MINISTRY OF NATURAL RESOURCES
AND ENVIRONMENTAL SUSTAINABILITY

BIOSYM
BIOSAFETY SYMPOSIUM 2025
21 AUGUST 2025

JABATAN BIOKESELAMATAN

BIOSAFETY SYMPOSIUM

STRENGTHENING BIOSAFETY FOR FUTURE SUSTAINABILITY

21 August 2025 | Thursday

DoubleTree by Hilton, Shah Alam

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Insights on Biosafety Regulatory Approach, Local Innovations and Public Engagement Initiatives in Indonesia

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1. Biosafety Regulatory Approach

What is the biosafety of GMOs?

- 'Biosafety' is a term used to describe efforts to reduce and eliminate the potential risks from biotechnology products, including GMOs and their production.
- Biosafety regulations for GMOs aim to minimize potential risks associated with genetically modified organisms and their products, ensuring human health, environmental protection, and biodiversity conservation. These regulations often involve risk assessments, containment measures, and monitoring of GMOs throughout their lifecycle, from research and development to commercialization.

KEY ASPECTS ?

Key aspects of biosafety regulations for GMOs

GMOs PRODUCT

❖ RISK ASSESMENT

- evaluation of potential hazards associated with GMOs before release into the environment or use as food or feed

❖ CONTAINMENT

- Measures to prevent the unintended release of GMOs from research facilities or during cultivation

❖ MONITORING

Tracking the performance and potential impacts of GMOs in the environment and on human health after release.

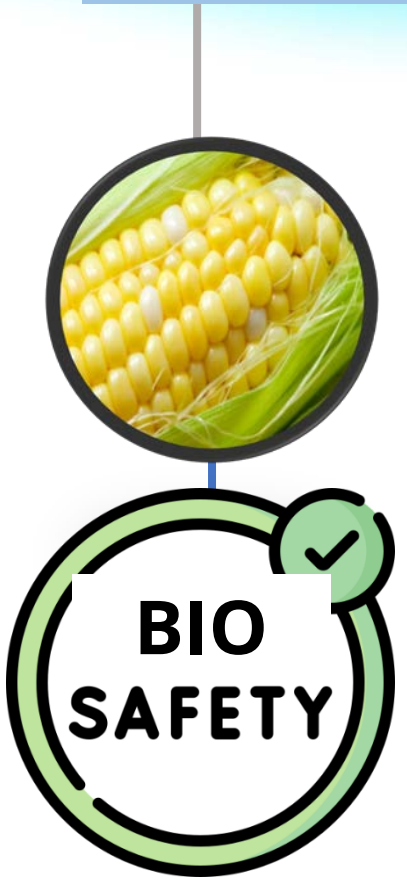
•Traceability

•Systems to track the movement of GMOs and their products through the supply chain.

•Public Awareness and Participation:

•Ensuring public access to information about GMOs and involving stakeholders in decision-making processes.

POLICY FOR BIOSAFETY REGULATION



- GMO foods must undergo a food safety assessment before distribution, applying **the precautionary approach.** This assessment is conducted to ensure the safety of GMO foods before they are consumed by the public.

- The precautionary approach to risk assessment of GMOs emphasizes the importance of taking precautionary measures, even when complete scientific evidence is not yet available, if there is a potential for serious risks to the environment or human health. This means that scientific uncertainty should not be a reason to delay necessary action to protect the environment and public health.

GMO Regulations in Indonesia

1 **Law No. 21/2004**

Ratification of The Cartagena Protocol on Biosafety to the Convention on Biological Diversity

2 **Government Regulation No. 21/2005**

Establishes biosafety protocols for genetically engineered products. This foundational regulation ensures environmental and health safety assessments.

