Capacity-Building to Promote Integrated Implementation of the CPB and CBD at the National Level

Desk Study Report

October 2016

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LIST OF ABBREVIATIONS

AF	Animal Feed
AFA	Animal Feed Additives
AIA	Advanced Informed Agreements
APEC	Asia-Pacific Economic Cooperation
ASEAN	Association of Southeast Asian Nations
ASM	Academy of Sciences Malaysia
BCH	Biosafety Clearing House
BERNAS	Padiberas Nasional Berhad
BiotechCorp	Malaysia Biotechnology Corporation
BRAC	Biosafety Regulations Advisory Committee
BSO	Biosafety Officer
BSL	Biosafety Level
BTP	Biotechnology Transformation Programme
CBD	Convention on Biological Diversity
CEBLAW	Centre of Excellence for Biodiversity Law
CFT	Confined Field Trials
CAN	Competent National Authorities
COP	Conference of Parties
COP-MOP 4	Fourth meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety
CPB	Cartagena Protocol on Biosafety
DG	Director General
DNA	Deoxyribonucleic acid
DOA	Department of Agriculture
DOF	Department of Fisheries
DVS	Department of Veterinary Services
EEP	Entry Points Projects
EIA	Environmental Impact Assesment
ERA	Environmental Risk Assessment
FAO	Food and Agriculture Organisation of the United Nations
FFP	Food, feed and processing
FOCC	Friends of the Co-Chair
FRIM	Forest Research Institute Malaysia
GEF	Global Environment Facility
GM	Genetically Modified
GMAC	Genetic Modification Advisory Committee
GMM	Genetically Modified Mircroorganisms
GMO	Genetically Modified Organism
IBC	Institutional Biosafety Committee
IBCH	International Biosafety Clearing House
ICT	Information and Communications Technology
ILSI	International Life Sciences Institute

IMR	Institute of Medical Research
IPTS	Private Higher Education Institute
ISBGMO13	Thirteenth International Symposium on the Biosafety of Genetically Modified Organism
LLP	Low Level Presence
LM	Living Modified
LMO	Living Modified Organism
MAQIS	Malaysian Quarantine and Inspection Services
MARDI	Malaysian Agricultural Research and Development Institute
MBCH	Malaysian Biosafety Clearing House
MDTCC	Ministry of Domestic Trade Cooperatives and Consumerism
MEXCOE	Meeting of State Environment Ministers and Executive Committee Members responsible for the environment
MIDP	Malaysian Institute for Debate and Public Speaking
MITI	Ministry of International Trade and Industry
MNRE	Ministry of Natural Resources and Environment
MOA	Ministry of Agriculture and Agro-Based Industry
MOE	Ministry of Education
MOH	Ministry of Health
MOSTE	Ministry of Science, Technology and Environment
MOSTI	Ministry of Science, Technology and Innovation
MPIC	Ministry of Plantation Industries and Commodities
MPOB	Malaysia Palm Oil Board
MU-BRIC	Missouri University-Biotech Regulation Immersion Course
NAP	National Agro-Food Policy
NBB	National Biosafety Board
NCP	National Commodities Policy
NFA	National Forestry Act
NFP	National Forestry Policy
NGO	Non-Government Organisations
NIBM	National Institutes of Biotechnology Malaysia
NKL SP	Nagoya-Kuala Lumpur Supplementary Protocol
NPBD	National Policy on Biological Diversity
NPBT	New Plant Breeding Techniques
NPCC	National Policy on Climate Change
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator
PNPVA	Protection of New Plant Varieties Act
PPP	Policies, Plans and Programmes
PSD	Pharmaceutical Services Division
PRF	Permanent Forest Reserve
PVP	Plant Variety Protection
Q+A	Question and Answer
RM	Ringgit Malaysia
R&D	Research and Development
SaBC	Sabah Biodiversity Centre

SBC	Sarawak Biodiversity Centre
SOP	Standard Operating Procedures
STA	Strategic Trade Act
TPPA	Trans-Pacific Partnership Agreement
TWN	Third World Network
UiTM	Universiti Teknologi MARA
UKM	Universiti Kebangasaan Malaysia
UM	University of Malaya
UMS	Universiti Malaysia Sabah
UNDP	United Nations Development Programme
UPM	Universiti Putra Malaysia
USDA	United States Department of Agriculture
WWF	World Wide Fund for Nature

01 INTRODUCTION

PART ONE

Introduction

The Cartagena Protocol on Biosafety (CPB) was adopted by Parties under the United Nations Convention on Biological Diversity (CBD) in January 2000. The Protocol aimed to address the need to develop appropriate procedures for the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. This international agreement entered into force in September 2003 and was ratified by Malaysia in the same year.

As part of its obligations, Malaysia established a taskforce, led by the Ministry of Science, Technology and the Environment (MOSTE), to develop the country's Biosafety Act, which was eventually tabled and passed by the Parliament in July 2007. This enabled the establishment of the National Biosafety Board (NBB), Genetic Modification Advisory Committee (GMAC) and Department of Biosafety which were assigned specific tasks dealing with biosafety issues in Malaysia. As a result, numerous other developments have occurred and biosafety has progressively been incorporated into biodiversity-related initiatives.

This report on 'Capacity-Building to Promote Integrated Implementation of the CPB and CBD at the National Level in Malaysia' was produced to document Malaysia's progress in fulfilling its obligations under CPB and as a precursor towards the mainstreaming of biosafety at the national level. The project was funded under CBD as part of a larger pilot study of ten countries where the integrated implementation of biosafety through sectoral and cross-sectoral policies, plans and programmes was recognised as a priority.

I. THE CONVENTION ON BIOLOGICAL DIVERSITY

The United Nations Conference on Environment and Development, held in Rio de Janeiro in 1992, represented an important milestone where a comprehensive strategy for sustainable development was agreed upon. One of the key agreements adopted at the Conference (also known as the Earth Summit), was the Convention on Biological Diversity (CBD) which recognised that biological resources were important for economic and social development for both present and future generations. However, the impact of non-sustainable development which had resulted in increasing species extinction rates and the degradation of ecological systems needed to be addressed. CBD was therefore framed upon three main goals, (1) the conservation of biological diversity, (2) the sustainable use of its components, and (3) the fair and equitable sharing of the benefits from the use of genetic resources. In 1994, Malaysia ratified CBD.

The utilisation of genetic resources, through biotechnology, was recognised under CBD for its potential contribution towards modern society in the sectors of healthcare, agriculture, industry and environmental protection. However, while its potential benefits had been demonstrated, it was understood that LMOs itself could pose a significant risk to biological diversity. These concerns, on the management, regulation and controlled use and release of LMOs, were directly addressed under the following articles of CBD:

a. Article 8(g): Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

b. Article 19.3: The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

c. Article 19.4: Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the [living modified] organisms… provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

II. THE CARTAGENA PROTOCOL ON BIOSAFETY

In November 1995, CBD's Conference of Parties agreed to develop protocols on biosafety to address the safe transfer, handling, and use of any LMOs. At this stage, the definition of LMOs was limited to those resulting from modern biotechnology. Under the Cartagena Protocol on Biosafety (CPB) a specific definition for 'modern biotechnology' was established and defined as the application of:

a. In-vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of the nucleic acid into cells or organelles; or

b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

After a series of negotiations among the Parties, CPB was adopted in January 2000 and entered into force on 11 September 2003. The Protocol represents a framework for the establishment of rights and obligations of its Parties with regards to the transboundary movement, handling and use of LMOs. From an operational perspective, the Protocol obligates each Party to develop an Advanced Informed Agreements (AIA) procedure where exporters of LMOs are required to notify the country (Party) of import in advance and submit relevant information regarding the LMO. The country of import will then have the opportunity to examine information related to the LMO, and subsequently decide to allow or reject its import, or attach conditions based on a risk assessment.

III. FORMAT OF THE REPORT

This report is divided into five main sections. In addition to this introductory section, the report contains the following sections:

Section 2: **National Framework for Implementing the Cartagena Protocol –** This section outlines the current implementation framework for biosafety in Malaysia which include the development of the Biosafety Act and Regulations.

Section 3: **Progress and Achievements –** This section document Malaysia's progress in implementing CPB i.e. through mainstreaming biosafety into programmes, activities and other initiatives.

Section 4: **Lessons Learnt and Challenges –** This section describes lessons that have been learnt in the process of mainstreaming biosafety in Malaysia. It leads to an assessment of present and future challenges.

Section 5: **Recommendations for the Integrated Implementation of Biosafety –** As a conclusion to the report, this final section documents the recommendations to address challenges in mainstreaming biosafety.

02 NATIONAL FRAMEWORK FOR IMPLEMENTING THE CARTAGENA PROTOCOL

PART TWO

National Framework for Implementing the Cartagena Protocol

Malaysia ratified the Cartagena Protocol on Biosafety (CPB) on 3 September 2003, which led to the appointment of a dedicated taskforce headed by the Ministry of Science, Technology and the Environment (MOSTE). The taskforce consisted of representatives from all relevant Ministries and agencies, who were responsible to develop provisions for Malaysia's first biosafety law. In 2004, MOSTE underwent reorganisation resulting in the creation of two new ministries, the Ministry of Science, Technology and Innovation (MOSTI) and Ministry of Natural Resources and the Environment (MNRE). MNRE then assumed the role of the lead agency for biosafety and held a series of consultations to establish Malaysia's national framework for implementing CPB. This resulted in the drafting of the Biosafety Bill which was eventually tabled and passed by Parliament on 11 July 2007 (**Table 2-1**).

Table 2-1
Chronology of Key Events on Developing Malaysia's Biosafety Framework

Date	Event
1996	Informal GMAC under MOSTE was formed.
22 Nov. 2006	First reading of the Biosafety Bill at Dewan Rakyat (House of Representatives)
Dec. 2006 to June 2007	Consultation and dialogues on the Draft Bill with relevant stakeholders, including industry players and NGOs.
25-27 June 2007	Second and Third reading of the Biosafety Bill at Dewan Rakyat
11 July 2007	Biosafety Bill tabled at Dewan Negara (Senate). Biosafety Act 2007 passed by Parliament.
29 Aug. 2007	Royal Assent for the Biosafety Act 2007.
30 Aug. 2007	Publication of the Biosafety Act 2007 in the Gazette
Jan. 2008	Biosafety Core Team and Biosafety Regulations Advisory Committee (BRAC) formed
22 Feb. 2008	Biosafety Core Team meeting with Ministry of Finance, Public Service Department and NRE's Human Resource Management on the formation of a Department of Biosafety
Feb. 2008 to Oct. 2010	Consultation with various stakeholders on the drafting of Biosafety Regulations
1 Dec. 2009	Biosafety Act 2007 comes into force
1 Nov. 2010	Biosafety (Approval and Notification) Regulations 2010 came into force

Source: Department of Biosafety (2012)

I. REGULATORY FRAMEWORK

A. Biosafety Act 2007

Malaysia's Biosafety Act was gazetted in August 2007 and is the country's main instrument for implementing obligations under CPB. The Act was drafted in cognisance of the National Biological Diversity Policy, 1998 and National Biotechnology Policy, 2005. The scope of the Act is limited to LMOs, which is defined as 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology' which is consistent with what is defined under CPB.

The Act cuts across all relevant sectors as provided by Section 2 of the Biosafety Act 2007 which states that the Act must be read together with other laws:

(1) This Act shall be read together with any other written law relating to import and export, human, plant and animal health, the environment and biological diversity, and the provisions of this Act shall be in addition to, and not in derogation of, the provisions of such other written laws.

(2) In the event of any inconsistencies between the provisions of this Act and any of the other written laws referred to in subsection (1) the provisions of this Act shall prevail.

The Act provides for the establishment of the National Biosafety Board (NBB) whose core function is to decide on applications and matters related to the approval for release and import of LMOs, and the notification for export, contained use and import for contained use of LMOs. The Act also provides for the establishment of the Genetic Modification Advisory Committee (GMAC) whose function is to provide scientific, technical and other relevant advice to the Board, and the appointment of a Director General of Biosafety (which resulted in the establishment of the Department of Biosafety in 2010).

The Act also includes provisions for the requirement for risk assessment and risk management reports, and emergency response plans. This directly address the need to assess the risk and adverse effect of LMOs on humans, plant and animal health, the environment and biological diversity, and subsequently measures to prevent, reduce or control these risks. Finally, the Act provides for the power of enforcement to allow officers of the Board, and other appointed officers to enforce provisions under the Act.

B. Biosafety Regulations 2010

The Biosafety (Approval and Notification) Regulation was gazetted in November 2010. It provides the formal framework for the approval and notification of the release, contained use, importation for release, importation for contained use, and exportation of LMOs. The Regulation states the application process for the approval for any release activity and importation of LMOs; the regulation describes the terms and conditions when approval is granted, i.e. through the issuance of a certification which specifies, among other things, the purpose and scope of activity, level of containment and risk management, and relevant procedures and documentation. It also states the requirement for notification for activities that involve the (a) exportation of living modified organisms, (b) contained use involving living modified organisms, (c) importation of living modified organisms for purposes of undertaking a contained use activity. One of the key elements of the Regulation is the requirement for Institutional Biosafety Committee (IBCs) to be established within institutes that undertake modern biotechnology R&D to provide guidance for the safe use of biotechnology.

II. ORGANISATIONAL FRAMEWORK

A. National Biosafety Board

The National Biosafety Board (NBB) was established in 2010 and is tasked to administer the biosafety regulatory scheme. The NBB is chaired by the Secretary General of the Ministry of Natural Resources and Environment (MNRE) with representatives from the following ministries:

a. Ministry of Agriculture and Agro-based Industry
b. Ministry of Health
c. Ministry of Plantation Industries and Commodities
d. Ministry of Domestic Trade Cooperatives and Consumerism
e. Ministry of International Trade and Industry, and
f. Ministry of Science, Technology and Innovation.

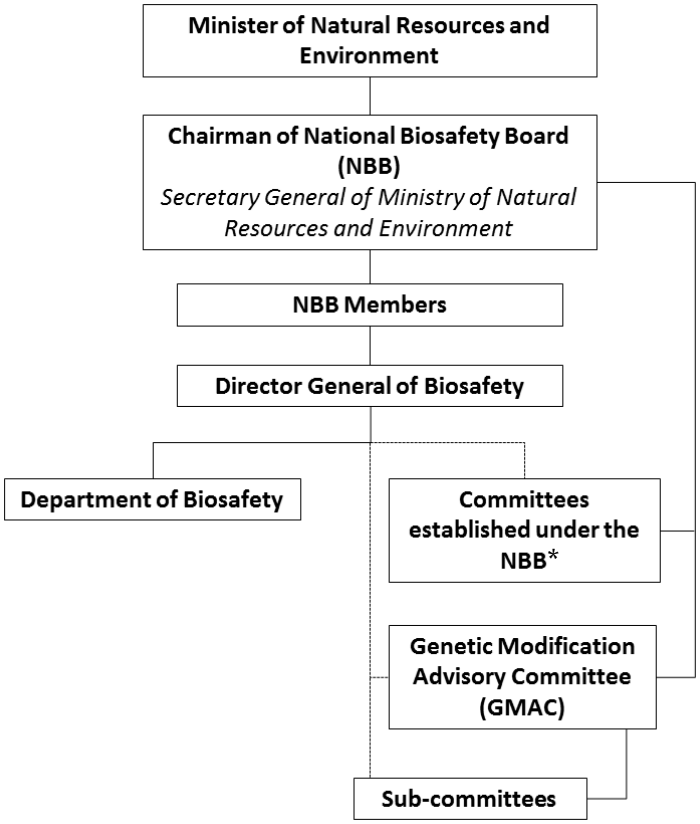
In addition, four other persons with knowledge of and/or experience in any disciplines or matters relevant to this Act may also be appointed. All members of the Board are appointed by the Minister of Natural Resources and Environment. The Director General of the Department of Biosafety acts as the Secretary of the NBB.

The main functions of the NBB are as follows:

1. Assess any risks posed by LMOs and products of LMOs;

2. Decide on all applications and matters relating to the release and import of LMOs as well as notifications in relation to export, contained use and import for contained use of LMOs;
3. Monitor activities related to LMOs and products of such organisms, including a review of decisions made;
4. Enforce the Biosafety law;
5. Promote research, development, educational and training activities relating to biosafety;
6. Establish mechanisms to facilitate the collection, storage and dissemination of data relating to biosafety; and
7. Perform, or provide for the performance of, obligations arising from agreements, conventions or treaties relating to biosafety to which Malaysia is a party, if directed by the Minister.

The Board may establish committees to assist them in the performance of their functions. At the time of this report, no such committees have been established yet. The organisation hierarchy of biosafety in Malaysia is shown in **Figure 2-1**. The current members of the NBB are listed in **Appendix A-1**.



* Committees have yet to be established

Figure 2-1 Organisation of Biosafety in Malaysia

B. Genetic Modification Advisory Committee

The Genetic Modification Advisory Committee (GMAC) was established in 2010 to provide scientific, technical and other relevant advice to the Minister and the NBB pertaining to the application for approval and notification. The Act requires members of GMAC to be experts from various science-based disciplines as well as other relevant disciplines such as public health and bioethics. When an application for approval and notification is received, GMAC will meet to discuss and carry out technical assessments for the application. A report of findings and recommendation by GMAC will be submitted to the NBB for approval and notification. GMAC may establish sub-committees to assist them in the performance of their functions.

The current members of GMAC are listed in **Appendix A-2**.

C. Department of Biosafety

The Department of Biosafety was established in 2010 as a Federal department under MNRE, through the upgrading of the Biosafety Core Team that was formed in 2008. The Department is the country's main authority for all activities related to biosafety and has the following roles:

1. Implementation and enforcement of the Biosafety Act;
2. Monitoring of all activities pertaining to LMOs and products of such organism;
3. Providing a platform for consultation with various parties in order to formulate and update policies, laws and guidelines related to biosafety;
4. Coordinate and integrate the efforts taken by Federal Government and State agencies, and Non-Government Organisations (NGOs) and the Modern Biotechnology Industries related to biosafety issues;
5. Build strategic partnerships with relevant agencies within and outside the country in the field of biosafety;
6. Establish mechanisms to facilitate the collection, storage and dissemination of data related to biosafety;
7. Help the Government to formulate the country's stand on the issues of biosafety at international fora; and
8. Increasing public awareness on biosafety.

