User's Guide to the Biosafety Act and Regulations

User's Guide to the Biosafety Act and Regulations

DEPARTMENT OF BIOSAFETY

Ministry of Natural Resources and Environment Malaysia

Level 1, Podium 2, Wisma Sumber Asli
No. 25, Persiaran Perdana
Precinct 4, Federal Government Administrative Centre
62574 Putrajaya
MALAYSIA.

T: +603 8886 1580 / 1579
F: +603-8890 4935
E: biosafety@nre.gov.my, letchu@nre.gov.my
W: http://www.biosafety.nre.gov.my

The Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010, Guidelines for Institutional Biosafety Committees and Biosafety Guidelines for Contained Use Activity of Living Modified Organism may be downloaded from the Malaysian Biosafety Website at http://www.biosafety.nre.gov.my

Any future regulations, guidelines and related documents will be posted to this website.

ACKNOWLEDGEMENT

The Department of Biosafety, Ministry of Natural Resources and Environment (NRE), acknowledges the work of the Centre of Excellence for Biodiversity Law (CEBLAW), in particular, Professor Gurdial Singh Nijar (assisted by Researcher Gan Pei Fern) in preparing this User's Guide.

GLOSSARY OF TERMS AND ACRONYMS USED

Act	Malaysian Biosafety Act 2007 (Act 678)
BRAC	Biosafety Regulations Advisory Committee
BSL	Biosafety Level
BSO	Biological Safety Officer
CBI	Confidential business information
CEBLAW	Centre of Excellence for Biodiversity Law
DOA	Department of Agriculture
DOB	Department of Biosafety
DG	Director General of Biosafety
GM	Genetically modified
GMAC	Genetic Modification Advisory Committee
GMO	Genetically modified organism
HRM	Human Resource Management Division, NRE
IBC	Institutional Biosafety Committee
IPD	information, particulars or documents
LMO	Living modified organism
MAQIS	Malaysian Quarantine and Inspection Services
MOA	Ministry of Agriculture and Agro-based Industry
MOH	Ministry of Health
MOSTE	Ministry of Science, Technology and Environment
MOSTI	Ministry of Science, Technology and Innovation
MPOB	Malaysian Palm Oil Board
NBB	National Biosafety Board
NGOs	Non-Governmental Organisations
NRE	Ministry of Natural Resources and Environment
OSHC	Occupational Safety and Health Committee
PI	Principal Investigator
TWN	Third World Network
UNDP	United Nations Development Programme
Regulations	Malaysian Biosafety (Approval and Notification) Regulations 2010

CONTENTS

ABOUT THIS USER'S GUIDE

What is the purpose of this User's Guide?

On 11 July 2007, Parliament passed the *Malaysian Biosafety Act 2007*. The Act came into force on 1 December 2009. The *Biosafety (Aproval and Notification) Regulations 2010* were passed and came into force on 1 November 2010 to implement the Act. Together they represent a new national scheme for the regulation of living modified organisms (LMOs)[1] and products of LMO. This User's Guide has been developed as a resource for organisations that conduct work with LMOs. The User's Guide will help organisations to understand and comply with the requirements of the new regulatory system for LMOs.

The User's Guide includes chapters on each of the key aspects of the scheme including:

- Activities involving LMOs that are, and are not, regulated under the national regulatory scheme;
- Regulation of import of LMO;
- Regulation of release activity involving LMO;
- Regulation of contained use of LMO;
- Regulation of export of LMO;
- Regulation of products of LMO;
- Confidential business information;
- Review of decisions made under the legislation;
- Reporting, monitoring and enforcement;
- The Malaysian Biosafety Website; and
- Fees and charges.

---

[1] The term "LMO" refers also to genetically modified organism (GMO).

The User's Guide should be read together with the following documents:

- Application forms for persons wishing to carry out activities involving LMOs under the legislation;
- The Guidelines for the establishment and operation of the Institutional Biosafety Committees (IBCs) published by the Ministry of Natural Resources and Environment (NRE) known as *Guidelines for Institutional Biosafety Committees: Use of Living Modified Organisms and Related Materials*;
- The *Biosafety Guidelines for Contained Use Activity of Living Modified Organism*; and
- Forms relevant to the establishment and operation of IBC.

It is expected that the User's Guide will be used as an ongoing resource for applicants or users of the regulatory scheme. Copies of the User's Guide may be downloaded from the Malaysian Biosafety Website at *http://www.biosafety.nre.gov.my.*

IMPORTANT NOTE

The User's Guide is explanatory only and is intended to help organisations and individuals undertaking activities involving LMOs to understand how the national regulatory scheme works. It does not dispense with the need to read and understand the Biosafety Act 2007 and the Biosafety (Approval and Notification) Regulations 2010 and, where necessary, obtain independent expert advice. Further information may also be obtained from the Department of Biosafety (DOB).

BACKGROUND INFORMATION ABOUT THE NATIONAL REGULATORY SCHEME FOR LMOs

CHAPTER 1

Part A: Development of the national regulatory scheme

The *Malaysian Biosafety Act 2007* was passed by Parliament on 11 July 2007 and received the Royal Assent on 29 August 2007. It came into effect on 1 December 2009. This marked a significant end to a long and arduous process for its promulgation. The Act represents Malaysia's fulfillment of its international obligations as a Party to the Cartagena Protocol on Biosafety, which it ratified on 3 September 2003.

Establishment of a Taskforce

A taskforce was established by the Prime Minister's office to produce a draft biosafety law. Professor Zakri Hamid, then deputy Vice Chancellor of Universiti Kebangsaan, was appointed by the Government as Chair of the taskforce. The Ministry of Science, Technology and Environment (MOSTE)[2] was the lead agency for the promulgation of the law. The taskforce consisted of representatives of relevant Ministries. It met over several years and finally produced a draft of the Biosafety Act in the form of a bill in accordance with established procedures for the promulgation of a law.

Cabinet approval

The draft bill was then presented to the Cabinet for its approval. The Cabinet approved the Bill. However as a result of

[2] MOSTE was later split into MOSTI and NRE in 2004. NRE then continued as the lead agency dealing with matters pertaining to biosafety.

representations made by the biotechnology industry, the Bill was returned to NRE and another round of consultations ensued. The bill was then finalized and re-presented to the Cabinet. Again, as a result of representations the Bill was returned for further consultations with key actors including the Biotech Corporation, a statutory body set up to facilitate and promote investments in the biotechnology sector. Further consultations were duly carried out with all stakeholders including Biotech Corporation, the Malaysian Manufacturers Association, Consumers Association and other NGOs. The draft that resulted was presented to the Cabinet which gave its approval for the Bill to be tabled in Parliament.

Introduction and passage of the legislation through parliament

The Biosafety Bill was tabled in the House of Representatives (Dewan Rakyat) for its first reading on 22 November 2006. The Dewan Rakyat approved the Bill on 27 June 2007. On 11 July 2007 the Dewan Negara (Senate) approved the Bill. The King gave his Royal Assent on 29 August 2007. The Minister brought the Biosafety Act into force on 1 December 2009. The *Biosafety (Approval and Notification) Regulations* came into force on 1 November 2010.

BOX 1: Chronology of events relating to the enactment of the Biosafety Act 2007 and the Biosafety Regulations 2010

Dates	Activities
22 Nov 2006	The first reading of the Biosafety Bill at Dewan Rakyat
09 May 2007	Second and third reading of the Biosafety Bill at Parliament postponed
16 May 2007	Secretary-General of NRE met with GMAC members
19 May 2007	GMAC members discussed industry concerns
24 May 2007	Secretary-General NRE met with Secretary-General MOSTI
29 May 2007	Industry dialogue on the Bill organised by Biotech Corporation and MOSTI

20 June 2007	NRE sends memorandum to Cabinet. Cabinet approves Biosafety Bill after amendments made
25-27 June 2007	Second and Third reading of the Biosafety Bill at Dewan Rakyat
11 July 2007	Biosafety Bill tabled at Dewan Negara The Biosafety Act 2007 was passed by Parliament on the same day
29 Aug 2007	Royal Assent for the Biosafety Act 2007
30 Aug 2007	Publication of the Biosafety Act 2007 in *Gazette*
31 Jan 2008	Biosafety Regulations Advisory Committee (BRAC) formed
22 Feb 2008	Meeting with Ministry of Finance, Public Service Department and HRM on the formation of a Biosafety Department
22 Feb 2008	Memo together with proposal paper on the formation of a Biosafety Department and positions to be filled was sent to HRM for further action
29 Feb 2008	BRAC meets
19 Sept 2008	GMAC meets to discuss biosafety regulations
23 Sept 2008	BRAC meets
23 Oct 2008	NRE meets related ministries and their agencies to discuss issues relating to the Biosafety Act and the comments received from Biotech Corporation, chaired by the Secretary-General of NRE
6 Nov 2008	NRE had consultancy meeting with NGOs and the Industry to discuss issues relating to the Biosafety Act, chaired by the Secretary-General of NRE
22 Jan 2009	NRE sends draft Biosafety Regulations to AG's Chambers
3 Mar 2009	NRE receives draft Biosafety Regulations as vetted and amended by AG's Chambers
19 Mar 2009	First Ministerial level meeting on the implementation of the Biosafety Act

24 Mar 2009	NRE meets AG's Chambers' representative to discuss the latest changes to the draft Biosafety Regulations
22 April 2009	Cabinet meets to consider Information Note for Cabinet on the status of the implementation of the Biosafety Act
15 May 2009	NRE meets MOSTI to discuss Biotech Corporation's comments on the draft Biosafety Regulations
26 May 2009	NRE meets Pesticides Board to discuss the draft Biosafety Regulations
2 Jun 2009	NRE meets MOSTI and industry representatives to discuss the draft Biosafety Regulations
11 Jun 2009	NRE and its legal adviser discuss the draft Biosafety Regulations
29 Jun 2009	NRE meets Centre of Excellence for Biodiversity Law (CEBLAW) to discuss the draft Biosafety Regulations
30 Jun – 1 July 2009	NRE's IBC Workshop, attended by researchers from higer education institutions and research institutions to discuss the IBC provisions in the draft Biosafety Regulations
22 July 2009	NRE has consultation with Small Medium Industries Development Corporation to discuss the draft Biosafety Regulations
21 Aug 2009	NRE meets relevant Ministries and agencies and industries to discuss the draft Biosafety Regulations
5 Nov 2009	Second Ministerial level meeting on the implementation of the Biosafety Act and the draft Biosafety Regulations and the annoucement of the agreed policy decision
13 Nov 2009	Cabinet agrees on the date the Biosafety Act comes into force
1 Dec 2009	Biosafety Act comes into force
3 Dec 2009	NRE's legal adviser sends the draft Biosafety Regulations and forms to Drafting Division, AG's Chambers for vetting
15 Mar 2010	Date of appointment of NBB members
24 May 2010	DOB established

25 May 2010	First NBB meeting. Key agenda: appointment of GMAC members
24 Jun 2010	First GMAC meeting
29 July 2010	AG's Chambers returns draft Biosafety Regulations to NRE with proposed amendments
5 Oct 2010	Second NBB meeting
1 Nov 2010	Biosafety Regulations come into force

Source: NRE (DOB)

The Act

The Act which finally emerged is hence a result of a rigorous and sustained consultative process which aimed to reconcile the various contending viewpoints of the stakeholders. It is generally acknowledged that the Act produces a positive and promising regulatory landscape which promotes investments in modern biotechnology without compromising the environment and protecting human health.

Part B: Instruments that form part of the national regulatory scheme

Summary

The ***Biosafety Act 2007*** describes the framework for the Malaysian system of regulation for LMOs and product of such organisms and is complemented by corresponding regulations and guidelines.

The Act follows the normal structure of laws in Malaysia. The Act sets out the main features and delegates the way in which the provisions are to be implemented to delegated legislation, in this case, by regulations.

The ***Biosafety (Approval and Notification) Regulations 2010*** facilitate the implementation of the Act and contains additional

information about the operation of certain provisions in the *Biosafety Act*. The Regulations are enacted as a result of powers conferred on the Minister by the *Biosafety Act 2007*. The Regulations deal with such matters as: the establishment of IBC, how an application for approval for release or import activity must be made, and the time period for the decision, matters relating to the certificate of approval, notification procedures for the export, contained use and import for contained use of LMOs and appeal procedures against the decision of the NBB.

The ***Guidelines for Institutional Biosafety Committees*** **(2010)** operate alongside the Biosafety Act and the Regulations. In effect, the Guidelines are the "operating instructions" issued by the DOB of NRE to provide guidance on the setting up of an IBC, its role and functions and the processes that must be followed when obtaining, using, transferring, storing or destroying LMO/rDNA materials. The Guidelines also provide for responsibilities of the Biological Safety Officers (BSO) and researchers, IBC membership, review done by IBC, actions required for reporting of incidents and spills and other related information.

The DOB has also issued the ***Biosafety Guidelines for Contained Use Activity of LMOs*** **(2011)**. This guideline will help any organisation that intends to carry out contained use activities involving LMO and related materials to determine the Biosafety Levels (BSL) and facility type required.

The Act, Regulations and Guidelines may be downloaded from the Malaysian Biosafety Website at *http://www.biosafety.nre.gov.my.*

Prescribed Forms

The Act requires applications and notifications for various activities to be made in prescribed forms. The following forms have been prescribed and appear on the Malaysian Biosafety Website.

- Form A: Approval for Release Activities of LMO (Research and Development Purposes in All Field Experiments) or Importation of LMO That Is A Higher Plant
- Form B: Approval for Release Activities of LMO (Research and Development Purposes in All Field Experiments) or Importation of LMO Other Than A Higher Plant

- Form C: Approval for Release Activities (Second Schedule 2-6) or Importation of LMO That Is A Higher Plant and Product of Such Organism
- Form D: Approval for Release Activities (Second Schedule 2-6) of LMO Other Than A Higher Plant and Product of Such Organism
- Form E: Notification for Contained Use and Import for Contained Use Activities Involving LMO for Biosafety Levels 1, 2, 3 and 4
- Form F: Notification for Export of LMO
- Form G: Registration of IBC
- Annex 2: IBC Assessment of Project Proposal Involving Modern Biotechnology Activities
- Annex 3: IBC Incident Reporting Form
- Annex 4: IBC Occupational Disease / Exposure Investigation Form
- Annex 5: Project Extension & Notice of Termination

Copies of the forms are available as Appendices of this User's Guide. They can also be downloaded from the Malaysian Biosafety Website at *http://www.biosafety.nre.gov.my.*

Part C: The main components of the national regulatory scheme

1. What is the objective of the Biosafety Act?

The objective of the Biosafety Act 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 requires that the risks posed by or as a result of modern biotechnology be identified and managed through regulating activities involving LMOs.

