



Biosafety Commission for Genetically Engineered Products

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FUNCTIONS

7. The implementation of assignments from the Minister of LHK, the authorized Minister and Head of LPNK to conduct examination and verification of reports regarding the emergence of negative impacts on the environment, human health, and / or animal health caused by the release, circulation and / or utilization of GEP;
8. Organizing cooperation and consultation with various institutions both domestic and foreign in environmental safety, food safety, and / or feed safety;
9. Implementation of evaluation and testing of environmental safety, food security, and / or feed safety due to the use of GEP;
10. Providing input to the Minister of Environment, authorized Minister and Head of LPNK in the establishment of guidelines for monitoring impact and managing risk of GEP;
11. Providing input to the Minister of LHK, Authorized Minister and Head of LPNK in the determination of procedures for withdrawal of GEP that cause negative impacts on the environment, human health, and / or animal health.



Biosafety Commission for Genetically Engineered Product

Secretariat

Biosafety Clearing House

Biosafety Technical Team

Assessment Team for Law, Social & Culture

Environmental Safety

Food Safety

Feed Safety



Risk Assessment

Assessment of the possibility of the occurrence of an adverse impact on the environment, human health and animal health arising from the development and utilization of genetically engineered products based on the use of valid scientific methods and statistics.

Government Regulation No. 21/2005 on Biosafety of Genetically Engineered Products (Article 1.21)