3 **Indonesia FDA Regulation No 19 /2024**

Concerning Genetic engineering product control

4 **Ministry of Agric Regulation No.35/2023**

Amendments to Regulation of the Ministry of Agriculture No 50/2020 concerning Post Market Monitoring of GM Crop Growing in Indonesia

5 **Regulation of the Minister of Environment and Forestry No 69/2016**

Procedures for Environmental Safety Testing of Genetically Modified Plant Products in Confined Field Trials

Implementation of Regulation

- Risk Assessment of Environment Safety (biotech crops)
  - Biosafety containment tests
  - Confined field trial
- Monitoring of Confined Field Trials
- Risk Assessment of Food Safety
- Risk Assessment of Feed Safety
- Variety Released for Commercialization

Regulatory Bodies

Biosafety Committee

- **Chair**
  - **Vice Chair of Food Safety:** Deputy of NDFCA
  - **Vice Chair of Feed Safety :** DG of IAARD/IASAI
  - **Vice Chair of Environment Safety :** Deputy of MOEF
- ***Member of Biosafety Committee***
  - ***Ex officio***
  - ***Representative of Professional Association***
  - ***Representative of NGO***

Biosafety Technical Team

- **Division of Food Safety** (Coordinator & vice)
- **Division of Feed Safety**(Coordinator & vice)
- **Division of Environment Safety**(Coordinator & vice)
  - **Plant**
  - **Animal**
  - **Fish**
  - **Microorganisms**

According to Goverment Regulation No. 21 Year 2005 on Biosafety Regulation of Geneticallly Engineered Products

Biosafety:

- Environment Safety
- Food Safety
- Feed Safety

Major Requirement

GEP/Biotech Crops

Derived in country or from abroad

***should fulfill the requirements*:**

Environment Safety

Food Safety, Feed Safety

and.....

Must Pay Attention & Take into Consideration

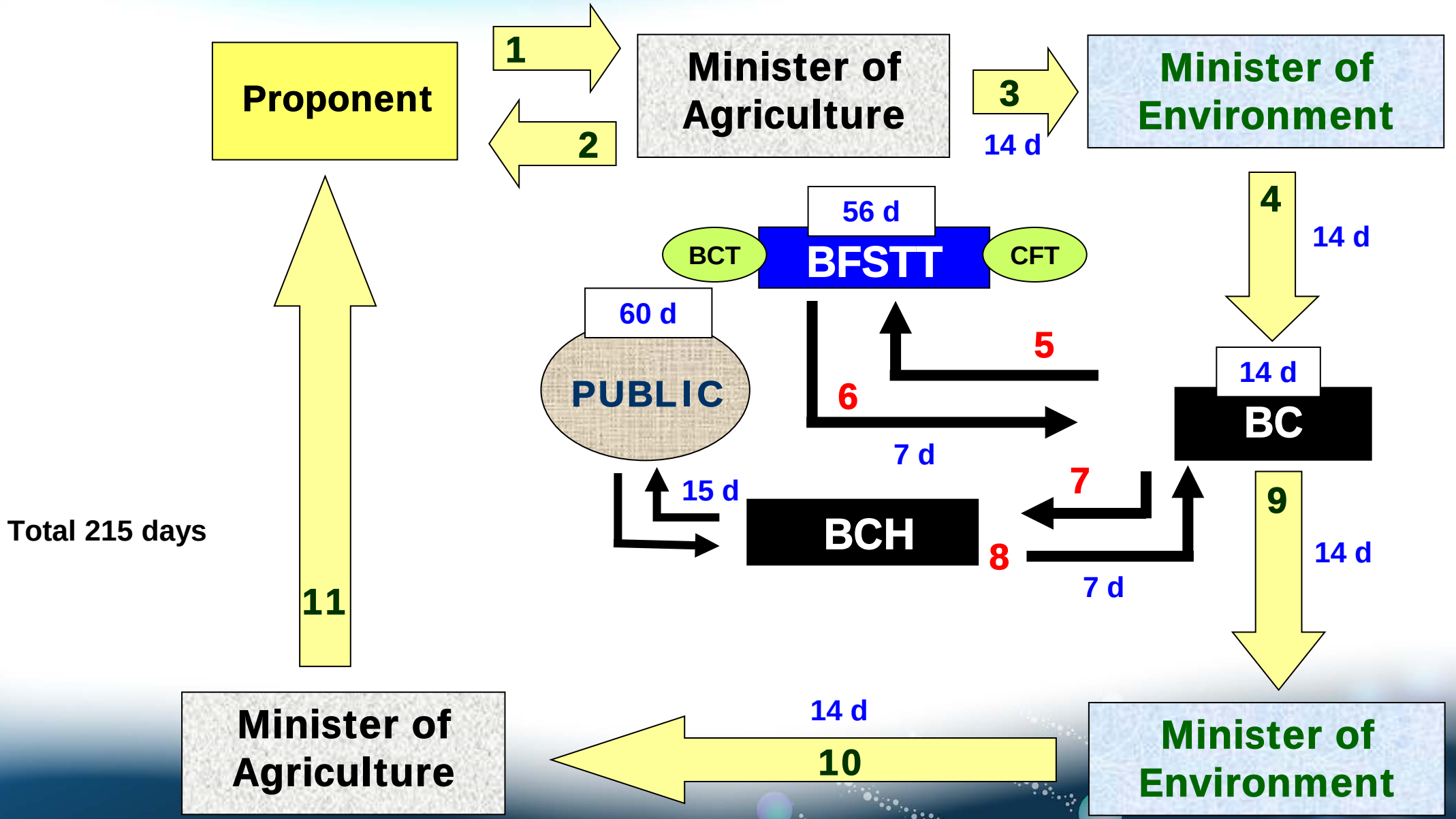
- **Religious and Ethical**
- **Socio-Cultural and Esthetical Norm**

