be seen at <u>this link</u>. FAS Jakarta's GAIN Report on <u>Food and Agricultural Import Regulations and</u> <u>Standards Country Report</u> 2021 also contains information on the biotechnology situation in Indonesia.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) RESEARCH AND 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 borerresistant 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 did not occur in 2021 as planned. 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 still in the growth chamber for efficacy testing. In 2021, LIPI was merged into a new government body that handles all the research and technology in Indonesia called the National Research and Innovation Agency (BRIN). GE crop research has stagnated during this transition period.

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 are finishing the food safety study. In addition, they are continuing to conduct trials for GE nitrogen efficiency in rice. The status of their stem borer resistant sugar cane is also in the trial phase. ICABIOGRAD has also continued researching Bt rice and genome editing for gemini virus resistant chili, greening disease resistant citrus, low cadmium absorbent rice, and herbicide resistant potato. In addition, ICABIOGRAD has collaborated with the Ministry of Health to research genome editing for high-yield *Artemisia annua*. However, the slow transition process surrounding the merger of all of Indonesia's research agencies, including ICABIOGRAD, into BRIN has slowed down research progress.

The University of Jember, in collaboration with a state-owned company, is developing a GE, high-glucose content sugarcane. The university has studied the environmental and food safety aspects of the GE sugarcane and has completed its confined field trials in four locations. However, due to budget and human resource constraints, this product is not yet ready for commercialization. Also pending is the University of Jember's research on golden rice. The research on mosaic virus resistant sugar cane, mosaic virus resistant sorghum, high-yield rice, and mosaic virus resistant tomato have also been completed, but they are only for scientific publication purposes. Since 2020, the University of Jember has been collaborating with Gyomngsang National University (South Korea) to conduct genome editing on sugarcane. Meanwhile, the Institut Pertanian Bogor (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 (MSU), 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 MSU 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. However, due to the establishment of BRIN as Indonesia's new research authority in 2022, the agreement between MSU and ICABIOGRAD is no longer valid. MSU is currently in the process of forming a new agreement with BRIN, and so all its research activities with Indonesia are on hold.

The efficacy test of the stacked genes from granola and diamant varieties of GE potato resistant to late blight disease continued in 2021 in a "limited field trial location" (LUT). The stacked gene GE potato granola and diamant varieties were planted in April 2021 and harvested in July 2021. The results of the efficacy study showed that both varieties of GE potatoes with stacked genes showed very high resistance to late blight disease, regardless of it pesticides were sprayed or not. The next steps are to conduct environmental safety studies in four LUT locations (Garut and Pangalengan in West Java, Kledung in Central Java, and Tosari in East Java), food safety studies, and multi-location studies for variety registration purposes. These GE potato varieties with stacked genes were originally expected to be commercialized in 2025; however, due to the hold on research activities during the development of a new agreement between MSU and BRIN, GE potato commercialization is expected to be delayed beyond 2025.

b) COMMERCIAL PRODUCTION:

Indonesia has authorized the planting of GE drought-resistant sugarcane developed by PTPN XI, a state-owned sugar plantation company, and the University of Jember. PTPN XI estimates total GE sugarcane planting area for 2021 reached 13,000 hectares. Previously, this GE sugarcane could only be cultivated on lands owned by PTPN XI, and its seeds were not freely available to other farmers for planting due to the lack of certification. In 2022, the Indonesian Sugar Research Institute certified the GE sugarcane seed, and it is currently available for general commercialization.

Total planting area for all GE corn varieties is estimated at 250 hectares for 2022 and forecast at around 2,000 hectares for 2023. Bayer and Syngenta are preparing to locally produce F1 seeds for GE corn cultivation beyond 2023 as they were unable to obtain authorization to continue directly importing F1 seeds. The importation of F1 seeds is prohibited by the Ministry of Agriculture.

Although Bio Granola potato has been authorized for commercialization, this GE potato has yet to be planted by farmers due to delays in seed propagation caused by the transition of ICABIOGRAD's researchers and technicians to BRIN.

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 2021, Indonesia imported nearly 2.5 million metric tons (MMT) of soybeans. U.S. soybeans account for approximately 95 percent of all of Indonesia's soybean imports and are mostly GE varieties. Soybean consumption in Indonesia is predominantly used to produce human food, with most imported soybeans going to tempeh and tofu production.

As one of the world's largest cotton importers, Indonesia imported over 675,000 tons of cotton in 2021, including over 163,000 tons of cotton from the United States. The majority of all cotton imports are of 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 2021, Indonesia imported over 5.3 million metric tons (MMT) of soybean meal, primarily from Argentina and Brazil. In 2021, corn imports reached over 996,000 MT, and Indonesian poultry producers imported over 236,000 MT of corn gluten meal and over 820,000 MT of distiller's dried grain and solubles (DDGS) originating primarily from U.S.-grown GE corn.