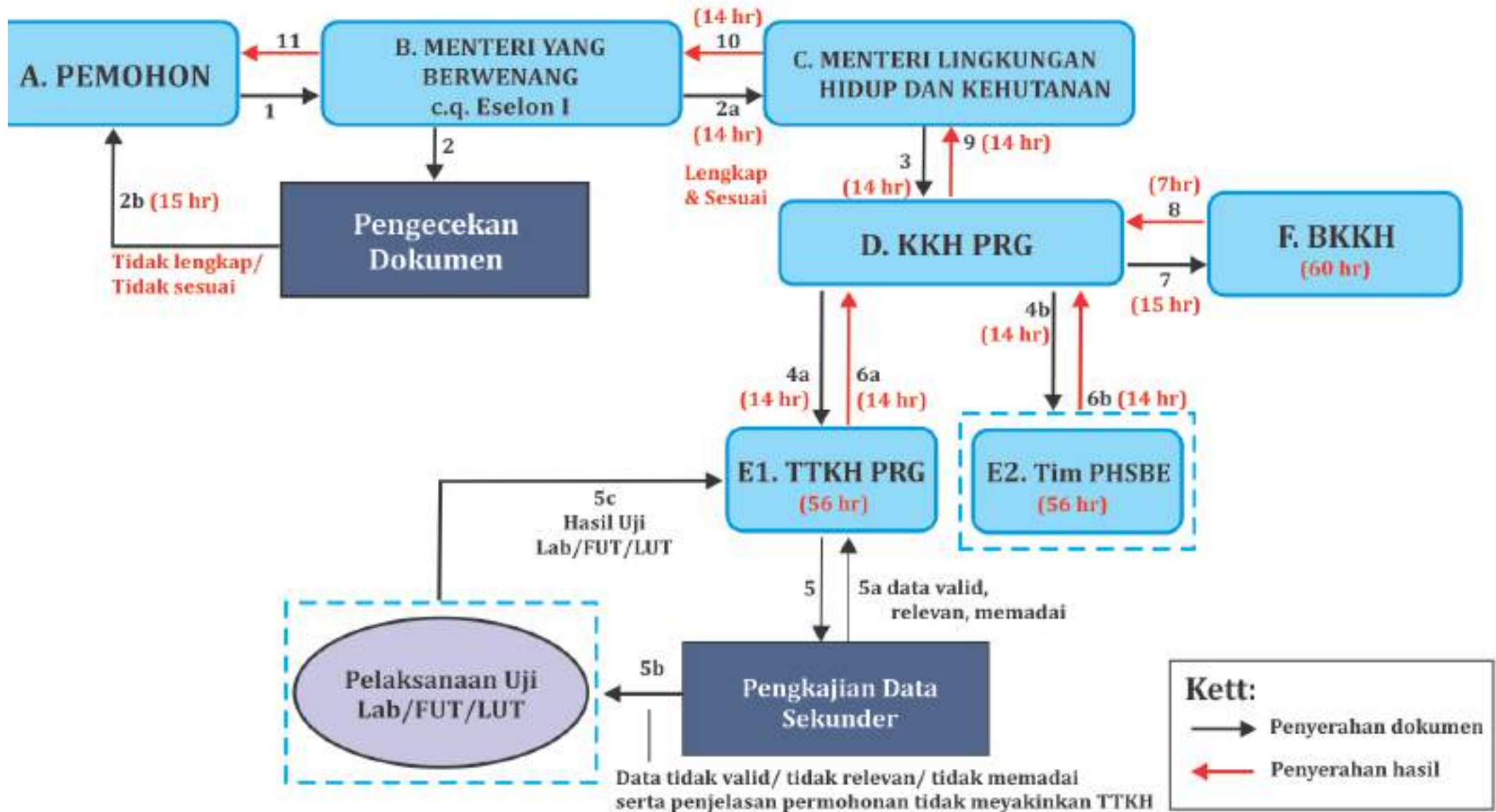


Guidance on risk assessment and supervision

- Minister of Environment Decree No 25/2012 on the guidelines for the preparation of documents of the environmental risk analysis of genetically engineered product.
- Ministry of Agriculture No 36/ Permentan/LB.070/8/2016 on Feed Safety Risk Assessment of genetically engineered product
- Ministry of Environment No P.69/Menlhk/Setjen/Kum.1/8/2016 on the procedures for testing the environmental safety of genetic engineering plant in the limited field trials
- Regulation of National Agency for Food and Drugs Control (BPOM) No 6/2018 on Supervision of Genetically Engineered Products. (Revoking the regulation No. No.19/2016 and the Regulation No HK.03.1.23.03.12.1564/2012 about Guidelines for Food Safety Assessment of Genetically Engineered Products, and Monitoring Food Labelling Genetically Engineered Products, respectively)
- **Monitoring and control system of genetically engineered plants as required by Government Regulation 21/2005 is being drafted by MoA.**

