Required Report - public distribution

Date: 11/18/2016

GAIN Report Number: ID1632

Indonesia

Agricultural Biotechnology Annual

2016

Approved By:
Ali Abdi
Prepared By:
Thom Wright and Titi Rahayu

Report Highlights:
This report updates the Indonesian 2015 Agricultural Biotechnology Annual Report. Indonesia has completed a regulatory framework for the risk assessment of genetically engineered (GE) plant products. However, new challenges, including changes to the variety release process, are hindering the commercialization of agricultural biotechnology in Indonesia

.

SECTION I: EXECUTIVE SUMMARY:

The United States exported over $1.2 billion of genetically engineered (GE) products to Indonesia in 2015, including Bt cotton, herbicide tolerant soybeans and meal, Bt corn and a variety of food products derived from GE crops.

At present, there are no imported or locally developed commercial GE seed varieties approved for planting in Indonesia. However, the Government of Indonesia (GOI) and local universities continue to research a number of GE crops, including virus resistance for tomato, rice, potato and sugar cane. As well, Indonesian researchers have begun genotyping Indonesian livestock, including poultry, sheep, Balinese cattle, and fish. Research includes identification of rapid growth and disease resistance in catfish and common carp. Practical applications in Indonesia for GE animals and animal products are still very long-term.

The GOI's overarching policy on agricultural biotechnology is to "accept with a precautionary approach" with respect to environmental safety, food safety, and/or feed safety based on scientific approaches as well as taking into consideration religion, ethical, socio-cultural, and esthetic norms. Therefore, several regulations and guidelines have been issued to protect the public from the possibility of negative consequences of biotechnology utilization. This includes the revision of BPOM food safety assessment guidelines for GE products on May 24, 2016.

The Ministry of Agriculture (MOA) issued guidelines for the feed safety evaluation of GE products in mid-2016. With the completion of Indonesia's regulatory framework for risk assessment of new genetically engineered crops, Indonesian technical committees were finally clear to evaluate GE crops. However, directly following the regulatory framework completion, MOA invoked Government Regulation 21/2005 on the Biosafety of Genetically Engineered Products requiring a "monitoring and control" system to regulate approved GE products. As a result, commercial cultivation of GE crops in Indonesia remains on hold.

To date, nine GE corn varieties, six GE soybean varieties, and three GE sugarcane varieties have undergone risk assessment for either food, feed or environmental safety. Only one crop, a GE corn product, has undergone all three, making it eligible for commercialization. This GE corn event, however, is delayed in the variety-release process, and will remain delayed until the GOI determines how to implement its "monitoring and control" system required by Government Regulation 21/2005.

TABLE OF CONTENTS

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

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) is developing stem borer resistant rice, and is currently awaiting field trial approval. MOA's Indonesia Center for Agricultural Biotechnology and Genetic Resources (ICABIOGRAD) is also preparing limited field trials for virus resistant tomato. The University of Jember, in collaboration with a state-owned company, is developing high glucose content sugarcane, with the expectation that it will undergo risk assessment in 2017. The University of Jember is 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 mozaic virus resistant sugar cane at the University of Jember is ongoing. 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, the JR Simplot Company and ICABIOGRAD, organized under the Feed the Future Biotechnology Partnership Project. Finally, Arcadia Biosciences Inc. is collaborating with the Ministry of Agriculture under a USAID grant to evaluate GE nitrogen use efficiency rice. This project is for research purposes only. Post sources speculate that GE rice, GE sugarcane, and GE tomato may be commercialized within the next five years, assuming a favorable policy environment.

b) COMMERCIAL PRODUCTION:

To date Indonesia has not cultivated any GE crops commercially, including GE seed production. Post sources report, however, that state-owned company PT Perkebunan Nusantara XI is prepared to cultivate and market GE sugarcane as soon the GOI issues feed safety approval for local GE sugarcane cultivars.

c) EXPORTS:

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

d) IMPORTS:

In 2015 Indonesian imported over 2.2 million metric ton (MMT) of soybeans. U.S. soybeans account for the vast majority of all soybeans consumed in Indonesia. Post notes that soybean consumption in Indonesia is predominantly for human food, with most imported soybeans going to tempeh and tofu production.