Please see GAIN Reports <u>ID2022-0007</u>, <u>ID2022-0008</u> and <u>ID2022-0011</u> 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 continues to import large quantities of GE products. There have been no trade disruptions reported so far.

PART B: POLICY

a) REGULATORY FRAMEWORK:

Legal Term (in	Legal Term (in	Laws and Regulations	Legal Definition (in
official language)	English)	where term is used	English)
Produk Rekayasa	Genetically	- Government	Genetically modified
Genetik	Engineered	Regulation No.	products or modified
	Product	21/2005 on Biosafety	organisms is a living
		of Genetically	organism, its parts
		Engineered Products.	and/or their
		- The Indonesian Ulema	processed products
		Council Decision No.	which have a
		35/2013 on	composition
		Genetically	new genetic material
		Engineering and Its	from the application
		Product.	of modern
		- Law No. 33/2014 on	biotechnology.
		Halal Product	
		Assurance.	
		- Ministry of	
		Agriculture	
		Regulation No.	
		36/2016 on Feed	

ГГ	
	Safety Assessment of
	Genetically
	Engineered Product.
	- <u>Ministry of</u>
	Environment and
	Forestry Regulation
	<u>No. P.69/2016 on the</u>
	Procedures for
	Environmental Safety
	Testing of Genetically
	Engineered Products
	in Limited Test Field
	(in Indonesian).
	- Head of BPOM
	Regulation No. 6/2018
	on Supervision of
	Genetically
	Engineered Food (in
	Indonesian).
	- Ministry of
	Agriculture
	Regulation No.
	<u>38/2019 on Plant</u>
	Variety Release
	- <u>Ministry of</u>
	Agriculture
	Regulation No.
	50/2020 on
	Supervision and
	Control on the
	Varieties of
	Agricultural
	Genetically
	Engineered Product
	(GEP) Plants
	Circulating in the
	Territory of the
	Republic of Indonesia.
	- <u>Ministry of</u>
	Agriculture
	Regulation No.
	<u>19/2021 on Genetic</u>
	Resources and Estate
	Crops Variety Release
	(in Indonesian).
	(in muonesian).

- The Head of Indonesia
Agency of Agricultural
Research and
Development Decree
No.337/2021 on
Guidelines for Testing
and Assessment of
Genetically
Engineered Plant
Varieties for the
Release of Food Crop
Varieties.
- Ministry of Religious
Affairs Decree No.
748/2021 on Types of
Products Mandatory to
be Halal Certified (in
Indonesian).

The GOI's policy on biotechnology is to, "accept with a precautionary approach," and use science to assess environmental, food, and/or feed safety. In addition, the GOI's policy is to consider religion, ethical, socio-cultural, and aesthetic 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. The risk assessment framework was completed by the issuance of monitoring and control guidelines by the Ministry of Agriculture in December 2020.

The Ministers of Environment & Forestry, Agriculture, Marine Affairs & 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 issuance of Presidential Regulation No. 11/2016 on the suspension of nine non-structural institutions, including the National Seed Agency (BBN), caused an obstacle to the commercialization of GE food crops and estate crop varieties. This is because BBN had previously authorized the release of all of food and estate crops varieties, including GE products. However, with the issuance of a new regulation on crop variety release (the 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 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 <u>the Indonesian</u> <u>Biosafety Clearing House (BCH)'s website.</u>

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

Table 1. The National Competent Authority for GE Products

The National Research and Innovation Agency (BRIN) is a new GOI agency in charge of government affairs in the field of research and technology mandated by Presidential Regulation No. 78/2021. The regulation stipulates that all government-owned research institutions, including the Indonesian Institute of Sciences (LIPI), the Agency for the Assessment and Application of Technology (BPPT), the National Nuclear Energy Agency (BATAN), and the National Institute of Aeronautics and Space (LAPAN), as well as work units that carry out the tasks and functions of research within the ministry/government agencies must be merged into BRIN.

The approval procedures for food, feed, processing, and environmental releases are described in the diagrams below, as per Government Regulation No. 21/2005.