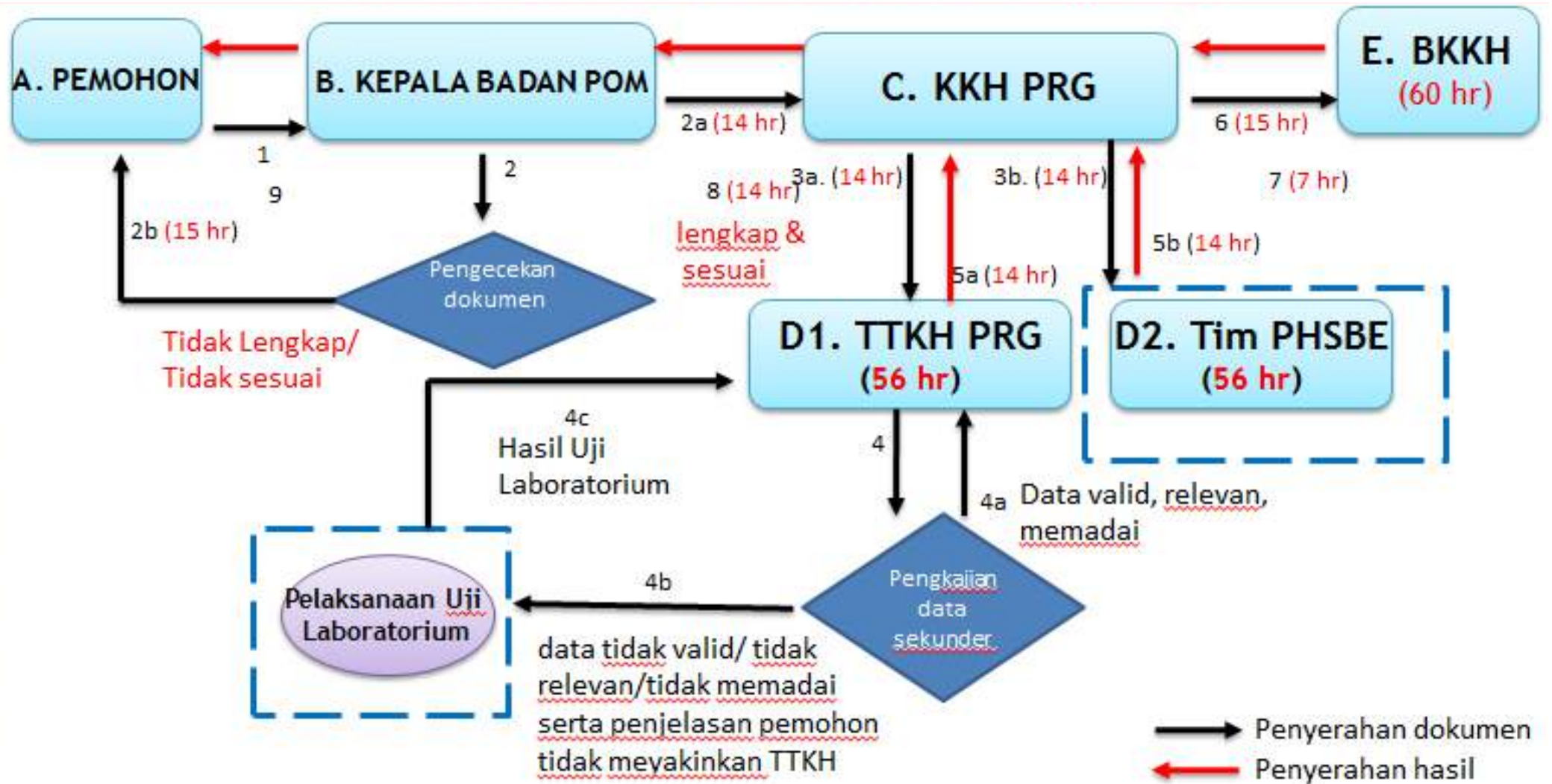


Environmental safety risk analysis procedures for certification



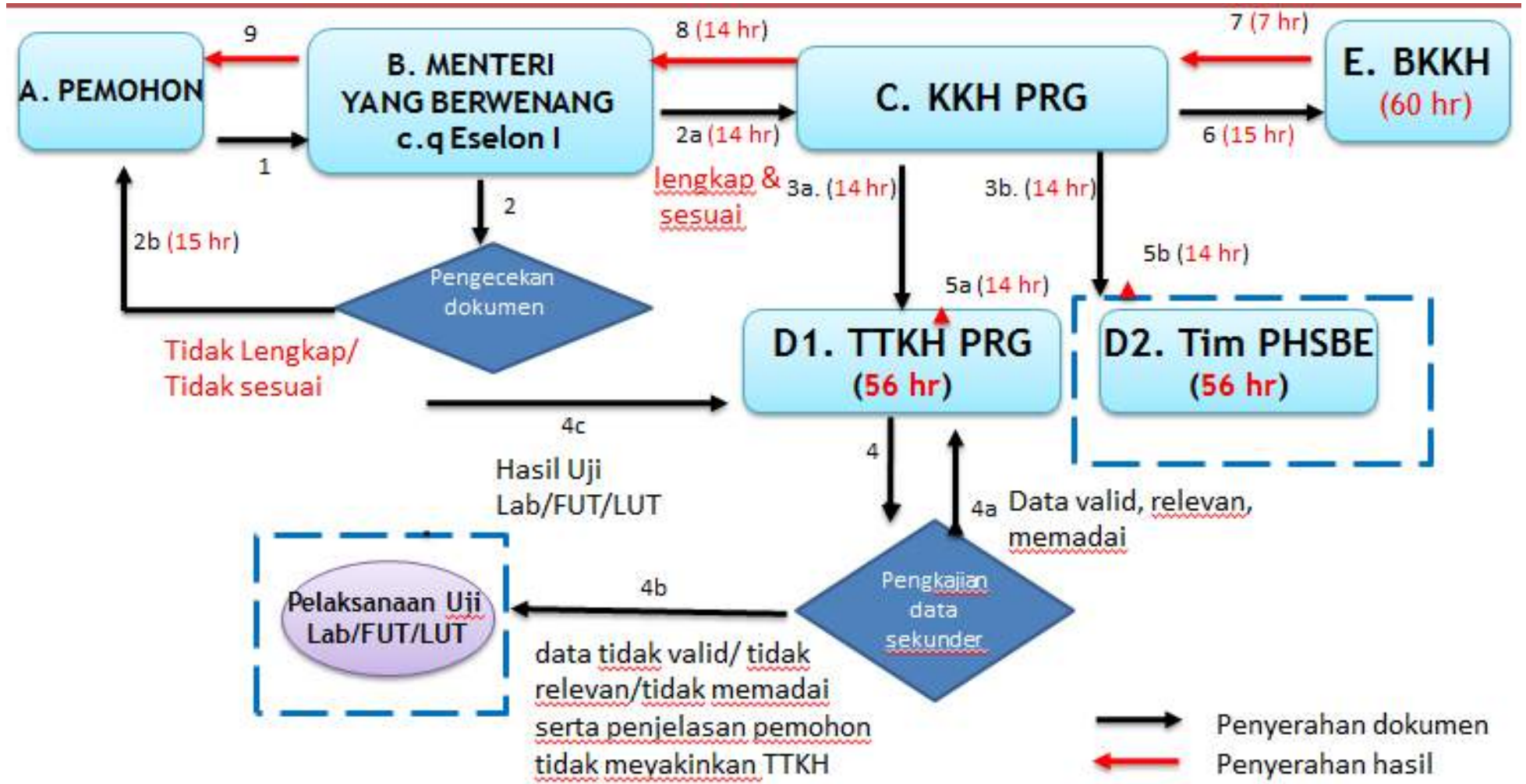


Food safety risk analysis procedures for certification





Feed safety risk analysis procedures for certification



Recommendation of Biosafety Certificates Issued by Biosafety Commission for Genetically Engineered Products - Environmental Safety

No	Products	Year
1	Tebu event (NXI-1T, NXI-4T, NXI-6T) toleran kekeringan	2011
2	Jagung event MON NK 603 toleran glifosat	2015
3	Ingelvac Circoflex (Vaksin untuk babi)	2015
4	Vectormune HVT NDV plus Rispens (Vaksin untuk ayam),	2015
5	Vectormune HVT NDV (Vaksin untuk ayam),	2015
6	Himmvac Dalguban N Plus Oil Vaccine (Vaksin untuk ayam),	2015
7	Himmvac Dalguban BEN Plus Oil Vaccine (Vaksin untuk ayam),	2015
8	Himmvac Dalguban BN Plus Oil Vaccine (Vaksin untuk ayam),	2016
9	Vaxxitek HVT + IBD Vaccine,	2016
10	Nobilis rHVT-ND Vaccine,	2016
11	Nobilis rHVT ILT Vaccine,	2017
12	Jagung GA21 Toleran Herbisida Glifosat	2018
13	Kentang Katahdin SP951 toleran Penyakit Hawar Daun Pytophthora infestans	2018
