

International Seminar and Workshop on Agricultural
Biotechnology and Biosafety

***“Environment Safety Assessment on
Agricultural Biotechnology Products”***

Universitas Negeri Jember, 10-12 July 2019

Presented by

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- Technical Team for Biosafety

National Regulation on Biosafety

- Law No. 21/2004 on the Ratification of Cartagena Protocol;
- **Government Regulation No. 21/2005 on the Biosafety of Genetically Modified Product (GMP);**
- Director of Indonesian National Agency for Drug and Food Control Regulation No. HK.03.1.23.03.12.1563/2012 on the Guidelines for the Assessment of Food Safety of GMP;
- **Minister of Environment Regulation No. 25/2012 on the Guidelines for the Compilation of Environment Risk Assessment of GMP;**
- **Ministry of Environment and Forestry Regulation No. P.69/MENLHK/SETJEN/KUM.1/8/2016 on Guidelines for Environmental Safety Testing of GM Product in Biosafety Containment**
- Minister of Agriculture Regulation No. 36/2016 on Feed Safety Assessment of GMP.
- Presidential Decree No. 53/2014 in Lieu of the Presidential Decree No. 39/2010 on the Biosafety Commission on Genetically Modified Product;
- Ministerial Decree of Agriculture No. 61/2011 on the Tests, Evaluation, Release and Withdrawal of Varieties ;
- Director of Indonesian National Agency for Drug and Food Control Regulation No. 2012 on the Supervision on Labeling of GMP;

Regulation and Institution on the Release of Varieties

REGULATION

- Law No. 12/1992 on Plant Cultivation System;
- Law No. 23/2010 Horticulture;
- PP No. 44/1995 on Seed Technology System;
- **Ministry of Agriculture Decree No. 61/2011 on the Tests, Evaluation, Release and Withdrawal of Varieties Varieties;**
- **Ministry of Agriculture Decree No. 40/Permentan/tp.010/11/2017 Varietal Release**
- **Ministerial Decree of Agriculture No.38/2011 on the Reg. of Horticulture Varieties**
- **Agency for Agricultural Research and Development-MOA Decree No/Kpts/Ot.140/...../2017 on the Guidelines for Routine Monitoring on GM plant Cultivated in Indonesia**

❑ INSTITUTION

- **Badan Benih Nasional (National Seed Agency) (Disbanded)**
- **Tim Evaluasi dan Pelepasan Varietas (Evaluation and Varietal Release Team) (Disbanded)**
- **Tim Penilai Varietas (TPV) Plant Variety Evaluation Team**
- **Pusat Perlindungan Varietas Tanaman dan Perizinan Pertanian (Pusat PVTTP) Cent for Plant Variety Protection and Agriculture Permit**

Government Regulation No. 21/2005

Biosafety of Genetically Modified Product

Principle :

- **Precautionary Approach;**
- **Based on scientific validity.**

Purpose :

- To ensure the environmental, food and feed safeties of GM Products and their application to the field of agriculture, fisheries, forestry, industry, environment and health (medical).
- To maximize the effectivity and efficiency of the application of GM Product for the well-being of the people based on the principles of health and biological resources management, consumer right/protection and business certainty.

Institutional Arrangements

- **Biosafety Committee on Genetically Modified Product (KKH PRG)**
- Conduct the assessment of Biosafety of GM Products
- Prescribed by Government Regulation No. 39/2010 amended by Government Regulation No 53/2014 and Presidential Decree No 181M/2014 on the Membership of the Biosafety Committee on GM Product,
- Presidential Decree No 5/2016 on the Dismissal and Appointment of Membership of the Biosafety Committee on GM Product.
- **Technical Team for Biosafety of GM Product (TTKH PRG)**
Assist KKH PRG: TTKH Environment, TTKH Food, TTKH Feed
(Decree of KKH PRG Head No 01/KKH/2011)
- **KKH PRG Secretariat**
- **Biosafety Clearing House (BCH)**
In accordance with Article 20 of Cartagena Protocol, Indonesia has BCH

Technical Team for Biosafety of Genetically Modified Product (TTKH)