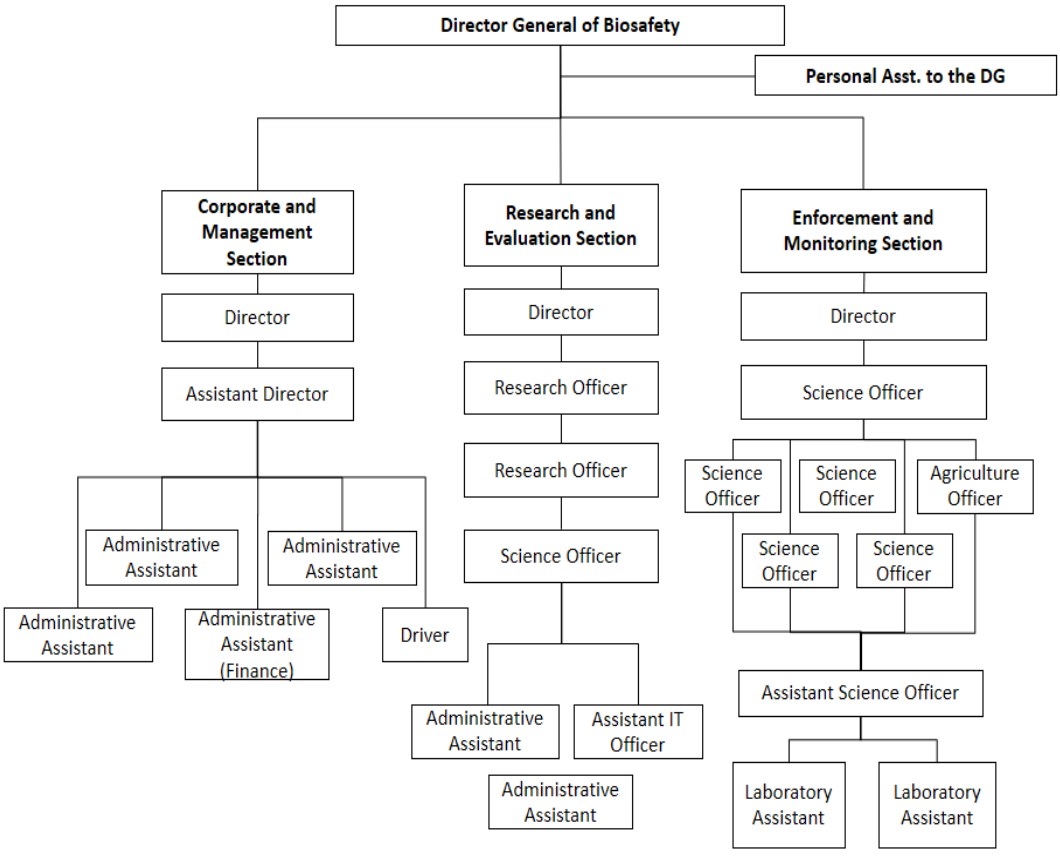
The Department is the Secretariat and the operational arm of the NBB, as well as the secretariat of GMAC. It is manned by 25 staff members (**Figure 2-2**), organised under three sections within the Department:

a. Research and Evaluation Section – As the Secretariat for GMAC, this section is responsible for preparing dossiers for GMAC's assessments, soliciting input from relevant government agencies, and consolidating the GMAC's recommendations. It is also tasked with considering and granting of claims for confidentiality of business information, and determining terms and

conditions to impose on applicants. In addition to that, this section is also responsible for processing applications (for approval, notification, and IBC registration) and issuing of certificates of approval. It is also tasked with distributing dossiers and information to relevant parties for review and comments, and informing applicants on decisions of the NBB.

b. Corporate and Management Section – This section is the Secretariat for NBB, and organises NBB meetings. It is responsible for consolidating public comments from the approval process, preparing and distributing NBB minutes of meeting, and preparing NBB decision documents for dissemination.

c. Enforcement and Monitoring Section – This section is responsible for all enforcement and monitoring activities. This includes the sampling and analysis of products suspected of being or containing LMOs, the conduct of searches for suspected non-compliance, and enforcement of NBB decisions on risky approvals and notifications.



Source: Department of Biosafety (2016)

Figure 2-2 Organisation Chart of the Department of Biosafety

D. National Focal Point

As a Party to the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety (CPB), Malaysia has designated three individuals as National Focal Points who represent the government in its engagements with the Secretariat of CBD:

CPB and CBD
Undersecretary
Biodiversity and Forestry Management Division
Ministry of Natural Resources and Environment
Name of Officer: Dr. Megat Sany Megat Ahmad Supian

Emergency Measures (Article 17)
Director General
Department of Biosafety
Ministry of Natural Resources and Environment
Name of Officer: Mr. Ramatha Letchumanan

Biosafety Clearing-House
Research Officer
Department of Biosafety
Ministry of Natural Resources and Environment
Name of Officer: Dr. Mohana Anita Anthonysamy

E. Competent National Authority

As designated under Article 19 of the Cartagena Protocol on Biosafety, Malaysia has appointed five Competent National Authorities (CNA) responsible for performing the administrative functions under the Protocol and who are authorised to act on its behalf with respect to those functions (**Table 2-2**).

Table 2-2
Competent National Authorities and Functions

Competent National Authority	Regulatory Functions	Types of LMOs Regulated
Ministry of Natural Resources and Environment Malaysia	Responsible for all administrative functions pursuant to the Cartagena Protocol on Biosafety.	Nil
Department of Biosafety	Regulating agency for all matters relating to biosafety. Responsible for all administrative functions pursuant to the Cartagena Protocol on Biosafety.	All types of organisms
Department of Veterinary Services	Responsible for the release of animal pharmaceuticals and animal feed containing	Animals

	LMOs and/or product of LMOs, and regulating the import and export of animals and their products.	
Food Safety and Quality Division, Ministry of Health	Responsible for food safety and food labelling, including labelling of genetically modified food and products containing the products of LMOs	Genetically modified food
National Pharmaceutical Control Bureau	Responsible for the release of pharmaceutical products containing LMOs and/or product of LMOs for human consumption.	Pharmaceutical products

Source: Department of Biosafety (2016)

F. Institutional Biosafety Committee

Institutional Biosafety Committees (IBCs) are committees established within an organisation undertaking modern biotechnology research and development. The establishment of these committees is provided by Regulation 5 of the Biosafety (Approval and Notification) Regulations 2010. The functions of IBCs are described in the Guidelines for Institutional Biosafety Committees which was developed by the Department of Biosafety in 2010. In general, IBCs have the following responsibilities:

1. Providing guidance for safe use of modern technology;
2. Monitoring modern biotechnology activities carried out by its respective organisation;
3. Establishing and monitoring the implementation of policies and procedures of handling LMOs; and
4. Determining the classes of Biosafety Levels for contained use activities of modern biotechnology carried out by its respective organisation.

III. REGULATORY FRAMEWORK FOR LMO

A. Approval Process

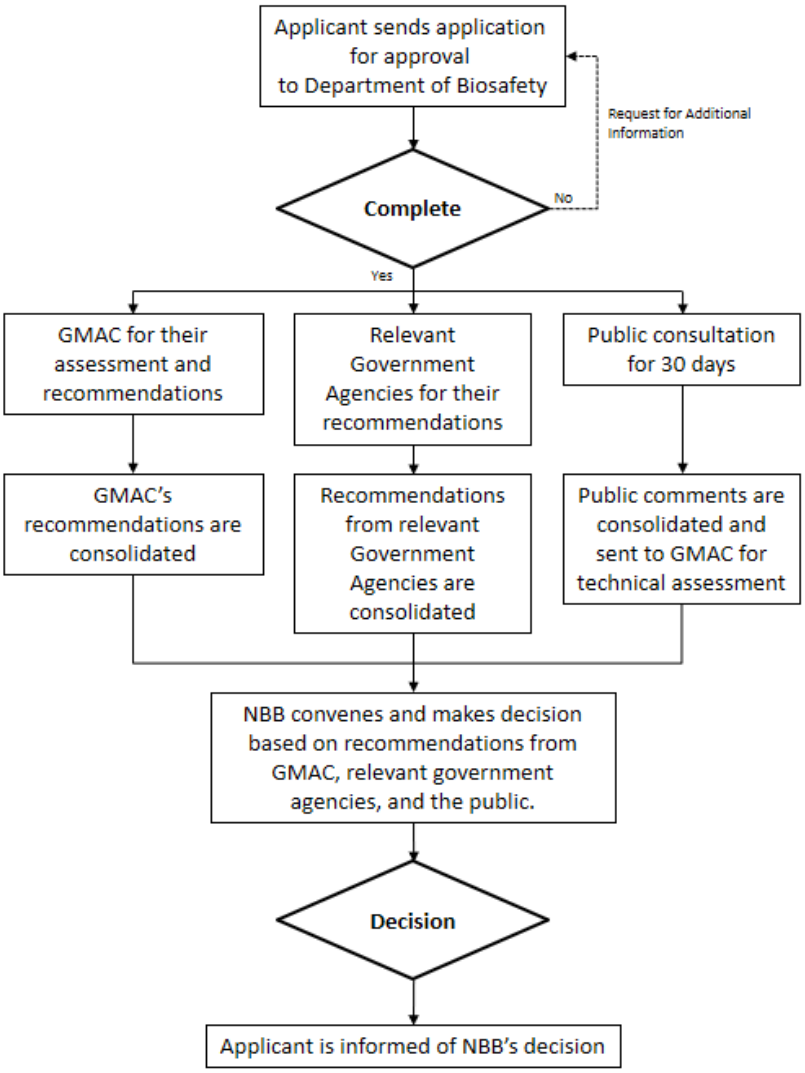
The Application for the release and import of LMOs and their products is mandatory under Part III of the Biosafety Act 2007 and Regulation 6 of the Biosafety (Approval and Notification) Regulations 2010. An application for approval must be completed and submitted to the Director-General together with the prescribed fees and be accompanied with (a) a risk assessment and risk management report, (b) emergency responses plan, and (c) other information as may be specified by NBB.

Upon receiving the application, the Director-General shall refer to GMAC for its recommendations; refer to relevant government agencies for specific matters; and invite the public to submit feedback. All comments received will be consolidated and any technical matters will be referred to GMAC. The final recommendations will then be forwarded to NBB for review, after which NBB will make a decision to either approve the application (by issuing a certificate of approval) or refuse the application. The approval process is illustrated in **Figure 2-3**.

B. Notification Process

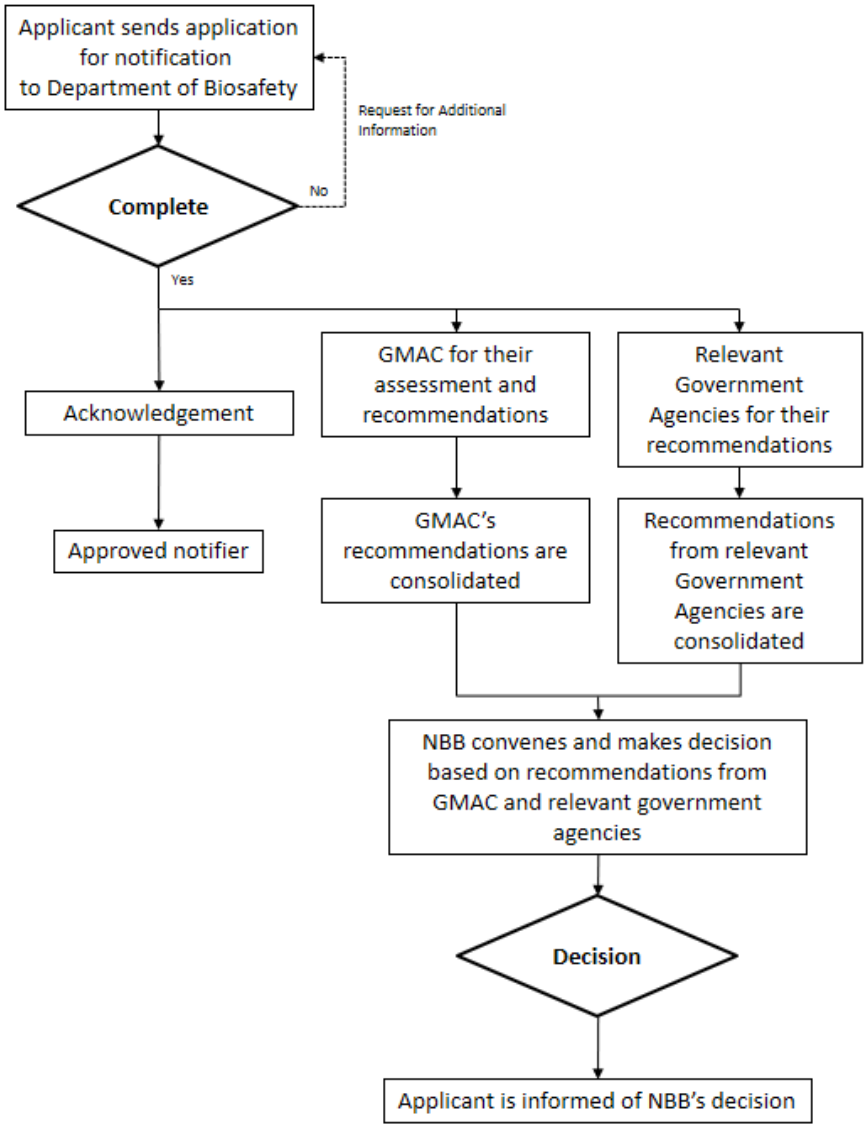
The Notification for contained use, import of LMOs for contained use, and export of LMOs is mandatory under Part IV of the Biosafety Act 2007. The Notification Process is similar to that of the Approval, except Notifications are not subject to public announcement. Applications for Notification must be completed and submitted to the Director-General and accompanied with (a) Emergency Responses Plan, and (b) specific measures for contained use activity. Upon receiving the submission, the Director-General shall issue an Acknowledgement of receipt and the applicant may undertake activities relating to the Notification.

The Director-General will then refer the notification to GMAC and relevant government agencies for comments. GMAC will review the application and forward its recommendations to NBB. Based on these recommendations, and comments from the relevant government agencies, NBB will make a decision to issue no order; issue a cessation order; impose terms and conditions, or order the applicants to make rectifications to the application. The Notification process is illustrated in **Figure 2-4**.



Source: Department of Biosafety (2010)

Figure 2-3 Approval Process Flow



Source: Department of Biosafety (2010)

Figure 2-4 Notification Process Flow

IV. SUPPORTING NATIONAL POLICIES

A. National Policy on Biological Diversity, 1998

Malaysia's National Policy on Biodiversity (NPBD 1998) was formulated in 1998 as a strategic document to address national needs and requirements for the conservation of biodiversity in the country. The Policy was based on eleven principles of which the aspect of biosafety was captured in the last principle: 'In the utilisation of biological diversity, including the development of biotechnology, the principles and practice of biosafety should be adhered to'. Biosafety was subsequently addressed under the sixth objective of the Policy which 'emphasised biosafety considerations in the development and application of biotechnology'. Under Strategy XI, six action plans were proposed:

1. Formulate legislation and regulations on biosafety, in relation to activities and products arising from biotechnology, especially genetic engineering, including the importation, experimentation, storage and release of genetically modified organisms.
2. Ensure measures are taken to prevent the country from becoming a location for hazardous research activities.
3. Establish a committee on biosafety that includes representatives from the environment, health and research fields, and keep abreast of developments in this field in the international arena.
4. Adopt an Environmental Impact Assessment (EIA) procedure for biotechnology research and activities, including assessment on safety and social impacts.
5. Establish an enforcement unit on biosafety within an appropriate government department.
6. Develop training programmes in biosafety management and practice.

B. National Biotechnology Policy, 2005

The National Biotechnology Policy, developed in 2005, aimed to spur the development of biotechnology as a new engine for economic growth, leveraging upon the country's rich flora and fauna diversity. The Policy's main undertaking was the creation of a conducive environment for R&D to support the development of the biotechnology industry through nine policy thrusts:

1. Agriculture biotechnology development;
2. Healthcare biotechnology development;
3. Industrial biotechnology development;
4. R&D and technology acquisition;
5. Human capital development;
6. Financial infrastructure development;
7. Legislative and regulatory framework development (including biosafety);

8. Strategic positioning; and
9. Government commitment.

This strategic document however does not have any specific mention on modern biotechnology.

C. National Policy on Biological Diversity, 2016-2025

In February 2016, a revised National Policy on Biological Diversity (NPBD 2016) was launched to replace the 1998 policy. The new policy takes into cognisance the CBD Strategic Plan for Biodiversity, while being adapted to meet the current and future needs of Malaysia. The new policy is now a comprehensive document with targets and indicators to monitor progress and achievements over a 10-year implementation period, i.e. from 2016 to 2025. The NPBD 2016 is based on five goals, which are as follows:

a. Goal 1: Empowering and harnessing the commitment of all stakeholders to conserve biodiversity;
b. Goal 2: Significantly reducing the direct and indirect pressures on biodiversity;
c. Goal 3: Safeguarding all key ecosystems, species and genetic diversity;
d. Goal 4: Ensuring that the benefits from the utilisation of biodiversity are shared equitably; and
e. Goal 5: Improving the capacity, knowledge and skills of all stakeholders to conserve biodiversity.

The scope of biosafety was addressed under Goal 3 which stated that while the country could benefit from modern biotechnology, the products of modern biotechnology should not pose unacceptable risks. However, the aspects of capacity building in regulatory compliance, confined field tests, monitoring for environmental impact, risk assessment and management, as well as risk communication to the beneficiaries, policy makers and the public, needed to be addressed. Target 12 of the Policy subsequently states that 'a comprehensive biosafety system inclusive of a liability and redress regime is to be in place to manage potential adverse impacts of modern biotechnology on the conservation and sustainable use of biodiversity and human health'. Under this Target, three actions were proposed:

1. Action 12.1: Enhance inspection and biosafety compliance;
2. Action 12.2: Assess impacts of modern biotechnology on human health and biodiversity; and
3. Action 12.3: Develop response to biosafety emergencies.

D. Other National Policies

In addition to the above, other national policies have taken into cognisance the potential benefits of biotechnology, although not explicitly making reference to modern biotechnology or LMOs:

1. *National Agrofood Policy, 2011-2020* – The Policy's main objective is to raise the efficiency of the agrofood industry across its value chain to become more productive, competitive, and knowledge intensive. Biotechnology will be pursued to increase the productivity of ruminant livestock through improved breeding techniques; to produce high yield and value crops; and for application in the floriculture industry. Strategic Action IV highlights the need to enhance academic programmes at institutes of higher education to develop human capital in critical areas which includes biotechnology. Strategic Action V highlights the need for the transfer and commercialisation of modern technology, including biotechnology, to stimulate R&D application in the field and in the food-processing industry.

2. *National Commodities Policy, 2011-2020* – The Policy's main objective is to strengthen the role and contribution of plantation commodities through its transformation into a dynamic and competitive sector. Thrust 7 highlights the need to develop and strengthen human capital in supporting institutions in critical areas required to support the sector, which includes biotechnology (for example, in the production of value-added crops).

V. ACTS AND REGULATIONS RELEVANT TO BIOSAFETY

There are a number of National Acts and Regulations that have implications on biosafety in Malaysia, some of which made reference to biosafety even before Malaysia ratified CPB in 2003. Many regulations were however amended to include GMOs and their products, while other regulations already had existing provisions for controlling the entrance of GMOs and their products at entry points. The following table highlights the major aspects of provisions for biosafety in National acts and regulations (**Table 2-3**) while a full review can be found in **Appendix A-3**.