The Act provides that where there are threats of irreversible damage, lack of full scientific evidence should not be used as a reason not to take action to prevent damage.

2. What does the Biosafety Act do?

In summary, the Biosafety Act does six key things. The Act:

i. Establishes a statutory body, the NBB, to administer and make decisions under and in accordance with the Act and the Regulations;

ii. Establishes the Genetic Modification Advisory Committee (GMAC) to provide scientific, technical and related advice to the NBB, and where appropriate the Minister;

iii. Prohibits persons from carrying out activities involving LMOs (release, importation, exportation, contained use) or products of such organisms unless they have obtained prior approval (for release into the environment) or provided notification (for all other activities: export, contained use or import for contained use) in accordance with the Act;

iv. Establishes a scheme to assess the risks to human, plant and animal health, the environment and biodiversity associated with various activities involving LMOs, and where applicable, products of LMOs, including opportunities for public consultation;

v. Provides for monitoring and enforcement of the law; and

vi. Creates a centralized, publicly accessible database of all LMOs and products of such organisms approved in Malaysia.

3. Who is the regulator of the Biosafety Act and what does it do?

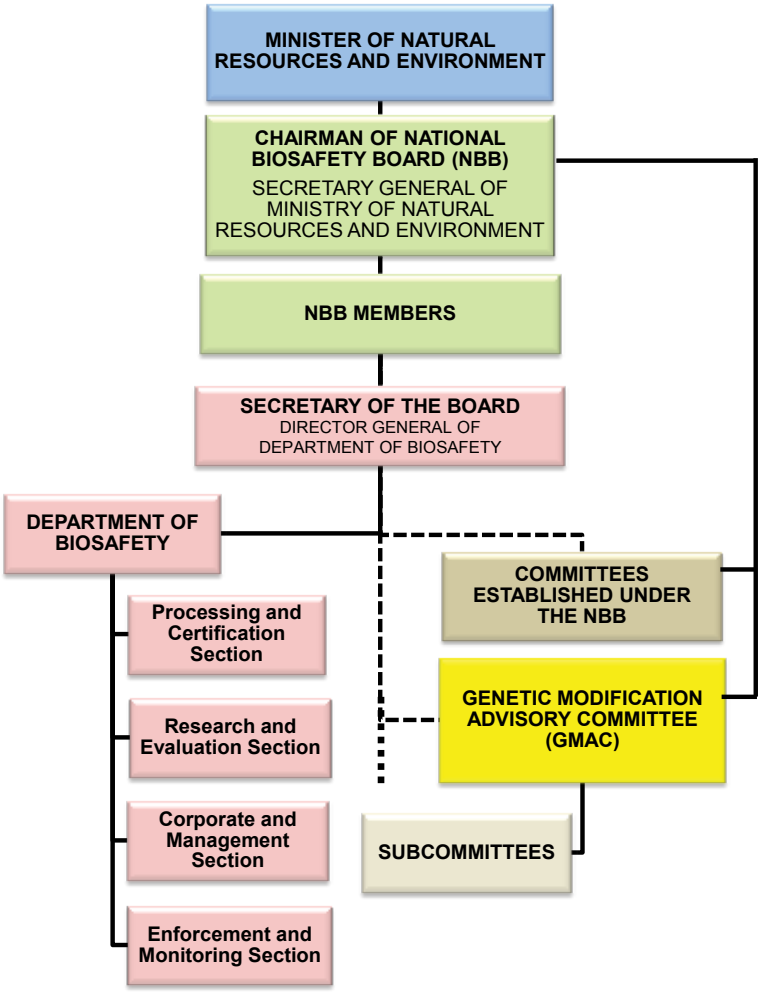


Figure 1: Biosafety Organisation Chart

3.1 The NBB and its functions

The regulatory scheme is administered by the NBB. The NBB is established by the Act which prescribes its functions. The NBB:

- assesses any risks posed by LMOs and products of LMOs;
- decides 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;

- monitors activities relating to LMOs and products of such organisms, including a review of any decisions made;
- enforces the law;
- promotes research, development, educational and training activities relating to biosafety;
- establishes mechanisms to facilitate the collection, storage and dissemination of data relating to biosafety; and
- performs, 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.

3.2 Composition of the NBB

The NBB consists of the Secretary General of the NRE (who is the Chairman), and representatives from:

- the Ministry of Agriculture and Agro Based Industry;
- the Ministry of Health (MOH);
- the Ministry of Plantation Industries and Commodities;
- the Ministry of Domestic Trade Cooperatives and Consumerism;
- the Ministry of International Trade and Industry;
- the Ministry of Science, Technology and Innovation; and
- not more than four other persons with knowledge and/or experience in any disciplines or matters relevant to this Act.

The secretary of the NBB is the Director General (DG) of Biosafety. He heads the newly formed DOB and acts under the general authority and direction of the NBB.

4. What are the roles and functions of the Committees under the Act?

The Act authorises the establishment of committees to assist in the carrying out of the functions of the NBB and the Minister.

4.1 The Genetic Modification Advisory Committee (GMAC)

A key advisory committee is the Genetic Modification Advisory

Committee (GMAC). It plays a crucial role and was established to provide scientific, technical and other relevant advice to the Minister and the NBB. Members of GMAC consist of experts from various science-based and other relevant disciplines. The appointments are personal to holder. Currently, GMAC consists of experts drawn from the following fields:

- Molecular Biology;
- Animal Breeding;
- Food microbiology;
- Risk assessment;
- Genetic Engineering;
- Biochemistry;
- Plant Breeding;
- Plant Biology/Botany;
- Virology;
- Environmental Microbiology;
- Genetics;
- Crop Physiology; and
- Agronomy.

It is noted that all members of the GMAC are drawn from science-based disciplines. The Act requires GMAC to also include experts from other relevant disciplines (epidemiology, public health, bioethics, etc).

The Act confers powers to the NBB and the GMAC to establish committees and subcommittees, respectively, to assist them in the performance of their functions. To date, no such committees or subcommittees have been established.

Section 6

4.2 Institutional Biosafety Committee (IBC)

An IBC is set up under the Regulations. They are committees set up in an organisation that undertakes modern biotechnology research and development. The NBB may direct any such organisation to set up an IBC. Its functions are prescribed by the

Regulations and include:

i. providing guidance for safe use of modern biotechnology;

ii. monitoring activities dealing with modern biotechnology;

iii. establishing and monitoring the implementation of policies and procedures for the purpose of handling LMOs; and

iv. determining the classes of Biosafety Levels (BSL) for contained use activity for the purpose of modern biotechnology research and development undertaken within a facility where the IBC is established.

Once established, the IBC must be registered with the NBB.

The *Guidelines for IBCs* provide some guidance as to the composition of the IBC. It should be chaired by the head of the organisation or his designate (senior officer). The head of the organisation refers to the Vice Chancellor/Rector of an educational institute, CEO of a body corporate, Director General/ Director/Head of an Agency, Cooperative Research Centre, Department, Division, Institute, or Industrial Research and Development Unit or its equivalent.

The IBC may form subcommittees, such as the Rapid Response Team (RRT), which is appointed by the Head of the organisation and is composed of the Biological Safety Officer (BSO), IBC Chair, and other relevant members. The purpose of the RRT is to review each incident[3] that involves LMO, within 24 hours of the occurrence and to immediately engage the different components of the organisation, including the IBC and the Occupational Health and Safety Committee (OHSC).

[3] Incident refers to unintended release, breach of containment, spill or occupational exposure to LMO materials.

CHAPTER 2

SCOPE: LMOs AND ACTIVITIES REGULATED UNDER THE NATIONAL REGULATORY SCHEME

1. What are the LMOs that are regulated?

The Act regulates all LMOs subject to the activities described in the next section. The activities and LMOs that are not regulated under the Act are set out in Chapter 4.

2. What about products of LMOs?

These are regulated only in respect of release activity and importation for release activity.

(see definition of "release activity" below; products of LMOs are discussed at length in Chapter 8)

3. What are the activities involving LMOs that are regulated?

There are five categories of activities involving LMOs that are regulated by the Act. These are:

i. Release;

ii. Contained use;

iii. Importation for release;

iv. Importation for contained use; and

v. Exportation.

"Release activity" and "contained use" are defined by the Act: *Section 3*.

"Release activity" means *any intentional introduction of LMOs or products of such organisms into the environment through the*

activities or for the purposes specified in the Second Schedule. These purposes, as provided, are:

i. R&D purposes in all field experiments;

ii. Supply or offer to supply for sale or placing on the market;

iii. Offer as gift, prize or free item;

iv. Disposal;

v. Remediation purposes; and

vi. Any other activity which does not amount to contained use.

The list of purposes is comprehensive. It makes clear that **every** activity other than for contained use involving LMOs and their products will be regulated under the section dealing with "release activity". The only qualification is that the activity must be **intended**. This excludes any unintended release. Accidental release will thus be excluded.

"Contained use" means *any operation including R&D, production or manufacturing operation involving LMOs, or storage of LMOs, undertaken within a facility, installation or other physical structure such that it prevents the contact and impact of the LMOs on the external environment*. This implies two things: one is that there has to be a physical structure and secondly, the physical structure must be such that there will be no contact of the LMO with, and no effect of the LMO on, the external environment. This would exclude mere buffer zones.

4. What is a "LMO"?

"Living modified organism" (LMO) is defined in the Biosafety Act to mean *any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology: Section 3*.

In order to understand the definition of LMO it is important that two further terms are understood – "living organisms" and "modern biotechnology": *Section 3*.

"Living organisms" is defined in the Biosafety Act to mean *any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.*

"Modern biotechnology" is 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.

In summary, the legislation regulates:

- Biological entities that are capable of transferring or replicating genetic material that have had their genes or genetic material modified by any technique aside from:
  - Traditional breeding;
  - Traditional selection; and
  - Techniques described in the Regulations (refer Chapter 4).

Traditional Biotechnology

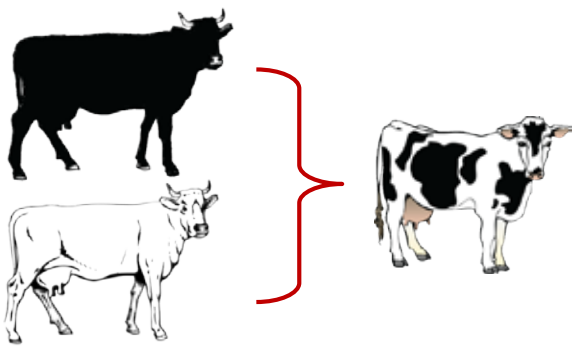
Selective breeding

Seeds for the next generation are chosen only from individuals with the most desirable traits.

Fermentation

Cheese, wine and beer are fermentation products – i.e. products made of yeast.

Cross breeding



Taking two breeds of animal and mating them together to produce a new breed.

Modern Biotechnology

Problem:
Crop infected by pest

Solution:
Introduce GM crop resistant to pest

Organism that has the gene to resist pest

Gene that can resist pest

Gene inserted into crop

Pest dies when feeding on any plant part

CHAPTER 3

THE SYSTEM OF APPROVALS FOR ACTIVITIES INVOLVING LMOs

1. What types of approvals are there for activities involving LMOs?

The Act prohibits the five activities earlier identified involving LMOs unless these have been either:

- approved by the National Biosafety Board; or
- notified to the National Biosafety Board.

Following is a brief summary of these two types of "approvals" under the Act.

Approval: all release activities and importation for release activities involving LMOs or products of such organisms require an approval from the National Biosafety Board. The approval is evidenced by a Certificate of Approval. The work involving LMOs or products of such organisms may commence only after the Certificate is issued. The approval process is elaborated in Chapter 5: *Part III of the Act; Part III and IV of the Regulations*.

Notification: all persons conducting exportation, contained use or importation for contained use involving LMOs must notify the National Biosafety Board. The DG of the DOB then sends an acknowledgement of the receipt of notification to the person who submits the notification. The work involving the LMO may commence only after receipt of such acknowledgement. The notification process is elaborated in Chapter 6: *Part IV of the Act; Part V of the Regulations*.

2. What if the person deals with a LMO without the appropriate approval or without notifying the NBB?

Then it becomes an unauthorized activity. The legislation establishes offences for unauthorized activities.

The penalties for unauthorized activities are:

- Individual – Fine not exceeding RM 250,000 and/or imprisonment not exceeding 5 years;
- Body corporate – Fine not exceeding RM 500,000;
- If the offence is a continuing offence – further fine not exceeding:
  - RM 10,000 for individual;
  - RM 20,000 for body corporate;

  for each day the offence continues after conviction: *Sections 12 and 22*.

EXEMPTIONS

CHAPTER 4

Part A: Activities and organisms and their products that are not regulated under the national scheme

1. What are the exemptions under the Act?

Relevant provision of the Biosafety Regulations 2010: Regulation 2; First Schedule

As noted earlier, the *Biosafety (Approval and Notification) Regulations 2010* deal with the process for seeking approval of LMOs and products as well as notification in respect of LMOs. Regulation 2 makes clear that there is no need to seek approval or notify in respect of the following:

i. Pharmaceutical products of LMO which are addressed by relevant international treaties or organisations, or regulated under any other written laws relating to pharmaceuticals;

ii. Techniques in relation to LMOs as set out in the First Schedule of the *Biosafety Regulations 2010*;

iii. Contained use activities in relation to LMOs as provided in the First Schedule of the Regulations. The Schedule provides for:

   a. contained use activities which are exempted from notification; and

   b. host/vector systems not regulated for contained use activities.