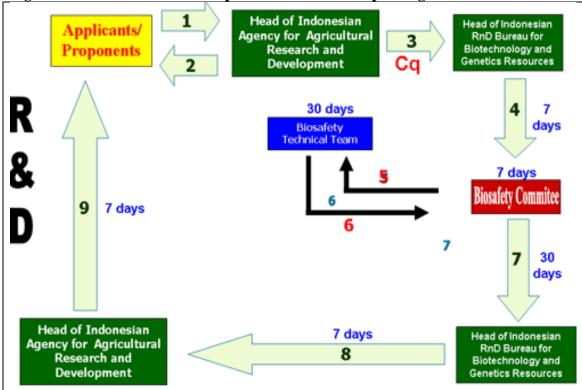


Figure 1. Research and Development Procedures as per Regulation 21/2005

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

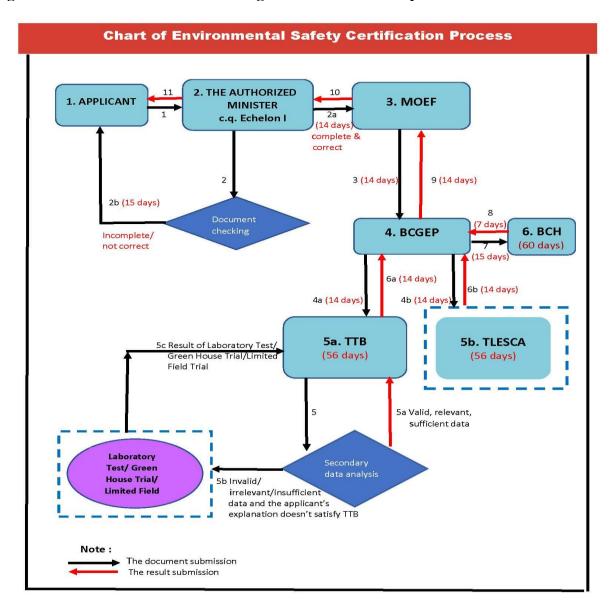


Figure 2. The Procedure for Obtaining Environmental Safety Certificate

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

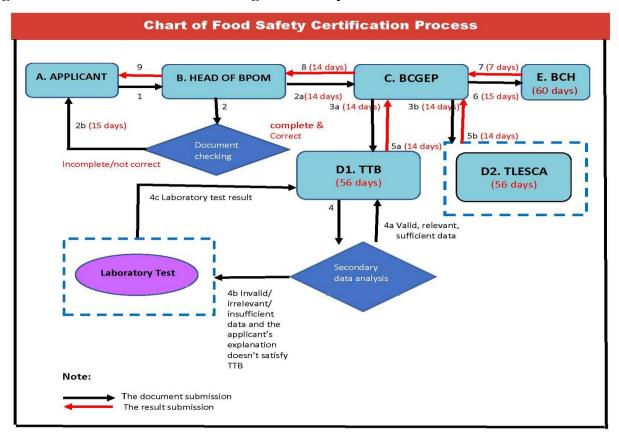
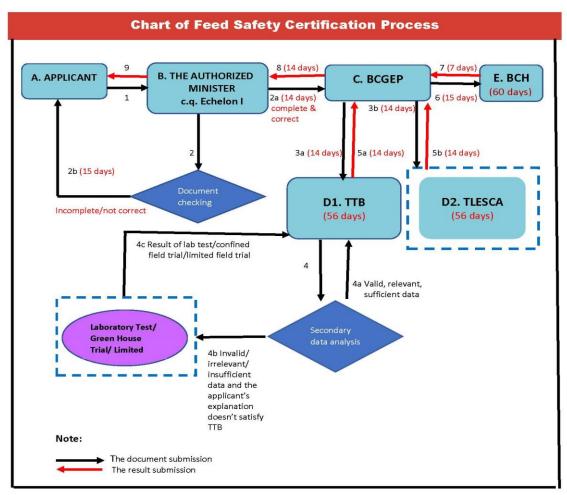


Figure 3. The Procedure for Obtaining Food Safety Certificate

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





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. Under new leadership, BCGEP, assisted by TTB, has actively conducted technical biosafety reviews, and provided biosafety recommendations for numerous GE products.

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 Cultural Assessment (TLESCA) in 2012.

b) APPROVALS:

On February 16, 2022, the MOA signed decrees releasing four GE seed varieties following the recommendations of the MOA's Variety Release Team in September 2021. These decrees officially authorized the cultivation and the commercial sale of these GE food crop seeds in Indonesia. These seed varieties and the producers are as follows:

- PT Bayer Indonesia: DK95-NK 603 (1 variety);

- PT Syngenta Seed Indonesia: NK7328s-GA21, NK212s-GA21, and NK6172-GA21 (3 varieties).

The other approved GE plants from each category can be seen at the below table.