Table 2-3
Acts and Regulations related to Biosafety

Act or Regulation	Overview	Relevance to Biosafety
Sales of Drugs Act 1952 (Revised 1989)	Regulates the sale of drugs which includes substances, products or articles used on humans or animals for medicinal purposes throughout Malaysia.	a. The Act and related regulations requires the import and sale of human vaccines and biologics (whether derived of GMO or non-GMO products) to be registered with the Pharmaceutical Services

Act or Regulation	Overview	Relevance to Biosafety
		Division of the Ministry of Health. Those that are not registered require an Approval from the Director General of Health. b. All activities related to human and animal pharmaceutical products (whether derived of GMO or non-GMO products) are regulated under this Act. c. Pharmaceutical products are exempted from the Biosafety Act 2007. However, the production phase of any GMO pharmaceutical products is still regulated under the Biosafety Act 2007.
Poisons Act 1952	The Act regulates the importation, possession, manufacture, compounding, storage, transport, sale and use of poisons in Malaysia.	a. Any human vaccines and biologics (whether derived of GMO or non-GMO products) that are not for medical treatment or clinical trials are controlled under this Act (as per the First Schedule Poisons List) b. However, the production phase of any GMO vaccines and biologics is still regulated under the Biosafety Act 2007.
Animals Act 1953 (Revision 2006)	The Act encompasses laws for preventing the introduction and spread of animal diseases, control of animal movements into, within, and from Malaysia, the control of animal slaughter, the prevention of animal cruelty, and measures pertaining to the general welfare, conservation and improvement of animals in the country.	a. The Act, with the authority of the Department of Veterinary Services, has the power to control: (1) Import or export of animals and associated products, (2) Import or export of vaccines or biologics for animals, (3) Local production of vaccines or biologics for animals (if LMOs are involved, it is regulated by the Department of Biosafety) b. Clinical tests and sale of GM vaccines or biologics for animals are regulated by the Department of Veterinary Services under this Act.
Pesticides Act 1974	The Act controls all import, manufacture, sale, storage, research, and use of pesticides throughout Malaysia. Also regulates the presence of pesticides in food and entitles	a. The Act regulates bio-pesticides and pesticides (whether derived of GMO or non-GMO products) and/or similar products of such derivation. b. The Act also provides an avenue to

Act or Regulation	Overview	Relevance to Biosafety
	the right to an officer to analyse food, and to ensure that all pesticides are registered before being marketed into the country.	monitor and regulate pesticide traces in food, such as products from pesticide-tolerant GM crops.
Plant Quarantine Act 1976	The Act control, prevent and eradicate agricultural pests, noxious plants and plant diseases and to extend cooperation in the control of the movement of pests in the international trade. It also provides the Department of Agriculture with legislative power to carry out preventive and eradicative measures to safeguard the agriculture industry.	a. The Act regulates the importation of plants, plant products and aquatic plants, as well as microorganisms that are pathogenic to plants, humans, animals, fish and the environment. The act also controls import and export from Peninsular Malaysia to Sabah and Sarawak. b. However, any importation of GM microbes, plants, plant products and aquatic plants requires approval from the Department of Biosafety.
Food Act 1983	The Act aims to protect the public against health hazards and fraud in the preparation, sale and use of food and other relevant matters throughout the country. The Act regulates hygiene and sanitary of food premises and all appliances used for preparation, preservation, packaging, storage, conveyance, distribution and sale of food.	a. The Act regulates both non-GMO and GMO food and food products. b. Only GMO events that have been approved by the National Biosafety Board can be used for foods and food ingredients.
Control of Drugs and Cosmetics Regulation 1984	The Regulation serves to strengthen the enforcement of the Sales of Drugs Act 1952 and provides regulations on registering and licensing of products.	a. The Regulations stipulates the requirement for an approval from the Pharmaceutical Services Division for any production, importing or selling of pharmaceutical products containing LMOs. b. However, the production phase of any LMO pharmaceutical products is still regulated under the Biosafety Act 2007. c.
Fisheries Act 1985	The Act provides for the conservation, management and development of maritime	a. All import and export, as well as local production of vaccines and biologics for fish (whether derived

Act or Regulation	Overview	Relevance to Biosafety
	and estuarine fishing and fisheries in Malaysia waters, turtles and riverine fishing.	of GMO or non-GMO products) in the country requires approval under the Act. b. The Department of Biosafety is however responsible for the control of the import of GM fish, vaccines and biologics into the country.
Prevention and Control of Infectious Diseases Act 1988	The Act aims to prevent and control infectious diseases that may harm human and animals, and lists the various infectious diseases (First Schedule)	a. Approval for import and export of human tissues, pathogenic organisms and substance, and microorganisms (GM or non-GM) used in producing human vaccines or biologics into Malaysia is regulated by the Disease Control Division under the Ministry of Health. b. Application of permits to import and export human remains, human tissues and pathogenic organism are also required and are issued by the Ministry of Health. c. However, the Department of Biosafety will regulate if GM pathogenic organisms, microorganisms are involved
Protection of New Plant Varieties Act 2004	The Act provides protection of breeder's rights also known as Plant Variety Protection (PVP) to their registered plant varieties for the purposes of breeding, research and commercialisation. Also recognises and protects contributions made by farmers, local communities and indigenous people towards the creation of new plant varieties and provides intellectual property protection for plant breeders.	a. Provides for the establishment of the Plant Varieties Board, which functions to consider, approve or reject applications for registration of new plant varieties. b. Plant varieties of GM origin requires approval from the Department of Biosafety.
Plant Quarantine Regulation 2005	The Regulation stipulates the requirements for the importation of plants, plant products, growing media/rooting compost, beneficial organisms, plant	a. The importation of plants or plant products requires a permit and a phytosanitary certificate will be issued to the exporter. The phytosanitary certificates verify that the products have been

Act or Regulation	Overview	Relevance to Biosafety
	pests and carrier of plant pest into Malaysia in order to prevent the entry and spread of noxious plants and pests.	inspected, treated and are pest and disease free. b. The Regulations further provide for restriction on imports of various plants, eradication and control of dangerous pests as well as inspection, quarantine or destruction of plants. c. Import of GM plants and plant products is however regulated by the Department of Biosafety.
Feed Act 2009	The Act ensures that animal feed satisfies nutritional requirements of animals and are not contaminated, and controls the use of antibiotics, hormones and other chemicals in relation to animal feed. *Note: This Act only applies to States in Peninsular Malaysia and the Federal Territory of Labuan.*	a. Regulates the import of animal feed and animal feed additives, including those that contain GMO. b. Import of GMO feed or related products without the necessary approvals from the Department of Biosafety can be rejected. These include cereals, grains, premixes, pigments, supplements, mould inhibitors and absorbents as well as chemicals.
Food Regulations 1985 (Amended 2010)	The Regulation regulates all import, manufacture, advertisement and sale related to labelling, food additives, packaging, standards and labelling requirements for a range of food and drinks.	a. The Regulation was amended in 2010 to include a new part on the approval and sale of food obtained through modern biotechnology as well as provisions on labelling matters. b. The Regulation specifically mentions all imports or sale of any food and food ingredients obtained through modern biotechnology must be approved and clear labelling of GMO products must be shown. c. Only GMO events that have been approved by the National Biosafety Board can be used for foods and food ingredients.
Strategic Trade Act 2010	The Act controls the export, transhipment, bring in transit and brokering of strategic items, including arms and related material, and other activities that may facilitate the design, development and	The Act requires an examination of whether a GMO-related research to be carried out would fall under the import control restrictions and will require approval from the Strategic Controller of the Ministry of International Trade and

Act or Regulation	Overview	Relevance to Biosafety
	production of weapons of mass destruction and their delivery systems consistent with Malaysia's national security and international obligations.	Industry.
Malaysian Quarantine and Inspection Services Act 2011	The Act controls quarantine, inspection and enforcements on entry points, quarantine stations and premises for plants, animals, carcasses, fish, agricultural products, soil and microorganisms. Also regulates Malaysia's imported and exported food. *Note: This Act only applies to States in Peninsular Malaysia and the Federal Territory of Labuan.*	a. The Act regulates import and export permits for all materials such as organisms, bio-fertilisers, vaccines/biologics for animals, fish and fish products, animal and associated products as well as animal feed (whether GM or non-GM). b. Only GMO materials approved by the Department of Biosafety are allowed to be imported and exported from Malaysia.
Animal Welfare Act 2015	*Not implemented yet.*	a. Use of animals in laboratory tests needs approval from Ethics Committee. b. If the animal is GM, it requires approval from the Department of Biosafety.

03 PROGRESS AND ACHIEVEMENTS

PART THREE

Progress and Achievements

Malaysia's efforts in implementing its obligations under the Cartagena Protocol on Biosafety (CPB) have resulted in numerous activities across various aspects of biosafety which include policies and regulations; institutional arrangements; research and development; information management; communication, education and public awareness; capacity-building and enforcement. Overall, these efforts have contributed significantly towards the integrated implementation of CPB, although more efforts will be required in the future. This section provides an overview of activities conducted, together with its progress and achievements.

I. POLICIES AND REGULATIONS

A. Incorporation of Biosafety into the Revised National Policy on Biological Diversity

In 1998, Strategy XI of the National Policy on Biological Diversity made reference to biosafety considerations in the development and application of biotechnology. This resulted in six action plans which aimed to institutionalise biosafety together with the development of a national legislative framework. Almost all of the action plans proposed have been implemented, including actions which led to the establishment of the Department of Biosafety in 2010. In 2015, the Policy was revised to reflect Malaysia's present challenges taking into cognisance the Convention on Biological Diversity (CBD) Strategic Plan for Biodiversity, 2011-2020. In the revised policy, biosafety received greater attention with its incorporation as a policy target (i.e. Target 12) with three action plans (see Section 2, Part V, Item C) which has strengthened policy measures for the implementation of biosafety in Malaysia. However, biosafety has yet to be addressed in other relevant national policies that have been revised since Malaysia became a signatory to CPB.

B. Incorporation of Biosafety in Regulations and Guidelines

The Food Regulations 1985, under the Food Act 1983, was amended in 2010 to include:

a. Two new definitions: 'GMO' (Genetically modified Organisms) and 'modern biotechnology';
b. A new part on the approval and sale of food obtained through modern biotechnology; and
c. A new provision on labelling matters.

As a result of the new amendments, food and food ingredients obtained via modern biotechnology are now required to be labelled. The Ministry of Health published the 'Guidelines for Labelling Biotechnology Food' in 2014 as guidance to food industries, consumers and authorised officers on this requirement. Under the section on Requirements of Labelling, Item 3.4 of the Guidelines specifically acknowledged that only events that have been approved by the National Biosafety Board (NBB) are deemed to be permitted for foods and food ingredients obtained through modern biotechnology.

Biosafety components were also incorporated into the National Food Safety Action Plan 2010-2020 with regard to GMO testing for imported agricultural produce and requirements of only using approved GM (Genetically-modified) materials for animal feed production. In addition, the Department of Biosafety is now engaging with relevant agencies to develop new policies and legislations related to biosafety such as biosecurity and low-level presence (LLP).

II. INSTITUTIONAL ARRANGEMENTS

At the forefront on biosafety implementation, Malaysia's Department of Biosafety is now widely recognised at both national and international levels through its membership in various committees and working groups. At the international level, Malaysia (through an appointed expert or representation of expertise in the Department) is a member of the following committees:

a. Member of the 8th Coordination Meeting for Governments and Organisations Implementing or Funding Biosafety Capacity-Building Activities (2010)
b. Member of the Genetically modified Food Testing Network under the Association of Southeast Asian Nations (ASEAN) (2010 – present)
c. Member of the Ad Hoc Technical Expert Group on the Second and Third Assessment and Review of the Cartagena Protocol on Biosafety under the Secretariat of CBD (2012 and 2016)
d. Member of the 9th, 10th and 11th Liaison Group on Capacity-Building for Biosafety under the Secretariat of CBD (2012, 2014, and 2016)
e. Member of the Technical Expert Group on Socio-economic Considerations on Genetic Modifications under the Secretariat of CBD (2014)
f. Member of the Ad Hoc Technical Expert Group on the project Protecting Biodiversity and Enhancing Food Security by Mainstreaming Biosafety into National Biodiversity Strategic Action Plans in Asia (2016)
g. Member of the Ad Hoc Technical Expert Group on Synthetic Biology
h. Member of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management
i. Member of the Informal Consultative Committee on Asian Biosafety Clearing House
j. Member of the Friends of the Co-Chair (FOCC) on Liability and Redress.

At the national level, the Department is a member of the following committees:

a. Member of the Technical Working Group for veterinary biologic (Feed Act 2009) (2015 – present)
b. Member of the National Bioethics Council of Malaysia (2011-present)
c. Member of the Technical Working Group for GMO Detection (2014 – present)
d. Member of the Coordinating Committee on Quarantine and Inspection Services (2014 - present)
e. Member of the Technical Working Group (Feed Act 2009) (2015 – present)
f. Member of the Technical Working Group for Importing Microorganism and Organic Material (2015 – present)
g. Member of the Steering Committee for Food Safety (2015 - present)
h. Member of the National Committee for ASEAN Consultative Committee on Standards and Quality-Prepared Foodstuff Products Working Group (2015 - present)
i. Member of the Technical Committee for the Convention of Biological and Toxins Weapons Convention Bill

III. RESEARCH AND DEVELOPMENT

A. Research Activities and Studies

Biosafety information on Living Modified Organisms (LMOs) and the aspect of biosafety is important for the conduct of risk assessments and the establishment of a response framework in Malaysia. Due to this, the Department of Biosafety conducted a series of studies to fill critical gaps in country-specific knowledge. Under the 10th Malaysian Plan (2011-2015), five studies were carried out and completed while eight studies have been planned under the 11th Malaysia Plan (2016-2020). The details and status of these studies are shown in **Tables 3-1 and 3-2** respectively.

Table 3-1
Research Studies under the 10th Malaysia Plan, 2011-2015

Title of Activity	Partner	Purpose
Establishment of a regulatory framework for liability and redress for damage caused by Living Modified Organisms in Malaysia	Nil	Identify viable options for the establishment for a regulatory framework for liability and redress for damage caused LMOs in Malaysia.
Public awareness on modern biotechnology and biosafety in Malaysia	Nil	Establish baseline data on stakeholder awareness and perception towards modern biotechnology particularly GMO, biosafety and regulatory body.

Title of Activity	Partner	Purpose
Effect on genetically modified feed on broiler performance in Malaysia	Universiti Putra Malaysia	Evaluate the growth performance and carcass yield of broiler chickens fed diet containing genetically modified corn.
Reference publication on biology of papaya (carica papaya l.)	Academy of Sciences Malaysia	Produce a reference document on the biology of papaya for risk assessment of genetically modified papaya.
Germination rate of GM corn and GM soya seeds imported into Malaysia for the purpose of food, feed, and processing	Universiti Teknologi MARA	Establish a baseline on the germination rate of genetically modified corn and soya seeds that are imported into Malaysia.

Source: Department of Biosafety (2015)

Table 3-2
Ongoing Research Studies under 11th Malaysia Plan, 2016-2020

Title of Activity	Partner	Purpose
Impact of genetically modified corn on the soil microbial communities.	Forest Research Institute Malaysia	Comparisons of soil microorganism communities between the cultivation of genetically modified corn and non-genetically modified corn.
Effect of genetically modified feed on egg layer performance and quality	Universiti Putra Malaysia	Evaluate the performance, egg quality and nutrient utilisation of laying hens fed diet containing genetically modified corn.
Unintended metabolic interactions in genetically modified plants with stacked events	Universiti Teknologi MARA	Determine if metabolomics analysis can (1) detect differences between a genetically modified plant and its non-genetically modified near isogenic counterpart grown under controlled environments, (2) detect unintended effects or interactions of multiple transgene insertions in a genetically modified plant with stacked events; and (3) evaluate if metabolomics analysis techniques can provide added value to the risk assessment process of genetically modified plants.
Risk of transforming endophytic bacteria/yeast	Universiti Malaya	Isolate, characterise, transform endophytic bacteria residing in the selected plant (cash crop) tissue; and to establish method for the detection and monitoring of genetically modified endophytic bacteria in various plant tissues, rhizosphere and rhizoplane soil.
Local environment impact assessment of genetically modified oil palm plant	Malaysian Palm Oil Board	Verify zero release of genetically modified pollen as evidence of no pollination occurrence between the genetically modified palms and the

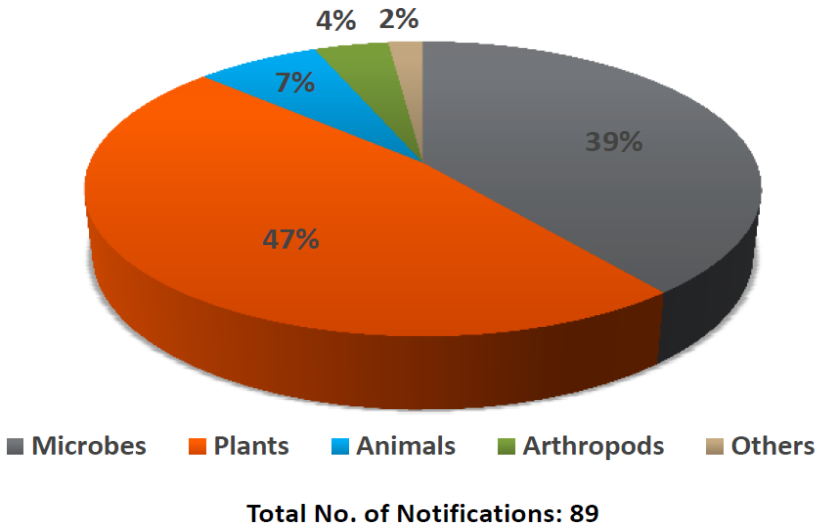
Title of Activity	Partner	Purpose
		palms surrounding the screen house, and compare the soil microbial populations between the genetically modified and control palms (within and outside of study area).
Equality nutrition food/nutrients and anti-nutrient for genetically modified foods (maize and soya bean)	Institute of Medical Research	Investigate genetically modified corn and genetically modified soybean are substantially equivalent in terms of nutritional content and anti-nutrients property as compared to the conventional products.
Development of detection method for genetically modified animals i.e. fish	Department of Chemistry	To develop, validate and verify the new genetically modified fish detection method.
Detection and persistence of living modified organism products produced by synthetic biology in local environments	University of Malaya	Detect and evaluate molecular techniques for living modified organisms and/or its products produced by synthetic biology in selected environments, notably tropical soil in Malaysia

Source: Department of Biosafety (2016)

B. Status of Modern Biotechnology Activities in Malaysia

At the time of this report, Malaysia has not yet produced GM crops for commercial uses, although several GM crops have been created at the experimental stage in contained facilities. Some of the research work done in local research institutes and universities include modified rice that resist the Tungro virus, as well as papaya that has been altered to resist ring-spot virus infection and for prolonged shelf life. Other crops such as pineapples have been manipulated to resist 'black heart', bananas and papaya for delayed ripening, and chilies for virus resistance. Malaysia is also developing genetically engineered oil palm, with a focus on increasing value-added products from the palms, such as high oleate and high stearate oil, nutraceuticals (vitamin A and E), bio-diesel and bio-plastics. However, none of the biotechnology research involving the Malaysian oil palm sector has extended beyond the experimental stage.

In the livestock and animal husbandry sectors, several animal recombinant and plant-based vaccines have been produced to assist the development of the industry. Marker-assisted breeding strategies are practiced to increase the efficiency of livestock breeding. In the treatment of industrial and agricultural wastes, the application of bioremediation techniques through bio-augmentation has been carried out. The breakdown of approved modern biotechnology activities that have been notified for contained use to the Department of Biosafety since 2010 until June 2016 is presented in **Figure 3-1**.