Risk Assessment

Environment

Safety

Assessment of Environment Safety



Approved GM Events for Environment in Indonesia

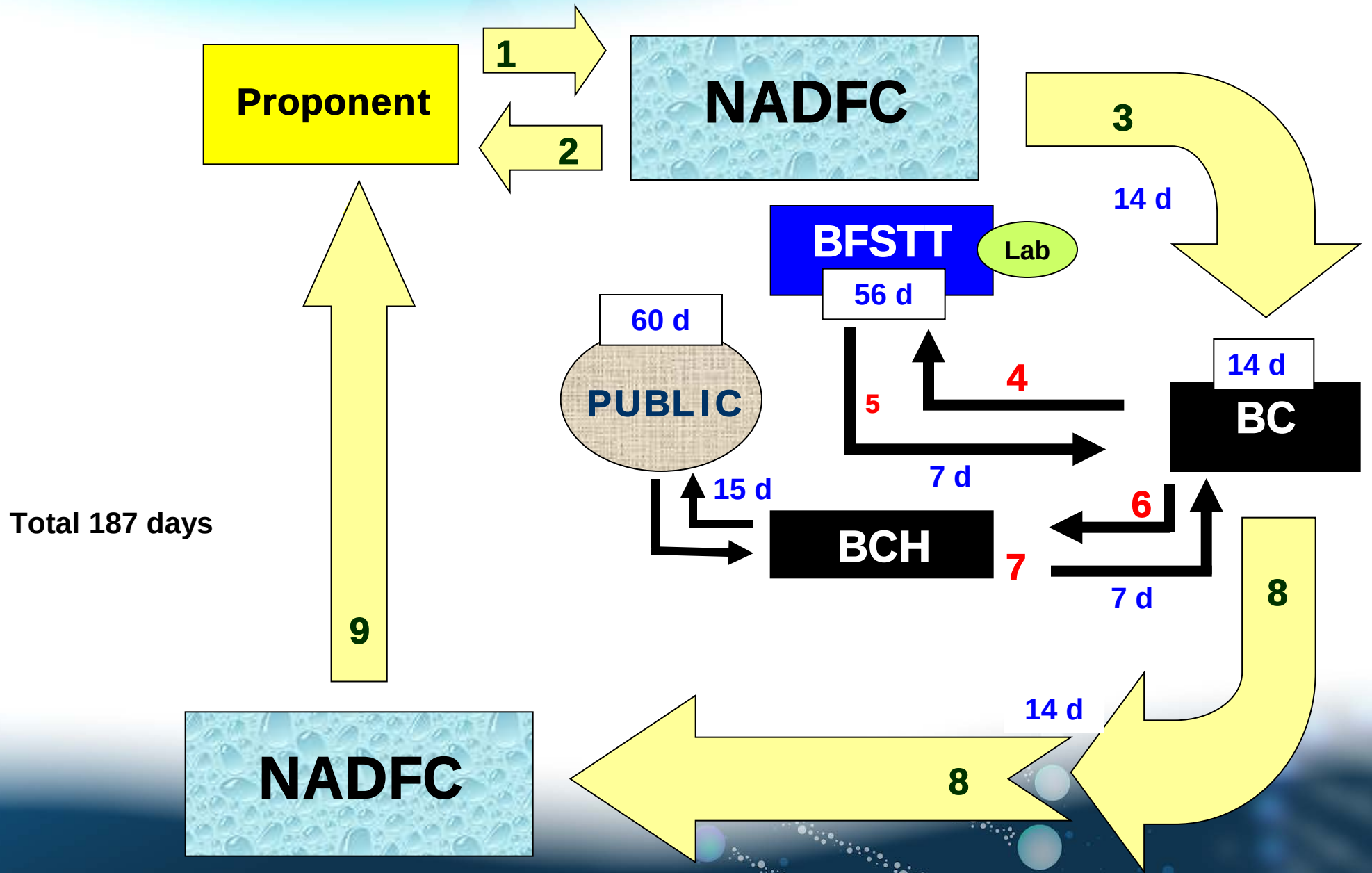
Indonesia has approved 51 genetically modified events for environment

