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

gef | UN environment programme | ASEAN MALAYSIA 2025 | MALAYSIA MADANI kemampanan | Visit Malaysia 2026 Truly Asia

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

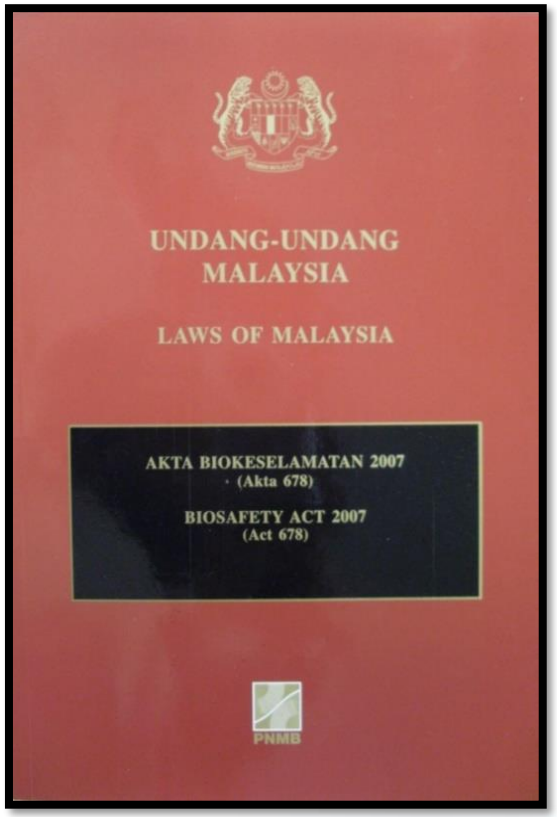
MALAYSIA

1. Biosafety Regulatory Approach

- What is the regulatory framework in your country for **Genetically Modified Food (GMF)/GMOs?**
- Describe the approval process for GMF/GMOs in your country.
- Is your regulatory framework related to GMF/ GMOs publicly accessible?
- Has your country made any decisions regarding GMF/ GMOs?
- If yes, how many decisions for GMF/GMOs have you made and are these decisions publicly accessible?
- How are GMF/GMOs monitored?

Biosafety Act 2007

National Biosafety Board to regulate the release, importation, exportation and contained use of living modified organisms (LMO*) & the release of products of such organisms, with the objectives of protecting human, plant and animal health, the environment and biological diversity



*The term LMO is used interchangeably with GMO

Two Regulatory Processes

1 **NOTIFICATION – PART IV OF ACT**

2 **APPROVAL - PART III OF ACT**

DEVELOPING LMO- FROM BENCH TO MARKET

- Contained use
- Import for Contained use
- Export of LMO

R&D

R&D

- Field Trial

- Direct introduction to environment
- Commercialized planting
- Placing in the market

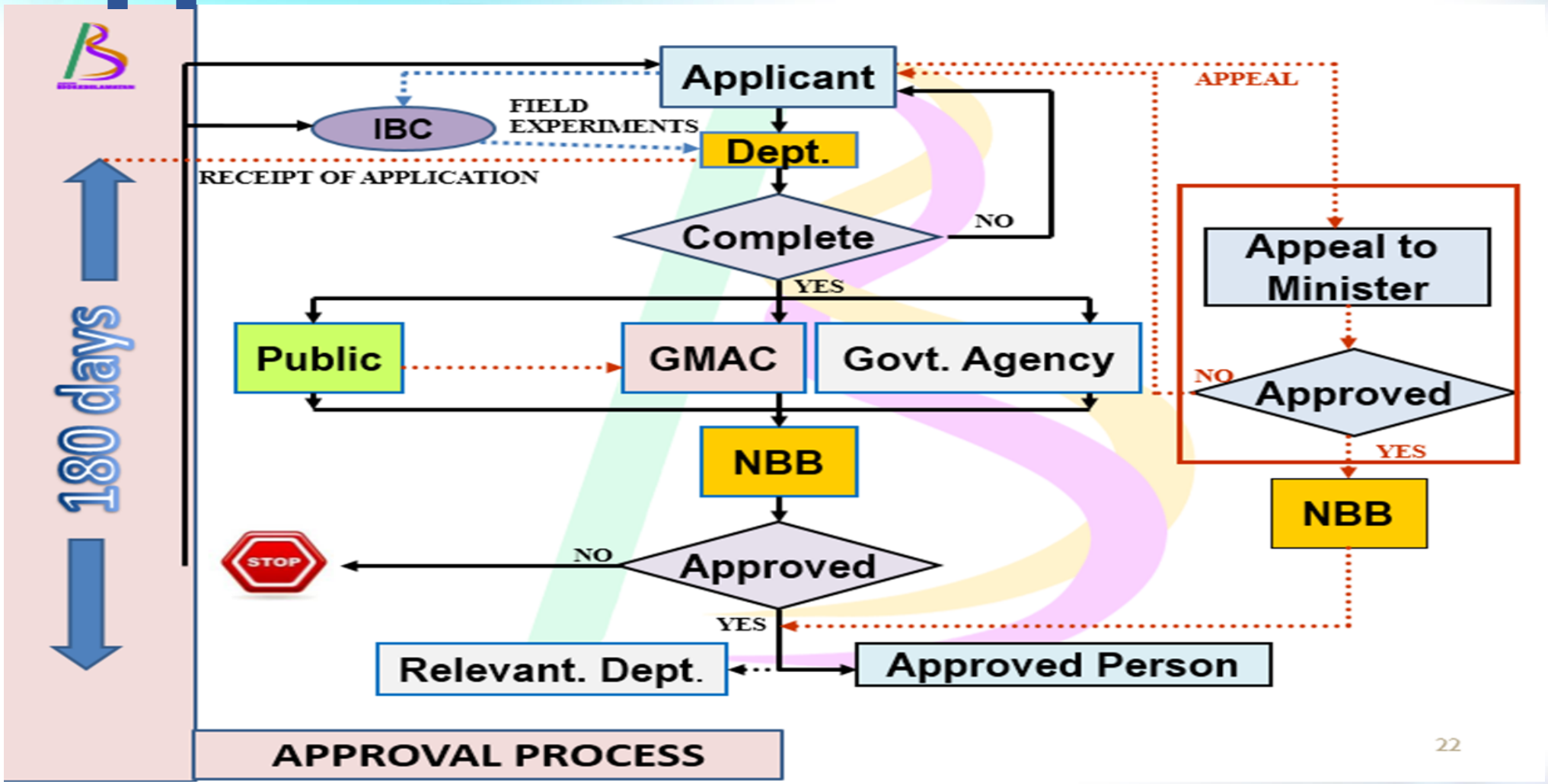
Commercialization

DIRECT COMMERCIAL USE – NO R&D

- **Export LMO**
- **Contained use for industrial production**

- **Import LMO/product for placing in the market or release**

Approval Process - Release



•A technical risk assessment is done by the Genetic Modification Advisory Committee (GMAC) and a recommendation is given to the NBB. In addition, in Malaysia public consultation as well as review by other relevant agencies are required prior to making a decision