These exemptions are made by the Minister pursuant to the power conferred by the Act under section 68, although the regulations do not recite this section. Nonetheless the Minister is

generally empowered to make regulations for the better carrying out of the provisions of the Act.

It is possible that, with the benefit of experience gained in assessing risks, the Minister may consider making further exemptions.

Each of these exemptions is explored below.

Pharmaceutical products of LMO

Pharmaceutical: drug or medicine that is prepared or dispensed in pharmacies and used in medical treatment

There are 2 key elements to be fulfilled under this category for the exemption to apply.

i. It must be a pharmaceutical product of LMOs; and

ii. It must be:

   a. addressed by relevant international treaties; or

   b. addressed by relevant international organisations, or

   c. regulated under any other written laws relating to pharmaceuticals.

The rationale for this is that if the safety aspect of such pharmaceuticals is addressed by international treaties or organisations or by any written law of the country, then it would be superfluous to regulate the pharmaceutical product of LMOs under the Act. For example, the WHO's "Certification Scheme on Pharmaceutical Products moving in International Commerce" incorporate risk assessment of any medicine intended for human use.[4] This scheme is consistent with the provisions of the 1970 Pharmaceutical Inspection Convention which provides for mutual recognition of pharmaceutical inspection and quality control standards among participating States and promotes the exchange of related information.[5]

The exemption applies to all LMO pharmaceutical products and not only those that are for humans (such as genetically engineered vaccines). This excludes as well LMO pharmaceuticals intended for veterinary purposes. This is a distinct departure

---

4 See WHO Guidelines on the Implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce: http://*www.who.int/medicines/teams/qsm/certifguide.html.*

5 Available at http://*www.auslii.edu.au/au/other/dfat/treaties/1993/2.html.*

from the Biosafety Protocol which limits the exclusion from its scope of LMOs which are pharmaceuticals for humans (Article 5). Despite this exemption, the Protocol reserves the right of Parties to subject all pharmaceuticals to risk assessment. The Malaysian law has chosen not to take advantage of this right.

Further, not all pharmaceuticals are exempted. The LMO must be dealt with by international treaties or organisations or regulated under any written laws relating to pharmaceuticals.

- The relevant international organisation that deals with medicines for human use or veterinary products administered for food-producing animals is the World Health Organisation (WHO). The pharmaceuticals within the scope of the WHO's regulatory scheme will be thus exempted from the approval/notification requirements of the Act. The modified pharmaceuticals will not be exempted if their regulatory scheme does not address their impact on the environment or biodiversity. In such a case, the LMO pharmaceutical will be subject to the provisions of the Act and the Regulations.

- Similarly if there is a written law that regulates the LMO pharmaceutical then the Act and the Regulations will not apply. Pharmaceutical products may be regulated by such laws as

  - the Sale of Drugs Act 1952 (revised 1989 - Act 368), and

  - the Control of Drugs and Cosmetics Regulations 1984 enacted under powers conferred by Section 28(1) of the Sale of Food and Drugs Ordinance 1952.

  In such situations, the Drug Control Authority and not the DOB will be the regulating authority.

  For more information, please refer to the National Pharmaceutical Control Bureau at http://www.pharmacy.gov.my.

Other exemptions: Techniques, contained use and host/vector systems

As noted earlier, the Regulations exempt techniques in relation to LMOs as well as contained use activities in relation to LMOs. These are set out in the First Schedule of the Regulations. It also

exempts host/vector systems not regulated for contained use activities.

The exemption will only apply if:

- it is mentioned in the First Schedule;
- it does not involve genetic modification other than a modification described in the First Schedule;
- it relates to contained use activity, that is it does not involve direct introduction into the environment.

All of these conditions must be met for the activity to be exempted. Persons proposing to carry out an activity that they feel is exempted should consult the prescribed lists carefully. This is especially because the lists set out limitations and qualifications to the activity

Each of these requirements is elaborated.

Activity must involve only specified genetic modification

The Act and the Regulations apply only to LMOs that possess a novel combination of genetic material obtained through the use of modern biotechnology. Modern biotechnology is defined in the Act. Broadly speaking, it refers to any technique for the modification of genes or other genetic material. However the Regulations – which implement the Act with regard to the provisions relating to approval and notification–expressly provide that the Regulations do not apply to techniques in relation to LMOs as specified in the First Schedule.[6] The intention is to exclude LMOs that result from these techniques from the ambit of the approval and notification procedures of the Act and the Regulations. Note that the activity must not involve any other type of genetic modification other than the one expressly exempted. If any other genetic modification is involved (for example, any subsequent genetic modification), the activity is not exempted.

---

[6] Normally, exemptions are set out in the Act. In this case they are set out in the Regulations only. The Act empowers the Minister to provide for exemptions (section 68). The Regulations do not state that they are being made pursuant to this provision. This needs to be rectified. A proviso to the definition of "modern technology" could be added as follows: "*Modern biotechnology does not include any other techniques specified in the First Schedule of the Regulations*".

There are six techniques specified. These are reproduced in Box 1.

BOX 1: Techniques in Relation to LMOs to Which the Regulations Are Not Applicable

(a) *in vitro* fertilization*;

(b) natural processes including conjugation, transduction or transformation*;

(c) cell fusion (including protoplast fusion) of prokaryotic species which can exchange genetic material through homologous recombination**;

(d) cell fusion (including protoplast fusion) of cells of any eukaryotic species within its taxonomic family, including production of hybridomas and plant cell fusions**;

(e) self-cloning, where the resulting organism is unlikely to cause disease or harm to humans, animals or plants**;

(f) mutagenesis***.

Notes:

(i) *Provided that the techniques do not involve the use of living modified organisms made by techniques other than those listed in paragraphs (c) and (e) or the use of recombinant nucleic acid molecules.

(ii) **Provided that the techniques do not involve the use of recombinant nucleic acid molecules or of living modified organisms other than those recombinant nucleic acid molecules or living modified organisms produced by one or more of the techniques under paragraphs (c) and (e).

(iii) ***Applicable for both items (i) and (ii).

(iv) "Self-cloning" –

(A) means the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent), whether or not altered by enzymic or mechanical processes, into cells of the same species or into cells of phylogenetically closely related species (able to hybridize naturally) which can exchange genetic material by homologous recombination; and

(B) may include the use of recombinant vectors, with an extended history of safe use in a particular organism, to manipulate and reinsert the nucleic acid sequences, but the vectors shall not consist of any genetic elements other than those designed for vector structure, vector replication, vector maintenance or marker genes.

Contained use activities

Similarly, the Regulations exempt certain contained use activities from the notification process. These are reproduced in Box 2. The nature of the contained use activity is carefully described. The limitations for the contained use activities that are exempted are also described in detail. Users are advised to examine these as in some situations the contained use activity with regard to specified LMOs may not be exempt.

BOX 2: Contained Use Activities Which Are Exempted From Notification

Item	Activity
1	An activity with genetically modified *Caenorhabditis elegans* and *Arabidopsis*, unless –
(a)	an advantage is conferred on the organism by the genetic modification; or
(b)	as a result of the genetic modification, the animal is capable of secreting or producing an infectious agent, toxins or other products that can potentially cause adverse effects on living organisms
2	An activity with an organism into which genetically modified somatic cells have been introduced, if –
(a)	the somatic cells are not capable of giving rise to infectious agents as a result of the genetic modification; and
(b)	the animal is not infected with a virus that is capable of recombining with the genetically modified nucleic acid in the somatic cells.

3	An activity involving a host/vector system mentioned in the Host/Vector Systems Not Regulated for Contained Use where the donor nucleic acid –
(a)	must be characterized and not known to alter the host range or mode of transmission, or increase the virulence, pathogenicity or transmissibility of the host or vector;
(b)	must not code for a toxin;
(c)	must not include a viral sequence unless the donor nucleic acid –
	(i) is missing at least 1 gene essential for viral multiplication that –
	• is not available in the cell into which the nucleic acid is introduced; and
	• will not become available during the activity; and
	(ii) is incapable of correcting a defect in the host/vector system leading to production of replication competent virions; and
(d)	must not confer an oncogenic modification.
4	An activity involving shot-gun cloning, or the preparation of a cDNA library, in a host/vector system mentioned in item 1 of the Host/Vector Systems Not Regulated For Contained Use, if the donor nucleic acid is not derived from either –
(a)	a pathogen; or
(b)	a toxin-producing organism.

Host/Vector systems

Finally certain approved host/vector systems used in contained use activity and described in the First Schedule are also exempted (see Box 3). These too would be exempted from the notification requirements of the Act and the Regulations.

Box 3: Host/Vector Systems Not Regulated for Contained Use Activities

Item	Class	Host	Vector
1	Bacteria	*Escherichia coli* K12, *E. coli* B or *E. coli* C – any derivative that does not contain – (a) generalized transducing phages; or (b) genes able to complement the conjugation defect in a non-conjugative plasmid	1. Non-conjugative plasmids 2. Bacteriophage – (a) lambda; (b) lambdoid; (c) Fd or F1 (eg M13). 3. Non-vector systems*
	Bacillus	– specified species – asporogenic strains with a reversion frequency of less than 10 - (a) *B. amyloliquefaciens*; (b) *B. licheniformis*; (c) *B. punilus*; (d) *B. subtilis*; (e) *B. thuringiensis*.	1. Non-conjugative plasmids 2. Plasmids and phages whose host range does not include *B. cereus*, *B. anthracts* or any other pathogenic strain of *Bacillus* 3. Non-vector systems*
		Pseudomonas putida – strain KT2440	
		Pseudomonas putida – strain KT2440	1. Non-conjugative plasmids including certified plasmids; pKT 262, pKT 263, pKT 264 2. Non-vector systems*
		Streptomyces – specified species – (a) *S. aureofaciens*; (b) *S. coelicolor*; (c) *S. cyaneus*; (d) *S. griseus*;	1. Non-conjugative plasmids 2. Certified plasmids: SCP2, SLP1, SLP2, PIJ101 and derivatives 3. Actinophage phi C31 and derivatives

		(e) *S. lividans*; (f) *S. parvulus*; (g) *S. rimosus*; (h) *S. venezuelae*.	4. Non-vector systems*
		Agrobacterium radiobacter *Agrobacterium rhizogenes* – disarmed strains *Agrobacterium tumefaciens* – disarmed strains	1. Non-tumorigenic disarmed Ti plasmid vectors, or Ri plasmid vectors 2. Non-vector systems*
		Lactobacillus *Pediococcus* *Photobacterium angustum* *Pseudoalteromonas tunicate* *Rhizobium* (including the genus *Allorhizobium*)	1. Non-conjugative plasmids 2. Non-vector systems*
2	Fungi	*Neurospora crassa* – laboratory strains *Pichia pastoris* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe* *Trichoderma reesei*	1. All vectors 2. Non-vector systems*
3	Slime moulds	*Dictyostelium* species	1. *Distyostelium* shuttle vectors, including those based on the endogenous plasmids Ddp1 and Ddp2 2. Non-vector systems*
4	Tissue culture	Animal or human cell cultures (including packaging cell lines)	1. Non-conjugative plasmids 2. Non-viral vectors, or defective viral vectors unable to transducer human cells 3. Avipox vectors (attenuated vaccine strains)

			4. Baculovirus (*Autographa californica* nuclear polyhedrosis virus), polyhedron minus 5. Non-vector systems*
		Plant cell cultures	1. Non-tumorigenic disarmed Ti plasmid vectors, or RI plasmid vectors in *Agrobacterium tumefaciens, Agrobacterium radiobacter* or *Agrobacterium rhizogenes* 2. Non-pathogenic viral vectors 3. Non-vector systems*

Note:

1. *In relation to non-vector systems, the approved hosts may also be used in experiments where DNA is inserted into the host cell without the use of a biological vector (non-vector system) (for example, by mechanical, electrical or other means), provided that the DNA –
   (a) is not derived from microorganisms able to cause disease in humans, animals or plants, unless the DNA to be introduced is fully characterised and will not increase the virulence of the host or vector;
   (b) does not code for a toxin for vertebrates and is not an oncogene;
   (c) must not include a viral sequence unless the donor nucleic acid –
      (i) is missing at least 1 gene essential for viral multiplication that
         • is not available in the cell into which the nucleic acid is introduced; and
         • will not become available during the activity; and
      (ii) is incapable of correcting a defect in the host/vector system leading to production of replication competent.

2. The exemption list for Notification includes any commercially available Host-Vector System fulfilling the criteria as specified under item 1.

Work must not involve an intentional release into the environment

Only activities undertaken within contained facilities (see earlier discussion as to what this means), are exempted. In other words, if there is any intentional introduction into the environment, then the exemption will not apply and approval for such release must be obtained.

2. Are there any other exemptions?

Yes. The Minister may upon recommendation of the NBB, exempt any person, class of person, activity, category of activities, LMO or products of such organism. Thus far the Minister has exempted under Section 68,

(a) any subsequent release activity for the purposes of supply or offer to supply for sale or placing on the market, and offer as gift, prize or free item, where the LMOs and products of such organisms have been approved for direct use as food or feed, or processing; (note that under Section 17 approvals are valid for subsequent release if they fulfill the specific circumstances set out in the section: see Chapter 5, Part C, item 6) and

(b) any release activity for disposal where

i. the LMOs and products of such organisms have been approved for direct use as food or feed, or for processing; and

ii. the LMOs are not introduced directly into the environment and is not able to propagate; or

iii. the risk management plan relating to disposal arising from the activity has been approved – both in respect of release activity and continuing the contained use activity;

(c) the products of LMOs as listed below:

i. cotton used as fiber for any purpose and in any form;

ii. wood used for building and furniture;

(d) any Notification for export, from having to go through the entire process of assessment by GMAC and NBB as required under Sections 28, 29, 30 and 31. Once the DG issues the letter

of acknowledgement of the notification, the process stops. With the exemption, the NBB is not required to make any decision as it does for other applications within 90 days; and

(e) any subsequent export

i. by the same approved person under the Act;

ii. for the same LMO;

iii. to the same country; and

iv. for the same purpose.