- Potato (1 event)
- Corn (7 events)
- Sugar cane (3 events)
- Bacteria (14 events)
- Vaccine (17 events)
- Animal Nutrition (9 events)

Risk Assessment

Food Safety

Assessment of Food Safety



Total 187 days

Approved GM Events for Food in Indonesia

Indonesia has approved 90 genetically modified events for food use by July 2025

Corn (42 events)

Potato (1 event)

Cotton (8 events)

Canola (9 events)

Soybean (21 events)

Rice (1 events)

Wheat (1 event)

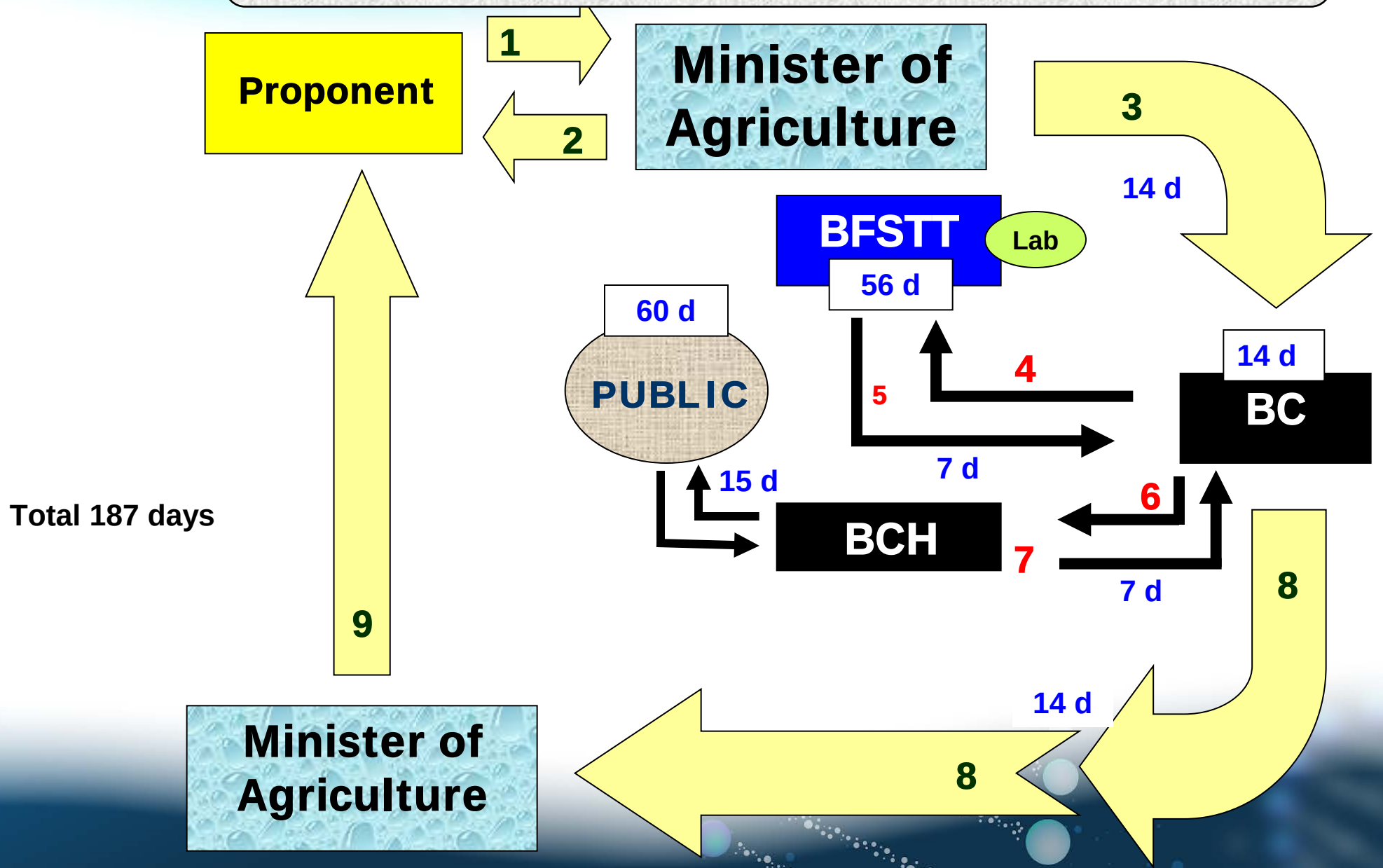