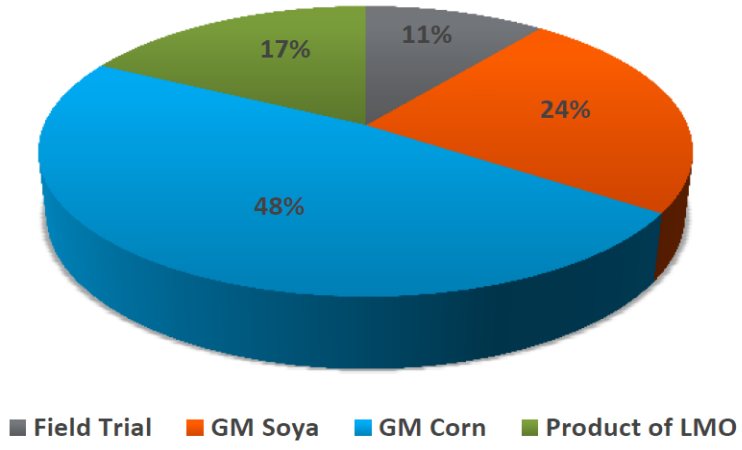


Note: Activities that have been notified to the National Biosafety Board until June 2016.
Source: Department of Biosafety (2016)

Figure 3-1 Approved Modern Biotechnology Research Activities in Malaysia (until June 2016)

In 2010, GM mosquitoes were released for field trials in Bentong, Pahang by the Institute of Medical Research (IMR) to control dengue by reducing the mosquito *Aedes aegypti* population. GM mosquito would mate with females in the wild, resulting in eggs that would hatch into offspring, but die before reaching adulthood. In 2015, IMR found that the plan was however not cost effective to be implemented. Other field trials that have been approved were to evaluate delayed ripening of transgenic Eksotika Papaya and to evaluate the expression of the transgenes in the leaf and latex of the GM rubber *Hevea brasiliensis* trees.

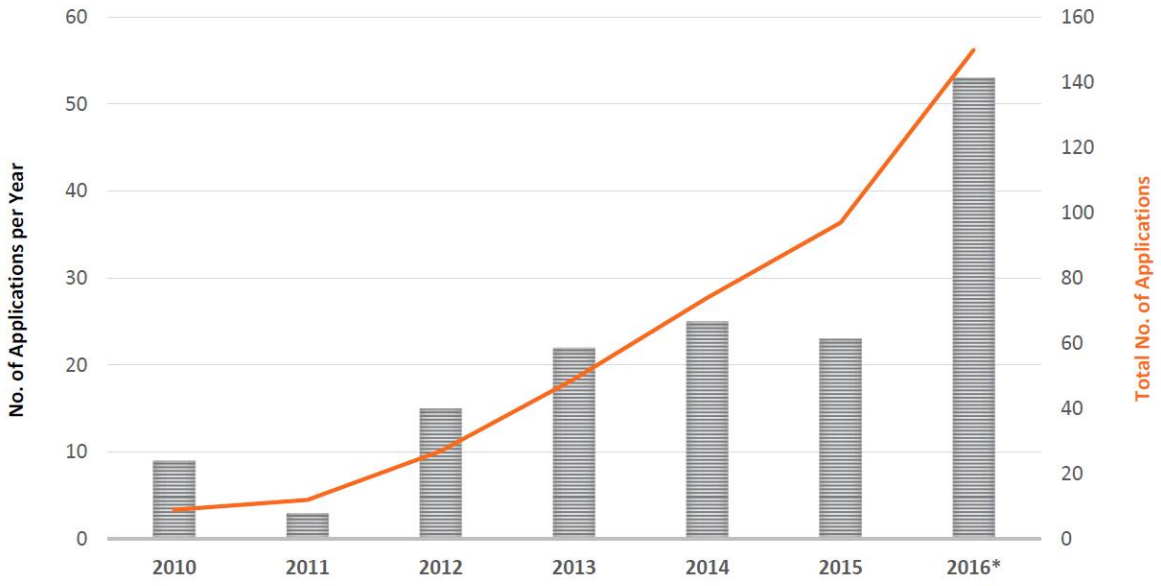
One of the major exporters of GM products to Malaysia is the United States of America, especially soybean and corn. The complete list of approved LMOs with their respective NBB decisions and GMAC assessments are displayed on the Malaysian Biosafety Database. Up till June 2016, Malaysia has approved 29 LMOs for the purpose of field trials; food, feed and processing; as well as placing of products in the market (**Figure 3-2**).



Note: Activities that have been notified to the National Biosafety Board until June 2016.
Source: Department of Biosafety (2016)

Figure 3-2 Approved Events, Products of LMO and Field Trials in Malaysia

Since the Biosafety Regulations came into force in 2010, the number of applications for both notification and approval has substantially increased. **Figure 3-3** illustrates the rising trend of applications received by the Department since 2010 until June 2016. For the first six months of 2016, the number of applications has already surpassed that of previous years.



** until June 2016 (including applications undergoing assessment)*
Note: The numbers do not include activities that are exempted under the Biosafety Act 2007.
Source: Department of Biosafety

Figure 3-3 Number of Applications Received by the Department of Biosafety Malaysia

IV. MALAYSIAN BIOSAFETY CLEARING HOUSE

The Malaysian Biosafety Clearing House (MBCH) was established by the Department of Biosafety and compiles all available local information related to biosafety since 2010. The database displays information on biosafety in the country including the current members of the NBB and the Genetic Modification Advisory Committee (GMAC), regulatory processes for approval and notification, public consultation notices on LMOs seeking approval, as well as the country's decision on LMOs for field trial; food, feed and processing; as well as products of LMOs for release. The database also lists Institutional Biosafety Committees (IBCs) registered in the country and softcopy versions of publications by the Department.

The database is updated regularly and enables public to have access to information related to biosafety. At the international level, biosafety information from Malaysia is regularly updated in the CBD's International Biosafety Clearing House Database as well as the Food and Agriculture Organization of the United Nations (FAO) Genetically-modified Foods Platform. The establishment of the MBCH has enabled transparency in information sharing where laws, regulations, procedures and administrative rulings related to biosafety are promptly published or otherwise made available to enable interested persons and Parties to become acquainted with them.

V. COMMUNICATION, EDUCATION AND PUBLIC AWARENESS

A. Public Perception on Modern Biotechnology and Biosafety

In 2012, the Department of Biosafety commissioned a study on stakeholders' perception towards modern biotechnology and biosafety in the Klang Valley. A total of 1,047 respondents were surveyed using the purposive sampling method. The stakeholders surveyed were from various sectors of the society including researchers, industry players, media personnel, policy makers, non-governmental organisations (NGOs), religious bodies and the general public. This study found that the various stakeholder groups in the Klang Valley differ in their levels of awareness and attitudes towards modern biotechnology and biosafety. For instance, researchers and industry players showed a higher level of awareness compared to consumers and religious bodies. It also provided a baseline snapshot of the knowledge levels of specific groups that the Department of Biosafety have engaged with since the Biosafety Act and Regulations came into force.

In 2015, the Department commissioned a second public perception study in Klang Valley and in Kota Kinabalu, Sabah. This survey was more in-depth than the previous one with questions related to the management and regulation of GMO matters but the respondents are only limited to the general public. Using a

stratified random sampling procedure, 1,512 respondents in the Klang Valley were surveyed. Meanwhile, in Kota Kinabalu, Sabah, 503 respondents were surveyed using the convenience sampling method. The study found that the public's level of awareness on the regulatory aspects of biosafety and the public consultation process on applications for GMO release is very low.

In the Klang Valley, only 12% of respondents aware that there are laws or regulations in Malaysia to regulate the dealings of GMOs, 16% aware of the Department of Biosafety and a mere 6% aware of the Biosafety Act 2007, the National Biosafety Board and the GMAC. The results in Sabah were lower, with 18% of respondents aware that there are laws or regulations in Malaysia to regulate the dealings of GMOs, 24% aware of the Department of Biosafety and 11% aware of the Biosafety Act 2007, the National Biosafety Board and the GMAC.

Since both studies had different purposes and target groups, the results were not directly comparable. However, these studies established a baseline understanding of stakeholders' and the public's perception on modern biotechnology and biosafety. It highlighted topics that respondents have little awareness of such as the Biosafety Act 2007, biosafety in the country, as well as its impact on research and industries. The results obtained from these studies will provide useful information identifying target groups to engage with and for designing future awareness-raising programmes as well as assessing their effectiveness.

B. Awareness-Raising and Information-Sharing

The Department of Biosafety has conducted and participated in a number of awareness-raising and information-sharing through workshops, seminars, and exhibitions. These events have targeted educational institutions (schools and universities), and the general public. The events were aimed at imparting general knowledge and information on the concerns of LMO and biosafety. For example, from 2009 to 2015, a total of 32 events were held for the general public (**Table 3-3**).

Table 3-3
Awareness-raising and information-sharing events, 2009-2015

Year	Workshop Title*
2009	Seminar on Biosafety Act
2010	Roadshow to Universities and Open Days
2011	a. Seminar on Biosafety Act (2) b. Student Awareness Seminar (3)
2012	a. Biosafety Awareness Programme b. Exhibitions at Carnivals and National Events (2) c. International Conference on Modern Biotechnologies: Sustainable Innovation and Regulatory Needs d. Roadshow to Universities and Open Days e. State Bio Events (Bio Borneo, Bio Johor)
2013	a. Biosafety Awareness Programme b. Biosafety One Day Seminar c. Dialogue between Scientists and Members of Parliament on GM Crops and its Impact on Sustainable Development and Food Security d. Exhibitions at Carnivals and National Events (3) e. National Biotechnology Seminar & Exhibition f. Radio Interview with the Director General of the Department of Biosafety on Hello g. State Bio Events (Bio Borneo, Bio Johor)
2014	a. Exhibitions at Carnivals and National Events (3) b. State Bio Events (Bio Borneo, Bio Johor) (2) c. Transformation Programme with Public Service Department
2015	a. Biosafety One Day Seminar b. Biotalent Boot Camp c. Seminar on Biosafety Act d. State Bio Events (Bio Borneo, Bio Johor)

* Number for events conducted more than once a year are shown in parenthesis

Information about biosafety is also shared through public notification which is a mandatory requirement for approval. Many details associated with the application are made transparent and available to the public for their feedback before any decisions are made by the NBB. In cases where public interest is high, the Department of Biosafety has organised a session with journalists to address any issues and provide clarifications, for example for the field trial for GM mosquitoes. All information shared during this session was subsequently made available in the MBCH. The Department has also responded to any issue raised by public in the mainstream printed media, such as the 'Letters to the Editor' column in newspapers.

VI. CAPACITY-BUILDING ACTIVITIES

A. Training Workshops for Government Agencies and Institutions

The Department of Biosafety has taken the lead in organising training workshops to increase the knowledge and competency among staff in government agencies and institutions that are involved, both directly and indirectly, in the implementation and enforcement of the Biosafety Act 2007. A training module was developed by the Department of Biosafety, in consultation with GMAC, to provide training for IBCs. The training workshops were formulated for ease of replication and to ensure consistency of the training. It is comprised of the following components:

a. Introduction to the Biosafety Act 2007, Regulation, and the IBC Guidelines;
b. Biosafety practices pertaining to movement, transport, storage, disposal of LMO and related materials;
c. Risk assessments consisting of defining and differentiating between hazard and risk, understanding likelihood and consequences, risks associated with LMO and matrix for risk assessment and skills in reviewing and monitoring activities related to living modified organism;
d. Risk management consisting of risk mitigation, control measures and emergency response plan; and
e. Containment facilities and work practices.

In addition to that, other capacity building activities such as risk assessment, technical training on risk management, and detection techniques have been organised. **Table 3-4** indicates the number of workshops and its themes for strengthening biosafety capacities carried out since 2009.

Table 3-4
Capacity Building Workshops, 2008-2015

Year	Workshop Title
2008	Seminar On Biosafety Awareness: Roles and Obligations of Researchers, Research and Academic Institutions Under the Biosafety Act 2007
2009	a. Management of Containment Facilities Workshop b. Risk Assessment Workshop for GMAC Members c. Risk Assessment Workshop on Transgenic Crop Plants d. Risk Assessment Workshop on Transgenic Trees
2010	a. Risk Communication Workshop on Transgenic Insect b. Workshop on the identification and documentation of living modified organism (LMO) c. Workshop on the Safety Assessment of Foods Derived from GM Crops
2011	a. ''Biosafety & DNA & U' Workshop b. Media/Crisis Communications Workshop c. Workshop on the Implementation & Enforcement of the Biosafety Act
2012	a. Biosafety Training Workshop (6)

Year	Workshop Title
	b. Workshop on Genetically modified Organisms Protein Detection Technique
2013	a. 'Towards Better Compliance' Seminar b. Biosafety Training Workshop (5) c. National Biotechnology Seminar d. Workshop on Biotechnology Commercialisation and Trade in APEC Economies – Biosafety Regulatory Perspective
2014	Biosafety Training Workshop (6)
2015	a. 3rd National Biosafety Report Workshop (2) b. Biosafety Training Workshop (3) c. Consultation Workshop on the Final Draft Report on the Study of Domestic Legislation for Liability and Redress d. Enforcement and Investigation Workshop in Collaboration with Department of Environment e. Lab Safety Workshop for Institutional Biosafety Committee 2015 f. Risk Assessment Workshop for GMAC Members g. Seminar on Food and Feed Safety of Genetically Engineered Crops Containing Stacked Traits

* Number for events conducted more than once a year are shown in parenthesis

B. Training Workshops on the International Biosafety Clearing House

The International Biosafety Clearing-House (IBCH) is established through the provision of Article 20 of CPB to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and assist Parties to implement CPB. The IBCH functions like a central information marketplace where the providers and users of biosafety information interact and exchange that information. All 170 Parties to CPB are required to provide country-related biosafety information into this database as part of their compliance to CPB. Interested users can freely search and retrieve a wide range of information through the BCH website.

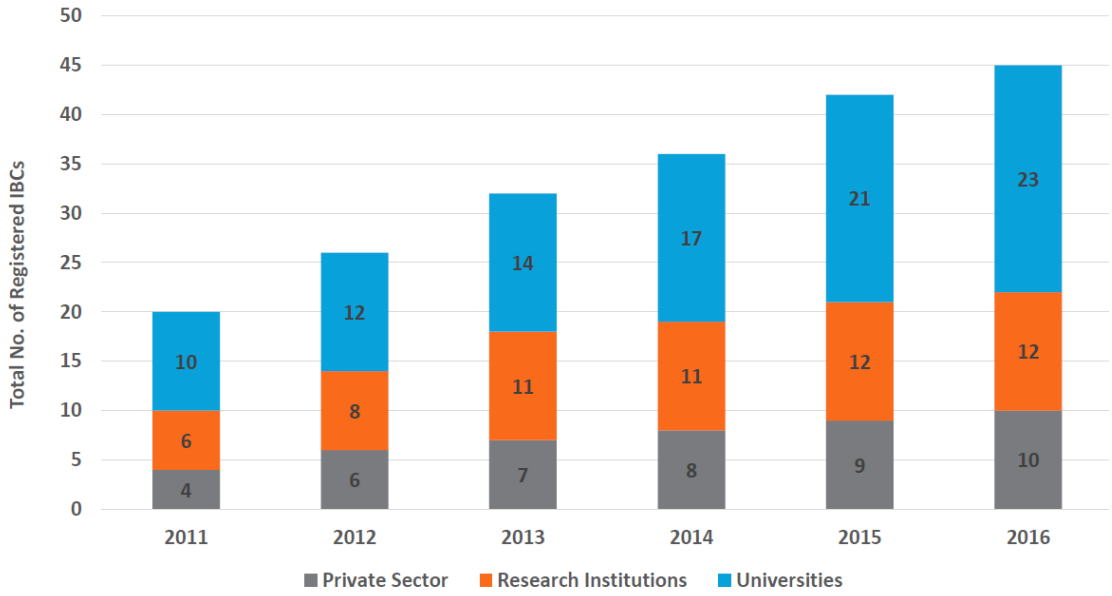
The Department of Biosafety has organised training workshops to enable participants to understand the format of the BCH and the procedures for registering and publishing biosafety-related records. The workshops targeted (1) government agencies with direct responsibilities in implementing the biosafety law, (2) other key stakeholders and (3) potential users of the BCH such as universities and research institutions. Six BCH-related training workshops were carried out from 2010 to 2015 (**Table 3-5**).

Table 3-5
Workshops on Biosafety Clearing House, 2010-2015

Year	Workshop Title
2010	Training Workshop on Data Management usage & the Accessing of Information from BCH
2012	a. Biosafety Clearing House Training of Trainers Workshop b. Biosafety Clearing House Workshop
2013	Biosafety Clearing House Workshop
2014	Biosafety Clearing House Training of Trainers Workshop
2015	Biosafety Clearing House Workshop

C. National Institutional Biosafety Committee Seminar

An annual seminar for IBCs has been held since 2012 to train IBCs, specifically Biosafety Officers, in carrying out their roles and responsibilities in compliance with the Biosafety Act 2007. These seminars have also created a network among participants to share and learn from common experiences and to exchange ideas to further improve biosafety practices in Malaysia. Since the Biosafety Act came into force in late 2010, 45 IBCs have been registered with the NBB. As of June 2016, 10 are from the private sector, 12 are research institutions and 23 registered IBCs are from tertiary education institutions (**Figure 3-4**).



Source: Department of Biosafety, 2016

Figure 3-4 Total of Registered IBCs, 2011-2016

VII. ENFORCEMENT

A. Integrated Enforcement on GMOs and Non-GMOs

The implementation of the Biosafety Act provides supplementary laws, in addition to any other written law relating to import and export, human, plant, and animal health, the environment, and biological diversity. Therefore, in 2014, the Department of Biosafety published a handbook to outline the roles and jurisdictions of enforcement agencies and their respective legislation. An integrated enforcement matrix was developed as an effort to strengthen enforcement across all related agencies.

The matrix represents an important reference for regulating the release, import, export, and contained use of GMOs, as well as the release of products from these organisms. The matrix also highlights the relevant acts and legal jurisdiction of various agencies related to the control and management of both GMO and non-GMO products (see **Appendix A-4**).

The Department works with four departments under the Ministry of Agriculture: Department of Veterinary Services, Malaysian Quarantine and Inspection Services, Department of Agriculture, and Department of Fisheries; as well as three divisions under the Ministry of Health: Food Safety and Quality Division, Disease Control Division, and Pharmaceutical Services Division. These agencies overlook products related to their respective sectors, however the Department of Biosafety is referred to when LMOs and its products are involved.

During the National Biodiversity Council (9 August 2016), members were briefed and provided with biosafety awareness materials.

The Council then decided that a high-level committee chaired by the Deputy Prime Minister is to be set up. The Terms of Reference of the high-level committee has been prepared for the consideration of the Minster of NRE. Issues at the policy level can be brought up in this committee. The Department is also planning to meet with the state-level Department of Agriculture in Sabah and Sarawak to establish biosafety monitoring in East Malaysia.

B. Sampling and Monitoring of LMO

The enforcement section of the Department of Biosafety actively conducts sampling and monitoring activities within Peninsular Malaysia mostly for products used for food, feed, and processing (FFP) such as soya and corn. The main focus are the key entry points of goods into the country i.e. the ports of Port Klang, Penang Port, and Port of Johor (Pasir Gudang). Sampling and monitoring activities are scheduled on a monthly basis, supplemented with ad-hoc programmes in Kuala Lumpur and across the Klang Valley. The sampling of products is progressively being expanded

to include non-FFP products such as vegetables and fruits. In addition, enforcement officers collect random samples in the general marketplace at various locations around the country.