The DOB will keep a register of the export permitted under the Act.

Part B: Responsibilities of persons proposing to undertake exempt activities

1. Is approval needed from the NBB to undertake activities involving LMOs that are exempt?

Relevant document: Guidelines for IBCs

No. To undertake exempt activities involving a LMO, it is not necessary to seek an approval or notify the DOB. However, the *Guidelines for IBCs* require IBCs to carry out exempted work under conditions of standard microbiological laboratory practice. The *Guidelines for IBCs* (4.2) propose the use of appropriate Biosafety Levels (BSL) in accordance with international standards (*Regulations* Schedule 2) by trained personnel. See further elaboration under Chapter 6 Part C Question 6. There is also an obligation to notify the IBC of the proposed project. Further the *Guidelines for IBCs* suggest that an ad-hoc subcommittee should review all submitted research projects to determine whether they are exempted. Persons wishing to undertake an exempt activity where an IBC is established must consult it. This is to ensure that they have correctly identified the work as an exempt activity involving a LMO.

2. What steps must a person undertaking exempt activities involving LMOs take?

The Act and the Regulations do not provide the steps to be taken

with regard to exempt activities. However where IBCs have been set up by an organisation to conduct research activities involving LMOs, the *Guidelines for IBCs* propose the desired steps.

Step 1 – Check that the work proposed to be undertaken falls within either one of the 4 categories listed earlier (see list of exemptions).

- If the work is on the list of exemptions, proceed to Step 2.
- If the work proposed is not on the list of exemptions, an approval or acknowledgement of notification from the NBB must be sought in order to undertake the work with the LMO (refer Chapter 5 and 6).
- If uncertain as to whether the work is on the list of exemption, proceed to Step 2.

Step 2 – the Principal Investigator (PI) who believes that the work falls within any of the exemptions should notify the IBC of the proposed project to ensure that the work has not been mis-classified and is in fact exempt.

Step 3 – An ad-hoc subcommittee, where established by the IBC, should review all submitted research projects to determine their exemption or non-exemption status. Otherwise the IBC itself determines this status.

- If the IBC (or the ad-hoc subcommittee) confirms that the proposed work is exempt, the work may be undertaken.
- If the IBC (or the ad-hoc subcommittee) confirms that the proposed work is not on the list of exemption, the work must not commence and an approval must be sought from, or notification must be given to, the NBB to undertake the work with the LMO.

Step 4 – Ensure compliance with the conditions that apply to the exempted work (refer below).

3. What conditions must a person comply with while undertaking exempt activities involving LMOs?

When conducting exempt work with LMOs the person must make sure that this done in accordance with the conditions of standard

microbiological laboratory practice. Appropriate BSL should be used for the exempted activities and personnel should have appropriate training.

The organisation or IBC may request information from the approved person to enable them to prepare an annual report to the NBB which includes information about exempted work.

4. What do I have to do when I finish the exempted work with LMOs?

If you cease doing the work (that is, if the project is completed or abandoned) you should advise your IBC as soon as possible.

Part C: Responsibilities of IBCs

1. What is an IBC?

This has been elaborated earlier: see Chapter 1, Part C, item 4.2.

2. What are the responsibilities of approved person, organisations and IBCs in relation to exempted work with LMOs?

In order to minimise the possibility of mis-classification of work with LMOs as "exempt', all researchers working within the organisations proposing to undertake exempt dealings with LMOs are advised to consult their IBC. The *Guidelines for IBCs* issued by the DOB set out the role of IBCs in relation to exempted work with LMOs. It provides that the IBC shall assist the person in appropriately classifying the work as exempt.

IMPORTANT NOTE

If the individual proposing to undertake exempted work with LMOs, the PI or the IBC has any doubts regarding the classification of the work as exempt, the issue should be referred to the DG for advice.

CHAPTER

5

APPROVAL FOR RELEASE AND IMPORT OF LMOs

Part A: Types of activities involving LMOs that require approval from the NBB

Relevant part of the Biosafety Act 2007: Part III; **Biosafety Regulations 2010:** Part III & IV

1. What activities involving LMOs require approval?

All activities involving LMOs that are not exempted (see Chapter 4) must be "approved" by the NBB. This Chapter deals with activities involving the intentional introduction of LMOs and products of LMOs into the environment. Such an introduction is referred to in the Act as a "release activity". There is a list of such activities in the Second Schedule of the Act.

They are:

i. research and development purposes in all field experiments;

ii. supply or offer to supply for sale or placing on the market;

iii. offer as gift, prize or free item;

iv. disposal;

v. remediation purposes; and

vi. any other activity which does not amount to contained use.

Thus any activity, other than in contained use or for the purpose of contained use, is categorized as "release activity". Any such activity is considered as releasing the LMO into the environment. A person must apply for a certificate of approval before undertaking any activity in relation to an LMO or product of an LMO.

For example, you must seek an approval if you are proposing to:

- grow a genetically modified (GM) crop in a field as part of a field trial;
- grow a GM crop commercially;
- release a GM fish into a waterway;
- release a GM microorganism into the environment (by way of bio-remediation);
- sell a GM crop in the market;
- dispose of a GM crop after research and development concluded.

Note: GM Products will be dealt with in detail under Chapter 8.

2. Do field trials of LMOs need approval?

Yes. Field trials/experiments involve the growing of an LMO in the open environment. This means that the LMO is released into the environment. It is a "release activity" and approval must be obtained for the field trial.

While the type of approval is the same for all types of release activities involving LMOs or products of LMOs, the approval application processes would differ. As the LMO is being released for experimentation purposes, it is expected that the NBB's assessment processes, and conditions applied to the approval will differ significantly.

For example, if an applicant is seeking approval to test a particular LMO in the field (as opposed to a contained facility such as a laboratory or a glasshouse), the NBB will need to be satisfied that there are certain mechanisms in place to ensure that there is no spread of the LMO or of its genetic material from the trial site into the broader environment.

The conditions that may be imposed for the approval may include:

- limiting the geographic area, and size of the trial, in which the LMO may be released;
- requiring buffer zones to be established to separate the LMO crop from other like crops;

- requiring monitoring of the trial site and the surrounding area at regular intervals to ensure that the LMO has not spread beyond the trial site area; and
- requiring post-trial monitoring of the trial site to ensure that the LMO that has been the subject of the trial does not persist in the environment beyond the period of the trial.

Such field trials form the basis for approving the LMO for commercial release into the country, including placing on the market. The results of the field trials will be used by the NBB as part of its assessment of whether it is safe for the LMO to be more generally commercially released in Malaysia.

Similarly if organisation overseas wishes to import LMOs into Malaysia for commercial release/growing in the Malaysian environment, the NBB would first require that field trials of the LMO be conducted under strict conditions to ensure that the LMO is safe to be commercially released. Information gained from the field trials (and information about the suitability of the applicant based on their conduct of the trials) would be used by the NBB as part of its assessment of any subsequent application for commercial release of the LMO.

A case in point relates to the release of genetically modified mosquitoes. The applicant was the Institute of Medical Research (IMR). The NBB approved limited small scale release. The purpose of the release was to compare and evaluate the longevity and dispersal distance of the *Aedes aegypti* OX513A (My1) strain (GM) mosquitoes in comparison with the non-GM mosquitoes. The GM mosquitoes were marked in a way that makes them easily recognizable when they are encountered again within a habitat. It is assumed that these marked mosquitoes will mix back into the rest of the local population – a technique known as mark-release-recapture. The conditions imposed for the approval included matters prior to, during and after the release. As examples: a prior condition was the prior consensus and approval from the inhabitants of the release site; during the trial: all extra insects/ recaptured insects are to be transported in shatter-proof double covered containers for subsequent identification, analytical studies or appropriate disposal; after the trial: fogging (twice) for a 400m radius according to the Ministry of Health Guidelines and community cleanup operations to eradicate all breeding grounds.

3. Is an additional/separate approval required for the disposal of approved LMOs used in R&D?

It depends. Generally the applicant would have provided a risk assessment and a risk management report as well as an emergency response plan to the NBB. The NBB would have gone through these reports and plan before granting the approval. These reports must include information on disposal of the LMO, including methods for elimination or inactivation of the LMOs at the end of the experiment, measures proposed for restricting the persistence of the LMO or its genetic material in the release site,[7] and methods for disposal of other plants, animals and any other thing exposed to the adverse effects. The NBB may then accept these proposals and include them as part of the terms and conditions relating to disposal. If the proposals are not satisfactory, the NBB may impose terms and conditions relating to the disposal. For example in the case of the approval granted for field trials of GM mosquitoes, one of the terms imposed was that the recaptured insects were to be disposed according to the Standard Operating Procedures at the applicant's Institute. Practically no further approval would be required.

Part B: Transitional arrangements for work commenced before 1 December 2009

1. What are the transitional arrangements for activities involving LMOs that commenced prior to 1 December 2009?

Relevant provision of the Biosafety Act 2007: Section 71

The *Biosafety Act 2007* came into force on 1 December 2009. Before then LMOs were not subject to any mandatory requirements. The GMAC, established by the then MOSTE, processed applications but this was on a purely voluntary basis. To minimise disruptions flowing from the commencement of the new Act, the legislation provides for transitional arrangements in relation to activities

[7] This information is specifically required to be supplied: see example, Form A, Part B Risk Management, B1 Information on control, monitoring, post-release plans, item 89. This information is required in all Forms A, B, C and D.

involving LMOs, that were being undertaken on the date of the coming into operation of the Act. The Act provides a three-month grace period – which expired at the end of February 2010.

Starting from 1 March 2010 onwards, however, the transitional period was administratively extended. It ends on 30 November 2011. Any person undertaking an activity involving LMOs to which the Act applies on 1 December 2009, and continues to undertake such activity, should apply for an approval before 30 November 2011. Else, his activity will be illegal and punishable under the Act with fine and/or imprisonment.

Part C: Applying for a certificate of approval after 1 December 2009

1. Who should apply for a certificate of approval?

Any person may apply. This includes an individual, an organisation or a legal entity such as a corporation. The applicant must provide an address of his/its place of residence, business premises or in the case of an agent, an address for service in Malaysia.

2. How does a person apply for an approval from the NBB to undertake release activity or importation for release involving a LMO?

Step 1 – Identify the correct form

Identify the correct application form for the proposed release activity or importation. There are four types of application forms. There are different forms depending on the purpose of the activity (R&D or non-R&D) and the LMO and their product (higher plant or non-higher plant) (see Table 1).

Application forms appear as Appendix 1, 2, 3 and 4 of this User's Guide (printed on blue paper) and are available from the Biosafety website: http://*www.biosafety.nre.gov.my*.

Step 2 – Filling up the form

Fill up the form identified. The critical information required by the NBB relate to:

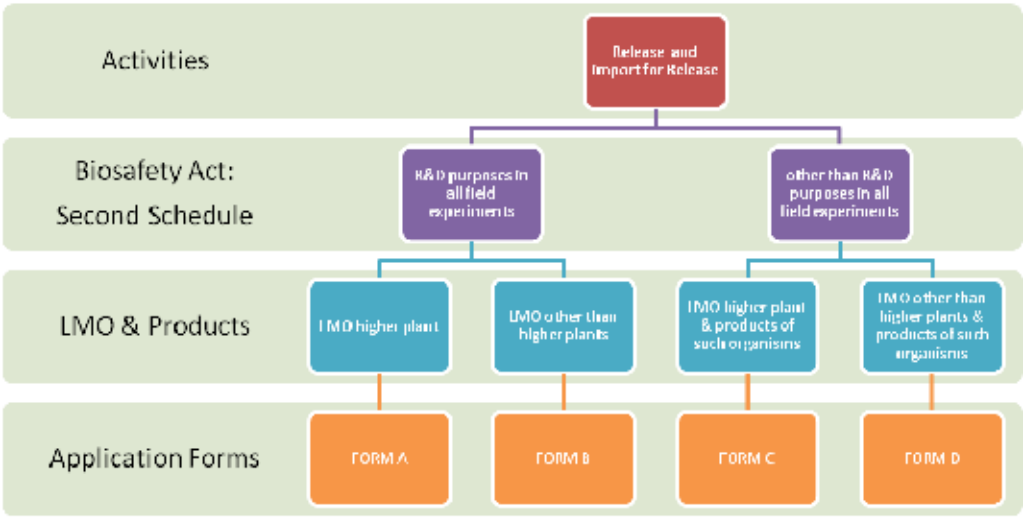


Figure 2: Types of Application Forms

A. Risk assessment;

B. Risk management;

C. Emergency response plan; and

D. Other information such as: specification of the genetic modification, information of the parent organism, data or results from previous release of the LMO, impact of the LMO on the host and the environment (the rest of the information required is set out in the form).

The Forms also require further information to be supplied according to the nature of the activity involved. For example, Form B requires applicant to fill in Part F if the LMO is a microorganism that lives in or on animals, or Part E if the LMO is a microorganism associated with plants.

Persons wishing to undertake any release activity are advised to peruse the Forms carefully.

Step 3 – Submission of the form

Once the application has been prepared, the application must be submitted directly to the Director General (DG) or through the organisation's registered IBC for consideration. This depends on whether the purpose for the activity is for R&D purposes in all field experiments; or for purposes other than those of R&D.

For R&D purposes in all field experiments: application to the DG through the IBC (from here proceed to *Step 4*);

For purposes other than of R&D: application directly to the DG (from here proceed straight to *Step 5*).

Step 4 – Assessment by the IBC and submission

The IBC must assess the activity in the application and fill up the sections in the appropriate form relating to their details and specified information relating to its assessment. The application is signed by the Chairperson of the IBC. The IBC completed form is sent to the NBB together with the IBC Assessment Report form: see for example, Form B, p. 6, instruction under item 9. See also *Guidelines for IBCs*, IBC/AP/10/ANEX2, p. 30.

The IBC Assessment Report form can be downloaded from the Malaysian Biosafety Website at http://*www.biosafety.nre.gov.my*.