14	Bakteri <i>Corynebacterium glutamicum</i> CJM107 (KCCM-10227) (US Patent No : US 9, 777, 282 B2)	2019
15	Bakteri <i>Escherichia coli</i> CJ285 (KCCM-10534) (US Patent No : US 7, 638, 312 B2)	2019

Recommendation of Biosafety Certificates Issued by Biosafety Commission for Genetically Engineered Products
- **Food Safety (1)**

No	Products	Year
1	Jagung event MON 89034 toleran lepidoptera	2011
2	Jagung event MON NK 603 toleran glifosat	2011
3	Kedelai event GTS 40-3-2 toleran glifosat	2011
4	Kedelai event MON 89788 toleran glifosat	2011
5	Jagung event MIR 162 toleran hama	2011
6	Jagung Event GA 21 toleran glifosat	2011
7	Jagung Event MIR 604 toleran penggerek batang	2011
8	Jagung Bt 11 toleran lepidoptera	2011
9	Jagung event 3272 enzim α -amilase	2011
10	Tebu event NXI-1T toleran kekeringan	2011
11	Ice Structuring Protein (ISP)	2011
12	Tebu NXI-4T toleran kekeringan	2011
13	Tebu NXI-6T toleran kekeringan	2011

Recommendation of Biosafety Certificates Issued by Biosafety Commission for Genetically Engineered Products
- **Food Safety (2)**