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-	PT. Branita Sandhini
	2	
4.	Herbicide tolerant soybean event MON	PT. Branita Sandhini
	89788	
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	PT. Syngenta Indonesia
	amylase enzyme for ethanol production)	
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	PT. Branita Sandhini
	soybean event MON 87705	
15.	Herbicide tolerant and insect resistant corn	PT. DuPont Indonesia
	event TC 1507	
16.	Herbicide tolerant soybean event MON	PT. Branita Sandhini
	87708	
17.	Higher nutritional value soybean event	PT. Branita Sandhini
	MON 87769	
18.	Herbicide tolerant corn event MON 87427	PT. Branita Sandhini

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

19.	Drought tolerant corn event MON 87460	PT. Branita Sandhini
20.	Late blight resistant potato Katahdin event	ICABIOGRAD, Ministry of
	SP951	Agriculture
21.	High oleic acid and herbicide tolerant	PT. DuPont Indonesia
	soybean event 305423	
22.	Herbicide tolerant soybean event SYHT0H2	PT. Syngenta Seed Indonesia
23.	Insect resistant corn event MON 810	PT. Branita Sandhini
24.	Herbicide tolerant and insect resistant corn	PT. Branita Sandhini
	event MON 87411	
25.	Insect resistant soybean event MON 87751	PT. Branita Sandhini
26.	Herbicide tolerant and insect resistant corn	PT. Branita Sandhini
	event MON 88017	
27.	Herbicide tolerant and insect resistant corn	PT. Syngenta Seed Indonesia
	event MZIR098	
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 Agrosciences Indonesia
32.	Herbicide tolerant and insect resistant corn	PT. DuPont Indonesia
	event 59122	
33.	Herbicide tolerant soybean event A55547-	PT BASF Indonesia
	127	
34.	Herbicide tolerant soybean event A2704-12	PT. BASF Indonesia
35.	Herbicides tolerant soybean event DAS-	PT. Dow Agrosciences Indonesia
	44406-6	
36.	Herbicide tolerant soybean FG72	PT. BASF Indonesia
37.	Herbicides tolerant and insect resistant corn	PT. Syngenta Seed Indonesia
	stacked event BT11xGA21	
38.	Herbicide tolerant corn event T25	PT. BASF Indonesia
39.	Herbicide tolerant and enzyme inhibitor	PT. BASF Indonesia
	canola event MS8	
40.	Herbicide tolerant and enzyme inhibitor	PT. BASF Indonesia
	canola event RF3	
41.	Herbicide tolerant and enzyme inhibitor	PT. BASF Indonesia
	canola event MS11	
42.	Herbicide tolerant and insect resistant	PT. Dow AgroSciences
	soybean event DAS-81419-2	Indonesia
43.	Herbicide tolerant and insect resistant cotton	PT. BASF Indonesia
	event GHB119	
44.	Herbicide tolerant cotton event LLCotton25	PT. BASF Indonesia
45.	Herbicides tolerant cotton event GHB811	PT. BASF Indonesia
46.	Herbicide tolerant cotton event GHB614	PT. BASF Indonesia
47.	Herbicide tolerant and insect resistant cotton	PT. BASF Indonesia
	event T304-40	

48.	Herbicide tolerant and insects resistant corn event DP4114	PT. DuPont Indonesia
49.	Herbicide tolerant soybean stacked event FG72xA5547-127	PT BASF Indonesia
50.	Herbicide tolerant and insect resistant soybean GMB 151	PT BASF Indonesia
For 1	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
12.	Herbicide tolerant soybean event SYHT0H2	PT. Syngenta Seed Indonesia
13.	Herbicide tolerant and insect resistant corn event MZIR098	PT. Syngenta Seed Indonesia
14.	Herbicides tolerant and insect resistant corn stacked event BT11xGA21	PT. Syngenta Seed Indonesia
15.	Herbicide tolerant corn event T25	PT. BASF Indonesia
16.	Herbicide tolerant soybean event A55547- 127	PT BASF Indonesia
17.	High oleic acid and herbicide tolerant soybean event 305423	PT. DuPont Indonesia
18.	Herbicide tolerant canola event DP73496	PT. DuPont Indonesia
19.	Herbicide tolerant and insect resistant corn event 59122	PT. DuPont Indonesia
20.	Herbicides tolerant soybean event DAS- 44406-6	PT. Dow Agrosciences Indonesia
21.	Herbicide tolerant and insect resistant	PT. Dow AgroSciences
	soybean event DAS-81419-2	Indonesia
22.	Herbicides tolerant corn event DAS-402789	PT. Dow Agrosciences Indonesia
23.	Herbicide tolerant soybean FG72	PT. Syngenta Seed Indonesia
For 1	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	ICABIOGRAD, Ministry of
	SP951	Agriculture
9.	Insect resistant corn event BT 11	PT. Syngenta Seed Indonesia
10.	Herbicides tolerant and insect resistant corn	PT. Syngenta Seed Indonesia
	stacked event BT11xGA21	

Source: <u>Biosafety Clearing House, Secretary of BCGEP</u>, and <u>the Directorate of Processed</u> <u>Food Standardization of NADFC</u> (in Indonesian) (2022)

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.