At points of entry, samples will be collected by enforcement officers from the Malaysian Quarantine and Inspection Services (MAQIS). These samples will then be forwarded to the Department of Biosafety where the initial test for LMOs detection is carried out. If the test results in a positive, the samples will then be sent to the Department of Chemistry for LMOs identification. At the time of this report, the Department of Biosafety has begun initiating discussion with relevant agencies in order to develop new sampling regulations.

The Department of Biosafety have also organised workshops on sampling procedures, partnering with other agencies. In 2015, the Department of Biosafety together with Padiberas Nasional Berhad (BERNAS), organised a workshop on commodity grain sampling for accurate detection of LMOs presence. Participants received practical training on sample taking of grain commodities at entry points. The workshop also provided a platform for participants to share their knowledge and experience on commodity grain sampling.

C. Self-regulation at the Institutional Level

IBCs are tasked to monitor activities related to modern biotechnology and play a fundamental role in ensuring safe conduct of modern biotechnology activities and handling of LMOs within their institutions. To empower IBCs to self-regulate at the institutional level, a number of annual seminars were carried out. The content of the annual seminars is tailored according to the capacity building needs of the IBCs, such as conducting inspection of premises and developing Standard of Procedures. A Training of Trainers session was conducted in 2016 to enable the Biosafety Officers to provide their institutions with the necessary knowledge on the Biosafety Act 2007 as well as to develop capacity building initiatives at the institutional level.

VIII. INTERNATIONAL NETWORKS

Malaysia played a fundamental role in the development of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (NKL SP). As part of the negotiation process, a group called Friends of the Co-Chairs Group (FOCC) was formed whereby Malaysia was one of the countries nominated to represent Asia Pacific. The group was instrumental in pushing the negotiation process forward and Malaysia hosted two of the FOCC meetings in 2010. A lot of progress was made during these FOCC meetings and resulted in the Parties reaching a compromise. This protocol was adopted in 2010 and provides for international rules and procedures on liability and redress for damage to biodiversity resulting from LMOs. The contribution by Malaysia in this process is reflected in the fact that the protocol is called after the capital of Malaysia.

The Department of Biosafety is now a referral point for biosafety implementation in the region. It has hosted study visits for officers from Bhutan and Brunei, and was invited for consultations in Laos. In addition, the Department has been invited to the international fora to share country experiences in implementing biosafety regulations. These include the Conference on 'Tough Choices: New Biosafety Decisions in High Stakes arenas' organised by GenØk Centre for Biosafety, Norway in 2011; World Congress on Risk in Australia, 2012; Second International Workshop for Regulation of Animal Biotechnology in Brazil, 2014; and Thirteenth International Symposium on the Biosafety of Genetically modified Organism (ISBGMO13) in South Africa, 2014. Malaysia was also invited to share experiences during the Third FAO/CBD/OECD webinar on international databases on biosafety held on 9 December 2015 on the topic of 'Effective use of data on the FAO GM Foods Platform: Malaysia'.

The Department has also been invited to attend various international training events such as the Workshop and International Seminar Synthetic Biology 'Biosafety and Contribution to Addressing Societal Challenges: From Simplicity to Complexity' in Bogor, May 2016; annual Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically modified Organisms in Norway; Biotech Regulation Immersion Course (MU-BRIC) co-organised by University of Missouri with the University of Ghent, Belgium in August 2016; and China-ASEAN Training Workshop on Biosafety Capacity Building in September 2016. In addition to that, several capacity building initiatives have been conducted in collaboration with various global agencies such as the U.S. Department of Agriculture (USDA), the International Life Sciences Institute (ILSI) and the Office of the Gene Technology Regulator, Australia (OGTR). The Department of Biosafety has also engaged experts in various relevant fields to share their knowledge from Australia, Austria, India, Philippines, USA and the European Union.

IX. PUBLICATIONS

Since the establishment of the Department of Biosafety, there has been a significant increase in publications related to biosafety, risk assessment of GMOs and LMOs, and CPB. The following section provides an overview of the major publications that have been released. In addition to all these, the Department of Biosafety also publishes the Biosafety Newsletter using its own funding. Since 2009, it has published seven issues of the newsletter reporting on developments in the field and activities that have been carried out.

A. The Biosafety Act of Malaysia: Dispelling the Myths

Published in 1998, this document was produced by MNRE in collaboration with the Centre of Excellence for Biodiversity Law (CEBLAW), University of Malaya, Kuala Lumpur. It was part of MNRE's on-going initiative to raise awareness on biosafety and to promote better understanding on biosafety matters to the public and other stakeholders. A major issue deliberated upon was whether the Biosafety Act 2007 was anti-biotechnology and contradicting the National Biotechnology Policy 2005. The document reiterated that the Act was carefully designed to protect the environment, health and safety of the public, while ensuring the advancement of biotechnology in the country.

B. Cartagena Protocol On Biosafety to The Convention On Biological Diversity

The document was first published by the Secretariat of the CBD in 2000. A bilingual version of the Cartagena Protocol on Biosafety was reprinted by MNRE in the national language, Bahasa Melayu, and in English.

C. Liability and Redress Under the Cartagena Protocol on Biosafety Volume 1: A Record of the Negotiations for Developing International Rules

Published in 2008 by CEBLAW in collaboration with MNRE, this publication records the negotiation processes leading to the adoption of international rules and procedures for liability and redress arising from the transboundary movement of LMOs. Based on Article 27 of the Cartagena Protocol on Biosafety, rules on liability and redress have to be negotiated and finalised within four years. The negotiations recorded were from the inception and negotiation of the Cartagena Protocol on Biosafety and at the six Working Group meetings held from February 2005 to March 2008. It also captured the proceedings of meetings held during the fourth Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 4) in Bonn, Germany in May 2008.

D. Standard Operating Procedures for Department of Biosafety

This document was produced in 2010 as a reference for officers from the Department of Biosafety in the course of performing functions for the department. The document is divided into three sections with Standard Operating Procedures (SOPs) for the (1) approval of release of LMOs, (2) notification for contained use activities involving LMOs, and (3) various other procedures involving investigation, sampling, meeting organisation for relevant committees. There are nine SOPs for the approval process, five SOPs for the notification process and eleven SOPs for miscellaneous actions such as Power to Take Sample and Conveying NBB Decision to the Public. The SOP will be reviewed from time to time to take into account the latest developments and experience of implementation of the SOPs by the Department.

E. Malaysian Biosafety Handbook

The Malaysian Biosafety Handbook is a collection of five biosafety guidelines and a user's guide produced by the Department of Biosafety in 2012. The set is reviewed as follow:

1. User's Guide to the Biosafety Act and Regulations

The first book in the set, the User's Guide was published to aid any organisations that conduct work with LMOs to understand the Biosafety Act 2007 and to comply with the requirements of the new regulatory system. The User's Guide provides a background about the national regulatory scheme for LMOs, the scope of activities regulated and those exempted. It outlines the approval process for LMO activities, including release and import, assessment process, as well as the forms and fees involved.

2. Guidelines for Institutional Biosafety Committees

This guideline was produced to provide guidance to organisations which undertakes modern biotechnology research and development on the setting up of their respective IBCs. It highlights the roles and functions of the IBCs such as reviewing modern biotechnology activities and their related requirements. Responsibilities of key persons of the IBC such as the IBC chair, the BSO, as well as the principal investigator are described in the Guidelines. Other requirements are also detailed in the Guideline such as the mandatory training to be obtained by IBC members, formulation and management of emergency responses plans, and carrying out laboratory inspections (which includes the review of the biosafety manual).

3. Contained Use Activity of Living Modified Organism

The Biosafety Guidelines for Contained Use Activity of Living Modified Organism is applicable to all R&D activities of modern biotechnology conducted in laboratories. The guideline is essential for safe handling, storage, transfer, and disposal of LMOs. The guideline outlines the Biosafety Levels (BSL) for containment of genetic modification activities, and safe practices for working with LMOs. For any genetic modification activities, the guideline provides a step-by-step guide to identify the BSL for containment of the activity, describe the suitable work practices for the respective containment level, outline the minimum facility requirements for the contained use, and to identify specifications required under the respective containment level.

4. Confined Field Trial of Living Modified Plants in Malaysia

The development of a living modified (LM) plants from containment needs to be progressively tested in a field trial before any large scale release or commercialisation. This Guideline serves to provide researchers with the necessary practices and precautions when conducting confined field trials (CFT) of LM plants or crops to fulfill biosafety regulatory compliance. It gives guidance for the application process, CFT management, disposal of organisms, and monitoring of post-harvest trial sites. It also outlines practices that will prevent pollen and seed dissemination into the environment, persistence of the LM plant and to prevent entry of the LM plant or its products into the food chain.

5. Risk Assessment of Genetically Modified Microorganisms

This Guideline on risk assessment of genetically modified microorganisms (GMM) is applicable to all individuals involved in R&D activities of modern biotechnology involving GMM. The Guideline is divided into two sections. Section 1 covers the risk assessment for human health and environmental protection of work involving the genetic modification of all microorganisms, including bacteria, fungi, protists, cell-lines and viruses, which are human and animal pathogens. Section 2 covers the risk assessment for work with GMM associated with plants. These sections also cover guidance relating to the assignment and implementation of containment and control measures.

6. Environmental Risk Assessment of Genetically Modified Plants in Malaysia

The Biosafety Guidelines on environmental risk assessment (ERA) of genetically modified (GM) plants is applied to the cultivation of GM plants, as well as the import of food and feed that contain, consist, or produced from GM plants. The main focus of the guidelines is the potential environmental risks arising from GM plants and does not cover socio-economical and ethical issues. The general

principle applied to the ERA of GM plants is comparative assessment which uses appropriate methods to compare the GM plant and its derived products with their non-GM counterparts. The Guidelines also contain a chapter on ERA for activities with plant-associated GMMs.

F. Liability and Redress Under the Cartagena Protocol on Biosafety Volume 2: Nagoya-KL Supplementary Protocol – A Record of Negotiations

Following Volume 1, the second volume was published in 2012, recording negotiations from after COP-MOP 4 until the adoption of the Supplementary Protocol in Nagoya, Japan in 2010. Similar to the previous volume, this document provides a snapshot of each element that was negotiated; the options proposed under each element; and the positions taken by the delegates and other participants. Volume 2 represents the conclusion of the Nagoya-KL Supplementary Protocol on Liability and Redress under CPB.

G. Biosafety Education Video

This video is part of the Department of Biosafety's effort to increase public awareness on LMOs and biosafety. The video was produced in both the national language, Bahasa Melayu, and in English, and is approximately 18 minutes long. The video is divided into seven chapters including an introduction to DNA and modern biotechnology, steps in genetic engineering, risks and benefits of genetic engineering, status of LMO development and the Biosafety Act 2007.

H. Biosafety Q+A

The Biosafety Q+A (Question and Answer) was initially published as a set of illustrated flash cards to educate the public on the fundamentals of biosafety and its related topics. Later on, the cards were converted into pocket-sized booklets for ease of reference. It is one of the best tools currently available for awareness-raising and engagement. The Biosafety Q+A includes general information on genetics, modern biotechnology, GMOs, as well as facts about the Biosafety Act 2007 while maintaining simplicity with the usage of laymen terms and attractive illustrations (Box 3-1). This concept transforms a topic that is perceived as difficult into something more approachable to the general public.

Box 3-1: Biosafety Q&A

Source: Department of Biosafety Malaysia (2012)

04 LESSONS LEARNT AND CHALLENGES

PART FOUR

Lessons Learnt and Challenges

Malaysia has developed significant experience since implementing the Cartagena Protocol on Biosafety (CPB) which has resulted in, among others, achievements related to institutional and organisational arrangements, capacity-building and awareness raising, and the development of technical procedures and protocols. As part of its progress there are numerous lessons that can be learnt as well as challenges that will need to be overcome in the future as part of the integrated implementation of the Protocol.

I. LESSONS LEARNT

A. Strengthen Biosafety with Legislation

The Biosafety Act 2007 reflects Malaysia's international commitment as a Party to take the necessary legal measures to implement its obligation under CPB. The legislation is instrumental in facilitating the establishment of the necessary organisational framework for implementing biosafety measures which includes the setting up of National Biosafety Board (NBB), Department of Biosafety, Genetic Modification Advisory Committee (GMAC) and Institutional Biosafety Committees (IBCs). With the Act in place, financial allocation and human resources were provided by the Government of Malaysia to the Ministry of Natural Resources and Environment (MNRE) as the implementing agency of the law. In addition, Global Environment Facility (GEF) supported the implementation of the law by funding the 'Capacity Building for Implementation of Malaysia's National Biosafety Framework' project through United Nations Development Programme (UNDP) to move the biosafety agenda forward. All these created an enabling situation to lay the foundation towards implementation of the law such as consultation with stakeholders; building capacity of the local experts, researchers and personnel of the Department of Biosafety; as well as raising awareness on biosafety.

B. Consultative and Enabling Approach in Implementing Biosafety

The formulation and the implementation mechanism of the Act was through a consultative process with various groups of stakeholders, which was important to develop the necessary 'buy-in'. Consultations took into cognisance the views of the biotechnology industry, NGOs, as well as researchers. This was to ensure that the Act would best advance the twin aspects of biotechnology – advancing the biotechnology policy of the country and protecting against the possible adverse

effects of LMO and its products. Some specific areas of discussion included socio-economic considerations in decision-making, mechanism of enforcement, exemptions, public participation, labelling and clarification on administration of the law.

Subsequent consultation was on the Integrated Enforcement Matrix among Government Agencies, which was developed together with all relevant enforcement agencies. This is to ensure that all parties were aware of their jurisdictional powers and their legal obligations. These platforms presently allow government authorities legal control over the transboundary movement of LMOs, while ensuring that biosafety is addressed in a holistic manner, involving all relevant stakeholders in the decision-making process.

The application process for Notification and Approval is also carried out in a consultative manner whereby the Department of Biosafety/GMAC/NBB is in constant communication with the applicant throughout the process. In specific cases, discussions on the risk assessment and risk management, as well as emergency response plans are carried out between the Department/GMAC/NBB and the applicant. This will enable compliance to terms and conditions.

C. Leveraging on Technical Expertise

The field of modern biotechnology is rapidly growing with increasing complexity. It has therefore been difficult for any single authority to develop a complete range of expertise on the subject matter. Coupled with the small number of personnel in the Department, there was a need to seek out subject experts in the public domain.

1. Continuous Training of Local Experts

The formation of GMAC in 2010 was critical as it enabled the NBB to tap into a wide range of technical experts across the country to provide competent technical assessments on LMOs. These appointed members are mostly senior-level personnel in their respective organisations with specific expertise in areas such as microbiology, animal breeding, environmental science, but not necessarily trained in biosafety. Therefore, they were provided training on the Biosafety Act and Regulations, as well as assessing LMO applications. Currently, there are limited opportunities for GMAC members for capacity building and training on skills related to their roles, such as risk assessment and risk communication. Since GMAC provides crucial support through their technical expertise to the Department, it is imperative to invest in their capacity building.

GMAC is further strengthened by two sub-committees which were formed in 2013. The first sub-committee was appointed to assist GMAC to monitor and ensure compliance of terms and conditions imposed on approved activities. This sub-

committee has conducted at least 30 inspection visits to various facilities. The second sub-committee was appointed to review queries and provide advice on activities exempted from the Biosafety Act. This committee has enabled the Department to have quick expert consultations and provide prompt responses to technical queries.

2. Utilising the International Biosafety Network

The Department of Biosafety has tapped the experience and expertise of external resources to share and educate the local stakeholders by utilising the established international biosafety network. Biosafety regulators from several countries, such as Australia, Austria and India, have come to share their experience on regulating and managing biosafety in their respective countries. Other than that, experts on specific subjects have been invited to educate their Malaysian counterparts on technical subjects such as risk assessment of crop plants, microbes, arthropods; detection methods of LMO; management of containment activities; and field trial monitoring. Other topics that have been shared include enforcement methods, socio-economic consideration in decision making, low-level presence, handling of stacked events, and skills on risk communication.

D. Enforcement and Monitoring

In addition to the current enforcement activities of food, feed and processing (FFP), the Department of Biosafety has widened the scope to include non-FFP products. One way of doing this is by collecting samples of produce from markets around the country. If the produce is found to be an LMO, the enforcement section will conduct focused enforcement actions for the particular type of produce and attempt to track its source. The Department gives more focus to detecting unapproved LMOs that may have slipped into the country. This helps address the limitation of enforcement resources.

The Department also employs additional tactics to ensure that the scope of enforcement is more comprehensive. It conducts searches for modern biotechnology projects, both online and at biotechnology related events. The findings can be in the form of published scientific papers, posters and presentations in conferences, seminar proceedings, annual reports, or research projects listed by organisations. These projects are cross-checked with those that have been approved by NBB to uncover those that are not in compliance with the Biosafety Act. This will enable the Department to identify companies and institutions that need to be engaged with to ensure compliance.

E. Prioritising Target Groups for Awareness Programmes

The Department of Biosafety has actively conducted programmes to raise awareness on biosafety. Initial programmes conducted by the Department to raise

awareness did not focus on any specific target groups. However, due to the limited resources, prioritising of target groups is required to raise the effectiveness of programmes conducted. The first priority group identified were industry players and researchers who were directly involved in modern biotechnology. This enabled the Department to engage with key individuals who became the focal points for disseminating information on biosafety awareness programmes.

For example, when engaging with the industry target group, an ad-hoc committee was set up to initiate discussions to help them comply with the terms and conditions related to FFP and to disseminate information relating to the processing of applications and compliance to the Biosafety Act. Based on feedback received, it was found that many researchers were unfamiliar with the regulatory process and application forms. Therefore, explanatory notes for the forms and a completed sample form have been developed for reference. Several training sessions have been conducted on filling up these forms. In addition, the application forms have been revised based on feedback from the users (IBCs and researchers).

These methods have successfully improved the awareness of the prioritised target groups (as reported in the first awareness survey carried out in early 2012). Of the 101 researchers surveyed, 83% indicated that they have heard of the Department of Biosafety, and nearly three-quarters of respondents are aware of the Biosafety Act. Sixty-one percent were aware that there are laws or regulations in the country to regulate the dealings of LMO. The rapidly increasing number of notifications and applications is a result of these efforts.

For the industry players, 100 individuals were surveyed and it was found that 52% have heard of the Department of Biosafety. Their awareness levels of laws or regulations in Malaysia to regulate the dealings of LMO and of the Biosafety Act were lower than that of the researchers at 43% and 38% respectively. Since the Biosafety Act only entered into force in 2010, the results of the survey are considered a satisfactory achievement within the two-year period.

In upcoming awareness programmes, new priority target groups will be identified, for instance politicians and non-government organisations (NGOs), and specific methods of engagement will be designed for them. Engagement with politicians is important because political will is crucial to mobilise biosafety, preferably leadership from a ministerial level. Biosafety matters will need to be brought into attention at higher levels to enable the initiation of more efforts.