Decision Making of NBB

2

Public Consultation

Risk Communication

Public perception

Policy Consideration

National interest

Local priorities

3

Scientific/ Technical Assessment

Risk Assessment

Risk management

Emergency Response Plan

1

Socio economics Consideration

Case by case basis

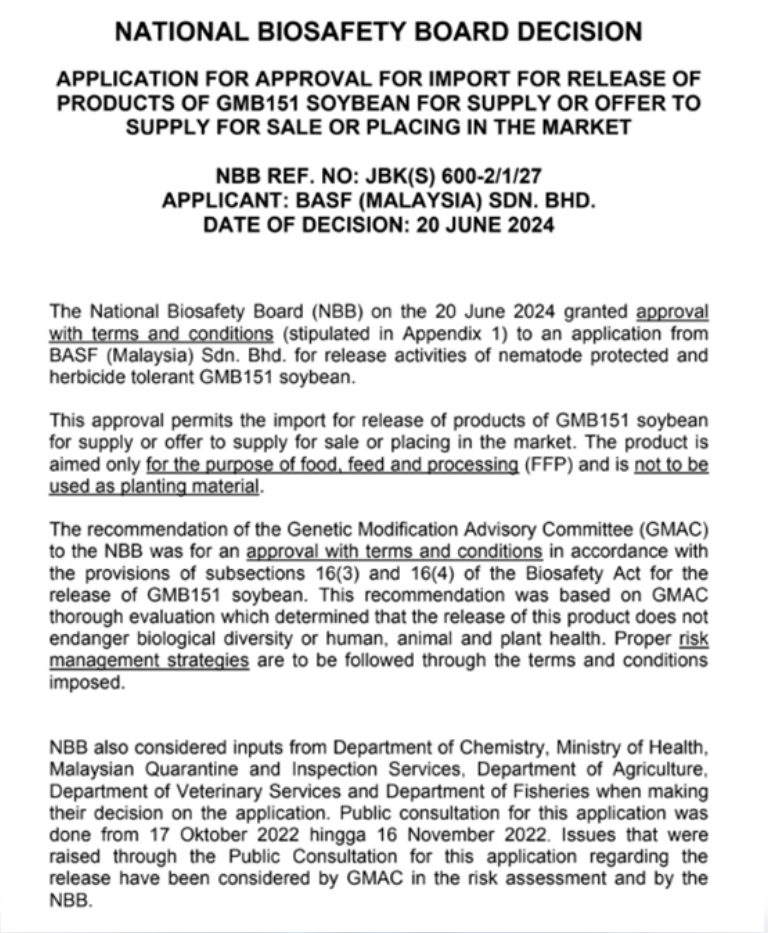
4

Public Disclosure of Decisions

- Public disclosure of decision is mandatory under the Biosafety Act.
- All decisions by the NBB are made available in the 3 different sites at the same time:

i) Department of Biosafety Official Website
ii) Biosafety Clearing House (BCH)
iii) FAO GM Foods Platform

- The duplication of information in a few platforms ensure availability at all times



NATIONAL BIOSAFETY BOARD DECISION

APPLICATION FOR APPROVAL FOR IMPORT FOR RELEASE OF PRODUCTS OF GMB151 SOYBEAN FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF. NO: JBK(S) 600-2/1/27
APPLICANT: BASF (MALAYSIA) SDN. BHD.
DATE OF DECISION: 20 JUNE 2024

The National Biosafety Board (NBB) on the 20 June 2024 granted approval with terms and conditions (stipulated in Appendix 1) to an application from BASF (Malaysia) Sdn. Bhd. for release activities of nematode protected and herbicide tolerant GMB151 soybean.

This approval permits the import for release of products of GMB151 soybean for supply or offer to supply for sale or placing in the market. The product is aimed only for the purpose of food, feed and processing (FFP) and is not to be used as planting material.

The recommendation of the Genetic Modification Advisory Committee (GMAC) to the NBB was for an approval with terms and conditions in accordance with the provisions of subsections 16(3) and 16(4) of the Biosafety Act for the release of GMB151 soybean. This recommendation was based on GMAC thorough evaluation which determined that the release of this product does not endanger biological diversity or human, animal and plant health. Proper risk management strategies are to be followed through the terms and conditions imposed.

NBB also considered inputs from Department of Chemistry, Ministry of Health, Malaysian Quarantine and Inspection Services, Department of Agriculture, Department of Veterinary Services and Department of Fisheries when making their decision on the application. Public consultation for this application was done from 17 Oktober 2022 hingga 16 November 2022. Issues that were raised through the Public Consultation for this application regarding the release have been considered by GMAC in the risk assessment and by the NBB.

Department of Biosafety website

biosafety.gov.my/main/article/keputusan-permohonan-pelepasan-lmo-and-produk-lmo

Home Introduction Services eParticipation Legislation Staff

LMO Releases and LMO Products

BIL.	TAJUK PROJEK	PEMOHON	NO. RUJUKAN	TARIKH KEPUTUSAN	DOKUMEN
73.	GMB151 SOYBEAN	BASF (MALAYSIA) SDN. BHD.	JBK(S) 600-2/1/27	20 JUN 2024	• Keputusan LBK • Laporan Penilaian Risiko
72.	MON94100 CANOLA	BAYER. CO. (MALAYSIA) SDN. BHD.	JBK(S) 600-2/1/26	20 JUN 2024	• Keputusan LBK • Laporan Penilaian Risiko
71.	MON88702 COTTON	BAYER. CO. (MALAYSIA) SDN. BHD.	JBK(S) 600-2/1/23	4 APRIL 2024	• Keputusan LBK • Laporan Penilaian Risiko
70.	MON95379 MAIZE	BAYER. CO. (MALAYSIA) SDN. BHD.	JBK(S) 600-2/1/25	2 Nov 2023	• Keputusan LBK • Laporan Penilaian Risiko
69.	MON87429 MAIZE	BAYER. CO. (MALAYSIA) SDN. BHD.	JBK(S) 600-2/1/24	2 Nov 2023	• Keputusan LBK • Laporan Penilaian Risiko
68.	MON88302 CANOLA	BAYER. CO. (MALAYSIA) SDN. BHD.	JBK(S) 600-2/1/22	2 Nov 2023	• Keputusan LBK • Laporan Penilaian Risiko

GMO Risk Assesmsents

RISK ASSESSMENT REPORT

OF THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

FOR

AN APPLICATION FOR APPROVAL FOR RELEASE OF PRODUCTS OF

GMB151 SOYBEAN FOR SUPPLY OR OFFER TO SUPPLY

NBB REF NO: JBK(S) 600-2/1/27

APPLICANT: BASF (MALAYSIA) SDN. BHD.

DATE: 21 MARCH 2023

A copy of the Risk Assessment report of the GMO for release is available at the website

Biosafety Clearing House

bch.cbd.int/en/countries/MY

Country's Decision or any other Communication (DEC)

Last updated on: 06 Jul 2024

JBK(S) 600-2/1/27

BCS-GM151-6 - Plant-Parasitic Nematode-Protected and Herbicide Tolerant Soybean

COUNTRY'S DECISION OR ANY OTHER COMMUNICATION | MALAYSIA | BCH-DEC-MY-270163-1 | APPROVAL OF THE IMPORT AND/OR USE OF THE LMO(S) WITH CONDITIONS | 06 JUL 2024

JBK(S) 600-2/1/26

MON-941ØØ-2 - Dicamba-tolerant canola

COUNTRY'S DECISION OR ANY OTHER COMMUNICATION | MALAYSIA | BCH-DEC-MY-270161-1 | APPROVAL OF THE IMPORT AND/OR USE OF THE LMO(S) WITH CONDITIONS | 06 JUL 2024

JBK(S) 600-2/1/23

MON-887Ø2-4 - Insect-protected cotton | Cotton

COUNTRY'S DECISION OR ANY OTHER COMMUNICATION | MALAYSIA | BCH-DEC-MY-267865-1 | APPROVAL OF THE IMPORT AND/OR USE OF THE LMO(S) WITH CONDITIONS | 14 MAY 2024