Step 5 – Submission to DG

Once all of the information required by the form has been completed, the application may be forwarded to the NBB through the DG, together with such fees as prescribed by the Regulations:

- R&D purposes in all field experiments per release site:
  - Less than 5 ha – RM100;
  - 5 ha – 10 ha – RM250;
  - More than 10 ha – RM500; and
- All release activities other than above – RM5000.

The fees submitted are not refundable and any fresh application shall come with new fees.

3. Who must sign the application Forms?

The application must be signed by the applicant, as well as the head of organisation or his authorized representative. The applicant must provide written proof of authorization. The head of the organisation referred to is the CEO of a body corporate, the Vice Chancellor/Rector of a university or other educational institute, or Director General/Director/Head of an Agency, Centre, Department, Division etc. Whereas the authorized representative

may be anyone that the organisation considers appropriate and who has been duly delegated by the organisation. This is expected to be a senior officer in the organisation. It is important that the head of the organisation (or the authorized representative) signs the application because the organisation will be the holder of the certificate of approval and will have responsibilities under it. It is therefore important that the organisation is fully cognisant of such obligations.

As noted in *Step 4* of *Question 2*, in the case of field experiments, the IBC chair also must sign the form.

4. How many copies must be sent to the DG?

One original and six copies of the completed applications must be submitted to the DG, along with a soft copy of the submitted application, including all supporting documents/attachments, if any, excluding any information that has been identified by the applicant as confidential business information (CBI). A copy of the application must be retained by the organisation.

5. What if the application contains confidential business information (CBI)?

The Act requires that an application must be made to the DG for declaring information as confidential: *Section 59(1) and (2)*. The instructions in the form (Form A, B, C and D, at p. 2) must be read accordingly to comply with the provisions of the Act. It is not for the applicant to declare unilaterally what he considers to be CBI. Practically, the applicant seeks the approval of the DG for any information which he wishes to be treated as confidential by marking that information in the Form as "CBI". Only if it is accepted as CBI by the DG can it be treated as such. The information then cannot be disclosed. Forms A, B, C and D provide that the CBI be omitted from the softcopy of the notifications submitted (see for example, Form A, p. 3, item 6 under "Application Check List" (The provisions on CBI are elaborated in Chapter 9).

6. Is a new application necessary each time a LMO is proposed to be released into the environment?

It depends. A person need not seek fresh approval if he has already been given an approval for:

- release activity involving the same LMOs; or
- release activity involving the same products of such LMOs; or
- importation for release into the environment involving the same LMOs.

This is the effect of section 17 of the Act.

Relevant provision of the Biosafety Act 2007: Section 17

The subsequent LMO or product must involve the same transformation event as the approved LMO. In other words, the first approval is valid for subsequent similar release activity involving the same LMOs or products of such organisms.

A fresh application is needed if it is not made by the approved person: Scenario 1; and if the subsequent LMO does not involve the same transformation event as the approved LMO: Scenario 2.

The subsequent release activity must be similar to the one approved: Scenario 3. The Act describes five different release activities (Second Schedule).

Scenario 1

Company A has been granted a certificate of approval for importing and selling product X (made from LMO Z). The approval is valid for the Company's subsequent import and sale of the product X. It need not apply for a new approval for each subsequent import of product X. If Company B wants to also import and sell product X, it is obliged by the law to apply for a certificate of approval [Note that the Minister has exempted Company B from applying for such approval: see Chapter 4, Part A, item 2].

Scenario 2

Company A in the above scenario wishes to import for sale the same product but it has been genetically modified by using a different transformation event. Then it needs a certificate of approval.

Scenario 3

Company A in Scenario 1 wishes to import the product for bio-remediation purposes. This is not a similar activity to that for which the approval was granted. A fresh approval is required.

7. Does the Act allow the NBB to control the release into the environment of the same LMO which otherwise comes within the purview of section 17 of the Act?

An approval certificate for release activity is nonetheless subject to terms and conditions: section 16(4) of the Act. Such conditions may relate to the scope of the release activity. This would include such matters as: the size of the release, the location of the release, the duration of the release (commencement and completion date for the release) and the number of releases allowed. The approval given by the NBB for GM mosquitoes is a case in point. The approval imposed conditions as to the geographical area of the release for field experiments, the duration of the release and the number of mosquitoes permitted for release. This implies that if, after completion of the release of the GM mosquitoes, the proponent wishes to undertake further releases of the LMO, the proponent must apply to the NBB to do so.

This means that the applicant cannot rely on section 17 of the Act for the subsequent release even though he may otherwise fulfill the requirements of the section.

This is an important biosafety regulatory safeguard. If the proposed new release poses additional, new or different risks to the environment (for example, because the size of the release is to increase or the location of the release is to change), the approved person may be required by the NBB to submit, through the DG, a new application for approval. This is important because the NBB can then undertake a full assessment of the additional or different potential risks to the environment.

Alternatively, if the proposed changes to the release are minor and do not pose any additional or different risks to the health and safety of people or to the environment, then the NBB may require the approved person to submit an application to the NBB, through the DG, for a variation of the existing approval to enable the additional work to occur.

Example:

The NBB may approve the field trial of a LMO on three sites in Johor. If the proponent wishes to extend this approval to include 15 new sites in Sabah and Sarawak, the NBB would be entitled

to require a new application to be submitted. This is because the NBB may consider that the environmental factors unique to Sabah and Sarawak require a detailed consideration by the NBB, before approval is granted. There may also be issues in terms of the applicant's capacity to manage a much larger trial of LMOs.

If, however, the applicant wishes to vary the existing approval to include one more site in the same region of Johor, it may be appropriate for the proponent to apply to the NBB, through the DG, for a variation of the conditions to the existing approval, if no additional risks to the health and safety of people or the environment are posed as a result of the variation.

Part D: The NBB's assessment process

1. What does the DG do upon receipt of an application?

The DG undertakes an initial screening of the application before accepting the application. This initial screening involves checking to ensure that all of the information requested has been provided and that the application has complied with the requirements of the Act and the Regulations; and where applicable, that the application has been assessed by the registered IBC: *Regulation 6(1)*.

If the application does not contain the necessary information, is inconsistent with the requirement of the law or contains any error or any unauthorized alteration, the DG may refuse to process the application. The DG will either require that it be amended, completed, resubmitted or that a fresh application be submitted. If the applicant fails to comply, the application will be treated as withdrawn: *Regulation 6(3), (4) and (5)*.

Relevant provision of the Biosafety Act 2007: Sections 14 and 15.

If the DG is satisfied that the application meets the basic requirements, the DG must proceed to process the application by issuing an acknowledgement of receipt to the applicant: *Regulation 8(1)*.

2. What are the steps taken then?

Step 1 – DG refers application

The DG then refers the application to GMAC, relevant Government department or agency, and initiates public consultation.

a) GMAC

The DG must refer the application to the GMAC for its recommendations. GMAC has been set up to provide scientific, technical and other relevant advice to the Minister or the NBB. GMAC assesses the impact of the proposed release activity or importation on the environment or on the health and safety of people. It will be recalled that the application consists of the risk assessment and the risk management report by the applicant. Hence GMAC evaluates these reports and advises on the safety facets of the application. GMAC in turn may also invite other experts, including international experts, to advise on any particular aspect of the application. GMAC may also establish subcommittees as it thinks necessary or expedient to assist it. After all this, GMAC makes recommendations to the NBB whether or not to approve the application; if it advises approval, then it also recommends any terms and conditions that the NBB should impose. It is seen that the NBB is provided with the widest possible expertise to help it to make its decision.

b) Government department or agency

If the application involves the expertise or is within the scope of a government department or agency, then the DG forwards the application for its comments on any specific matter in its area of expertise.

c) Public participation

Simultaneously, the DG must invite public participation for their views on the application. This would normally relate to the possible risks involved and the management of those risks. Practically, the DG will invite public participation by placing advertisements in newspapers and in Malaysian Biosafety Website. Their views will be sought within a prescribed time period. In addition, depending on the type and magnitude of the release, the DG may require the applicant to conduct consultation(s) with the local people affected by the release of LMO at the cost of the applicant. Both

these avenues were pursued as required by the NBB with regard to the field trial of the GM mosquitoes. The requirement for public consultation of the local people potentially affected was a decision made by the NBB as part of the condition for approval of the field experiment.

For the consultation to be meaningful, the public may be granted access to relevant information relating to any application for approval. It is left to the discretion of the NBB to decide whether, and how, this access may be given or done. There is no access allowed to information that has been accorded confidentiality. The provisions of CBI are elaborated in Chapter 9.

Step 2 – Submit feedback to the NBB

The views of the public, the comments by the Government agency or department and the recommendations by GMAC are then forwarded to the NBB.

Step 3 – The NBB decides

The NBB then makes its decision on the application.

3. What decision can the NBB take?

The NBB may decide to:

i. refuse to issue the certificate of approval; or

ii. approve the application by issuing the certificate of approval. In this case, it may impose terms and conditions for the approval.

4. Can the applicant be required to supply additional information, particulars or documents (IPD)? If so, when?

Yes the applicant can be asked to supply additional IPD. There are four such situations.

a. First, the DG can request for the IPD after he receives the application and before he sends the application on to any government agency, GMAC or for public consultation: Subsection 13(2).

b. Secondly, GMAC can also request for IPD when it is considering the application: *Subsection 15(2)*.

c. Thirdly, the NBB can request for IPD after it has received the GMAC's recommendation and before it makes any decision: *Subsection 16(1)*.

d. Fourthly, the NBB may request for additional IPD after approving the application, with or without conditions: *Subsection 16(6)*.

In case (b), the request has to be made through the DG.

The purpose for seeking such IPD is mainly to facilitate the processing of the application. The applicant may not have submitted the appropriate documentation or necessary information; or the IPD may be needed before a final decision to approve the application is made.

4.1 What if the applicant fails to provide the IPD?

Then the processing of the application ends at the stage at which the information is sought. If the applicant does not provide the further information within the specified timeframe, the DG must deem the application to have been withdrawn. This does not affect the right to make a fresh application: *Subsections 13(3), 15(3) and 16(2)*.

However it is an offence not to provide the IPD requested by the NBB directly, *after* the approval has been granted (see d above): *Subsection 16(7)*.

4.2 How is the request for information made?

The request is made to the applicant in writing. The notice should state clearly and with precision what is required, as well as the timeframe within which the information must be supplied.

In the case where the information sought is, after the certificate of approval is granted, for the application for variation of the terms and conditions imposed by the NBB, the information must be supplied in 30 working days. The time for supplying the information may be extended: *Regulation 10(3)*.

The time limit for considering an application is suspended for the duration of the time during which the DG/NBB is awaiting a response to the request for additional IPD: *Regulation 23*.

5. What does the NBB need to take into account when making a decision?

To make a decision, the NBB must consider the following:

- recommendations of GMAC on the assessment of the application;
- comments of the relevant Government department or agency;
- views of members of the public, if any; and
- any additional IPD furnished: *Subsection 16(3)*.

The decision for approval application will necessarily be based primarily upon the evaluation by GMAC of the risk assessment report, the risk management plan, and emergency response plan; as well as the fulfillment of any other requirements under the *Biosafety Act 2007* (For example, Form A, at p. 1).

The NBB's decision is based on its satisfaction that any possible risk and adverse effect posed by the activity relating to such release or importation of LMOs or products of such organisms to be authorised by the approval can be prevented, reduced or controlled in a way which protects human, plant and animal health, the environment and biological diversity.

6. What if there is insufficient relevant scientific evidence?

The NBB may refuse an application, or take other decisions, even when there is lack of scientific certainty of the safety of the LMO. This is where there is insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of LMOs on human, plant and animal health, the environment and biological diversity: *Section 35*. In other words, if the scientific community is divided on the extent of the adverse impact of the LMO and there is not enough evidence to resolve the issue, the NBB can still make a decision.

7. Can the NBB also take into account socio-economic considerations?

Yes. It may also take into account socio-economic considerations of the impact of the LMO: *Regulation 25*. For example, the introduction of the LMO may have an effect on the existing

social and economic patterns and means of livelihood of the communities. It may impact the religion, social, cultural and ethical values of communities.[8]

8. Can the application be refused on the basis of the suitability of the applicant?

No. The application cannot be refused on the basis of the general suitability of the applicant. See however Section 19(1)(d) and (e).

9. Can the NBB impose terms and conditions?

Yes as noted earlier, the NBB can impose such terms as it deems fit.

The Act does not state the precise terms and conditions that the NBB may impose on the issuance of the certificate of approval. However these may be implied from the factors that it may take into account when issuing such a certificate:

- Authorized scope of the activity; and the right to vary;
- Purposes for which the activity may be undertaken; and the right to vary;
- Documentations and record-keeping requirements;
- Waste disposal requirements;
- Measures to manage risks posed to the health and safety of human or the environment;
- Data collection, including studies to be conducted;
- Auditing and reporting including, where appropriate, condition for entry into premises where the activity is being undertaken;
- Geographical area in which the authorized activity may occur;

[8] Several studies have pointed to the impact of LMOs on the distribution of benefits, public sector research, labour, global markets, competition, organic agriculture, IPRs and ethics, culture and religion. See Lindsey Fransen *et al* (2005). *Integrating Socio-economic Considerations into Biosafety Decisions: the Role of Public Participation*, WRI White Paper, WRI Washington DC; Elenita C Dano (2007). *Potential Socio-economic, Cultural and Ethical Impacts of GMOs*, TWN, Penang, Malaysia.

- Compliance with any code of practice or technical or procedural guideline that may be issued;
- Supervision and monitoring by the IBC;
- Contingency plan relating to unintended effects of the authorized activity;
- Limiting the dissemination or persistence of LMOs or its genetic material in the environment;
- Conditions requiring the approved person to be adequately insured against any loss, damage or injury that may be caused to human health, property or the environment;
- Any other factors as the NBB thinks fit.

Regulation 9(2)

10. How long is the NBB given to make a decision?

The NBB must make a decision - whether to approve or refuse the application - within 180 working days from the date of issue of the acknowledgement of receipt of the application: *Regulation 8(1)*.

The time for making the decision can be extended by a maximum of 60 working days, if necessary: *Regulation 8(2)*.