Sugar Cane (3 events)

Food Ingredient (4 events)

Risk Assessment

Feed Safety

Assessment of Feed Safety



Total 187 days

Approved GM Events for Feed in Indonesia

Indonesia has approved 64 genetically modified events for animal feed

- **Corn (29 events)**
- **Soybean (17 events)**
- **Canola (9 events)**
- **Cotton (7 event)**
- **Sugar Cane (1 event)**
- **Wheat (1 event)**

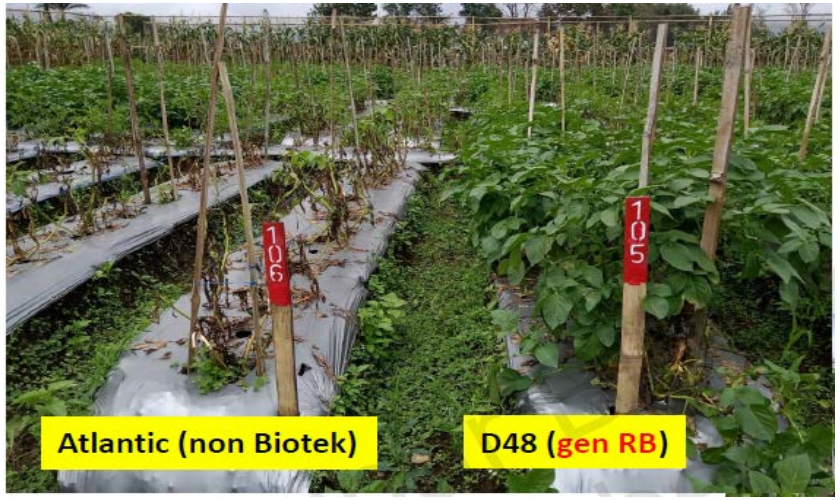
Regulation on Variety Released for Commercialization