JBK(S) 600-2/1/25

MON-95379-3 - Insect-protected maize | Maize, Corn, MAIZE

COUNTRY'S DECISION OR ANY OTHER COMMUNICATION | MALAYSIA | BCH-DEC-MY-266538-1 | APPROVAL OF THE IMPORT AND/OR USE OF THE LMO(S) WITH CONDITIONS | 07 FEB 2024

JBK(S) 600-2/1/24

MON-87429-9 - Dicamba, glufosinate, quizalofop and 2,4-dicholorophenoxyacetic acid tolerant maize with tissue-specific glyphosate tolerance | Maize, Corn, MAIZE

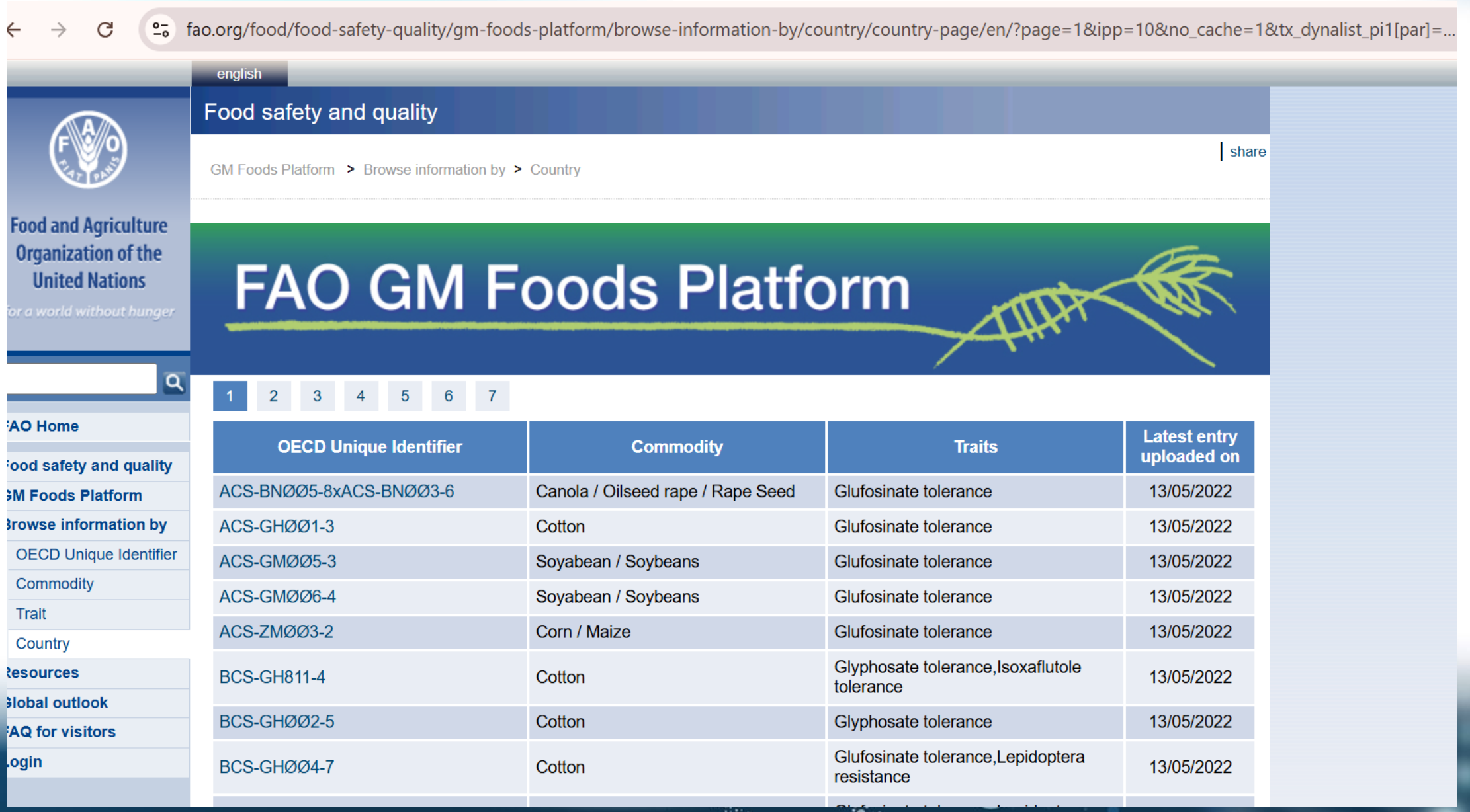
COUNTRY'S DECISION OR ANY OTHER COMMUNICATION | MALAYSIA | BCH-DEC-MY-266537-1 | APPROVAL OF THE IMPORT AND/OR USE OF THE LMO(S) WITH CONDITIONS | 07 FEB 2024

Malaysia

Party to the Cartagena Protocol

3	National Focal Points
5	Competent National Authorit
0	Supplementary Protocol Competent Authority
15	Biosafety Law, Regulation, Guidelines and Agreements
71	Country's Decision or any ot Communication
71	Risk Assessment generated regulatory process
1	National Biosafety Website c Database
0	Fifth National Report on the Implementation of the Cartag Protocol on Biosafety
1	Fourth National Report on th Implementation of the Cartag Protocol on Biosafety
1	Third National Report on the Implementation of the Cartag Protocol on Biosafety
7	Biosafety Expert
1	Country Profile for Biosaf Clearing-House

FAO GM Foods Platform



OECD Unique Identifier	Commodity	Traits	Latest entry uploaded on
ACS-BNØØ5-8xACS-BNØØ3-6	Canola / Oilseed rape / Rape Seed	Glufosinate tolerance	13/05/2022
ACS-GHØØ1-3	Cotton	Glufosinate tolerance	13/05/2022
ACS-GMØØ5-3	Soyabean / Soybeans	Glufosinate tolerance	13/05/2022
ACS-GMØØ6-4	Soyabean / Soybeans	Glufosinate tolerance	13/05/2022
ACS-ZMØØ3-2	Corn / Maize	Glufosinate tolerance	13/05/2022
BCS-GH811-4	Cotton	Glyphosate tolerance,Isoxaflutole tolerance	13/05/2022
BCS-GHØØ2-5	Cotton	Glyphosate tolerance	13/05/2022
BCS-GHØØ4-7	Cotton	Glufosinate tolerance,Lepidoptera resistance	13/05/2022