No	Products	Year
14	Kedelai MON 87708 toleran herbisida	2015
15	Kedelai MON 87769 (peningkatan nilai gizi protein)	2015
16	Kedelai 305423	2015
17	Jagung MON 87427 toleran herbisida	2016
18	Jagung MON 87460	2016
19	Kentang Katahdin event SP951	2016
20	Kedelai SYHT02H2	2017
21	Jagung MON 810	2018
22	Jagung MON 87411	2018
23	Kedelai MON 87751	2018
24	Jagung MON 88017	2018
25	Kanola PRG <i>Event</i> DP73496	2019

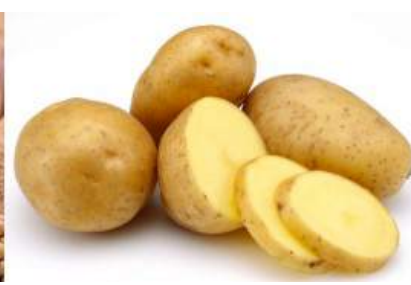
Recommendation of Biosafety Certificates Issued by Biosafety Commission for Genetically Engineered Products

- Feed Safety

No	Products	Year
1	Ronozym AX (CT) food additive	2011
2	Jagung event MON 89034 toleran lepidoptera	2013
3	Jagung event MON NK 603 toleran glifosat	2013
4	Tebu event NXI-4T	2018
5	Jagung event BT 11	2018
6	Jagung event GA21	2018
7	Jagung PRG event MIR604	2019
8	Jagung PRG event MIR162	2019

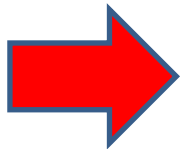
The National Competent Authority for GE Products in Indonesia

No	Area of authority	Competent Authority	
		Ministry / Agency	The authorized institution
1	Environmental safety	Ministry of Environment and Forestry	Directorate General for Conservation of Natural Resources and Ecosystem
2	Food Safety	National Agency for Drug and Food Control	Deputy for Processed Food Control
3	Feed safety	Ministry of Agriculture	Indonesian Agency for Agriculture Research and Development
4	Seed imports permit	Ministry of Agriculture	Center for Plant Variety Protection and Agricultural License
5	Research permit	Ministry of Agriculture	Indonesia Agency for Agriculture Research and Development
6	Plant and animal imports	Ministry of Agriculture	Indonesian Agency for Agriculture Quarantine
7	Fisheries products and fish feed	Ministry of Marine Affairs and Fisheries	Research Center for Marine and Fisheries Product Processing and Biotechnology
8	Forestry Plants	Ministry of Environment and Forestry	Agency of Research, Development and Innovation



AGENDA

1. Background
2. Regulation of Genetically Engineered Products in Indonesia
3. Strategic Issues and Way Forward



Strategic issues

1. Regulation
2. Institutional
3. Public Services
4. Human Capital Development
5. Networking
6. Partnership
7. Commercialization
8. Risk communication
9. Performance of Biosafety Commission for Genetically Engineered Products

Way forward: Proposed solutions

1. Regulation

- Perception equalization
- Harmonization,
- Clear, predictable
- Efficient regulatory pathway
- Readiness of implementation,
- Consistency of implementation
- Unavailability of guidance (e.g. monitoring and control system of genetically engineered plants),
- Risk-based regulation
- New technology development (e.g. gene stacked event, genome editing)

2. Institutional

- Clear mandate
- Capacity
- Resources

Way forward: Proposed solutions

3. Public services

- Certainty
- Predictable
- Transparent
- Accountable
- Compliance with Service Level Agreement
- Quality of assessment

4. Human Capital Development

- Competence
- Capacity
- Capacity building

Way forward: Proposed solutions

5. Networking

- Strengthening Interagency cooperation
- Perception equalization
- Trust building
- National, regional and global networking

6. Partnership

- Enhancing mutual benefit partnership (academia, business, government, and community/farmers)

7. Commercialization

- Technology transfer
- Enhancing R&D and Innovation
- Innovation friendly regulation without ignoring precautionary approach
- Incentive scheme
- Business certainty