Indonesia is one of the world's largest cotton importers, reaching 210 MMT in 2015. The United States surpassed Brazil as the largest cotton supplier to Indonesia in 2015.

Indonesia's livestock feed industry relies on imported soybean meal and corn. In 2015 Indonesia imported around 4.1 MMT of soybean meal. Brazil, Argentina, and the United States were the primary suppliers. Corn imports reached3.3 MMT in 2015, with exports originating in Argentina, Brazil, India, and the United States. Indonesian poultry producers imported nearly 20 thousand tons

of corn gluten meal and 274 thousand tons of distillers dried grain and soluble in 2015. These originated primarily in United States in 2015.

Please see GAIN Reports ID1606, ID1607and ID1610 for more information regarding the trade of soybean, soybean meal, cotton, and corn.

e) FOOD AID RECIPIENT COUNTRIES:
At present Indonesia is not a recipient or donor of food aid.

f) TRADE BARRIERS:
Indonesia's regulatory framework, and its newly implemented monitoring and control requirements (regulation 21/2005) prevent the commercialization of GE crops. Indonesia, however, imports GE foods and products.

PART B: POLICY

a) REGULATORY FRAMEWORK:
The GOI's policy on biotechnology is "accept with a precautionary approach" with respect to environmental safety, food safety, and/or feed safety based on scientific approaches as well as taking into considerations of religion, ethical, socio-cultural, and esthetical norms. Indonesia's regulatory framework for the evaluation and approval of GE crops was incomplete, however, until August 4, 2016, when MOA issued regulation 36/2016. Regulation 36/2016 establishes risk assessment guidelines for feed safety, completing the risk assessment framework along with environmental and food safety guidelines. Despite the recent completion of Indonesia's risk assessment framework, approvals for 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 monitoring and control system has yet to be developed, and MOA officials have commented that its creation could take several years.

The Ministers of Environment, Agriculture, Forestry, Marine Affairs and Fisheries, and the Head of BPOM are the authorities responsible for approving and releasing GE products (See Table 1). Please note that the Ministry of Environment and the Ministry of Forestry were merged in 2014. The Indonesian Council of Ulama (MUI) oversees all issues relating to halal. In 2013, MUI declared that GE food, pharmaceutical, and cosmetic products are halal.