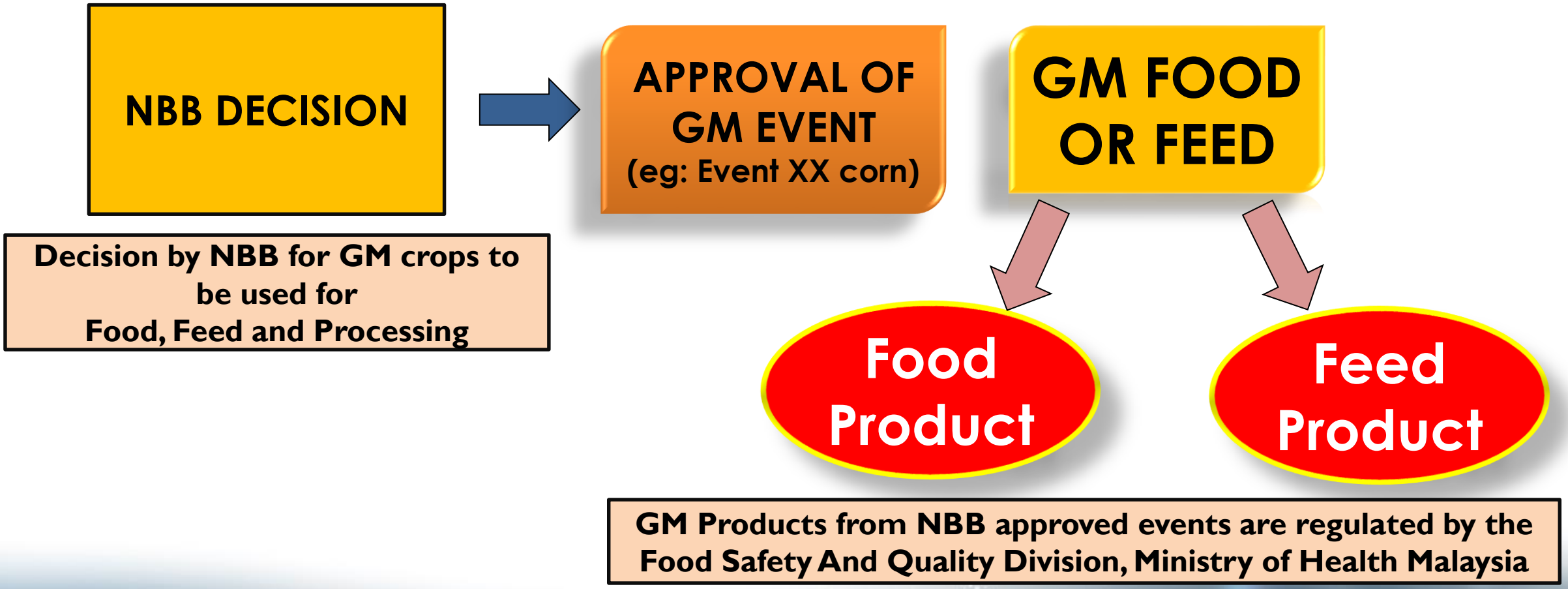
Simplified Procedures

- A simplified procedure is embedded for GMOs used as food, feed and processing (FFP).
- If a GM event or crop is approved to be used for FFP, any subsequent use of the GM crop for the same purpose is exempted from any further regulatory requirements.

Enforcement and Monitoring

Development of an Integrated Enforcement Matrix among Government Agencies to improve multi-agency enforcement since the form of LMOs can involve overlapping regulatory mechanisms with other agencies

Joint Regulatory Approach



Decision by NBB for GM crops to be used for Food, Feed and Processing

GM Products from NBB approved events are regulated by the Food Safety And Quality Division, Ministry of Health Malaysia

Joint Regulatory Approach Enforcement and Monitoring

In Malaysia it is a joint collaboration with the Ministry of Health to regulate GM food.

- The NBB does an assessment and makes decision on whether the GMOs and its products is approved for use.
- After a GM event or crop is approved, the Food Safety and Quality Division under the Ministry of Health regulates the specific GM products in the market.
- Only approved GM events or crops may be use for food, feed and processing.

Biosafety Regulatory Approach – Enforcement and Monitoring

ENTRY POINTS

01

Land : 12 Entry points

Sea : 29 Entry points

Air : 15 Entry points

FIELD

02

Farm

Field

Industry/ Warehouse

MARKET

03

Supermarket

Market

Shop

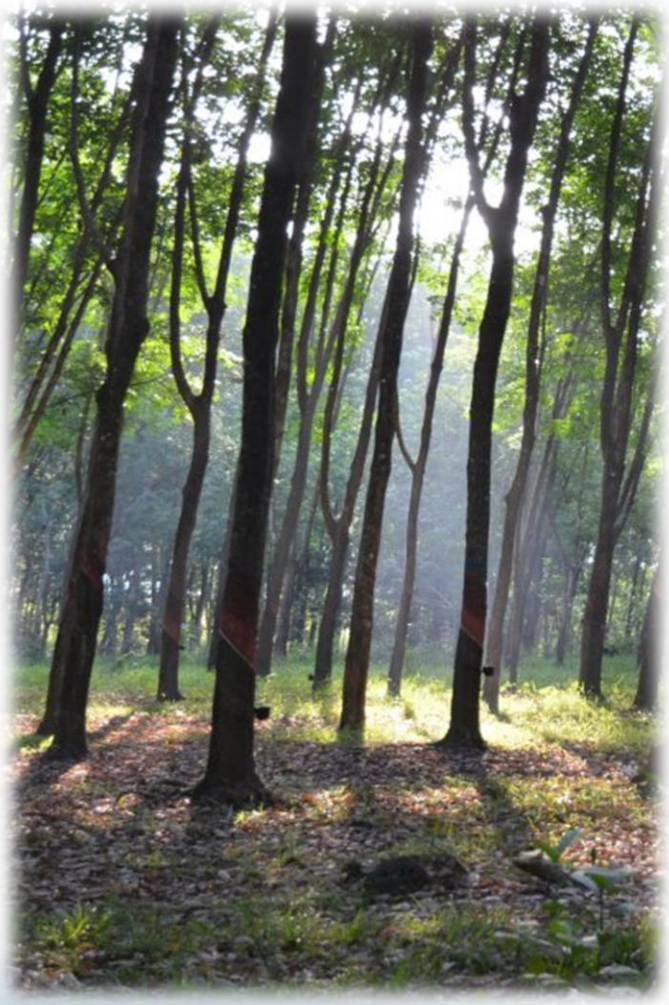
Stall

Biosafety Regulatory Approach – Enforcement and Monitoring

2. Local GMO related innovation

- Any GMOs developed locally that you wish to highlight? Locally developed GMOs highlighted does not necessarily have to be related to food or feed
- If yes, please share the details of the GMOs
- Do you have any GMOs field trial in your country (both imported or locally developed)?
- Any local GMO products that are due to be commercialized, already commercialized?