F. Engagement with Government Agencies to Integrate Biosafety

The nature of LMOs gives the Department of Biosafety a unique stand where an LMO or its product can be in the form of an animal, fish, plant, pesticide, or microbe where it involves overlapping regulatory mechanisms with other agencies. The Department of Biosafety has developed the Integrated Enforcement Matrix

among Government Agencies which is a framework for all related enforcement agencies to work together. By doing so, enforcement agencies are more aware of LMOs and its products, as well as the necessary actions to be taken when the event arise.

The Department has taken a proactive role towards mainstreaming of biosafety by being members of numerous national committees [see PART THREE (III)]. There are many national committees where the subject of biosafety should be a scope. Committees that are involved in LMOs and products of LMO should involve the Department of Biosafety in their decision-making process. Biosafety regulators should identify these committees so that biosafety can be integrated into other sectors.

Other methods of engagement can also facilitate the regulation of biosafety, such as partnering with research funders to ensure compliance. For example, the Department of Biosafety partnered with the Ministry of Science, Technology and Innovation (MOSTI) and the Ministry of Agriculture and Agro-Based Industry (MOA), which are agencies that disburse grants for research, to make it compulsory for fund-applicants to notify and obtain approval from the IBCs for their research projects prior to applying for a grant. This mechanism ensures that all projects funded by the respective ministries involving LMOs comply with Biosafety Act 2007. There is a compulsory requirement for recipients of the grant to show proof of approval from the Department of Biosafety during their performance review. This has also increased awareness within agencies on their role and responsibilities with regards to biosafety requirements.

II. KEY CHALLENGES

A. Gaps in Technical Knowledge and Skills

Modern biotechnology is rapidly growing and constantly evolving with increasing complexity. As such, personnel involved with biosafety must constantly upgrade their technical knowledge and skills. At present, there is a gap in technical resources that needs to be addressed.

1. Technical Competency in Department of Biosafety Personnel

The Department of Biosafety is heavily dependent on GMAC to review applications on approvals and notifications. As applications are increasing each year, GMAC capacity is now being stretched. Members of GMAC are appointed among professionals from government agencies, higher education institutions, research institutions and the private sector. Members of GMAC are therefore expected to perform their roles, in addition to responsibilities at their respective organisations.

With increasing demands, GMAC members may at times be reluctant to continue with their services on the committee and the Department is unable to retain the valuable expertise and experience of these members.

Therefore, the technical competence and human resources should be increased to enable the Department to conduct a more thorough initial assessment before GMAC reviews the approvals and notifications. The areas where knowledge and skills are required include:

a. Risk assessment and risk management of LMOs;
b. Detection of LMOs (e.g. sampling methods, laboratory procedures etc.);
c. Identification of LMOs of unknown origin;
d. Inspection of facilities and monitoring field trials; and
e. Socio-economic considerations.

2. Detection and Management of Emerging Complex Issues

The Department's personnel and GMAC members also need continuous capacity building to remain current. An example of continuous capacity needs is for the issues surrounding 'stacked events'. Due to the advancements of technology in developing genetically modified crops, currently there are occurrences of stacked events that combine two or more transgenic traits originally present in different parental GM events. The problem arises when products with stacked genes are not detected as such because the current capacity is able to detect it as an individual event. Therefore, it becomes a challenge to monitor such products.

Another emerging issue is the management of low level presence (LLP) in imports. As Malaysia mainly imports corn and soya for food and feed, LLP has proven to be a challenge to deal with as there is no control of the exporter's agricultural practices. This is due to the variation in decisions by the countries, whereby countries that are producing the GM corn and soya have no restrictions in the mixing of the approved GM products in their agricultural handling and practices. However, these mixed products may not be approved in Malaysia. A thorough and continuous engagement is being done with regards to this issue with the relevant stakeholders to find a feasible approach in addressing this to enable uninterrupted trade in GMO products[1]. Any chosen approach will be adopted after weighing its implications on the protection of human, plant and animal health, the environment and biological diversity of Malaysia. A review of products that are likely to be imported will therefore be essential.

The other emerging challenge is the increase in activities using New Plant Breeding Techniques (NPBT) that are being developed. Examples of NPBTs are Nuclease-mediated site-directed mutagenesis and marker-assisted-selection (MAS). These

[1] Malaysia is a signatory of the Trans-Pacific Partnership Agreement (TPPA), a trade agreement among twelve Pacific Rim countries. In the TPPA, Article 2.29 on 'Trade of Products of Modern Biotechnology' aims to ensure market access and uninterrupted trade in GMO products.

techniques may be used unaided in the breeding process of a certain crop, in combination with other NPBTs, with conventional breeding approaches, or together with GM technology in breeding. This will result in a product that will be challenging to assess due to the complexity. Some considerations that are necessary for risk assessment of LMOs are not at all related with the NPBT involved, thus it may be necessary to incorporate some additional issues in the assessment. Newer technologies that are developed fall into the gray area of definition in the regulatory scope and may not be subject to the regulatory process. Therefore, the assessors need to be at par with these developments and equip themselves to ensure that a robust and effective risk assessment can be done.

B. Resource Constraints

The Department of Biosafety's current staff capacity is 25 persons with only six officers tasked to anchor biosafety enforcement nationwide. However, enforcement is now only limited to Peninsular Malaysia as there are no resources and enforcement mechanisms established to expand to Sabah and Sarawak. Specifically, in cases of release such as field trials, all State Governments should be aware and be more involved in biosafety implementation. This includes providing input in decision-making for LMO release activities in their respective state, monitoring of these activities, as well as being involved in the response mechanism if any unapproved release is found. Agencies charged with the responsibility for biodiversity should play a more prominent role in providing input on risk management to protect native species and protected areas.

The Department also does not have a dedicated legal officer to handle legal matters related to compliance as well as for developing related legislations and procedures. There has also been a backlog in organising biosafety training workshops for registered IBCs as the Department has been unable to fulfill requests for training due to staff constraints. The Department relies on the laboratory of the Department of Chemistry to conduct analysis on LMO samples. However, laboratory facilities were limited which hampered the number of samples that could be collected and sent for analysis. Additional partnerships have to be identified to have access to more laboratory facilities, specifically with agencies under MNRE. For instance, the Department of Wildlife and National Parks Peninsular Malaysia (PERHILITAN) have forensic laboratories that can be used for the purpose of LMO detection.

The number of applications and notifications has more than doubled in the past six months compared to the whole of 2015 [refer to Part 3(IV)(B)]. Under the Law, there is a mandatory requirement to complete the processing of these applications: approval in 180 days while notification has to be processed in 90 days. Although the trend of applications received is increasing, human resource remains the same. As part of the processing, other activities need to be carried out in parallel, such as inspection of facilities. This adds to the administrative costs and requires additional funds and resources due to the surge of applications.

Funding for the Department remains a critical issue as its operating budget is limited and has not sufficiently increased to meet the demands of the responsibilities under its portfolio (**Table 4-1**). For instance, funds are needed to engage experts for the inspection of facilities and other matters.

Table 4-1
Annual Budget for the Department of Biosafety from 2012 to 2016

Year	Development Budget (RM)	Operational Budget (RM)
2012	-	1,500,000.00
2013	-	1,647,320.00
2014	425,000.00	1,611,796.00
2015	1,000,000.00	1,797,000.00
2016	900,000.00	1,722,900.00

Source: Department of Biosafety (2016)

C. Low Levels of Awareness and Understanding on Biosafety

A survey on public awareness on modern biotechnology and biosafety conducted in 2015 (sample size, *n = 1,512*) showed that only 12% of respondents were aware about regulations dealing with LMOs in Malaysia, with only 6% having knowledge on the existence of the Biosafety Act 2007, NBB and GMAC. Although various engagement programmes have been conducted over the past few years, awareness and understanding on matters related to biosafety still remains low among the general public. Low levels of awareness and understanding limit the level of participation of the public who form an important stakeholder group. For other groups, such as researchers within the scientific community, there is a perception that biosafety requirements result in an administrative burden which hampers research activities. Therefore, more efforts are required to increase awareness and understanding across all stakeholder groups on the importance and relevance of biosafety.

PART FIVE

Recommendations for the Integrated Implementation of Biosafety

The Department of Biosafety, together with other related agencies, have been instrumental in facilitating initial efforts for the integrated implementation of biosafety measures in Malaysia (refer to PART THREE). However, there are still many challenges to address due to the complexity of the subject matter, its multidisciplinary and multi-sectoral nature, and generally low awareness among stakeholders. The following section represents general recommendations and suggested actions that can be taken to address these challenges.

I. ADDRESSING GAPS IN TECHNICAL KNOWLEDGE AND SKILLS

There is a high priority to increase the technical knowledge and skills of stakeholders involved in the implementation of biosafety measures. This can be done through the intensification of capacity-building for the various target groups identified below:

a. Members and Alternate Members of Ministries at the National Biosafety Board (NBB)
b. Newly appointed Genetic Modification Advisory Committee (GMAC) members
c. Members of the proposed Integrated Committee on Enforcement and Monitoring of LMOs (refer to Section II(A) of this chapter)
d. Enforcement officers across all relevant Federal and State agencies
e. Biosafety officers and Institutional Biosafety Committee (IBC) members
f. Any other related councils and agencies

A. Enhance Capacity of the National Biosafety Board Members

Members of NBB, representing the ministries need to possess a strong understanding of biosafety in order to associate and relate the effects of biosafety-related events to issues under the purview of their respective ministries. Increasing the technical capacity of the related staff within the ministries will enable a more robust and critical deliberation, prior to any decision-making as NBB members.

Board members could play the role of a "Biosafety Officer" or as a focal person for biosafety to champion biosafety in their respective ministries and to fulfill their responsibilities in promoting awareness on biosafety and in relation to modern biotechnology, which is one of the functions of the Board. Board members can

incorporate biosafety into their ministries' events to promote research, development, educational and training activities related to biosafety. In addition, NBB members can work to provide solutions to any complications in biosafety implementation by agencies under their respective ministries. This will further strengthen their role as the biosafety focal point in their respective ministries. All these efforts require a formal top-down mechanism to assign responsibilities from higher management to each Board member to integrate the implementation of biosafety.

Due to the nature of the Malaysian civil service system, the turnover of Board members representing the various ministries has been high as officers are often transferred or promoted to other positions. Therefore, nearly all members appointed, representing the various ministries, do not complete their full three-year term. For example, since the NBB was established in 2010, the representative from most ministries has changed at least three or four times within the last five years. A mechanism has to be established to preserve the institutional and technical knowledge within the Board to ease handovers when a change of Board member representation occurs.

The Department of Biosafety suggested that the portfolio of a Board member should be made personal to holder, but retained within a ministry/agency. This will enable the appointment of competent technical officers as Board members instead of Public Administration officers who are more prone to be transferred among departments. In addition, it is proposed that an induction session by the Department of Biosafety is carried out for new Board members to introduce the subject of biosafety and to clarify their roles and responsibilities.

B. Elevate the Status of the Genetic Modification Advisory Committee Members

The role of the GMAC is pivotal to the implementation of biosafety regulations. GMAC members should be provided with recognition for their contribution as expert members of a national-level committee. These contributions are considered as a "national service" and must be formally supported by the organisations that GMAC members are employed with. For example, a Professor at an institution of higher learning can be provided flexibility in workload by the university and professional recognition in service as a GMAC member. These can be extended to include the provision of appropriate professional fees to offset the time and expertise required to conduct technical assessments.

C. Expand Network of Technical Expertise

In addition to the available expertise in GMAC, the network of local expertise available that are relevant to biosafety needs to be broadened. More experts should be identified in each specialised area so that at any one time, the expertise of several individuals are available for consultation, if needed. This also provides some

level of contingency when any GMAC members relinquish their post. It is proposed that an introductory session by the Department of Biosafety is carried out for new GMAC members to introduce them on the subject of biosafety and to clarify their roles and responsibilities.

At the same time, for expertise and support for enforcement programmes, it was suggested that IBCs in selected regions, for example, Northern, Southern, and Central Peninsular Malaysia, as well as in Sabah and Sarawak, shall be empowered to support enforcement officers.

D. Strengthen Competence of the Department of Biosafety Personnel

The level of technical competence of personnel within the Department of Biosafety personnel needs to be strengthened. The areas of biosafety relevant expertise available within the Department should be varied so that the Department's dependency on GMAC can be reduced. In addition to increasing the number of personnel, the Department needs to obtain officers who have the suitable academic background and experience. Ideally, each officer in the Department should specialise in at least two risk assessment categories (e.g. plants, fish, microbes, animals). In order to fully implement the biosafety regulation (i.e. including prosecution of non-compliance), the enforcement capacity of the Department's personnel need to be strengthened. Other skills needed are in risk communication and the diplomacy to handle public engagements and the media.

E. Improve Detection and Identification Methods

Although there is currently a sampling mechanism in place, it is only limited to the sampling of some selected Food, Feed and Processing (FFP) materials. There is no standard mechanism for the detection of other organisms, such as microbes and fish. Therefore, the Department of Biosafety has taken proactive measures to develop these detection methods, for example the collaboration with the Department of Chemistry to develop methods for GM fish detection. Similarly, novel GM traits pose a challenge for detection and identification. Studies to evaluate methods (such as the metabolomics analysis) to detect GM traits in stacked events are being carried out. However, more studies can be done as preparation for monitoring LMOs and products of emerging technologies.

II. ADDRESSING RESOURCE CONSTRAINTS

Constraints in terms of human resources, facilities, financial resources and equipment are key factors that impact the comprehensive implementation of biosafety measures in Malaysia. Even with the Government's commitment on implementing its obligations under the Cartagena Protocol on Biosafety (CPB), the human resources, facilities, financial resources and equipment remain limited and priority will ultimately be given to sectors identified as critical. The implementation of biosafety is to prevent any possible damages caused by LMOs and its products to human, plant, and animal health; the environment; and biological diversity. As no adverse effects have yet to be identified as serious, the biosafety sector is often deprived of appropriate allocations.

However, should damages occur, the consequences can be severe and irreversible, for instance, genetic pollution to the biological diversity or the unintended introduction of allergens to food. Therefore, committed funding for biosafety measures is imperative over the long term and consistent with the Government's pledge under CPB to protect the country's biological diversity from any possible damages caused by LMOs. In the short term, other opportunities can be identified to leverage upon the resources of existing government agencies (and other stakeholders) through the delegation of responsibilities and the coordination of activities.

A. Establish an Integrated Committee on Enforcement and Monitoring of LMO

The establishment of an Integrated Committee on Enforcement and Monitoring of LMO will function as a platform to coordinate and harmonise inter-agency efforts to implement biosafety measures. This will formalise the mobilisation of the Integrated Enforcement Matrix among Government Agencies (GMO/Non-GMO Enforcement) developed by the Department of Biosafety. The Integrated Committee will also provide a top-down commitment from each relevant agency to the biosafety enforcement mechanism. Each member of the Committee is expected to promote awareness on biosafety and ensure its integration within their respective agencies' enforcement framework. The Committee shall be established under the MNRE while the Department of Biosafety will function as the Committee's secretariat. Members of the Committee will comprise of appointed senior officers from the agencies listed in the Integrated Enforcement Matrix (**Appendix A-4**).

B. Implement State-Level Enforcement Framework

At the State-level, the regulation of biosafety needs to be undertaken by either an existing agency handling biodiversity or new State agency. The appointed agency will also represent this portfolio, in addition to their present portfolios at State committee meetings which would enable the integration of biosafety measures and

its relevance to biodiversity at State-level. The appointed agency will then replicate the functions of monitoring and enforcement of the Department of Biosafety at the State-level, in coordination with the Department. This would enable each State to monitor modern biotechnology activities and support outreach and awareness raising programmes. This will also strengthen State consultation if there are any applications for field trial or release activities in the respective States.

C. Mainstream Biosafety in Sectoral Policies, Plans and Programmes

Biosafety measures need to be mainstreamed across the policies, plans and programmes (PPPs) of other relevant sectors to further support the development of an integrated implementation framework. Numerous existing PPPs are undergoing review and the inclusion of a biosafety component will increase the opportunity to gain influence and financial resources to address constraints. Priority for integrating biosafety should be placed on all PPPs related to biodiversity conservation and sustainable use. As an example, Protected Areas should be safeguarded from genetic pollution by having provisions to create buffer zones from areas carrying out activities involving LMOs. Sectoral agencies should also monitor the progress of modern biotechnology activities within their portfolio.

Other possible entry points for mainstreaming biosafety include:

a. Sectoral PPPs on forestry, agriculture, commodities and health etc.;
b. Climate change adaptation and mitigation plans;
c. International trade and cooperation PPPs; and
d. National and State economic development plans.

III. ENHANCING AWARENESS AND UNDERSTANDING

Biosafety mainstreaming remains a challenge in Malaysia due to the low level of awareness and understanding of the subject matter at all levels. Since modern biotechnology is likely to continue to grow and evolve, education will be essential for the public to better understand the potential benefits and risks of modern biotechnology on society and the environment. This would allow for Malaysians to make informed decisions about the use of LMOs and to participate effectively in biosafety decision-making processes.

A. Engage with New Priority Groups

Previously, the Department of Biosafety has actively engaged with modern biotechnology industry players and research institutions leading to a niche of stakeholders that are more aware and involved with regard to biosafety requirements and regulations. Moving forward, priority groups should be expanded

to enable both top-down and bottom-up awareness mechanisms to help mainstream biosafety:

1. *Politicians and Government Officials* – Politicians and government officials involved in related disciplines such as agriculture, environment, health and biotechnology should have a more in-depth understanding of the biosafety regulatory framework. In 2012, it was found that 36% of government officials from regulatory bodies, enforcement bodies, and policy makers were not sure if there are any laws or regulations in the country to regulate GMO, while 48% of them have not heard or read about the Biosafety Act 2007.

   The Department of Biosafety could promote biosafety awareness to this target group by distributing awareness materials at official meetings attended by them. Platforms that are currently in place includes the National Biodiversity Council meeting, the National Biodiversity Technical Committee meeting, and the meeting of state Environment Ministers and Executive Committee Members responsible for the environment (MEXCOE). With increased knowledge on biosafety, they are able to incorporate biosafety into PPPs related to their portfolios.

2. *Institutions of Education* – Awareness of modern biotechnology and biosafety should begin in schools, for example at the secondary level, where biosafety can be introduced as part of the science syllabus in fundamental topics such as genetics. At institutes of higher learning, biosafety can be incorporated in subjects dealing with modern biotechnology. The Ministry of Education and the Ministry of Higher Education should work together with the Department of Biosafety to determine and develop suitable content for the syllabus.

3. *Non-Government Organisations (NGOs)* – NGOs represent partners and pressure groups that can contribute towards discussions on biosafety and generate public awareness. For example, Third World Network (TWN), World Wide Fund for Nature (WWF-Malaysia), Malaysian Biosafety and Biosecurity Association (MBBA), Malaysian Nature Society (MNS) and consumer associations have been instrumental in representing civil society on matters related to biosafety. The Department of Biosafety should collaborate and participate in NGO activities to talk about biosafety and initiate information exchange.

B. Meaningful Participation in National Level Events

In Malaysia, numerous national level events are organised by ministries and agencies in the Federal Government. These include BioMalaysia (Ministry of Science, Technology and Innovation), National Environment Week (Department of Environment), and World Biodiversity Day. By capitalising on these events, the

reach of biosafety awareness can be expanded. As a Department under the Ministry of Natural Resources and Environment, biosafety should be incorporated by default into all environment and biodiversity related events.