- TTKH members are elected by the Biosafety Commission (KKH) Head based on the proposals from Ministries or Institutions.
 - The duties of TTKH are to assess technical documents, decide further requirements of testing when needed, and evaluate submitted proposals on GM testing in laboratories, contained facilities (glass houses) and confined field trials.
 - TTKH for Environment Safety: Ministry of Environment and Forestry
 - TTKH for Food Safety : National Agency for Drug and Food Control Regulation
 - TTKH for Feed Safety: Ministry of Agriculture
- Assessment Team for Law, Social Cultural, and Economic Aspects of Genetically Modified Products (TIM PHSBE – PRG)
(Head of Biosafety Commission Decree No. 02/KKH PRG/01/2012)

GUIDELINES FOR THE ASSESSMENT OF BIOSAFETY O GMO

1. Guidelines for the Assessment of Food Safety
2. Guidelines for the Assessment of Feed Safety
3. Guidelines for the Assessment of Environment Safety
 - a. Environment Safety for GM Plant;
 - b. Environment Safety for GM Microbes;
 - c. Environment Safety for GM Animal (**in progress**)
 - d. Environment Safety for GM Fish (**in progress**)

Scope of ERA of GM Crops

Minister of Environment Regulation No. 25/2012 on the Guidelines for the Compilation of Environment Risk Assessment of GMP

- A. Information of GM Crops**
- B. Genetic Information**
- C. Information on Environment Safety**
- D. Risk Communication**
- E. Management of Post-Release of GM Crops (the guidelines is in progress to be enacted)**

Information requested for ERA include

A. Information of GM Crops

1. General Description of the GM Crop (a. name(species, variety name, physical traits and stability); b. purpose; c. transformation process; d. organism origin of gene/trait; e. history of use of same or similar organism in Indonesia; f. history of use outside Indonesia; g. rejection history; h. prospective risk in Indonesia compared to overseas; i. country of origin; j. purpose of use)
2. Description and Use of Parents/tetua (a. name includes taxonomy; b. Data on on origin, distribution, distribution of wild relatives; c. cultivation history; d. detail distribution; e. description of biological traits compares to GM (morphology, mode of generative and vegetative propagation); f. history of safe use as food and feed)
3. Description and distribution of its species (a. origin; b. distribution in Indonesia; c. presence in CFT; d. presence of wild relative in Indonesia)
4. Description of Donor Organism (a. common and taxonomic name; b. description of related known family; c. origin of donor organism; d. history of food safety; e. history of biosafety)

B. Genetics information

1. Description of genetic modification (a. Detail transformation method; b. Detail description gene/fragment of interest; c. Detail character of GOI (origin, regulation, transferability of vector to other organisms, presence of backbone in GM crops)
2. Character of the Genetic Modification (a. GOI information, expression, regulation and the new phenotypes; b. Genetic stability (includes information on genetic marker, stability over generation, survivability in environment, viability)

C. Information on Environment Safety

1. Potential impact to non-target (a. plant, human, animal including natural enemy (predator, parasites); b. Effect to key species (life cycle, fertility, egg hatchability); c. soil fertility; d. toxicity (plant, human, animal including non-target organisms); e. impact to key species)
2. Weediness potential (a. information on weediness of parental genus; b. seed fall out; c. seed dispersal; d. seed dormancy; e. survivability)
3. Gene Flow Potential (a. pollen dispersal; b. ability to pollinate (distance); c. pollen viability; d. pollinators; e. history of cross pollination to wild relatives; f. ability to pollinate wild relatives; g. and its impact).