2. Local GMO related innovation

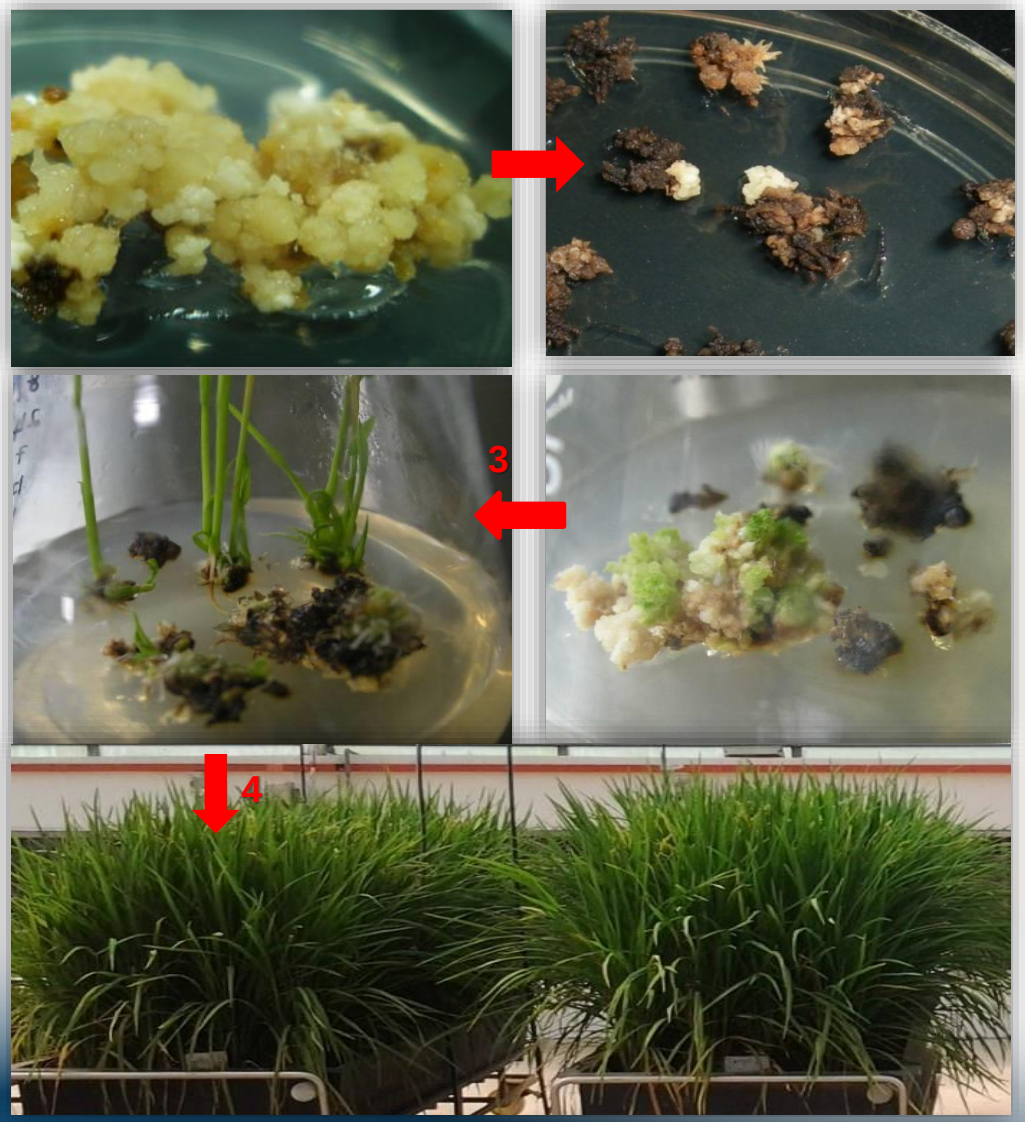


- Confined Field Trial GM Crop

Confined Field Evaluation of Delayed Ripening Transgenic Eksotika Papaya
MARDI (2013)

Confined Fied Trial of Genetically Modified Rubber (*Hevea brasiliensis*) Trees for Research and Development Purpose
Malaysian Rubber Board (2015)

2. Local GMO related innovation



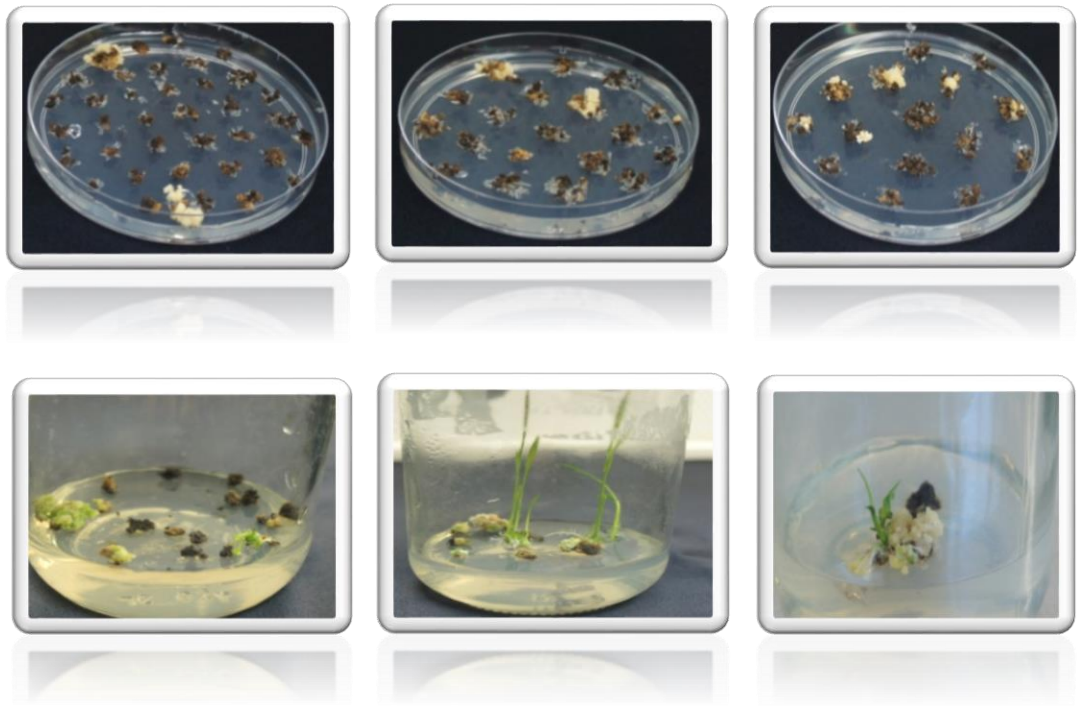
Picture from MARDI

- GM rice for quality improvement

Transgenic rice :

- ✓ **Sheath blight resistance**
- ✓ **Bacterial leaf blight resistance**
- ✓ **Herbicide tolerance**
- ✓ **Drought resistance**
- ✓ **High yield**

2. Local GMO related innovation



E.g:

Genetic Engineering of Malaysia Rice Cultivar MR 219 towards Xanthomonas Oryzae PV Oryzae (XOO) Bacterial (BLB) and Glyphosate Herbicide Resistance using Transgene Stacking

Picture from MARDI

2. Local GMO related innovation

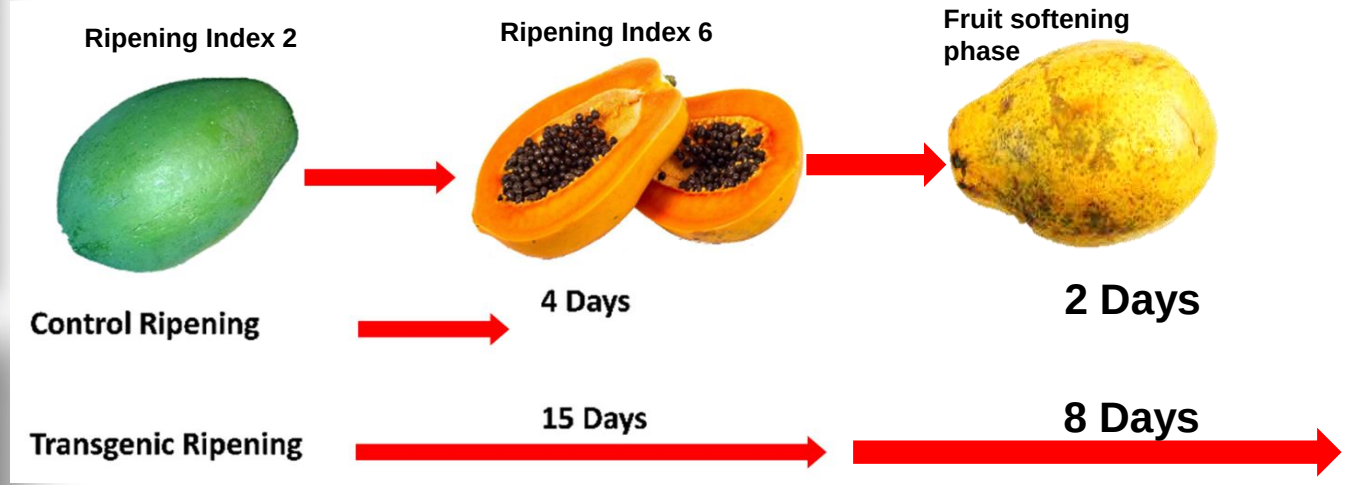
- GM Papaya:

✓ **Extended shelf life**
✓ **Disease resistance**

2. Local GMO related innovation

Picture from MARDI

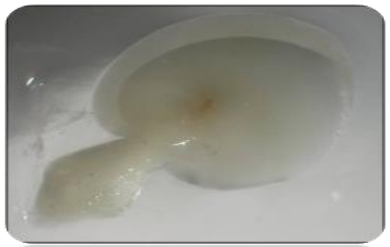
Confined Field Trial of Antisense Transgenic Papaya