Time does not run during the period that the applicant does not provide information required of him; and time is computed on the basis of working days. This means that Saturdays, Sundays and public holidays are not taken into account.

11. Who will be informed of the decision?

Both the applicant and the public will be informed of the decision: *Sections 16 and 60*.

12. How will the NBB inform its decision?

The law does not prescribe how the decision will be conveyed to the applicant. The DG sends the notice to the applicant either personally or by A.R. registered post. The notice is sent:

- in the case of a company incorporated in Malaysia, to the address of the registered office of the company;

- in the case of a company incorporated outside Malaysia, either to the individual authorized to accept service of process under the Malaysian Companies Act, or to the address filed with the Registrar of Companies or to the registered office of the company;
- in the case of an individual or a body of persons, to the last-known business or private address of such individual or body of persons.

Section 63

The Regulations state that the applicant must have a place of residence, business premises or in the case of an agent, an address for service in Malaysia: *Regulation 6(2)*. In the case, for example, of a company incorporated outside Malaysia, the authorized individual would be served at the address for service in Malaysia which is required to have under *Regulation 6(2)*. However for the service of the notice to be valid, *Section 63* of the Act must be complied with. Any decision made by the NBB on the application is also posted on the Malaysian Biosafety Website. For more information regarding the website, please refer to Chapter 12.

Part E: Rights and responsibilities of holders of approval

1. Is there a need to label the LMO?

The Act provides that all LMO, items containing LMOs and products of LMOs must be clearly identified and labeled: *Section 61*. This is in addition to any other written law in relation to labeling currently in force in Malaysia. In 2010, Parliament passed the Food (Amendment) Regulations 2010 (P.U. (A) 229) which obliges the applicant to label GM food and food ingredients before releasing them into the market.

2. If an approval has been granted, when can the approved activity involving LMO commence?

Release or import of LMO may commence when the certificate of approval is issued. However any preconditions imposed must be complied with. The other requirements imposed by the Act or

other laws must also be complied with – such as the identification and labeling of all LMOs, items containing LMOs and products of such organisms. The applicant proposing to undertake the activity involving LMO must also ensure that they have any other necessary approvals or consents from other regulators in relation to the LMO.

3. If the NBB has approved the proposed activity involving LMO, does the approved person need approval from any other Government department/agencies?

Yes. An approval from the NBB does not give a holder of approval the right to undertake the work with the LMO. Approvals from other Government department/agencies – where required by other laws – must be obtained, depending on the particular activity and the particular LMO, as indicated earlier.

For example:

- approvals thus far by the NBB have required the applicant to furnish the requisite consents/approvals by the Pesticide Board and by the Department of Veterinary Services;
- the approval for field trials of the GM mosquitoes required "documentation from District Council or relevant authorities on the presence or otherwise of aquaculture, poultry and pharmaceutical industries within a vicinity of 500 meters of the release site, and information on whether any of these industries regularly use tetracycline in their operations". Another condition required a consent letter from the Local Council for the field trials sites.

It is the responsibility of the approved holder to ensure that any other relevant Federal, State or local government legislation is complied with.

4. Can the approval be varied once it has been issued?

Yes. The Act provides that an approved person may propose to vary the terms and conditions. He must do this in writing to the NBB through the DG. The proposal must include the proposed dates for the proposal to become valid, the details of the

proposal and the reasons for such variation: *Subsection 16(5)* and *Regulation 10*.

5. What does the NBB do before deciding on the variation proposal?

The NBB:

1 may request the approved person to submit further information or documents within 30 days. The applicant may ask for an extension of time (in writing) to submit this information or supply the documents. If he/she fails to submit the additional information or documents within the designated timeframe, the application for variation will be treated as withdrawn. The applicant may however submit a fresh application: *Regulations 10(3), (4) and (5)*;

2 must refer the proposal and the information submitted to the GMAC or relevant Government department or agencies for their recommendation.

The NBB must then communicate the decision whether to approve or refuse the proposal in writing to the approved person: *Regulation 11*.

6. Can the applicant appeal against a decision made by the NBB?

Yes. If the NBB refuses to grant the certificate of approval, the applicant may appeal to the Minister of Natural Resources and Environment.

If the NBB grants the approval but imposes terms and conditions that are not acceptable to the applicant, (and any variation proposal by the applicant is refused), the applicant can then appeal to the same Minister: *Section 20*.

7. How does the applicant proceed with the appeal?

He must:

1 give notice to the Minister in writing of the intention to appeal within 30 working days from the date he received the decision; and

2 submit the grounds of appeal and other relevant documents within 30 working days after giving the notice.

Regulation 20

8. What if the certificate of approval is lost or destroyed?

Every certificate holder has a duty to ensure that the certificate granted is kept safely. If it is lost or destroyed, the holder must immediately inform the NBB and lodge a police report. The approved person may make an application to the NBB in writing for a replacement, together with the police report. The NBB may issue a "duplicate" certificate if it is satisfied that the application is not fraudulent: *Regulation 12*.

9. Can the certificate be assigned or transferred?

Yes. The approved person must apply to the NBB through the DG (in writing) to assign or transfer the certificate. He must provide the relevant particulars of the proposed assignment or transfer and the proposed assignee or transferee. The DG may ask for further information or other document relating to the application from the approved person and these must be submitted within 10 working days from the date of the notification. The approved person may request for an extension of time in writing. If the information or document is not provided, the application will be treated as withdrawn. The applicant can however make a fresh application: *Regulation 13*.

After considering the application, the NBB must inform the approved person in writing, its decision whether to approve or refuse the application. He must give his reasons for the refusal. It is an offence to assign or transfer the certificate without the approval of the NBB: *Regulation 14*.

APPLICATION CHECK LIST

1. Check to see if the proposed activity involving LMO is exempt from the Act. If it is not, the proposed activity must be approved by the NBB. The activity may commence after the certificate of approval is granted by the NBB.	☐
2. If the activity is release for field experiments or importation, complete application Form A or B, depending on whether the LMO is higher plant. The Forms are included at Appendix 1 and 2 of this User's Guide. If it is intended for release other than field experiments or importation of LMO or product of such organism, complete application Form C or D, depending on whether the LMO is higher plant. The forms are included at Appendix 3 and 4. The forms are available from the Malaysian Biosafety Website. http://www.biosafety.nre.gov.my	☐
3. For release activity involving field experiments, submit the completed application form to the relevant IBC. For other release activity, submit to the DG. In former case, the IBC completes those parts of the form that deals with verification of information supplied by the applicant in the form. It must also provide an assessment report. The applicant must also provide relevant supporting IPD.	☐
4. Make sure that the signatures of the applicant, head of organisation or authorized person and the IBC chairperson, if necessary, accompanied by their official stamps are obtained.	☐

5. For import of LMO, provide date of importation, or intended importation; and a copy of documentation on clearance or assessment from the relevant authorities such as DOA, MOH.

   For field experiments, provide the clearance document from the state office where the release is to take place.

   For production of food consumption that contains LMO or GM products, comply with the assessment requirements under the Malaysia Food Safety Act 1983 and the labeling law under the Food (Amendment) Regulations 2010.

   Comply with any other relevant laws.

6. Apply to DG if any information is intended to be treated as confidential business information. The information in the application form must be clearly marked "CBI".

7. Submit the completed application form to the DG as follows: 1 original copy, 6 copies and a soft copy (including all supporting documents/attachments, if any).

   Exclude from the soft copy information that the applicant has identified as CBI.

   Keep a copy.

8. Prepare fees in Money order/Bank draft.

Note: for any queries or concerns at any time, contact the DOB on +603 8886 1580 or 1579 or email biosafety@nre.gov.my

CHAPTER 6

NOTIFICATION FOR EXPORT, CONTAINED USE AND IMPORT FOR CONTAINED USE

Part A: Types of activities involving LMOs that require notification to the NBB

1. What activities involving LMOs require giving the NBB notification?

Relevant part of the Biosafety Act 2007: Part IV; **Biosafety Regulations 2010:** Part V

The activities that require notification to the NBB may be summarized as follows:

i. Activities that do not involve the intentional release of a LMO into the environment. Such an activity is referred to in the Act as a "contained use" activity;

ii. Importation of LMOs for purposes of undertaking a contained use activity;

iii. Export of LMOs; and

iv. Activities involving LMOs that are not exempted (see Chapter 4).

2. What is "contained use" activity?

Section 3 of the *Biosafety Act 2007* defines "contained use". *Any operation including R&D, production or manufacturing operation involving LMOs, or storage of LMOs, undertaken within a facility, installation or other physical structure such that it prevents the contact and impact of the LMOs on the external environment* are "contained use" of LMOs.

The key characteristics of the definition are:

- There must be a physical facility within which the LMO activity is confined. Non-physical barriers – such as biological or chemical barriers by themselves are insufficient.
- The facility must prevent the LMO from coming into contact with the external environment. In this sense it appears a much stricter requirement than the Biosafety Protocol which requires measures that effectively limit their contact and impact on the external environment.

In essence, if you are proposing to undertake work within a facility so that the LMO is physically contained and is not released into the environment, you must give prior notification to the NBB in accordance with this Chapter.

IMPORTANT NOTE

Products of LMO are not covered by the law under the notification process. In other words, there is no need to notify the NBB with regard to such a product that is for contained use, import for contained use and for export.

Part B: Transitional arrangements for work commenced before 1 December 2009

1. What are the transitional arrangements for activities involving LMOs that commenced prior to 1 December 2009?

The *Biosafety Act 2007* came into force on 1 December 2009. Before then LMOs were not subject to any mandatory requirements. The GMAC, established by the then MOSTE, processed applications but this was on a purely voluntary basis. To minimise disruptions flowing from the commencement of the new Act, the legislation provides for transitional arrangements in relation to activities involving LMOs, that were being undertaken on the date of the coming into operation of the Act. The Act provides a three-month grace period – which expired at the end of February 2010.

Starting from 1 March 2010 onwards, however, the transitional period was administratively extended. It ends on 30 November 2011. Any person undertaking an activity involving LMOs to which the Act applies on 1 December 2009, and continues to undertake such activity, should submit a notification before 31 August 2011. Else, his activity will be illegal and punishable under the Act with fine and/or imprisonment.

Part C: Giving Notification after 1 December 2009

1. Who should give the notification?

Any person may give. This includes an individual, an organisation or a legal entity such as a corporation.

2. How does a person give notification to the NBB to undertake exportation or contained use activity involving LMO or importation of LMO for contained use?

Step 1 – Identify the correct form

Identify the correct notification form for the proposed activity. There are two types of notification forms. There are different forms depending on the purpose of the activity - contained use or export (see Table 2).

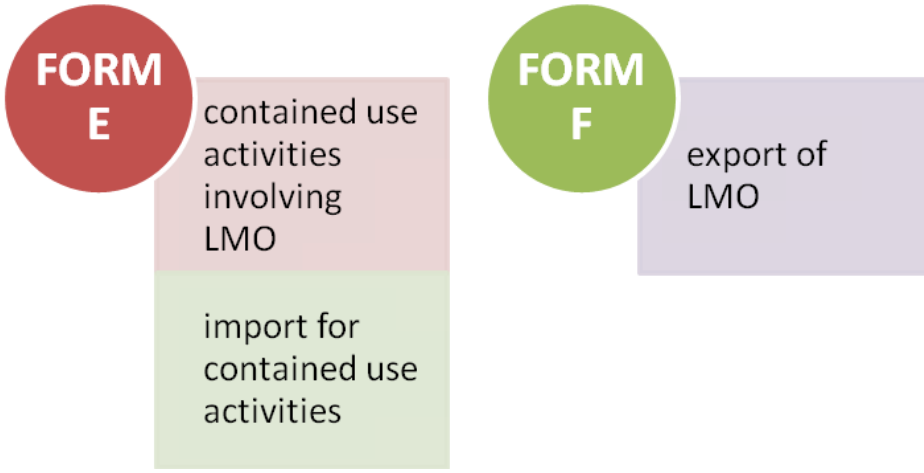


Figure 3: Types of Notification Forms

Notification forms appear as Appendix 5 and 6 of this User's Guide. They may be downloaded from the Malaysian Biosafety Website at http://*www.biosafety.nre.gov.my*.

Step 2 – Filling up the form

Fill up the form identified. The critical information required by the NBB depends on the nature of the activity.

i. For contained use and importation for contained use, the following information must be supplied:

   a. Risk assessment;

   b. Risk management;

   c. Emergency response plan; and

   d. Other information such as: description of the LMO and the facilities being used for the confined activities. (The rest of the information required is set out in the form.)

   Note: For contained use only, the applicant must also inform the NBB, and supply any document on the specific measures he proposes to take in relation to the activity: *Section 24(b)*. These measures are not specified in the Act or the Regulations. Logically, they should relate to measures that ensure the containment of the activity. They must be approved by the NBB. The approved person must then take these approved specific measures.

ii. For export, the following information must be supplied:

   a. The requirements of the importing country on the importation of LMO; and

   b. Evidence of such compliance: *Section 23*.

   The Forms also require further information to be supplied. Persons wishing to undertake any contained use activity, importation for contained use, or exportation of LMOs are advised to examine the Forms carefully.

Step 3 – Submission of the form

Once the notification has been prepared, the notification must be submitted directly to the DG or through the organisation's

registered IBC for consideration, where the NBB has directed the establishment of the IBC. This will be only in cases of R&D involving LMOs: *Regulation 16(2)(b) read with Regulation 5(1)* (From here proceed to *Step 4*.)

In all other cases, including where there has been no direction for the establishment of an IBC, the notification is made to the DG: *Regulation 16(2)*. (From here proceed to *Step 5*)

For export of LMO: the notification is made to the DG: *Form F.* (From here proceed to *Step 5*)

Step 4 – Assessment by the IBC and submission

The IBC must assess the activity in the notification and fill up the sections in the Form E relating to their details and specified information relating to its assessment. The notification is signed by the Chairperson of the IBC. The IBC must submit the completed form to the NBB together with the IBC Assessment Report form: see Form E, p. 7, instruction under item 9. See also *Guidelines for IBC*, IBC/AP/10/ANEX2, p. 30.