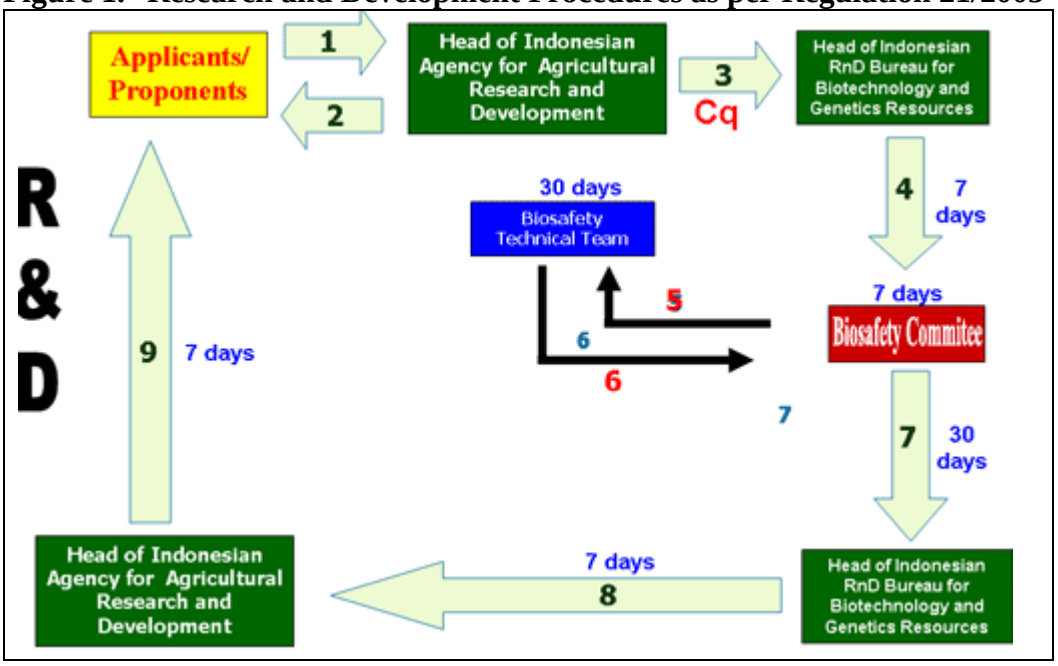
Recent changes to Indonesian regulations governing the use of genetic engineering include BPOM's amendment to their guidelines for food safety evaluation (regulation 19/2016). This regulation includes the new requirements for the evaluation of GE processing aids. Also, the Ministry of Environment and 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		Responsible for
	Ministry	Office	
1.	Ministry of Environment and Forestry	Directorate General for Conservation of Natural Resources and Ecosystem	Environmental safety
2.	Ministry of Agriculture		Feed safety
3.	Ministry of Agriculture	Center for Plant Variety Protection and Agricultural License	Seed imports permit
4.	Ministry of Agriculture	National Seed Agency	Crop variety release
5.	Ministry of Agriculture	Indonesian Agency for Agriculture Research and Development	Research permit
6.	Ministry of Agriculture	Indonesian Agency for Agriculture Quarantine	Plant and animal imports
7.	National Agency of Drug and Food Control (BPOM)		Food safety
8.	Ministry of Marine Affairs and Fisheries	Research Center for Marine and Fisheries Product Processing and Biotechnology	Fisheries products and fish feed
9.	Ministry of Environmentand Forestry		Forestry plants

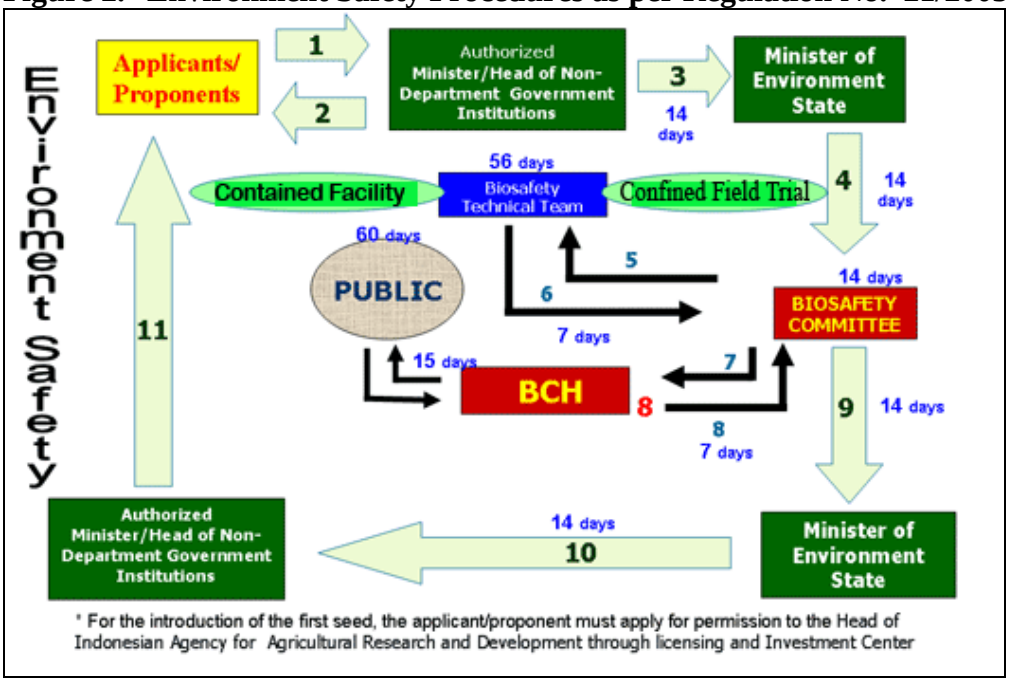
The procedures for the approval of food, feed, processing and environmental releases are described in the diagrams below, as per government regulation No. 21, 2005.