BCGEP has provided recommendations on the food safety of herbicide tolerant and altered growth/yield corn event DP-202216-6 and submitted this recommendation to BPOM for their consideration to issue the food safety certificate for this GE event. In addition, currently BCGEP conducts an environmental safety assessment of semi-dwarf rice (a genome editing product). This product is a result of collaboration among ICABIOGRAD, IPB University, International Rice Research Institute (IRRI), and University of Sebelas Maret.

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

No.	Product	Applicant		
For Feed Safety				
1.	Ronozyme AX (CT)	PT. DSM Nutritional Product		
		Indonesia		
For E	nvironmental 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.	Corynebacterium glutamicum CJM107	PT. Ajinex International		
	(KCCM-10227) (U.S. Patent No: U.S.			
	9,777,28282)			
0	Dissofate Cleaning House and Connetomy of DCC			

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

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

BCGEP has provided recommendation on the environmental safety of GE seed Escherichia Coli (KCCM-80236) for production of Poly Hydroxy Alkanoate (PHA)/Polyhydroxybutyrate (PHB) in 2021, Enzyme Phytase Granular, Mannanase Granular, Xylanase Granular, and Xylanase Liquid. Enzyme AGal-Pro 280P, AGal Pro280Pc, and AGal-Pro 280 Lc have also received the environmental safety recommendation from BCGEP and are waiting the environmental safety approval from the Ministry of Agriculture.

c) STACKED or PYRAMIDED EVENT APPROVALS:

Environmental safety approval for stacked events is similar to a single event approval. Such GE crops must undergo laboratory and biosafety containment tests (i.e. proving the crop will not leave the laboratory), 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, meaning that stacked events made up of approved single events do not need separate approval. In April 2021, BPOM issued <u>Regulation No. 10/2021</u> on Standards of Business Activities and Products on the Implementation of Risk-Based Business Licenses in the Drug and Food Sector. This regulation has included a guideline on the food assessments addressing stacked event products.

d) FIELD TESTING:

Limited GE plant field trials are conducted under Government Regulation No. 21/2005 and are subject to 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.

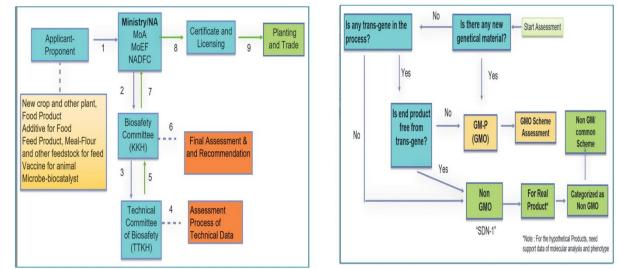
e) INNOVATIVE BIOTECHNOLOGIES:

In January 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 LIPI's Biotech Research Center and resulted in a draft regulation for innovative biotechnologies. According to BCGEP, a basic concept for genome editing product to be approved is:

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

Therefore, genome editing products will be excluded from the regulatory framework of GE products. BCGEP will appoint a team to reformulate more detailed criteria and requirements for genome editing products. The following process flow was prepared to demonstrate the scheme for approving genome edited products:

Figure 5. Genome Editing Regulation



Source: Prof. Bambang Prasetya's Presentation on "APEC HLPDAB Webinar: The Regulation of Genome Edited Products and Its Challenges" 2022

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 <u>Regulation No. 6/2018</u> (link in Indonesian) 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. In December 2020, the Ministry of Agriculture issued <u>Regulation No. 50/2020</u> regarding the monitoring and control on crop varieties of agricultural GE products distributed in Indonesia. The monitoring on GE crops is conducted by routine monitoring and case reporting. The routine monitoring conducted by the permit holder must be done in the third year since the GE crop is traded. This monitoring which is carried out for three consecutive years is to find out the impact of the GE crop on livestock health and environment. This routine monitoring will be conducted through a survey by interviewing the farmers using a questionnaire, analyzing scientific papers, and analyzing agriculture environmental data. A case reporting will be conducted in cases where any negative impacts of the GE crop on the health of human and/or animal, as well to the environment are found. This case report is submitted to the Minister of

Agriculture by the permit holder, the related government institutions, and/or the farmers or the public.