Similarly, NBB members representing the various ministries should take the opportunity to incorporate biosafety into their events such as during trade fairs, agricultural exhibitions, health and safety week, conferences and seminars etc. The participation should be meaningful with higher visibility such as a speaking slot for the Department of Biosafety to share the aspects of biosafety related to the event. The Department of Biosafety can also partner with the Malaysian Institute for Debate & Public Speaking (MIDP) to include debate or public speaking topics on the risks and benefits of modern biotechnology and its products. This will indirectly expose the public to issues on biosafety and the regulations that exist in the country.

C. Maximising Media Usage

According to public awareness surveys conducted in 2012 and 2015, the media was the main source of information on biosafety for the general public. Awareness raising efforts should take advantage of both traditional media and social platforms to increase the audience base. The Department of Biosafety and related agencies can develop a working relationship with media partners:

a. Establish and maintain a database of relevant media professionals (editors, journalists and reporters in the field of technology, environment, science and health)
b. Conduct media engagement activities which include workshops, awareness talks and field visits.
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Social media today represents a major platform to reach out to the masses, especially the young and urban generation. Information can be easily and quickly shared through virtual communities and networks such as on Facebook, Twitter, Reddit, YouTube as well as quick-messaging applications. For example, educational videos on biosafety can be produced and uploaded to YouTube for dissemination among the general public.

Media content sites, although less conventional compared to regular news portals, also represent good outlets for awareness raising. Websites like these operate by curating news and local issues and rewriting them into casual articles so that information can be digested easily. Although the language and presentation are informal, articles like these, coupled with 'clickbait' headlines usually drive up the interest among the general public.

To do this, the Department needs to either have a dedicated personnel to manage media topics and contacts or to work with interested parties to develop content for the public's consumption. The Department can also explore opportunities to work with drivers of science and technology on public awareness programmes, such as the Academy of Sciences, to highlight biosafety.

05 RECOMMENDATIONS FOR THE INTEGRATED IMPLEMENTATION OF BIOSAFETY

PART FIVE

Recommendations for the Integrated Implementation of Biosafety

The Department of Biosafety, together with other related agencies, have been instrumental in facilitating initial efforts for the integrated implementation of biosafety measures in Malaysia (refer to PART THREE). However, there are still many challenges to address due to the complexity of the subject matter, its multidisciplinary and multi-sectoral nature, and generally low awareness among stakeholders. The following section represents general recommendations and suggested actions that can be taken to address these challenges.

I. ADDRESSING GAPS IN TECHNICAL KNOWLEDGE AND SKILLS

There is a high priority to increase the technical knowledge and skills of stakeholders involved in the implementation of biosafety measures. This can be done through the intensification of capacity-building for the various target groups identified below:

a. Members and Alternate Members of Ministries at the National Biosafety Board (NBB)
b. Newly appointed Genetic Modification Advisory Committee (GMAC) members
c. Members of the proposed Integrated Committee on Enforcement and Monitoring of LMOs (refer to Section II(A) of this chapter)
d. Enforcement officers across all relevant Federal and State agencies
e. Biosafety officers and Institutional Biosafety Committee (IBC) members
f. Any other related councils and agencies

A. Enhance Capacity of the National Biosafety Board Members

Members of NBB, representing the ministries need to possess a strong understanding of biosafety in order to associate and relate the effects of biosafety-related events to issues under the purview of their respective ministries. Increasing the technical capacity of the related staff within the ministries will enable a more robust and critical deliberation, prior to any decision-making as NBB members.

Board members could play the role of a "Biosafety Officer" or as a focal person for biosafety to champion biosafety in their respective ministries and to fulfill their responsibilities in promoting awareness on biosafety and in relation to modern biotechnology, which is one of the functions of the Board. Board members can

incorporate biosafety into their ministries' events to promote research, development, educational and training activities related to biosafety. In addition, NBB members can work to provide solutions to any complications in biosafety implementation by agencies under their respective ministries. This will further strengthen their role as the biosafety focal point in their respective ministries. All these efforts require a formal top-down mechanism to assign responsibilities from higher management to each Board member to integrate the implementation of biosafety.

Due to the nature of the Malaysian civil service system, the turnover of Board members representing the various ministries has been high as officers are often transferred or promoted to other positions. Therefore, nearly all members appointed, representing the various ministries, do not complete their full three-year term. For example, since the NBB was established in 2010, the representative from most ministries has changed at least three or four times within the last five years. A mechanism has to be established to preserve the institutional and technical knowledge within the Board to ease handovers when a change of Board member representation occurs.

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B. Elevate the Status of the Genetic Modification Advisory Committee Members

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C. Expand Network of Technical Expertise

In addition to the available expertise in GMAC, the network of local expertise available that are relevant to biosafety needs to be broadened. More experts should be identified in each specialised area so that at any one time, the expertise of several individuals are available for consultation, if needed. This also provides some

level of contingency when any GMAC members relinquish their post. It is proposed that an introductory session by the Department of Biosafety is carried out for new GMAC members to introduce them on the subject of biosafety and to clarify their roles and responsibilities.

At the same time, for expertise and support for enforcement programmes, it was suggested that IBCs in selected regions, for example, Northern, Southern, and Central Peninsular Malaysia, as well as in Sabah and Sarawak, shall be empowered to support enforcement officers.

D. Strengthen Competence of the Department of Biosafety Personnel

The level of technical competence of personnel within the Department of Biosafety personnel needs to be strengthened. The areas of biosafety relevant expertise available within the Department should be varied so that the Department's dependency on GMAC can be reduced. In addition to increasing the number of personnel, the Department needs to obtain officers who have the suitable academic background and experience. Ideally, each officer in the Department should specialise in at least two risk assessment categories (e.g. plants, fish, microbes, animals). In order to fully implement the biosafety regulation (i.e. including prosecution of non-compliance), the enforcement capacity of the Department's personnel need to be strengthened. Other skills needed are in risk communication and the diplomacy to handle public engagements and the media.

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reach of biosafety awareness can be expanded. As a Department under the Ministry of Natural Resources and Environment, biosafety should be incorporated by default into all environment and biodiversity related events.

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To do this, the Department needs to either have a dedicated personnel to manage media topics and contacts or to work with interested parties to develop content for the public's consumption. The Department can also explore opportunities to work with drivers of science and technology on public awareness programmes, such as the Academy of Sciences, to highlight biosafety.

A-1 List of Current National Biosafety Board Members

Appendix A-1 : Malaysia's Current National Biosafety Board Members

Chairperson:

- **YBHG. DATO' SRI AZIZAN AHMAD**
  Secretary General of The Ministry of Natural Resources and Environment (NRE)

Members:

- **EN. MOHD SALLEHUDDIN HASSAN**
  Ministry of Agriculture and Agro Based Industry (MOA)
- **DATUK DR. SHAHNAZ MURAD**
  Ministry of Health (MOH)
- **MR. MOHAMAD MAHIL AHMAD**
  Ministry of Plantation Industries and Commodities (MPIC)
- **TUAN HAJI MOHD HILMI MOHD NOOR**
  Ministry of Domestic Trade Cooperatives and Consumerism (MDTCC)
- **CIK NORZITA ABU SAMAH**
  Ministry of International Trade and Industry (MITI)
- **PROF. MADYA DR. RAMZAH DAMBUL**
  Ministry of Science Technology and Innovation (MOSTI)
- **DR. ABDUL FATAH AMIR**
  Sabah Biodiversity Centre
- **PROF. DR. ROFINA YASMIN OTHMAN**
  University Malaya (UM)
- **PROF. DR. HELEN NAIR**
  Academy of Sciences Malaysia (ASM)

A-2 List of Current Genetic Modification Advisory Committee Members

Appendix A-2 : Malaysia's Current Genetic Modification Advisory Committee

Chairperson

- **DR. AHMAD PARVEEZ HJ. GHULAM KADIR**
  Malaysia Palm Oil Board (MPOB)
- **MADAM T.S. SARASWATHY**
  Institute for Medical Research (IMR)
- **PROF. DR. JOTHI MALAR PANANDAM**
  Universiti Putra Malaysia (UPM)
- **ASSOC. PROF. DR. MOHD FAIZ FOONG ABDULLAH**
  Universiti Teknologi MARA (UiTM)
- **MADAM ATIKAH ABDUL KADIR JAILANI**
  Department of Agriculture (DOA)
- **DATO. DR. SIM SOON LIANG**
  Sarawak Biodiversity Centre
- **DR. NORLIZA TENDOT ABU BAKAR**
  Malaysian Agricultural Research and Development Institute (MARDI)
- **DR. NORWATI MUHAMMAD**
  Forest Research Institute Malaysia (FRIM)
- **DR. KODI ISPARAN KANDASAMY**
  Malaysian Biotechnology Corporation (BiotechCorp)
- **DR. RAHIZAN ISSA**
  Institute for Medical Research (IMR)
- **DR. ADIRATNA MAT RIPEN**
  Institute for Medical Research (IMR)
- **MADAM LAILA RABAAH AHMAD SUHAIMI**
  Ministry of Health
- **MADAM ELLIZA MAT NOR**
  Department of Chemistry Malaysia
- **ASSOC. PROF. DR. CHOONG CHEE YEN**
  Universiti Kebangsaan Malaysia (UKM)
- **ASSOC. PROF. DR. CHAN KOK GAN**
  Universiti Malaya (UM)
- **PROF. DR. ABD RAHMAN MILAN**
  Universiti Malaysia Sabah (UMS)
- **DR. TEO TZE MIN**
  Entomological Society of Malaysia/Advanced Agriecological Research Sdn. Bhd.

A-3 Institutional Support in Relation to Biosafety

Appendix A-3 : Institutional Support in Relation to Biosafety

I. NATIONAL POLICIES

There is a total of nine national policies relevant to biosafety issues were reviewed. Of the nine, only two national policies have included strategies for biosafety while three policies explicitly include biotechnology. Ideally, biosafety should be incorporated into all policies where applicable.

A. National Policy on Biological Diversity 1998

Malaysia's National Policy on Biodiversity (NPBD) was formulated in 1998 as a comprehensive document to address national needs and requirements for the conservation of biodiversity in the country. The Policy was based on eleven principles of which the biosafety aspect was captured in the last principle: "In the utilisation of biological diversity, including the development of biotechnology, the principles and practice of biosafety should be adhered to."

This biosafety aspect was directly addressed as the sixth objective of the Policy – *To emphasise biosafety considerations in the development and application of biotechnology*, and a total of six action plans under Strategy 11 on the objective were proposed:

1. Formulate legislation and regulations on biosafety, in relation to activities and products arising from biotechnology, especially genetic engineering, including the importation, experimentation, storage and release of genetically modified organisms.
2. Ensure measures are taken to prevent the country from becoming a location for hazardous research activities.
3. Establish a committee on biosafety that includes representatives from the environment, health and research fields, and keep abreast of developments in this field in the international arena.
4. Adopt an Environmental Impact Assessment (EIA) procedure for biotechnology research and activities, including the assessment on safety and social impacts.
5. Establish an enforcement unit on biosafety within an appropriate government department.
6. Develop training programmes in biosafety management and practice.

The establishment of Department of Biosafety and the National Biosafety Board had geared towards the implementation for most of these action plans. In 2007, the Malaysian Biosafety Act was enacted, followed by the Biosafety (Approval and Notification) Regulations 2010, as well as several Guidelines to operate alongside the Act and Regulations. These Guidelines include the Environmental Risk Assessment for GMO plants and the Risk Assessment for GMO microorganisms.

B. National Policy on Biological Diversity 2015-2020

The National Policy on Biological Diversity 2015-2025 (NPBD) is a revised policy to the National Policy on Biological Diversity 1998. Launched in February 2016, the NPBD has five goals on enabling stakeholder empowerment, reducing pressures on our biodiversity, safeguarding our ecosystems, species and genetic diversity, ensuring equitable sharing of benefits from biodiversity and building the capacity of all stakeholders.

Biosafety is specifically addressed in **Goal 2, Target 12**: *a comprehensive biosafety system inclusive of a liability and redress regime is in place to manage potential adverse impacts of modern biotechnology on the conservation and sustainable use of biodiversity and human health*. The target was formulated in line with the Aichi Biodiversity Targets 9 & 10.

Three actions were proposed in achieving Target 12 in the NPBD. The Ministry of Natural Resources (NRE) in partnerships with the Ministry of Agriculture and Agro-Based Industry (MOA), with support from Department of Biosafety, will carry out these following actions within the NPBD's timeline namely:

- Action 12.1 Enhance inspection and biosafety compliance
- Action 12.2 Assess impacts of modern biotechnology on human health and biodiversity
- Action 12.3 Develop response to biosafety emergencies

C. National Agrofood Policy 2011-2020

The National Agro-Food Policy (NAP) 2011-2020 was developed to serve as a reference for agriculture development in the country. Its main objectives are to ensure sufficient food supply and to increase farmers' income. The NAP does not include any element on biosafety for agriculture while biotechnology was highlighted in two Strategic Actions:

- Strategic Action IV: Empowering human capital – agricultural programmes in institutions of higher learning will be strengthened and improved to focus on areas such as biotechnology, agricultural mechanisation, horticulture, and farm supply management.
- Strategic Action V: Strengthen the R&D activities, innovation and use of technology – Stimulate the use of modern technology by extending the reinvestment allowance to all agricultural activities such as precision farming, the use of ICT and biotechnology will be enhanced in the field and the food processing industry.

From the policy, biotechnology is a potential means of cultivating high-value agricultural crops, namely livestock, herbs and spices, as well as floriculture. These areas should integrate biosafety at the planning stage as well as acknowledge the necessary requirements and regulations under the Biosafety Act.

D. National Commodities Policy 2011-2020

The National Commodities Policy (NCP) 2011-2020 addresses commodity industries separately from agriculture activities, which was previously placed together under the Third National Agriculture Policy. The main objectives of the NCP 2011-2020 are to increase the contribution of commodities industries to the national economy, to encourage growth and to raise income levels of industry players.

The NCP does not mention biosafety however biotechnology was mentioned in **Thrust 7** of the Policy.

- Thrust 7: Develop and strengthen human capital

With regards to Biotechnology in the commodities industry, collaboration with local and foreign higher education institutions towards improving skills and knowledge in biotechnology as well as mechanisation and agricultural engineering is required to increase commodity production. The policy also proposed research and development (R&D) for all major commodities to increase the production of value-added crops. Specifically, for areas in R&D, the NCP should integrate biosafety at the initial stages of planning as well as acknowledge requirements and regulations under the Biosafety Act.

E. National Biotechnology Policy 2005

The National Biotechnology Policy aims to spur biotechnology as a new engine for economic growth which will leverage upon the country's rich flora and fauna diversity. The implementation of the National Biotechnology Policy encompasses three phases starting from capacity building (2005-2010), transforming biotechnology to business by developing drugs based on natural resources (2011-2015) and forging a global presence in drug discovery and development (2016-2020). It is intended that by 2020 Malaysia will be a global player in biotechnology and will generate at least 20 global Malaysian companies. The key features to achieving these goals were to establish of the Malaysian Biotech Corporation, the creation of BioNexus Malaysia (a network of centres of excellence in specific biotech sub-sectors), and by providing competitive financial incentives. Although this Policy was specifically developed for biotechnology, it should integrate biosafety and recognise the Biosafety Act in the planning of all biotechnology research in areas such as agriculture, healthcare as well as R&D.

F. National Forestry Policy 1978 (Revised 1992)

The National Forestry Policy 1978 (revised 1992) recognises the importance of tropical rain forests as a renewable resource that has vital socio-economic benefits. The Policy aimed to conserve and manage the nation's forest, based on the principles of sustainable management while protecting the environment and the conservation of biological diversity and genetic resources. The Policy highlights the need to intensify research in forestry to achieve environmental stability, sustainable forest management and maximum forestry production.

The Policy has no specific relation to biosafety or biotechnology.

G. National Green Technology Policy 2009

The National Green Technology Policy aims to accelerate the national economy and to promote sustainable development. Progress and improvements towards achieving a green economy were focused on four areas namely:

1. Application of green technology in energy supply and utilisation sectors
2. Adoption of green technology;
3. Green technology in water and waste management sector
4. Incorporation of green technology in the transportation sector.

The Policy does not reference biosafety or biotechnology. However, it is necessary for all future planning of a green economy to acknowledge the requirements and regulations of the Biosafety Act.

H. National Policy on Climate Change 2009

The National Policy on Climate Change (NPCC) aims to ensure that development is climate-resilient to fulfil national aspirations for sustainability. The Policy recognised that the impacts of climate change could affect the environment and threatened the sustainability of natural resources, including food, water and energy.

Biosafety is not explicitly addressed in this Policy. However, climate change should be taken into account in the Environmental Risk Assessment (ERA) of LMO's receiving environment.

Biosafety activities can fit into Principle 3 of the NPCC - *Incorporate climate change considerations into the implementation of development programmes,* where Strategy Thrust 7 supports knowledge-

based decision making through intensive climate-related research and development as well as capacity building of human resource. Biosafety can be incorporated into activities such as:

- KA28 - ST7: Establish and implement a national R&D agenda on climate change in areas such as Agriculture and food security, Public health services and delivery, Vulnerability due to extreme weather events and natural disasters and Policy analysis harmonising national and international issues.
- KA31 - ST7: Promote pragmatic cooperation programmes through effective mechanism and tools for technology cooperation, collaborative R&D to access knowledge and technologies, support endogenous development and diffusion of technology and lastly regional cooperation on technology development.
- KA32 - ST7: Identify a coordinating mechanism to oversee R&D activities, information dissemination, avoidance of duplication, and to support decision making.

I. National Policy On the Environment 2002

The National Policy on the Environment was developed in 2002 taking into cognisance that the nation's growth has drawn from the country's natural resources, for economic, social, and cultural progress. Thus, there is a need to develop and utilise natural resources sustainably, avoiding indiscriminate resource utilisation, over-consumption, and non-sustainable development practices.

The NPE does not specifically include biosafety however biotechnology is mentioned in Strategy 4.9 - *Agricultural practices and technologies which minimise the use of pesticides and inorganic fertiliser shall be encouraged.* The requirements and regulations of the Biosafety Act should be recognised especially in planning biotechnology R&D for agriculture practices.

Strategy 5 of the NPE can also be applicable to biosafety as it emphasised on the need to streamline and coordinate all decision-making mechanisms related to the environment.

II. NATIONAL ACTS AND REGULATIONS

A. Malaysian Biosafety Act 2007

The Biosafety Act 2007 describes the Malaysian regulation and guidelines framework on LMOs and the product of such organisms. The Act's objective is to protect human, plant and animal health, the environment and biological diversity, by regulating the release, importation, exportation and contained use of LMOs, and the release of products of such organisms. The Act provides regulations on the release and import approval; export and contained-use notification; enforcement; risk assessment and emergency response plan for LMOs. The Biosafety Act creates a centralised public access database of approved LMOs and products of organisms in Malaysia. This database is available within the Malaysia Biosafety Clearing House website.

The Act also establishes the National Biosafety Board (NBB), as the statutory board to administer and make decisions under and in accordance with the Act and the Regulations; as well as to establish the Genetic Modification Advisory Committee (GMAC) in order to provide scientific, technical and related advice to the NBB. The Biosafety Act 2007 requires all LMOs, products containing LMOs and products of such organisms to be identified and labelled in a prescribed manner.