D. Risk Communication

1. Describe socialization prior to CFT
2. Proposed Socialization Scheme Post Release

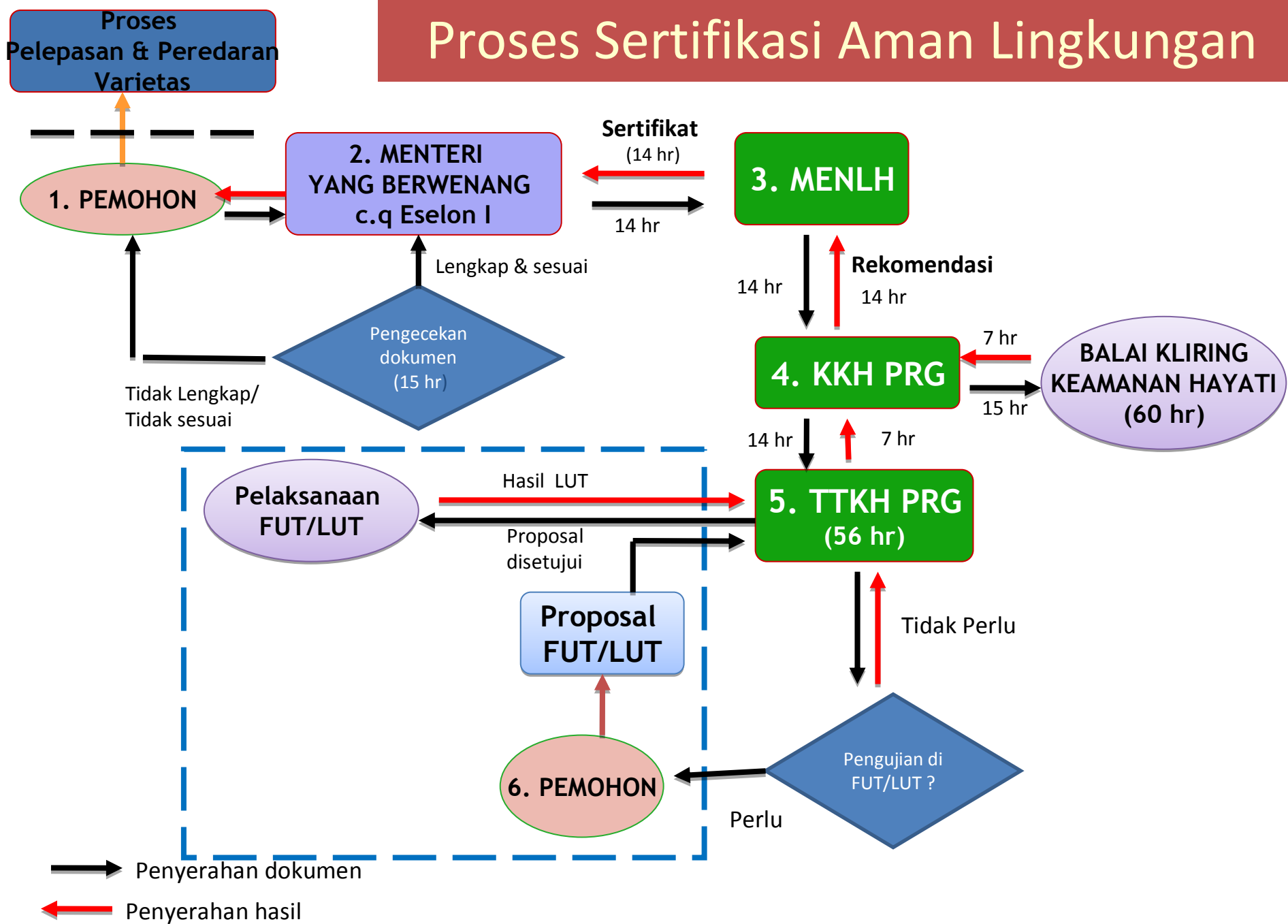
E. Proposed Management and Monitoring of Post-Released GM Crop
(Management and Monitoring, Reporting) (Guidelines is under preparation by MoA)