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



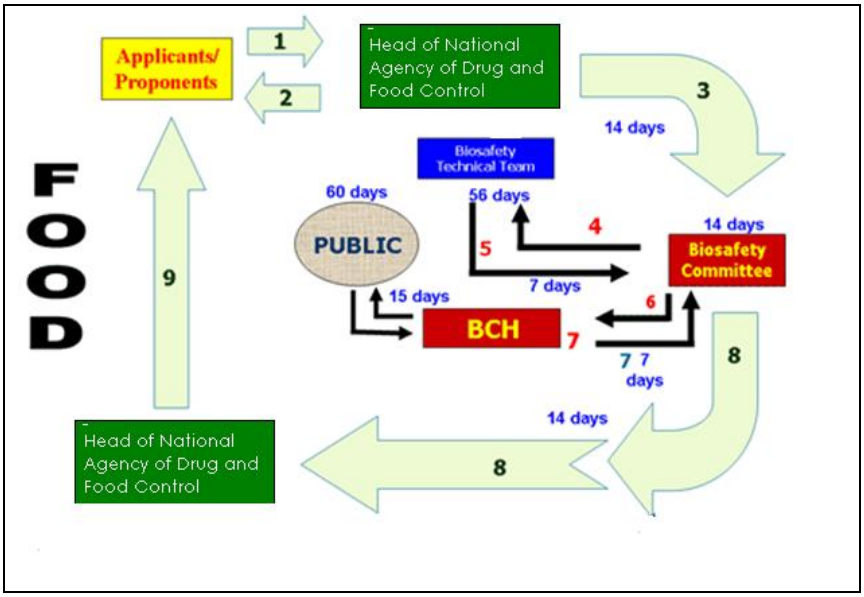
(Source: Indonesia Bio-safety Clearing House, 2010)

Figure 2. Environment Safety Procedures as per Regulation No. 21/2005



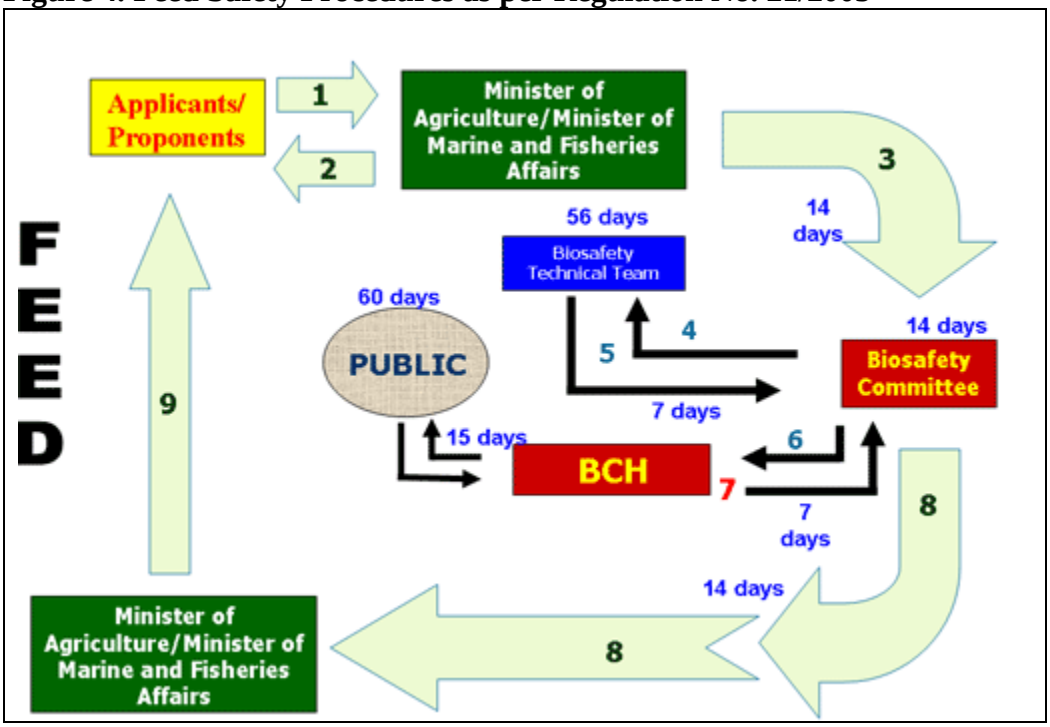
(Source: Indonesia Bio-safety Clearing House, 2010)