B. Biosafety (Approval and Notification) Regulations 2010

The Biosafety (Approval and Notification) Regulations came into force in 2010 to facilitate the implementation of the Act and its operation of certain provisions of the Act.

The Regulations cannot be applied to products of such organisms deemed as pharmaceuticals which are addressed by relevant international treaties or organisations or regulated under any other written laws relating to pharmaceuticals.

The Regulation specifies the techniques for LMOs in the First Schedule, the classes of modern Biotechnology activities in the Second Schedule and the fees in the Third Schedule. Other provisions under the regulation entail the purpose of establishing an institutional biosafety committee such as:

a) Provide guidance for safe use of modern biotechnology;
b) Monitor activities dealing with modern biotechnology;
c) Establish and monitor the implementation of policies and procedures for the purpose of handling LMOs; and
d) Determine the classes of Biosafety Levels for contained use activity for the purpose of modern biotechnology research and development.

C. Animals Act 1953 (Revision 2006)

The Animals Act was gazetted in 1953 and later on revised in 2006. The Act describes the laws for preventing the introduction into, and the spreading within Malaysia of animal diseases; the control of animal movements into, within and from Malaysia; the control of animal slaughters; the prevention of animal cruelty; measures pertaining to the general welfare, conservation and improvement of animals in Malaysia.

With regards to biosafety, the Animal Act 1953 (revised 2009) authorised by the Department of Veterinary Services (DVS) under the purview of the Ministry of Agriculture and Agro-based Industries, has the power to control activities such as:

- Import or export of GM animals and associated products
- Import or export of GMO vaccines or biologics for animals
- Local production of GMO vaccines or biologics for animals

However, the Department has not dealt with cases related to biosafety as imports or exports of GM animals are currently quite rare.

D. Feed Act 2009

The Feed Act 2009 only applies to the States in Peninsular Malaysia and the Federal Territory of Labuan. The Animal Feed Section under the Division of Livestock Resources and Technology Development of DVS enforces the feed quality by controlling importation, manufacture, sale and use of feed and feed additives. The Act also ensures that feed should satisfy the nutritional requirement of animals and are not contaminated in order for both animals and animal products to be safe for human consumption and other uses.

The Feed Act states that no person is allowed to import any feed or feed additive without a valid license. The application for a license to import feed or feed additive can be made to the National Animal Feed Board. It is also a requirement that all feeds imported, manufactured, distributed, possessed, sold or utilised for the feeding of animals must comply with the prescribed feed specifications under this Act. This Act also controls the use of antibiotics, hormones and other chemicals in relation to animal feed.

With regards to biosafety, the Feed Act 2009 has the power to regulate the import of Animal Feed (AF) and Animal Feed Additives (AFA) that contains GMO. These include cereals, grains, premixes, pigments, supplements, mould inhibitors and absorbents as well as chemicals.

E. Fisheries Act 1985

The Fisheries Act 1985 is related to all fisheries activity in Malaysia including conservation, management and development of maritime and estuarine fishing and fisheries in Malaysian waters, turtles as well as riverine fishing in the country.

With regards to Biosafety, the Fisheries Act requires the approval of the Director General for all import and export as well as the local production of GMO vaccines and biologics for fish in the country. The Fisheries Biosecurity Division under the Department of Fisheries, together with Department of Biosafety, are responsible for the control of GM fish importation into Malaysia.

F. Food Act 1983

The Food Act 1983 aims to protect the public against health hazards and fraud in the preparation, sale and use of food and other relevant matters throughout Malaysia. The Ministry of Health is responsible for the implementation and enforcement of the Act in Malaysia.

The Act regulates the hygiene and sanitary of food premises and all appliances used for preparation, preservation, packaging, storage, conveyance, distribution and sale of food. Importation of food that does not comply with the provisions of the Act or any regulation made under the Act is prohibited. Manufacturers or distributors of any food are not allowed to sell to any vendors without a written warranty or other written statement given that the food complies with the Act and food regulations.

With regards to biosafety, the Food Act 1983 regulates both non-GMO and GMO food and food products. Under this Act, the Ministry of Health Malaysia developed the Guidelines for Labelling Biotechnology Food in 2014 which requires food and food ingredients obtained through biotechnology to be labelled. The labelling guidelines include the following:

i. Labelling requirements do not apply when GMO content is not more than three percent "provided that this presence is adventitious or technically unavoidable";
ii. For single ingredient foods, the words "genetically modified (name of ingredient)" must appear in the main display panel;
iii. For multi-ingredient foods, the words "produced from genetically modified (name of ingredient)" must be stated on the main display panel;
iv. Highly refined foods, defined as those where processing has removed all novel DNA and protein, is exempt from the labelling requirement. (e.g.: vegetable oils, corn syrup, acidic foods, and salty foods);
v. Meats from animals fed with genetically modified grains are exempt;
vi. The only GMO events that can be used for foods and food ingredients are those that have been approved by the National Safety Board.

A number of regulations were gazetted to strengthen the enforcement of the Food Act. This includes the Food (Amended) Regulations 2010 which enforces the labelling of GMO ingredients in food products. This provides consumers with more information to make decisions on products they are buying and consuming.

G. Food Regulations 1985 (Amended 2010)

In September 1985, the Food Regulations was gazetted to regulate all import, manufacture, advertisement and sale activities related to labelling, food additives, packaging, standards and labelling requirements for a range of food and drinks product as well as the use of water, ice and steam.

The Food Regulations was later amended in 2010 to include a new part on approval and sale of food obtained through modern biotechnology as well as the provision on labelling matters. The Regulation specifically mentions all imports or sale of any food and food ingredients obtained through modern biotechnology must be approved and for clear labelling of GMO products must be shown.

H. Malaysian Quarantine and Inspection Services Act 2011

This Act controls the quarantine, inspection and enforcements on entry points, quarantine stations and premises for plants, animals, carcasses, fish, agricultural products, soil and microorganisms. It also regulates Malaysia's imported and exported food which adhere to the aspects of human, animals, plants and fish health and food safety. The Malaysian Quarantine and Inspection Services (MAQIS) Act 2011 should be used conjointly with other written laws including:

a) Plant Quarantine Act 1976
b) Animals Act 1953
c) Fisheries Act 1983
d) Federal Agricultural Marketing Authority Act 1965
e) Malaysia Fisheries Development Board Act 1971

Any enforcement and inspection at entry points or quarantine stations related to food will be in accordance with the Food Act 1983. The Act also states the requirement for a valid permit or certificate for importing any plant, animal, carcass, fish, agricultural product, soil and microorganisms. The issuance of any permit, licence or certificate by MAQIS must be in accordance with any policies, directives and requirements determined by DVS, DOA and DOF.

With regards to biosafety, the MAQIS Act regulates both import and export permits for GMO-related materials such as organisms, bio-fertilizers, vaccines/biologics for animals, fish and fish products, animal and associated products as well as animal feed.

I. Pesticides Act 1974

The Pesticides Act 1974 is enforced by the Pesticide Control Division under the purview of DOA. The Act controls all import, manufacture, sale, storage, research and use of pesticides throughout Malaysia. All import and manufacturing of pesticides must be registered and application for a licence has to be made. The Act also regulates the presence of pesticides in food and entitles the right to an officer to analyse food. Under the Pesticides Act, there are Guidelines on Application for Permit to Import Pesticide for Education or Research Purposes.

This Act was gazetted to ensure that all pesticides are registered before being marketed into the country and registration has to be renewed within every three years. Under the relevant sections of the Act, seven sets or rules and regulations have been gazetted as below:

- Pesticides (Pest Control Operator) Rules 2004
- Pesticide (Advertisement) Regulations 1996
- Pesticide (Highly Toxic Pesticides) Regulations 1996
- Pesticides (Licensing for Sale and Storage for Sale) Rules 1998
- Pesticides (Labelling) Regulations 1984
- Pesticides (Registration) Rules 1976

In relation to biosafety, the Pesticides Act regulates bio-pesticides and pesticides that contain GMO and/or similar products of such derivation. It also provides an avenue to monitor and regulate pesticide traces in food, such as products from pesticide-tolerant GM crops.

J. Plant Quarantine Act 1976

The Plant Quarantine Act 1976 provides DOA Malaysia with the legislative power to carry out preventive and eradicative measures to safeguard the agriculture industry. The Act aims to control, prevent and eradicate agricultural pests, noxious plants and plant diseases and to extend cooperation in controlling the movement of pests in international trade.

With regards to biosafety, the Plant Quarantine Act regulates the importation of GM microorganism deemed pathogenic to plants, humans, animals, fish and the environment as well as to GM plants, plant products and aquatic plants. The Act also controls the import and export of GM microorganisms from Peninsular Malaysia to Sabah and Sarawak.

K. Plant Quarantine Regulation 2005

In 1981, the Plant Quarantine Regulations came into force to strengthen the Plant Quarantine Act and was later amended in 2005. The Regulations stipulate the requirements for the importation of plants, plant products, growing media/rooting compost, beneficial organisms, plant pests and carrier of plant pest into Malaysia in order to prevent the entry and spread of noxious plants and pests. Importation of plants or plant products requires a permit and a phytosanitary certificate will be issued to the exporter. The phytosanitary certificates verify that the products have been inspected, treated and are pest and disease free. The Regulations further provide for restriction on imports of various plants, eradication and control of dangerous pests as well as inspection, quarantine or destruction of plants.

L. Poisons Act 1952

The Poisons Act regulates the importation, possession, manufacture, compounding, storage, transport, sale and use of poisons in Malaysia. The Act establishes the Poisons Board consisting of 13 members, four of which are government officers and five Malaysian residents who are not in the service of any government department. The Board has the power to regulate its own procedures.

All poison sold or supplied must be kept as a record in a Prescription Book. Licence to import, sell, store and manufacture must be applied and registered in each state. There are five types of licence that can be issued under this Act including licences issued to pharmacists as well as persons who store and sell such products and are verified by the licencing officer.

In relation to biosafety, the Poisons Act and the related Regulations below requires all import and sale of human vaccines and biologics derived of GMO and non-GMO products to be registered with the Pharmaceutical Services Division (PSD) of the Ministry of Health. Locally produced vaccines and biologics made of GMO are also required to be registered with the PSD.

M. Poisons Regulation 1952

The Poisons Regulation 1952 came into operation to regulate the imports, storage, labelling and colouring of poisons as well as the controlling and prohibition of lead tetra ethyl. The Poisons Regulation also regulates the supply of poisons in hospitals and institutions as well as provides forms for licensing and fees.

N. Poisons (Psychotropic Substance) Regulations 1989

In April 1989, the Minister also gazetted the Poisons (Psychotropic Substance) Regulations 1989 to regulate and control the possession, import and export, sale and supply, issuance of permits, storing, labelling and manufacturing psychotropic substances.

O. Prevention and Control of Infectious Diseases Act 1988

The Prevention and Control of Infectious Diseases Act was gazetted in 1988 and later amended in 2006. The Act applies throughout the states in Malaysia and aims to prevent and control infectious diseases that may harm human and animals. Under this Act, a Minister can declare an area infected upon receiving notification from the International Health Regulations as well as prescribe measures to prevent the introduction or spread of infectious disease into Malaysia from the supposed infected area. The Act also lists the infectious diseases in the First Schedule.

With regards to Biosafety, the approval for import and exports of GM human tissues, pathogenic organisms and substance and GM microorganisms used in producing human vaccines or biologics into Malaysia is regulated by the Disease Control Division under MOH. Application of permits to import and export human remains, human tissues and pathogenic organism are also required and are issued by the MOH. Under this Act, the Prevention and Control of Infectious Disease (Importation and Exportation of Human Remains, Human Tissues and Pathogenic Organisms or Substance) Regulations 2005 was drafted.

P. Prevention and Control of Infectious Disease (Importation and Exportation of Human Remains, Human Tissues and Pathogenic Organisms or Substance) Regulations 2005

In 2005, the Prevention and Control of Infectious Diseases (Importation and Exportation of Human Remains, Human Tissues and Pathogenic Organisms or Substance) Regulation came into place. The Regulation specifies all activities related to imports and exports of human remains, human tissues and pathogenic organisms, issuance of permits, prescribed feed as well as penalties and offences.

In relation to biosafety containment, the regulation specifically mentions in the terms and conditions the need to conduct tests on imported human remain, tissues or pathogenic organisms in laboratory facilities which are of biosafety level 2 and 3.

There are four biosafety levels (BSL) for containment based on existing international approaches to pathogenic organisms. These include BSL 1, 2, 3 and 4, which are arranged in order of increasing stringency reflecting the levels of risk involved.

Q. Protection of New Plant Varieties Act 2004

The Protection of New Plant Varieties Act 2004 (PNPVA) came into effect on 20 October 2008 and provides protection of breeder's rights also known as Plant Variety Protection (PVP) to their registered plant varieties for the purposes of breeding, research and commercialization. The Act also recognises and protects contributions made by farmers, local communities and indigenous people towards the creation of new plant varieties and provides intellectual property protection for plant breeders, particularly those looking to exploit the rich local biodiversity for research in natural products and traditional medicine. The responsibility for implementing the PNPVA 2004 has been entrusted to the DOA Malaysia.

The PNVA also provides for the establishment of the Plant Varieties Board. The Board comprises of the Director General of various government agricultural departments as well as a representative of the Ministries of Agriculture and Agro-Based Industry, Plantation Industries and Commodities, Domestic Trade, Cooperatives and Consumerism, Domestic Trade and Consumer Affairs and Science, Technology and Innovation. There are two categories of applicants under the PNPVA namely a plant variety which is new, distinct and identifiable and a plant variety which is new, distinct, uniform and stable.

R. Sale of Drugs Act 1952

The Sale of Drugs Act was gazetted in 1952 and later revised in 1989. The Act is related to the sale of drugs which includes all substance, product or article used on humans or animal for medicinal purposes throughout Malaysia. Officers and inspectors are appointed by the Chief Minister of each State and are responsible for conducting duties as described in the Act.

With regards to biosafety, the Sale of Drugs Act regulates the approval of GM vaccines or biologics for human as well as other GM pharmaceutical products.

S. Control of Drugs and Cosmetics Regulation 1984

In 1984, The Control of Drugs and Cosmetics Regulation was gazetted to strengthen the enforcement of the Drug Act 1952 and provide regulations on registering and licensing of products (which means drugs in a dosage unit or a drug to be used as an ingredient). The Regulation provides for the establishment of the Drug Control Authority and the manufacturing, sale, supply, import and possession of any related products must be registered with the Drug Control Authority. Following this Regulation, a Drug Registration Guidance Document was produced to serve as a reference guide for the registration process including quality control and licensing and post-registration activities for medicinal products.

In relation to Biosafety, any production, importing or selling of pharmaceutical products containing LMOs requires approval from the Pharmaceutical Services Division of MOH.

T. Strategic Trade Act 2010

The Strategic Trade Act (STA) 2010 is the legislation that controls the export, transhipment, bring in transit and brokering of strategic items, including arms and related material, and other activities that may facilitate the design, development and production of weapons of mass destruction and their delivery systems consistent with Malaysia's national security and international obligations. This Act is consistent with Malaysia's international obligations on national security. A valid permit or registration certificate is required for all export, tranship, transit of brokering of any strategic items from the relevant Authorities.

With regards to biosafety, the STA 2010 regulates and requires a permit to export, tranship and bring in transit of strategic items specifically GMOs that contain nucleic acid.

A-4 Integrated Enforcement Matrix among Government Agencies

Appendix A-4 : Integrated Enforcement Matrix among Government Agencies

MINISTRY	RELATED GOVERNMENT AGENCIES AND NATIONAL ACTS / BIOTECHNOLOGY RESEARCH / PRODUCT		Microorganisms involved with:								Human Tissue / Others		Fish*		Animals and Associated Products		Plants and Associated Products, Controlled Articles & Aquatic Plants			Vaccine / Biological						Others		
			Approval																	Human		Animal		Fish				
			Human	Human Food	Biopesticides	Biofertilizer	Bioremediation	Pathogenic	Import / Export to Sabah and Sarawak	Import Permit	Approval	Import / Export Permit	Approval	Import / Export Permit	Approval	Import / Export Permit	Approval	Import Permit	Export Permit	Approval	Import / Export Permit	Approval	Import / Export Permit	Approval	Import / Export Permit	Pharmaceutical Product	GMO Detection	Pet Food and Plant Material
MOA	**Department of Veterinary Services**																											
MOA	Animals Act 1953 (Revision 2006)	Quarantine and Import / Export Section													✓													
MOA	Animals Act 1953 (Revision 2006)	Zoonosis and Public Health Section (ZOOKA)																				✓ [a]						
MOA	Feed Act 2009	Animal Feed Section																										✓ [c]
MOA	**Malaysian Quarantine and Inspection Services Department (MAQIS)**																											
MOA	Malaysian Quarantine and Inspection Services Act 2011 (Act 728)	Permit Division								✓ [b]				✓		✓							✓		✓			✓ [c]
MOA	**Department of Agriculture**																											
MOA	Plant Quarantine Act 1976 (Act 167)	Plant Biosecurity Division (JKTPMOBO)	✓	✓	✓	✓	✓	✓	✓	✓																		
MOA	Plant Quarantine Act 1976 (Act 167)	Plant Biosecurity Division (Pest Risk Analysis Committee)															✓	✓										
MOA	Pesticides Act 1974	Pesticide Control Division (Pesticide Board)			✓																							
MOA	**Department of Fisheries**																											
MOA	Fisheries Act 1985 (Act 317)	Fisheries Biosecurity Division											✓															
MOA	Fisheries Act 1985 (Act 317)	Director of Fisheries																						✓				
NRE	**Biosafety Department**																											

	Biosafety Act 2007	National Biosafety Board / Enforcement and Monitoring Section		**GM**	**GM**	**GM**	**GM**	**GM**					**GM**		**GM**		**GM**[d]			**GM**[d]		**GM**[d]		**GM**		**GM**[e]	**SPP**	**GM**
MOH	**Food Safety and Quality Division**																											
	Food Act 1983 (Act 281)	Food Safety and Quality Division		✓[f]																								
	Disease Control Division																											
	Prevention and Control of Infectious Diseases Act 1988 (Act 342)	International Health Sector / Infectious Disease Branch	✓					✓			✓	✓							✓[M]	✓[M]								
	Pharmaceutical Services Division																											
	Poison Act 1952	National Pharmaceutical Control Bureau																	✓[D]							✓		
	Sale of Drugs Act 1952																											
MOSTI	**Department of Chemistry Malaysia**																											
	Biosafety Act 2007	GMO Unit																									✓	

Note:

✓[a]	Clinical test and sale
✓[b]	Biofertilizer that contains animal ingredients such as animal stools
✓[c]	MAQIS controls animal feed and DVS controls animal feed additives
GM[d]	Controlled use and production
GM[e]	Regulated by Sale of Drugs Act 1952
✓[f]	“Only involves human food, enforcement on food labelling under Food Regulations 1985 {Part IV, Regulation II[3A], II[6] and II[7]}”
Fish[*]	Fish as defined in Fisheries Act 1985
✓[M]	Microorganism
✓[D]	Drug
SPP	Enforcement and Monitoring Section
JKTPMOBO	Technical Committee for Import of Microorganisms and Organic Matter