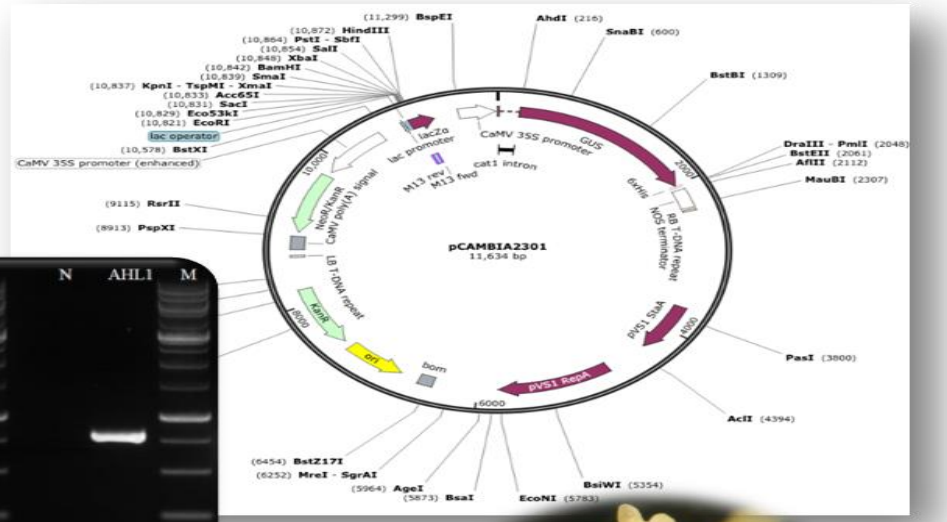


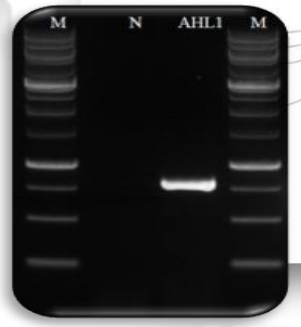
The ethylene production which causes early ripening is greatly reduced.

2. Local GMO related innovation

Development of Eksotika Papaya Resistant to Papaya Dieback Disease







- ✓ Genes used in papaya transformation:
  - i) Anti-pathogenic genes
  - ii) Plant vascular defense related gene
- ✓ Several potential resistance lines have been successfully recovered.

Putative Transgenic Plantlets

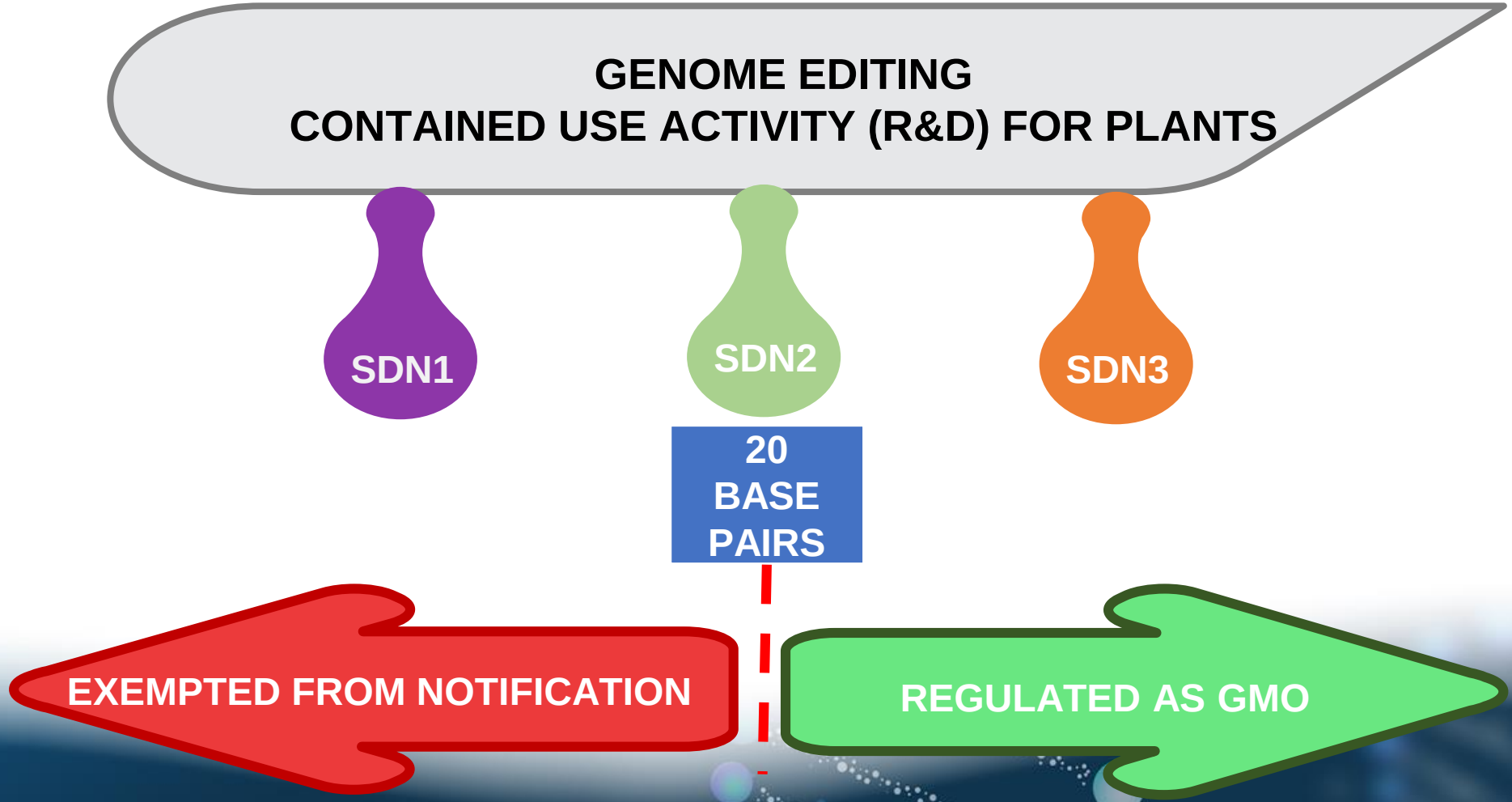
Picture from MARDI

2. Local GMO related innovation

- Way forward in innovation : New Plant Breeding Techniques, e.g. genome editing.
- Genome editing is a game changer for crop improvement.
- GM crops have been largely targeted for resistance against herbicides/pesticides or insects.
- Time to turn research focus towards GM crops tolerant to climate change, high nutrient content and increased crop yield in order to withstand the effect of global warming and meet the raising demand for food security.