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. In October 2020, Indonesia became the co-chair of GLI meeting that was held virtually, due to the Covid 19 pandemic.

j) ADDITIONAL REGULATORY REQUIREMENTS:

MOA Regulation No. 38/2019 distinguishes the procedure on the testing, evaluation, and releasing of non-GE (conventional) and GE seed varieties. The requestor of proposed conventional seed varieties must submit the application to the respective Director General. For example, the corn seed variety release application should be sent to the DG of Food Crops, while a potato seed application is addressed to the DG of Horticulture. However, the process of GE seed varieties release, either GE food crops, estate crops, horticulture, or plants for animal feed, is under the authority of the DG of Agricultural Research and Development Agency. The requestor sends the application that is addressed to the DG of ARDA through the CPVPAL electronically. The Minister of Agriculture establishes a Variety Release Team – Genetically Engineered Product (VRT – GEP), which is led by the DG of ARDA. The DG of ARDA determines the adaptation/conformity, observation, and seed producibility testing methods. The adaptation or conformity trial can be done after or parallel with the limited field trial for an environmental safety assessment. The requestor must also submit a socio-economic study. The VRT-GEP verifies and supervises the testing, receives the testing result report from the requestor, evaluates and assesses the report, as well as issues the recommendation letter for variety release. A variety can be released if it has had the following documents:

- a. biosafety certificates, which include an environmental safety certificate, a food safety certificate, and/or a feed safety certificate;
- b. a recommendation for release from the VRT;
- c. a summary of final testing result report;
- d. an approval letter for variety name;
- e. a statement from the owner that the breeder seed will be available in sufficient amounts for further propagation; and
- f. a plan of production seed development for the next five years.

To import a new hybrid GE seed variety, the importer must provide a guaranteed letter states that the F1 hybrid seed will be produced in Indonesia within two years after the date of release. In the case of F1 hybrid paddy seed, they must guarantee that the seed will be produced in Indonesia within three years after the release. Meanwhile, the F1 estate crops hybrid seed must be produced in Indonesia within three years for seasonal crops and six years for annual crops after the release. The variety name of GE crops must be added with the GE event code. Meanwhile, the variety name of GE crops that is originated from the released variety must use the released variety name with the added GE event code.

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 plants varieties. The breeder or the plant variety's right holder may use their own plant variety or license it to others to use for a specified period. The MOA's Center of Plant Variety Protection and Agricultural License manages new plant variety registration.

1) 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 has not 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 Testing Network (GMFNet) and is involved in its activities. In July 2021, Indonesia virtually participated in the ASEAN GMFNet workshop.

n) RELATED ISSUES:

In July 2019, the Deputy for Food and Agriculture Coordination, Coordinating Ministry for Economic Affairs, in collaboration with the Director General (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. The 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.

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

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

			Assembly		Х	Х
			Production			Х
		TH	Research on herbicide	Х	v	
			tolerance	Λ	Λ	
			Assembly		Х	Х
			Production			Х
		TSH	Research on resistance	v	v	
3.	Souhaan		to pest attacks	Λ	Λ	
5.	Soybean		Assembly		Х	Х
			Production			Х
		TCL	Research on tolerance	v	v	
			to abiotic stress	Λ	Λ	
			Assembly		Х	Х
			Production		X X X X X X X X X X X X X X X X X X	Х
		TP	Research on disease	v		
			resistance	Λ	Λ	
			Assembly		Х	Х
4	Potato		Production			Х
4	Polato	TSH	Research on resistance	v	v	
			to pest attacks	Λ		
			Assembly		Х	Х
			Production	X X X X X X X X X X X X X X X X X X X X		Х
		TCL	Research on tolerance			
			to drought, low pH,	Х	Х	
			heat, salinity			
	Sugar		Assembly		Х	Х
5.	Sugar cane		Production			Х
	Calle	PR	Research on increasing	v	x	
			sugar content	Δ		
			Assembly		X	Х
	TH 1 and 1		Production	T :	-4	Х

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. R	Table 6. Roadmap of GE Seed Development ROADMAP of GE SEEDS DEVELOPMENT				
OBJECT	ROADN 2020 - 2025	2026 - 2035	DEVELOPMENT 2036 - 2045	SUBJECT	
Market	Farmer, industry, export (Accelerated commercialization with the existing technology)			Farmer, Cooperative, Industry player, Association, Exporter, BULOG, Government	
Product	 HT corn seed (Period I) TSH paddy seed (Period I) TCL sugar cane seed (Period I) TP potato seed (Period I) 	 TSH, TH, TCL soybean seed (Period II) TP, TH potato seed, (Period II) TSH, TVP, TH, TCL, EPUH paddy seed (Period II) TCL, RT sugar cane seed (Period II) 	 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	
Technology	 Assembly of GEP New character exploration and integration Genetic engineering Reverse cross with popular varieties 	 Seed Improvement Genetic engineering Reverse cross with popular varieties 	Seed Development • Genetic engineering Reverse cross with popular varieties	Government, University, Research and Development Institution, Industry, State-own Enterprises	
Research and Development	Applied Resea	urch, Development Re ion, and Continuous I		Government, University, Research and Development Institution, Industry, State-owned Enterprises	
Resource	and infrastrue	s, existing technology cture, human resource ntellectual property ri information	es, science and	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, especially food crop that has superiority over biotic and abiotic stresses and is in accordance with Indonesian conditions.	 Strengthening of research on various superior characteristics of GE crop seeds. 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.	 Conservation and protection of genetic resources that have superiority for providing GE superior seeds. Superiority characteristics utilization of the superior genetic resources for GE superior seed assembly. Strengthening of regulations for guaranteed development and utilization of GE products. 				
 Guaranteed biosafety for produced superior GE seeds 	 Strengthening of systems and legislation in the GE biosafety assessment and examination. Strengthening of GE biosafety assessment and examination institution. Revitalization and strengthening of biotechnology institutions/organizations which promote and advocate GE products. Strengthening of regulations for guaranteed development and utilization of GE products. 				
 Fulfilment of private sector engagement in providing GE superior seeds. 	 Strengthening of research and development GE seed partnership collaboration between government/ university research institutes with R&D industrial/private. Provision of incentives and facilities for actively involved industries in the research and development of GE superior seeds. Strengthening of regulations for the guaranteed development and utilization of GE products. 				