Figure 3. Food Safety Procedures as per Regulation 21/2005 and BPOM Regulation HK.03.1.23.03.12.1563/2012



(Source: Indonesia Bio-safety Clearing House (2010) modified by FAS Jakarta, 2012)

Figure 4. Feed Safety Procedures as per Regulation No. 21/2005



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

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 BCGEP, established in 2010 based on Presidential Regulation 39/2010, was inactive until June 2, 2014, when it was reauthorized through Presidential Regulation 53. The reauthorization contained two significant changes. First, the commission was reduced from 21 to 19 members, which will include members of government, the community, and academia. Of the 19 seats, five are newly reserved for members of the Indonesian community at large. Second, academic and community membership is limited to four years with the possibility of one reappointment for an additional term.

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, due to incomplete biosafety assessments, no imported or locally developed GE plants have yet been commercialized. Please see the table below for the biosafety approved GE products.

Table 3. GE Products with Environmental, Feed or Food Safety Approvals

Food Safety		
No.	**Product**	**Applicant**
1.	Insect resistant corn event MON 89034	PT. BranitaSandhini
2.	Herbicide tolerant corn event NK 603	PT. BranitaSandhini
3.	Herbicide tolerant soybean event GTS 40-3-2	PT. BranitaSandhini
4.	Herbicide tolerantsoybeanevent MON 89788	PT. BranitaSandhini
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. BranitaSandhini
14.	Herbicide tolerant and fatty acid change soybean event MON 87705	PT. BranitaSandhini
15.	Herbicide tolerant and insect resistant corn event TC 1507	PT. DuPont Indonesia
16.	Herbicide tolerant soybean event MON 87708	PT. BranitaSandhini
17.	Higher Nutritional value soybean event MON 87769	PT. BranitaSandhini
18.	Herbicide tolerant corn event MON 87427	PT. BranitaSandhini
For Feed Safety		
1.	Herbicide tolerant corn event NK 603	PT. BranitaSandhini

2.	Insect resistant corn event MON 89034	PT. BranitaSandhini
For Environmental Safety		
1.	Drought tolerant sugarcane event NXI-1T	PT. Perkebunan Nusantara XI
2.	Drought tolerant sugarcane event NXI-4T	PT. Perkebunan Nusantara XI
3.	Drought tolerant sugarcane event NXI-6T	PT. Perkebunan Nusantara XI
4.	Herbicide tolerant corn event NK 603	PT, BranitaSandhini

Source: Biosafety Clearing House (2016)

Post sources report that late blight resistant potato event SP951 is still waiting for food safety approval from the Head of BPOM, that drought tolerant sugar cane event NXI-4T is under assessment by the TTB for feed safety approval, and that herbicide tolerant corn event NK603 has completed all three risk assessments and is now waiting to undergo the varietal release process by the team at the Ministry of Agriculture.