The IBC Assessment Report form may be downloaded from the Malaysian Biosafety Website at http://*www.biosafety.nre.gov.my*.

Step 5 – Submission to DG

Once all the information required by the form has been completed, the notification may be forwarded to the NBB through the DG. No fee is levied on the submission of notification.

3. Who must sign the notification forms?

The notification must be signed by the applicant, as well as the head of organisation or his authorized representative. The applicant must provide written proof of authorization. The head of the organisation could be the CEO of a body corporate, the Vice Chancellor/Rector of a university or other educational institute, or Director General/Director/Head of an Agency, Centre, Department, Division etc. Whereas the authorized representative may be anyone that the organisation considers appropriate and who has been duly delegated by the organisation. This is expected to be a senior officer in the organisation. It is important that the head of the organisation (or the authorized representative) signs the notification because the organisation will be the "approved

person" and will have responsibilities under it. It is therefore important that the organisation is fully cognisant of such obligations.

As noted in *Step 4* of *Question 2*, where R&D is to be undertaken, the IBC chair also must sign the form.

4. How many copies must be sent to the DG?

One original and six copies of the completed notification must be submitted to the DG, along with a soft copy of the submitted notification, including all supporting documents/attachments, if any, excluding any information that has been identified by the applicant as CBI. A copy of the notification must be retained by the organisation.

IMPORTANT NOTE

The applicant will also need to comply with any other relevant laws.

For example, in the case of exportation of LMO, the person must also comply with laws governing export and foreign trade: *Subsection 23(3)*.

For an *imported LMO* – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like DOA or MOH is required.

5. What if the notification contains confidential business information (CBI)?

The Act requires that an application must be made to the DG for declaring information as confidential: *Section 59(1) and (2)*. The instructions in the form (Form E and F, at p. 2 and 1 respectively) must be read accordingly to comply with the provisions of the Act. It is not for the applicant to declare unilaterally what he considers to be CBI. Practically, the applicant seeks the approval of the DG for any information which he wishes to be treated as confidential by marking that information in the Form as "CBI". Only if it is accepted as CBI by the DG can it be treated as such. The information then cannot be disclosed. Forms E and F provide that the CBI be omitted from the softcopy of the notifications submitted (see Form E, p. 4, item 5 under "Notification Check List"; and Form F, p. 3, item 3 under "Notification Check List"). (The provisions on CBI are elaborated in Chapter 9).

6. What are Biosafety levels?

The person carrying out contained use activities or importation for contained use involving LMOs must in their notification form indicate the relevant biosafety level applying to the activities. This is to ensure that the containment facilities are appropriate in accordance with the risk posed by the activities involving LMOs to protect human health and environment. The assignment of containment levels are based on existing international approaches to pathogenic organisms. The genetic modification BSL dictates the minimum level of containment required for carrying out activities with LMO and related materials originating from these organisms. Biosafety containment consists of three parts, namely, facility design, administrative controls, and engineering controls or use of Personal Protective Equipment. To determine the biosafety containment levels required for the LMO, the risk assessment should be done.

The organisation's IBC has the duty to determine the classes of Biosafety Levels.

The *Regulations* provide four classes of activities involving modern biotechnology: *Second Schedule*.

Biosafety Level 1 (BSL1): refers to activities of no or negligible risk.

Biosafety Level 2 (BSL2): refers to activities of low risk.

Biosafety Level 3 (BSL3): refers to activities of moderate risk.

Biosafety Level 4 (BSL4): refers to activities of high risk.

For more information regarding Biosafety Levels, please refer to the *Biosafety Guidelines for Contained Use of Activity of LMO*.

7. Is a new notification necessary each time a LMO is proposed to be exported?

There is no provision in the Act or the Regulations exempting from the need for notification of an LMO for subsequent similar activity. However, the Minister has extensive power to exempt, on the recommendation of the NBB. On this basis, an exemption has been granted for subsequent notification for export of an LMO for which there has been an Acknowledgement of Receipt of Notification. This exemption is:

b. for the same LMO;

c. to the same country; and

d. for the same purpose as stated in the Acknowledgement of Receipt.

If however the country of import requires approval or notification for any subsequent export of the LMO exempted by Malaysia, this requirement must be complied with. Exporters are therefore advised to find out and fulfill the requirements of the importing country before exporting any LMO.

Part D: The NBB's assessment process

1. What does the DG do upon receipt of a notification?

The DG undertakes an initial screening of the notification before accepting the notification. This initial screening involves checking to ensure that all of the information requested has been provided and that the notification has complied with the requirements of the Act and the Regulations; and where applicable, that the notification has been assessed by the registered IBC: *Regulation 16(2)*.

If the notification does not contain the necessary information, is inconsistent with the requirement of the law or contains any error or any unauthorized alteration, the DG may refuse to process the notification. The DG will either require that it be amended, completed, resubmitted or that a fresh notification be submitted. If the person fails to comply, the notification will be treated as withdrawn: *Regulation 17*.

If the DG is satisfied that the notification meets the basic requirements, the DG sends an acknowledgement of receipt to the person giving the notification: *Section 25; Regulation 18*.

The person to whom the acknowledgement is issued – the "approved person" can then start to undertake the activities relating to the notification and may continue subject to any further order made by the NBB: *Section 25*.

IMPORTANT NOTE

The main difference between the approval process (for direct release activity, as earlier discussed) and a notification process is that:

- For the approval process – the activity can only start after the approval is given;
- For the notification process – the activity can start after the acknowledgement of receipt is given.

In both cases the applicant becomes an "approved person".

2. What are the steps taken then?

Step 1 - DG refers notification

The DG then refers the notification to GMAC and relevant Government department or agency.

a) GMAC

Relevant provision of the Biosafety Act 2007: Sections 28 and 29.

The DG must refer the notification to the GMAC for its recommendations as to whether or not the activity relating to the notification should continue as proposed, and the terms and conditions to be imposed by the NBB, if any: *section 29(1)*. GMAC assesses the impact of the proposed export, contained use or importation for contained use activity involving LMO on the environment or on the health and safety of people. It will be recalled that the notification consists of the risk assessment and the risk management report by the applicant. Hence GMAC evaluates these reports and advises on the safety facets of the notification. GMAC in turn may also invite other experts, including international experts, to advise on any particular aspect of the notification. GMAC may also establish subcommittees as it thinks necessary or expedient to assist it. After all this, GMAC makes recommendations to the NBB whether or not the activities relating to the notification should continue as proposed and if it should, then it also recommends any terms and conditions that the NBB should impose. It is seen that the NBB is provided with the widest possible expertise to help it to make its decision.

b) Government department or agency

If the notification involves the expertise or is within the scope of a government department or agency, then the DG forwards the notification for its comments on any specific matter in its area of expertise.

Step 2 – Submit feedback to the NBB

The comments by the Government agency or department and the recommendations by GMAC are then forwarded to the NBB.

Step 3 – The NBB decides

The NBB then makes its decision on the notification.

3. What decision can the NBB take?

The NBB may decide to:

a. Order the approved person to make rectifications to the notification;

b. Impose terms and conditions for the activity;

c. Issue a cessation order;

d. Make any other order as it thinks fit in the interest of biosafety; or

e. Make no order.

Relevant provision of the Biosafety Act 2007: Section 30(3).

4. Can the applicant be required to supply additional information, particulars or documents (IPD)? If so, when?

Yes the applicant can be asked to supply additional IPD. There are four such situations.

a. First, the DG can request for the IPD after he receives the notification and before he sends the notification on to any government agency, GMAC: *Subsection 27(1)*.

b. Secondly, GMAC can also request for IPD when it is considering the notification: *Subsection 29(2)*.

c. Thirdly, the NBB can request for IPD after it has received the GMAC's recommendations and before it makes any decision: *Subsection 30(1)*.

d. Fourthly, the NBB may request for additional IPD after getting the further IPD under c. above: *Subsection 31(1)*.

In case (b) and (c), the request is made through the DG.

The purpose for seeking such IPD is mainly to facilitate the processing of the notification. The applicant may not have submitted the appropriate documentation or necessary information; or the IPD may be needed before a final decision to the notification is made.

4.1 What if the applicant fails to provide the IPD?

Then the processing of the notification ends at the stage at which the information is sought. If the applicant does not provide the further information within the specified timeframe, the DG must deem the notification or the acknowledgement of receipt issued to have been withdrawn. This does not affect the right to make a fresh notification: *Subsections 27(2), 29(3) and 30(2)*.

However it is an offence not to provide the IPD requested by the NBB directly, after the Board has requested for additional IPD (see d above): *Subsection 31(2)*.

4.2 How is the request for information made?

The request is made to the applicant in writing. The notice should state clearly and with precision what is required, as well as the timeframe within which the information must be supplied.

The time limit for considering a notification is suspended for the duration of the time during which the DG/NBB is awaiting a response to the request for additional IPD: *Regulation 23*.

5. What does the NBB take into account when making a decision?

To make a decision, the NBB must consider the recommendations of the GMAC: *Subsection 30(3)*. Although not specifically provided in the Act, the NBB would have before it as well:

- The comments of the relevant Government department or agency; and
- Any additional IPD furnished.

The decision for notification regarding contained use and importation for contained use will necessarily be based primarily

upon the evaluation by GMAC of the risk assessment report, the risk management plan, and emergency response plan; as well as the fulfillment of any other requirements under the *Biosafety Act* 2007: Form E.

The NBB's decision is based on its satisfaction that any possible risk and adverse effect posed by the activity relating to such notification can be prevented, reduced or controlled in a way which protects human, plant and animal health, the environment and biological diversity.

For exportation, the NBB will take into account the fact that the applicant has complied with the requirements of the importing country on the importation of LMO.

Precautionary Principle – Relevant provision of the Biosafety Act 2007: Section 35**; Biosafety Regulations 2010:** Regulation 25

6. What if there is insufficient relevant scientific evidence?

The NBB may take a decision even when there is lack of scientific certainty of the safety of the LMO. This is where there is insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of LMOs on human, plant and animal health, the environment and biological diversity: *Section 35*. This is referred to as the precautionary principle. In other words, if the scientific community is divided on the extent of the adverse impact of the LMO and there is not enough evidence to resolve the issue, the NBB can still make a decision.

7. Can the NBB also take into account socio-economic considerations?

Yes, it may also take into account socio-economic considerations of the impact of the LMO: *Regulation 25*. For example, the activity relating to a LMO may have an effect on the existing social and economic patterns and means of livelihood of the communities. It may impact the religious, social, cultural and ethical values of communities.[9]

[9] Several studies have pointed to the impact of LMOs on the distribution of benefits, public sector research, labour, global markets, competition, organic agriculture, IPRs and ethics, culture and religion: Lindsey Fransen *et al* (2005). *Integrating Socio-economic Considerations into Biosafety Decisions: the Role of Public Participation*, WRI White Paper, WRI Washington DC; Elenita C Dano (2007). *Potential Socio-economic, Cultural and Ethical Impacts of GMOs*, TWN, Penang, Malaysia.

8. Can the notification be refused on the basis of the suitability of the applicant?

No, the notification cannot be refused on the basis of the general suitability of the applicant. See however Section 33(1)(d) and (e).

9. How long will the NBB take to make a decision?

The NBB must make a decision - either to make no order, or to issue an order - within 90 days from the date it receives the notification: *Subsection 30(4)*.

The time for making the decision cannot be extended.

Times does not run during the period that the applicant does not provide information required of him.

10. Who will be informed of the decision?

Both the applicant (*Section 30*) and the public (*Section 60*) will be informed of the decision.

11. How will the NBB inform its decision?

The NBB must communicate its decision in writing to the approved person: *section 30(4)*. It must be sent either personally or by A.R. registered post. The notice is sent:

- in the case of a company incorporated in Malaysia, to the address of the registered office of the company;
- in the case of a company incorporated outside Malaysia, either to the individual authorized to accept service of process under the Malaysian Companies Act, or to the address filed with the Registrar of Companies or to the registered office of the company;
- in the case of an individual or a body of persons, to the last-known business or private address of such individual or body of persons

Section 63.

Any decisions made by the NBB on the notification is also posted on the Malaysian Biosafety Website. For more information regarding the Malaysian Biosafety Website, please refer to Chapter 12.

Part E: Rights and responsibilities of approved person

1. If the NBB issues a cessation order, what should the approved person do?

The approved person must:

1 stop all activities involving LMOs immediately; and

2 surrender the acknowledgement of receipt of a notification to the NBB. He must do this within 7 days from the date of the notification of the cessation order: *Subsection 30(5)*.

The approved person also has the right to appeal against the decision: see below item 7.

Any approved person who fails to comply with the order made by the NBB commits and offence and is liable, on conviction to be punished by the imposition of a fine and/or imprisonment.

2. If the NBB orders to make rectifications, what should the approved person do?

First, the approved person must notify the NBB through the DG in writing of the rectification he has done.

Secondly, he must submit any additional information or document if requested to do so by the NBB. This must be done within 15 working days from the date of the request. The person may ask for an extension of time in writing to supply the information/ document. The NBB may grant the extension as it deems fit. If the additional information or documents required are not provided within the timeframe, the rectification will be treated as withdrawn.

2.1 Fresh rectification

The approved person may however submit a fresh rectification. If the additional information or documents are provided, the NBB will either approve the rectification and rectify the original notification, or direct a fresh notification to be submitted as if it is a totally new notification.

2.2 Can the activity be continued pending the decision by the NBB?

Yes, during this period, the approved person is allowed to continue undertaking the activities as specified in the original Notification: *Regulation 19*.