Table 7. The Targets and Strategies of GE Seed Development

5. The utilization of GE seeds by farmers.	 The evidence that GE seeds can increase production and productivity of biotech crops. 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).	 Outreach to the consumers about food safety and environmental safety of biotech crops. 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

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		plant superior seeds application for the
		farmers' welfare.
5.	Strengthening of regulations for guaranteed GE development and utilization.	 Review and anticipation of changes to the valid legislations, anticipating the biotech product utilization new development sharing. 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 legislations in biosafety assessments and examinations of GE products.	 The existing legislations assessment; revision, enhancement, and creation of new legislation. Revising the existing framework so that it can function properly. 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.	 Revitalizing and strengthening of BCGEP and its supporting organization means. Strengthening and capacity building of BCGEP and TTB members through knowledge and skills enhancement activities. Streamlining of existing rules and mechanisms, so they are more efficient.
8.	development partnership collaboration between the government research institutes/universities with the research and development industries/privates.	 Identification and inventory of the universities and government institutions research results that have opportunities to be offered to the industries/R&D privates. 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.	1. Tax relief (tax holiday/exemption) for institutions that are developing the R&D by themselves/collaboration with the government research institutions/ universities.

Table 9. The Action Plan

NO.	ACTION DI AN		TA	ARGET YEA	RS	RESPONSIBLE	RELATED
NU.	ACTION PLAN	INDICATOR	2020 - 2025	2026 - 2035	2036 - 2045	AGENCIES	INSTITUTIONS
1.	Strengthening of research on various superior characteristics of GE plant seeds.	The availability of GE food crop seeds that have superiority to stress biotic and abiotic as well as appropriate with the Indonesian conditions.	х	х	х	MOALIPIMORT HE	 CMEA NPA MOF MOH MOT BPOM
		The achievement of basic research on plants superior characteristics identification to biotic and stress abiotic for GE plants development.	х	х	х		BPOMUniversitiesBusiness actors
		The achievement of basic research on identification of plants superior characteristics in terms of productivity and nutritional prevalence for the GE plants development.	Х	Х	Х		
		The achievement of research and development of superior characteristics integration in assembly GE plant superior seeds.	Х	Х	Х		
2.	Provision of financial support for applications of GE superior seed products by	The establishment of financing availability collateral for applications of GE plant superior seeds.	Х	Х	Х	MOAMOF	CMEANPAMOHAMOH

	government research institutions/universi ties.	The availability of incentives for GE plant superior seeds inventors and developers.	Х	Х	Х		 MOT LIPI BPOM LG
		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.	Х	Х	Х		UniversitiesBusiness actors
3.	The conservation and protection of genetic resources that have advantages of providing GE superior seeds.	The arrangement of regulations on conservation, protection, and utilization of national genetic for GE superior varieties development.	Х	Х	Х	MOAMOEFLIPI	 CMEA MOF MOH Universities Business actors
		The arrangement of regulations on strengthening of conservation and protection of superior plants genetic resources through the establishment of gene bank facilities.	Х	Х	х		
		The arrangement of regulations on strengthening of conservation and protection of superior plants genetic resources	Х	Х	Х		