PROCEDURE OF THE REQUEST FOR ASSESMENT

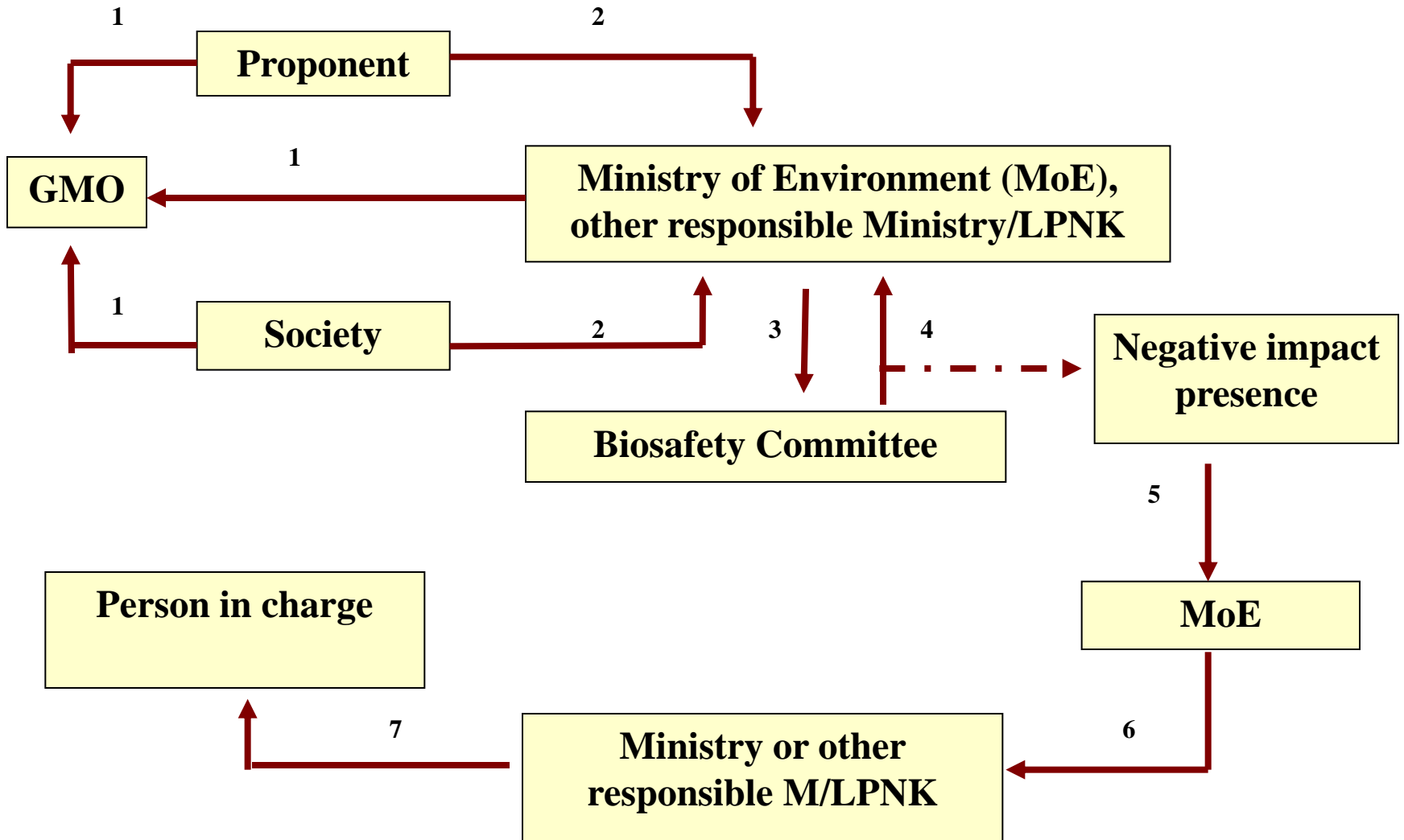
PROPONENT/PROPOSER HAS TO SUBMIT:

- Completed Application Form as Requested;
- For Environment Safety Proponents are requested to submit completed ERA documents with the supporting data (primary and secondary data).

Proses Sertifikasi Aman Lingkungan



SCHEME FOR THE MONITORING AND CONTROL OF GMO



No	Environment Safety Decisions	Year
1	Sugarcane event (NXI-1T, NXI-4T, NXI-6T) tolerant kekeringan	2011
2	Corn event MON NK 603 glyphosate tolerant	2015
3	Ingelvac Circoflex (for swine)	2015
4	Vectormune HVT NDV plus Rispens (for chicken),	2015
5	Vectormune HVT NDV (for chicken),	2015
6	Eimovac Dalguban N Plus Oil Vaccine (for chicken),	2015
7	Eimovac Dalguban BEN Plus Oil Vaccine (for chicken),	2015
8	Eimovac Dalguban BN Plus Oil Vaccine(for chicken),	2016
9	Vaxxitek HVT + IBD Vaccine,	2016
10	Nobilis rHVT-ND Vaccine,	2016
11	Nobilis rHVT ILT Vaccine,	2017
12	Corn GA21 Glyphosate tolerant	2018
13	Potato Katahdin SP951 <i>Pytophthora infestans</i> tolerant	2018
14	Bacteria <i>Corynebacterium glutamicum</i> CJM107 (KCCM-10227) (US Patent No : US 9, 777, 282 B2)	2019
15	Bacteria <i>Escherichia coli</i> CJ285 (KCCM-10534) (US Patent No : US 7, 638, 312 B2)	2019

Summary

- Guidelines for the assessment of food, feed, and environment safety are in place
- Guidelines for environmental safety assessment of crops and microbes are available, fish and animal are in progress
- Many GMO have been granted food, feed or environment safety, or their combination (www.indonesiabch.menlhk.go.id)
- Post-Released Management and Monitoring guidelines is being prepared by the MoA
- Guidelines on laboratory work and biosafety containment of GMO are still not available
- Harmonization between Ministry and other responsible Institutions need to be strengthen

THANK YOU