2. Local GMO related innovation

- Regulatory status of Genome editing in Malaysia:

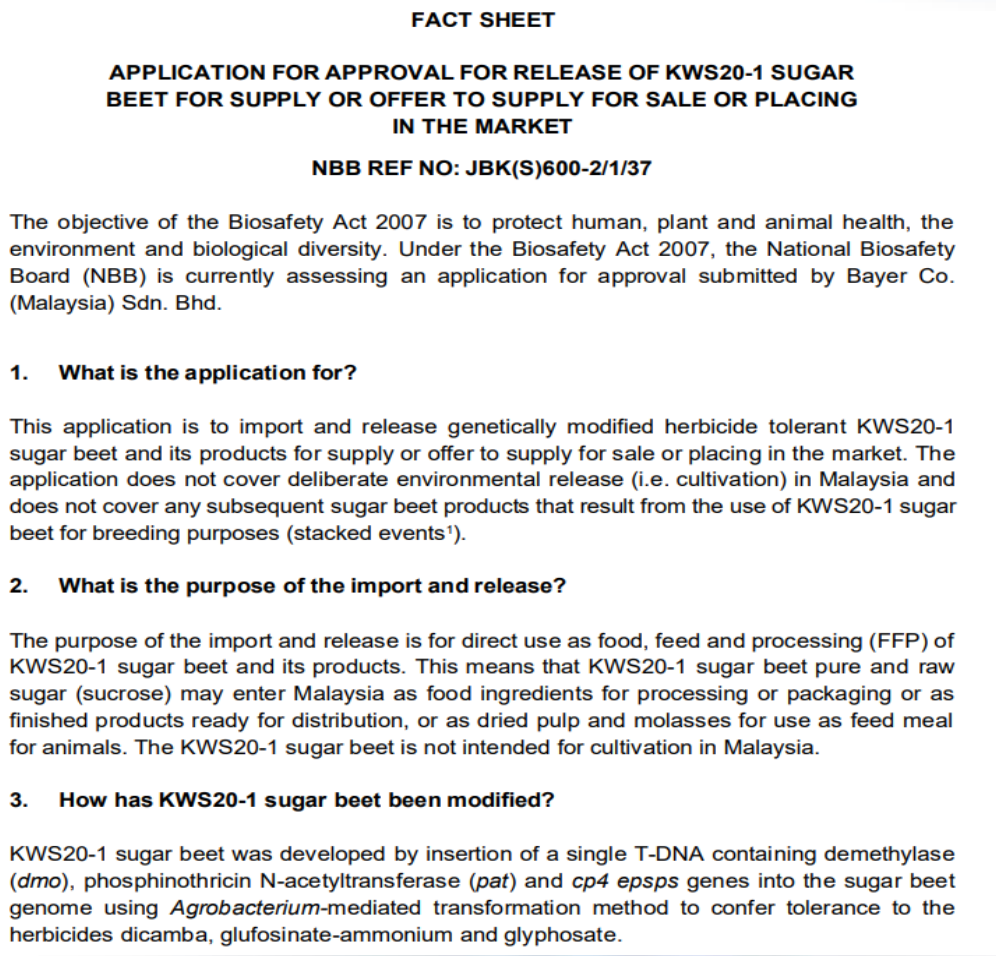


3. Public engagement/ public awareness

- What is the level of public awareness about GMOs in your country?
- Share your country experience in conducting public engagement/consultation related to GMOs (it may be consultation on an application or policy etc.)
- What are the public awareness activities related to GMOs in your country?
- Do you have any Communications, Education and Public Awareness materials that you can share? Please mention details of the material and who is the target group

Public Consultation

- Independent process
- 4 national newspapers (Malay, English, Mandarin & Tamil)
- 2 announcements in each newspaper
- Cost borne by applicant
- The applicant will submit the draft fact sheet (in Malay and English) about the application and announcement to be approved by Dept. of Biosafety
- Guidelines and templates will be provided by Dept. of Biosafety)



FACT SHEET

APPLICATION FOR APPROVAL FOR RELEASE OF KWS20-1 SUGAR BEET FOR SUPPLY OR OFFER TO SUPPLY FOR SALE OR PLACING IN THE MARKET

NBB REF NO: JBK(S)600-2/1/37

The objective of the Biosafety Act 2007 is to protect human, plant and animal health, the environment and biological diversity. Under the Biosafety Act 2007, the National Biosafety Board (NBB) is currently assessing an application for approval submitted by Bayer Co. (Malaysia) Sdn. Bhd.

1. What is the application for?

This application is to import and release genetically modified herbicide tolerant KWS20-1 sugar beet and its products for supply or offer to supply for sale or placing in the market. The application does not cover deliberate environmental release (i.e. cultivation) in Malaysia and does not cover any subsequent sugar beet products that result from the use of KWS20-1 sugar beet for breeding purposes (stacked events[1]).

2. What is the purpose of the import and release?

The purpose of the import and release is for direct use as food, feed and processing (FFP) of KWS20-1 sugar beet and its products. This means that KWS20-1 sugar beet pure and raw sugar (sucrose) may enter Malaysia as food ingredients for processing or packaging or as finished products ready for distribution, or as dried pulp and molasses for use as feed meal for animals. The KWS20-1 sugar beet is not intended for cultivation in Malaysia.

3. How has KWS20-1 sugar beet been modified?

KWS20-1 sugar beet was developed by insertion of a single T-DNA containing demethylase (*dmo*), phosphinothricin N-acetyltransferase (*pat*) and *cp4 epsps* genes into the sugar beet genome using *Agrobacterium*-mediated transformation method to confer tolerance to the herbicides dicamba, glufosinate-ammonium and glyphosate.

Public Consultation

Besides newspaper notices, the invitation for public consultation of an application is also communicated via the Department's website and social media platforms such as X, Facebook and Instagram

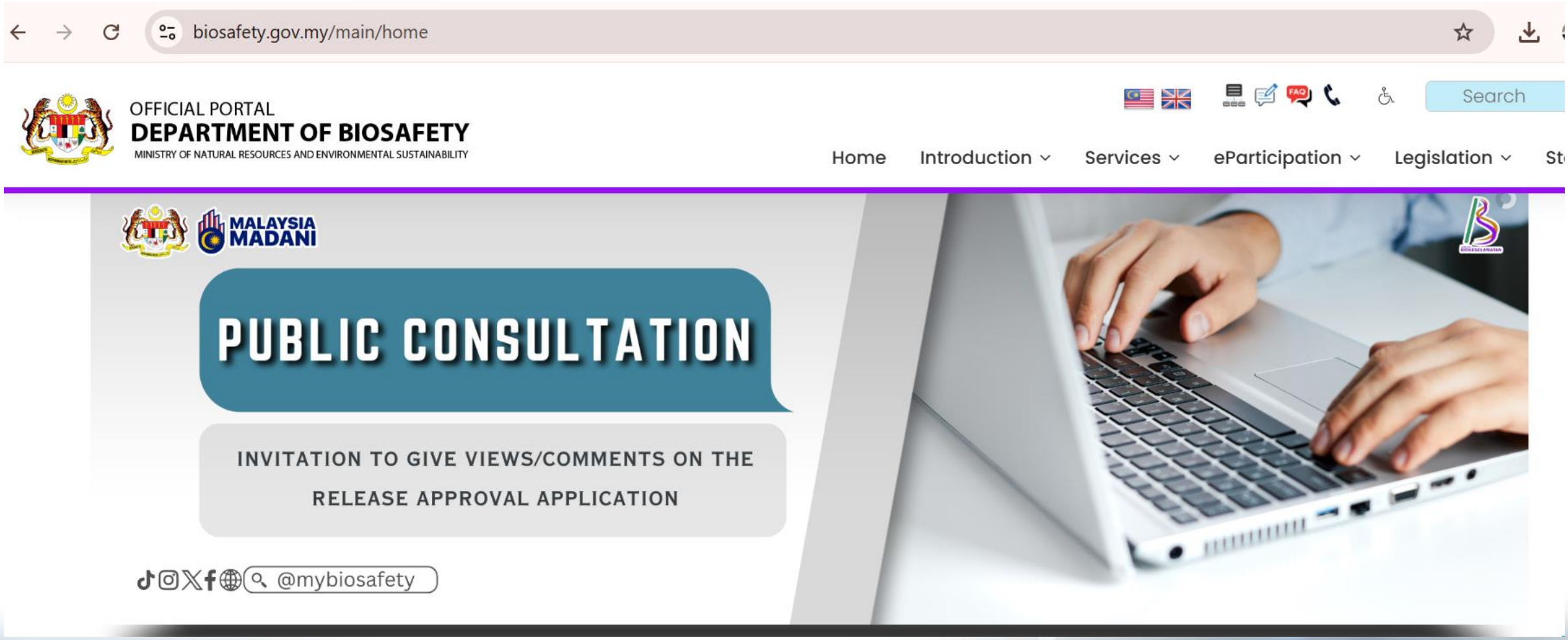
This is to inform the public that the National Biosafety Board (NBB) is currently assessing an application for approval submitted by **Bayer Co. (Malaysia) Sdn. Bhd. (7563M)** to release genetically modified **KWS20-1 sugar beet (*Beta vulgaris* L. ssp. *vulgaris* var. *altissima*)** for the purpose of supply or offer to supply for sale/placing in the market with the Reference Number of NBB: **JBK(S) 600-2/1/37**.