4.	The superiority	through collection laboratories and nurseries development. The availability of incentives for local genetic resources superior seeds breeders/developers. The achievement of	X	x	Х	• MOA	CMEA
т. 	characteristics utilization of the superior genetic	applied research for producing GE plants superior seeds	Х	Х	Х	IIPI	Universities
	resources for GE superior seeds assembly.	The arrangement of socio-economic assessments of GE plants superior seeds application for farmers' welfare.	Х	Х	Х		
5.	Strengthening of the systems and the legislations in the biosafety assessment and examination of GE	The arrangement of new guidelines for anticipating the science and technology development of GE seeds production.	Х	Х	Х	 BCGEP MOA MOEF BPOM 	 CMEA LIPI Universities Business actors
	products.	The arrangement of the revisions to the published regulations (BPOM, MOA, MOEF) that can hamper the GE products release.	Х	Х	Х		
6.	Strengthening of the biosafety assessment and examinations	The establishment of revitalization and strengthening BCGEP and its supporting organization means.	Х	Х	Х	BCGEPMOAMOEFBPOM	CMEALIPIUniversities

	institution of GE products.	The establishment of strengthening and capacity building of BCGEP and TTB members through knowledge and skills enhancement activities.	Х	х	х		
7.	Strengthening of GE seeds research and development partnership collaboration	The establishment of partnerships with the business actors/ private sector in providing superior GE seeds.	Х	Х	Х	MOANPAMORT HEMOF	 CMEA MOI LIPI BPOM Universities
	between the government research institutes/ universities with the research and development industries/private institutions.	The arrangement of the identification and inventory of the government institutional and universities research results that have chances to be offered to R&D industries/private institutions.	Х	Х	Х		Business actors
		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.	Х	Х	Х		
8.	The provision of incentives and facilities for the national industries that are actively	The arrangement of regulations on tax relief (tax holiday/ exemption) for industries/private sectors that developed	X	Х	Х	MOAMOF	 CMEA MOI The Cabinet Secretary

	involved in the R&D of superior GE seeds.	R&D by themselves/in cooperation with government research institutes/universities.					 The State Secretary LIPI Universities
		The arrangement of a draft of Government Regulation on provision of incentives and facilities for the industries that are actively involved in the research and development of superior GE seeds.	Х	Х	Х		
9.	Strengthening the regulations to ensure the development and utilization of GE products.	The availability of legislations that are able to arrange GE products in accordance with the needs and developments of the latest science and technology.	Х	Х	Х	• MOA	 CMEA MOEF LIPI BPPOM Universities Business actors
		The availability of an integrated system to speed up the process of GE assessments and examinations to shorten the waiting period of biosafety approval accomplishment.	Х	Х	Х		

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 that develop GE crops.

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 <u>ID1226</u>. In addition, the National Outstanding Farmers and Fishermen 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. To gain a better understanding of the Indonesian public's understanding, perception, and attitude towards agricultural biotechnology and in particular GE food crops, Post collaborated with Michigan State University, CropLife Indonesia, and the Indonesia Biotechnology Information Center (IndoBIC) to conduct a consumer survey of public acceptance towards GE foods in 2020. The summary of the study can be seen in the form of an infographic at this link and the full report of the study can be found <u>here</u>.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) RESEARCH AND 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, except for catfish. Sources reported that the University of Padjadjaran succeeded in developing transgenic Mutiara catfish (*Clarias gariepinus*). The third generation of this fish was 2-3 times larger compared to non-transgenic fish in the commercial feed test for 6 weeks of rearing. 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: Indonesia does not export any GE animal to the United States or any other country.
- d) IMPORTS: Indonesia has not imported any GE animals from any other countries.
- e) TRADE BARRIERS: No information is available.

PART E: POLICY

a) REGULATORY FRAMEWORK:

Currently, there is no regulatory framework specifically for GE animals. However, the Ministry of Agriculture is planning to begin creating the regulation in the near future. Therefore, at this moment the assessment of GE animals, including cloning, will be similar GE crops. Please refer to regulatory framework section 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: No information is available.
- d) LABELING AND TRACEABILITY: Similar to plant biotechnology requirements. Please refer to labeling and traceability section of Part B: Policy section of Plant Biotechnology.

- 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), and APEC High-Level Policy Dialog on Agricultural Biotechnology. Therefore, Indonesia frequently sends their officials to these 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 biotechderived food ingredients. In 2021, Indonesia imported nearly 685,000 tons of dairy products, nearly 185,000 tons of processed food products such as snack foods, prepared foods, condiments, and breakfast cereals, and over 3,200 tons of wine and beer. Additionally, Indonesia imported over 7,400 metric tons of various enzymes, an increase of over 11 percent from 2020. Although Post is unable to discern the precise number 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.

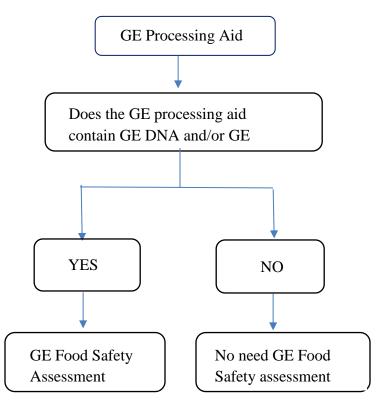
PART H: POLICY

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
Foo	l Safety	
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 No information is available.

Attachments:

No Attachments