c) STACKED or PYRAMIDED EVENT APPROVALS:
Environmental safety approval for stacked events is similar to single event approval.GE crops must undergo laboratory and biosafety containment tests, confined field trial, as well as environmental risk analysis. However, the GOI has not yet decided if the existing food and feed safety approval process for single events can be used for stacked events.

d) FIELD TESTING:
Ministry of Agriculture regulation 61/2011 on the procedures for testing, evaluating, releasing, and withdrawing GE plant varieties speeds up the approval process, including aspects of the environmental safety approval process and field trials for GE crops. Under this regulation, limited field trials for the environmental safety assessment can be done in parallel with the adaptation trial for variety release. In addition, if the GE crop comes from approved conventional hybrids, that product will not require multi-location field trials and will only require one location field trial from one planting period.

e) INNOVATIVE BIOTECHNOLOGIES:
The GOI has not decided whether the regulations for innovative biotechnologies will follow the regulatory framework of GE products, although Post sources report that some government research institutions have conducted research using gene editing and Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology.

f) COEXISTENCE:
Indonesia has no national policy on co-existence.

g) Labeling:
BPOM issued the 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 five percent of GE products must be labeled with the statement "Food Containing Genetically Engineered Material."

The five percent threshold level is measured as the content percentage of Deoxyribo Nucleid Acid (DNA) of GE product against the DNA of non GE product. For more information, please refer to GAIN Report ID1217. Post notes that no food products containing five percent GE materials have been registered to BPOM. As a result, there are no products labelled according to this standard in Indonesia.

h) MONITORING AND TESTING:
MOA is drafting guidelines for a monitoring and control system, as required by Government Regulation No. 21/2005 on Biosafety of Genetically Engineered Products.

i) LOW LEVEL PRESENCE POLICY:
LLP is still a pending issue in Indonesia. The Ministry of Agriculture indicates that Indonesia would endorse the International Statement on LLP and fully support the initiative to develop approaches to manage LLP.

j) ADDITIONAL REGULATORY REQUIREMENTS:
Post is not aware on the 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 address IPR. Law No. 29/2000 on Plant Variety Protection regulates the intellectual property of new plants varieties. 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 Bio-safety 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 to be the National Competent Authority of the Cartagena Protocol;
- published Government Regulation No. 21/2005 concerning the Biosafety of Genetically Engineered Products;
- established the Biosafety Clearing House (BCH)

More details can be found at the Indonesia BCH's website.

m) INTERNATIONAL TREATIES/FORA:
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 fora. Indonesia actively participates in the APEC High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB). Indonesia was the host-venue of the 2013 APEC annual meeting, including the APEC HLPDAB. In addition, Indonesia has participated in the Global low level presence (LLP) Initiative fora. Since the ASEAN Secretariat is located in Indonesia, Indonesia representatives have actively involved in ASEAN Genetically Modified Food (GMF) Testing Network.

n) RELATED ISSUES:

Not applicable

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 (MNC) 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 in Indonesia. Post expects that the technology will be rapidly adopted following commercialization.

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.

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 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. Note that this research is far away from commercial release.

b) COMMERCIAL PRODUCTION:
There is no commercial production of GE animals in Indonesia.

c) EXPORTS:
Not applicable

d) IMPORTS:
Not applicable

e) TRADE BARRIERS:
Not applicable

PART E: POLICY

a) REGULATORY FRAMEWORK:
Although the GOI has several regulations permitting animal biotechnology, there are no clear guidelines for their assessment and approval.

b) INNOVATIVE BIOTECHNOLOGIES:
Not applicable

c) LABELING AND TRACEABILITY:
Not applicable

d) 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.

e) INTERNATIONAL TREATIES/FORA:
Not applicable

f) RELATED ISSUES:
Not applicable

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS:
Not applicable

b) MARKET ACCEPTANCE/STUDIES:
Not applicable