NBB welcomes written submissions of opinions/comments from the public regarding the application. More information on the application can be obtained from www.biosafety.gov.my under **eParticipation>Public Consultation.** Please quote the NBB Reference number for all correspondence.

Submissions must be addressed to:
The Director General, Department of Biosafety, Level 4, Block F11, Complex F, Lebuh Perdana Timur, Precinct 1, Federal Government Administrative Centre, 62000 Putrajaya, MALAYSIA.
E-mail: dob@biosafety.gov.my / Fax: 03-80917371

The closing date for submissions is **30 July 2025.**

Public Consultation



Public Consultation

Information regarding the activities proposed by the applicant will be included in the Fact Sheet (in Malay and English) as a public announcement. Information provided includes:

a. Purpose and description of activities in the application
b. Description of how living organisms are modified
c. Characteristics of modified living organisms
d. Risk assessment to human health
e. Assessment of risks to the environment and biodiversity
f. Description of the emergency response plan

Public Consultation

Applicant to inform JBK on both dates of publication and closing date (30 days)

JBK will upload Fact Sheet and announcement on JBK website (first day of publication)

Applicant to provide scanned copy of public announcement as proof from all newspapers

JBK will consolidate inputs for a period of 30 days

1. Technical/scientific input will be given to GMAC
2. Requested clarifications answered
3. Other non technical inputs compiled

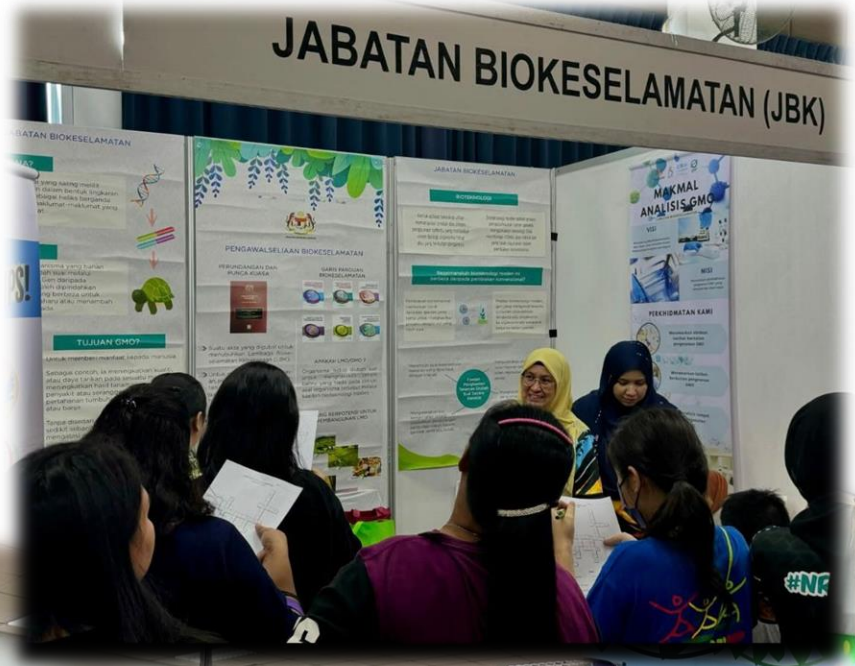
Complete report of inputs will be given to NBB during assessment of the application

3. Public engagement/ public awareness

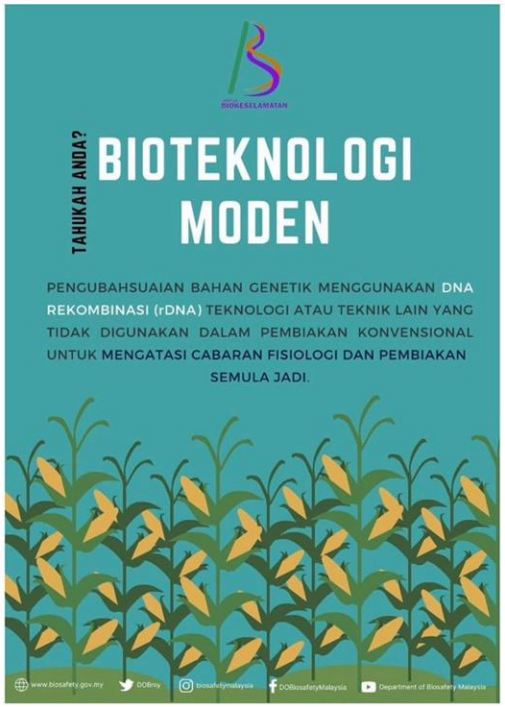
- Public awareness is generally low but some initial work has been done through the GEF project and Department of Biosafety as well as Ministry's activities to increase public awareness and knowledge on GMO through educational programs and social media interaction.
- Awareness level is reasonably good among regulatory bodies and research institutions group
- Awareness level has to be intensified in NGOs, industry players, media, educators and consumers group

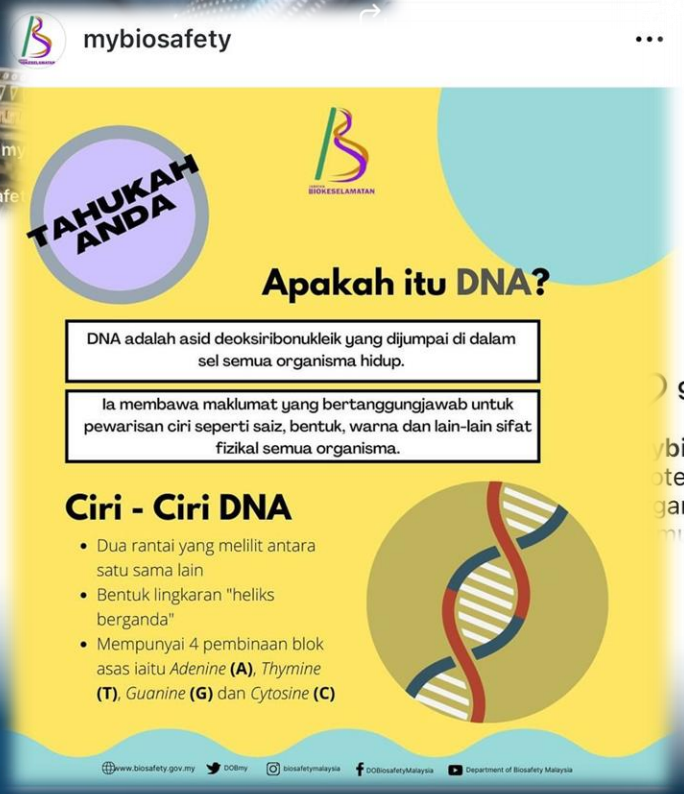
Publications

Awareness activities



Social Media Posts





THANK YOU