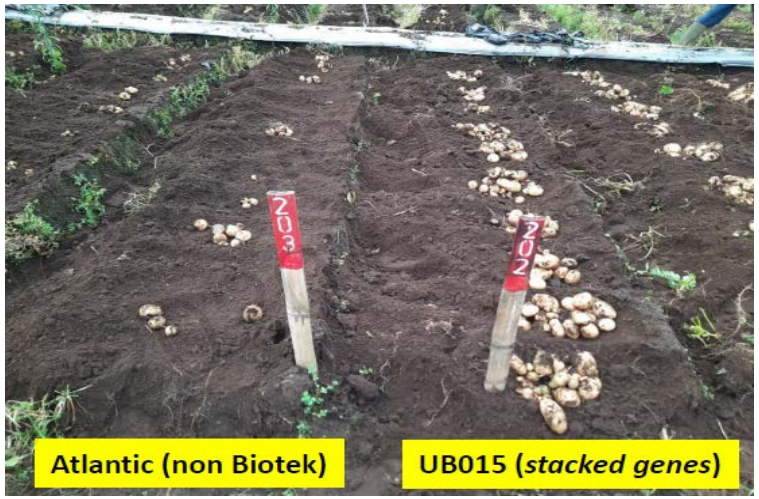
Released GM Crop Varieties

No	Crop	Variety	Proponent	Decision
1	Sugarcane	NXI-4T	PTPN XI	2013
2	Potato	Bio Granola	BRMP	2021
3	Maize	DK95-NK603	Bayer	2022
4	Maize	NK7328s-GA21	Syngenta	2022
5	Maize	NK212s-GA21	Syngenta	2022
6	Maize	NK6172-GA21	Syngenta	2022
7	Maize	NK7828s-Bt11xGA21	Syngenta	2023
8	Maize	NK212s-Bt11xGA21	Syngenta	2023
9	Maize	NK6172-Bt11xGA21	Syngenta	2023
10	Maize	NK603-Bt11xGA21	Syngenta	2023

2. Local GMO related innovation

GM Potato resistant to Late Bligth





GM Tomato resistant to multivirus

2. Local GMO related innovation

Research on GMO Crops/Events

Potato	**resistence to *Phytophtora infestan (stacked gene)***
Rice	Golden rice

R & D Using Genome Editing

Rice	**Lodging tolerance, pest and disease resistance, high productivity**
Shallot	Disease resistance
Chili pepper	Resistance disease resistance
Tomato	Heat tolerance, virus resistance
sorghum	Low tannin
Citrus	Resistance to HLB and CVPD

3. Public engagement/ public awareness

GMO Testing Activities

Internal Workshop on 8-14 November 2023

Technical Meeting for Indonesian Food Testing Laboratories Network

Discussion the socio-economic impact of the GMO & Risk Comm workshop

Potato value chain experts from the major potato growing regions of Indonesia gathered in Bandung recently to discuss the socio-economic impact of a late blight disease resistant potato

INDONESIA

Potato value chain stakeholders visit confined field trials in Pangalengan and Kledung

Potato value chain stakeholders in Pangalengan and Kledung Indonesia got an up close and personal look at the Global Biotech Potato Partnership's 3-R gene late blight resistant Granola potato variety during recent confined field trial visits.

CONCLUSION

- Indonesia's robust GMO regulatory framework are crucial for ensuring the safety of GMO before they are consumed by the public and livestock, released to the environment.
- Public access to information about GMOs must be easily accessible and biosafety regulations must involve stakeholders in the decision-making process.

THANK YOU