Way forward: Proposed solutions

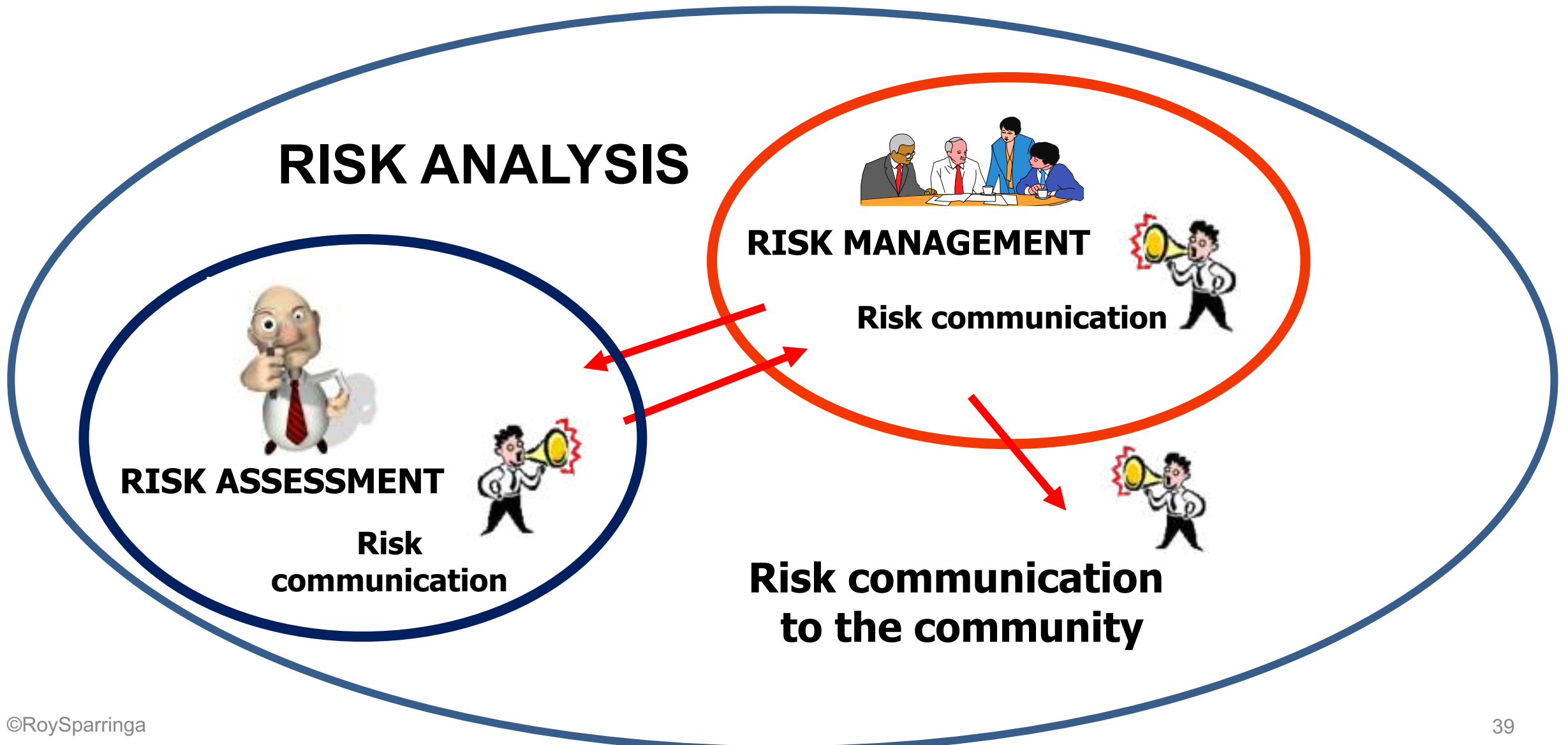
8. Risk Communication

- Enhancing risk communication within risk assessor, risk manager and the community, such as addressing health issues, environmental issues like gene flow, biodiversity, food sovereignty, pest resistance, non target organisms, IP, ethics, religion, social, culture, economy.
- Developing public outreach program to targeted audience
- Influence the influencer
- The power of personal stories
- Continuing effort

9. Performance of Biosafety Commission for Genetically Engineered Product

- Arrangement of Strategic Plan (2019-2023) addressing the strategic issues
- Capacity building of biosafety commission including technical team, biosafety clearing house
- Issuance of policy brief
- Public advocacy and strengthening partnership networking
- Management of Biosafety Commission

Risk communication presents in the whole risk analysis framework





KOMISI KEAMANAN HAYATI
PRODUK REKAYASA GENETIK

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