3. What terms and conditions can the NBB impose if it decides to do so?

The Act does not state the precise terms and conditions that the NBB may impose relating to the notification. However these may be implied from the factors that it may take into account when deciding on the notification:

- Authorized scope of the activity;
- Purposes for which the activity may be undertaken;
- Documentations and record-keeping requirements;
- Required level of containment in respect of the activity;
- Waste disposal requirements;
- Measures to manage risks posed to the health and safety of human or the environment;
- Data collection, including studies to be conducted;
- Auditing and reporting including, where appropriate, condition for entry into premises where the activity is being undertaken;
- Actions to be taken in the case of release of LMOs from a contained environment;
- Geographical area in which the authorized activity may occur;
- Compliance with any code of practice or technical or procedural guideline that may be issued;
- Supervision and monitoring by the IBC;
- Contingency plan relating to unintended effects of the authorized activity;

- Conditions requiring the approved person to be adequately insured against any loss, damage or injury that may be caused to human health, property or the environment;
- Any other factors as the NBB thinks fit.

Regulation 9(2)

- The specific measures as indicated by the applicant and approved by the NBB: *Section 26*.

4. If the NBB decides to make no order, can the approved person continue carrying out the approved activity?

Yes.

5. Can the terms and conditions imposed be varied?

No. But the approved person may appeal against such terms and conditions. Then depending on the decision, the terms and/or conditions may indeed be varied or revoked.

6. What happens if the approved person contravenes an order of the NBB?

If the approved person fails to respond to, or comply with, the order of the NBB within the timeframe designated by the law or the NBB, he has committed an offence and is liable on conviction to a fine and/or imprisonment: *Subsection 30(6)*.

7. Can the approved person appeal against a decision made by the NBB?

Yes. Any approved person may appeal against any decision relating to the notification made by the NBB. The appeal is made to the Minister of NRE: *Section 34*.

8. How does the applicant/approved person proceed with the appeal?

He must:

1. give notice to the Minister in writing of the intention to appeal within 30 working days from the date he received the decision; and

2. submit the grounds of appeal and other relevant documents within 30 working days after giving the notice: *Regulation 20*.

NOTIFICATION CHECK LIST

1. Check to see if the proposed activity involving LMO is exempt from the Act. If it is not, the proposed activity must be notified to the DG. The DG issues an acknowledgment of receipt of notification. The activity may then commence.	☐
2. If the activity is for contained use or import for contained use, complete notification Form E. The form is included at Appendix 5 of this User's Guide. If it is intended to export the LMO, complete notification Form F. The form is included at Appendix 6. The forms are available from the Malaysian Biosafety Website http://www.biosafety.nre.gov.my	☐
3. For contained use and importation for contained use involving R&D of LMO, submit the completed notification form to the relevant IBC. For other importation, contained use activities, or exportation which are not involving R&D of LMO, submit to the DG. In former case, the IBC completes those parts of the form that deals with verification of information supplied by the applicant in the form. It must also provide an assessment report. The applicant must also provide relevant supporting IPD.	☐
4. Make sure that the signatures of the applicant, head of organisation or authorized person and the IBC chairperson, if necessary, accompanied by their official stamps are obtained.	☐

5. For import of LMO, provide date of importation, or intended importation; and a copy of documentation on clearance or assessment from the relevant authorities such as DOA, MOH. Comply with any other relevant laws, such as on quarantine, customs, etc. For export of LMO, comply with relevant laws on export and foreign trade.	☐
6. Apply to DG if any information is intended to be treated as confidential business information. The information in the application form must be clearly marked "CBI".	☐
7. Submit the completed notification form to the DG as follows: 1 original copy, 6 copies and a soft copy (including all supporting documents/attachments, if any). Exclude from the soft copy information that the applicant has identified as CBI. Keep a copy.	☐

Note: For any queries or concerns at any time, contact the DOB on +603 8886 1580 or 1579 or email biosafety@nre.gov.my

EXPORT, IMPORT AND TRANSPORT OF LMOs

CHAPTER 7

Part A: Export of LMOs

1. Is the export of LMOs regulated under the *Biosafety Act 2007*?

Yes. One of the activities involving LMOs that is regulated under the *Biosafety Act* is the export of LMOs. This means that anyone wishing to export a LMO must first notify the NBB to do so. He must comply with the requirements of the importing country and must inform the NBB of such requirement and provide evidence that he has complied with these requirements. The export can commence once the acknowledgement of receipt of notification is issued by the DG. There is no need to submit a further notification for any subsequent export of the same LMO where an acknowledgement of Receipt is given. Please refer to Chapter 6 for further requirements to qualify for the exemption.

IMPORTANT NOTE

It is important to note that the requirements for export of LMOs are in addition to any requirements under other laws, such as the *Quarantine and Inspection Services Act 2011* as administered by the Malaysian Quarantine and Inspection Services (MAQIS), under the Ministry of Agriculture and Agro-based Industry.

Part B: Import of LMOs

1. Is the import of LMOs regulated under the *Biosafety Act 2007*?

Yes. One of the activities involving LMOs that is regulated under the *Biosafety Act* is the import of LMOs. This means that anyone wishing to import a LMO, or product of a LMO, into Malaysia must have approval to do so. The type of approval necessary will depend on the intended purpose of the use of LMO to be imported. That is, whether the LMO is imported for contained use; or for releasing into the environment, that is, "release activity". These are defined as (*2nd Schedule, Section 3*):

- import for R&D purposes in all field experiments;
- supply or offer to supply for sale or placing on the market;
- offer as gift, prize or free item;
- disposal;
- remediation purposes;
- any other activity which does not amount to contained use.

IMPORTANT NOTE

For an *imported LMO* – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like DOA or MOH will be required to be submitted together with the notification or approval application: Form A, item 10; Form B, item 10; Form C, item 6, Form D, item 6; and Form E, item 9. As to the activity for which the form is used, see Chapter 1, Part B: "Prescribed Forms".

It is important to note that the requirements for import of LMOs are in addition to any requirements under other laws such as the *Quarantine and Inspection Services Act 2011* as administered by the Malaysian Quarantine and Inspection Services (MAQIS), office of the Ministry of Agriculture and Agro-based Industry.

2. When does an applicant become an "approved person"?

Any person or legal entity who applies for the approval of an activity involving a LMO that is regulated by the Act and the Regulations becomes an "approved person":

a) if the LMO is imported for contained use, when an acknowledgement of the receipt of notification is issued by the DG (See Chapter 6 for further details); or

b) if the LMO is imported for activities other than contained use, when a certificate of approval is granted by the NBB (See Chapter 5 for further details).

3. Is a new approval required for the importation of a LMO, or product of a LMO, that has already been approved by the NBB?

It depends. A person need not seek fresh approval if he has already been given an approval for importation for release into the environment involving the same LMOs or products of such LMOs. The subsequent importation must involve the similar purpose of importation, and the same transformation event as the approved LMO. In other words, the first approval is valid for subsequent similar importation involving the same LMOs. And it must be undertaken by the same approved person: *Section 17*.

A fresh application is needed if it is not made by the approved person, or if the importation is for a different purpose, or if the subsequent LMO does not involve the same transformation event[10] as the approved LMO.

4. Does the person approved to import a LMO also need approval from other department/ agencies?

Yes, he must comply with any other applicable law.

For example, under the *Quarantine Act 1976*, plants imported into Malaysia are subject to controls to manage the risk of introduction, establishment and spread of pests and diseases

[10] An LMO, typically and LM plant, with a specific modification that is the result of the use of modern biotechnology applying in vitro nucleic acid techniques.

that may endanger Malaysia's plant, animal and human health environment. The pest and disease risks associated with a plant (including GM plant material) will be assessed and monitored by the MAQIS of the MOA.

For animals and birds, the Department of Veterinary Services is empowered to impose the quarantine.

For microorganisms and organic material (GMO and non-GMO), the importation is under the purview of the Department of Agriculture.

If you are proposing to import a LMO or products of a LMO into Malaysia, you should familiarize yourself with any such requirements and ensure that you comply with them.

Part C: Transport of LMOs

1. What are the requirements for transport of LMO materials?

The transportation involving LMO must be carried out in compliance with national and international regulations and guidelines. The LMO being transferred should be packaged in secure containers capable of preventing material loss during transportation. The LMO should also be kept separate from other materials. Additionally, the regulatory authorities, which are the IBC and the NBB, must be notified through the application form. Detailed explanation on the procedures for packaging and transport of LMOs are tabulated according to the type of LMO in the *Biosafety Guidelines for the Contained Use Activity of LMOs*. These LMOs are categorized as follows:

- Microorganism and cell lines;
- Plant;
- Animal;
- Arthropod; and
- Aquatic Organism.

For further details, please refer to Chapter 16 of the *Biosafety Guidelines for the Contained Use Activity of LMOs*.

CHAPTER 8

REGULATION OF "PRODUCTS OF SUCH ORGANISMS"

1. What are GM products?

GM products are referred to in the Act as "products of such organisms". It is defined in the Act as *any product derived from a LMO or part of a LMO*

(a) if the product contains detectable recombinant deoxyribonucleic acid (DNA); or

(b) where the profile, characteristic or properties of the product is or are no longer equivalent to its conventional counterpart irrespective of the presence of the recombinant deoxyribonucleic acid (DNA).

Section 3

In essence, a GM product is a non-viable product of a LMO that cannot propagate or grow in the environment.

Some examples of GM products include:

- GM food that is not live or viable (for example, processed food); and
- GM agricultural and veterinary chemicals that are not live or viable LMOs, but have been produced from LMOs.

The essential difference between LMOs and GM products is that LMOs are organisms that are viable, capable of transferring or replicating genetic material. GM products are derived from LMOs but are not viable, capable of reproduction or capable of transferring genetic material.

2. Why are GM products regulated when the Cartagena Protocol on Biosafety does not?

First, national law can be wider, if any party to the protocol deems it necessary to regulate LMOs and products coming into the country – to ensure that these do not harm human health and the environment.

Secondly, as the book 'Introduction to the Cartagena Protocol on Biosafety' by the Convention of Biological Diversity Secretariat explains: the concept of 'biosafety' refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology.

Thirdly, the risk assessment principles in the Cartagena Protocol on Biosafety talk of the evaluation of risks associated with LMOs or products thereof (Annex III of the Cartagena Protocol).

Several countries regulate GM products, in some form. Examples: Norway, Brazil, European Union (placing on the market) and Australia (Regulator to maintain a Record of GMO and GM Product Dealing).[11]

3. Are all GM products regulated?

It depends on the purpose the GM products are being used. The Act only regulates GM products imported or used for release activities. These activities include the following:

(a) Supply or offer to supply for sale or placing on the market;

(b) Offer as gift, prize or free item;

(c) Disposal;

(d) Remediation purposes; and

(e) any activity which does not amount to contained use.

In practice, the application forms exclude the use of GM products for release activities involving R&D purposes for all field experiments, although this is also defined by the Act as a "release activity".

---

11 CEBLAW, Framework Study on Biosafety Laws, February 2010, unpublished.

The product must of course come within the definition of a product of an LMO as described earlier. That is, it must have rDNA or is significantly different to its conventional counterpart. For example, the importation for sale of cornflakes made of GM corn is regulated by the Act.

The Minister has exempted from the requirements of the Act products made from LMOs or from products of LMOs that have been approved for direct use as food, feed and processing. This is where such products are for the purpose of:

- sale or placing on the market; and
- offered as gift, prize or free item.

Thus any product made from a GM corn that has been approved under the Act for food, feed or processing is not regulated by the Act if the product is for sale or given as a gift, prize or as a free item.

The Minister also has exempted the following products of LMOs:

- Cotton used as fiber for any purpose and in any form;
- Wood used for building and furniture.

IMPORTANT NOTE

Any person intending to import products of LMOs exempted under the *Biosafety Act* are required to comply with other applicable laws, such as, Food (Amendment) Regulations 2010. The Regulations 2010 oblige any person who wishes to import, prepare or advertise for sale or sell any food and food ingredients obtained through modern biotechnology to obtain the prior written approval of the Director of Health, MOH. Currently, the MOH takes about two weeks to process the application. The MOH is formulating guidelines for the process.

4. Is there a need to label the products of LMO?

It is important to note that all GM food products and ingredients must be labelled: *Section 61 of the Act; Food (Amendment) Regulations 2010, Regulation 11*. The former requires all GM products to be identified and labelled. The latter obliges the applicant to label GM food and food ingredients before releasing

them to the market. This includes food and feed ingredients produced from, but that do not contain, GMOs.

Mandatory and not voluntary labeling was preferred as the latter is considered ineffective. Further, it is the paramount interest of the consumer to know what he is buying. Malaysia imposes labeling requirements for a large range of food products.

5. Who regulates GM products?

As noted earlier, the *Biosafety Act* regulates GM products. Such products may also be regulated by other laws, as emphasized earlier.

6. How does the NBB regulate GM Products?

GM products for release activities have to go through the same process as other release activities involving LMOs. The applicant has to fill up the form (Form C or D) and follow the same process.

The difference would be in the type of information to be provided to the NBB. For example, the applicant has to only fill up Part E of the form. Thus, questions like survival rate, persistence of transgene in the environment, and the release site will not apply. For an elaboration of the application process and the NBB's assessment process, please refer to Chapter 5.

7. Can the approved person sell the products derived from the approved LMO for R&D either for field experiments or contained use?

Strictly, no. Sale of an LMO product is a separate release activity that requires a separate approval process. The original approval for a field trial will not cover any product that is developed out of the R&D arising from the field trial. So too, the notification for contained use will not extend to the sale of the product arising out of the R&D in contained use.

For example, an applicant may apply for an approval to undertake field experiments of GM cotton. Following harvest of the LMO, the applicant may wish to use the cotton seed that has been rendered unviable as animal feed. This use of the product derived does not form part of the approval process. Then there is no approval and the approved person would be required to apply afresh as regards the release activity (which includes sale) of the LMO product.

CONFIDENTIAL BUSINESS INFORMATION (CBI)

CHAPTER 9

1. Can the applicant apply for treatment of information as CBI?

Yes. An applicant may apply to the DG for confidentiality of any commercial and industrial information relating to the approval application or notification.

Relevant provision of the Biosafety Act 2007:
Section 59

For example:

- applicants for an approval may apply for parts of their application to be treated as CBI;
- persons providing information to the DG as part of a notification may apply for parts of their notifications to be treated as CBI.

2. How does the applicant apply for treatment of information as CBI?

Any information within the approval application or the notification which is to be treated as CBI, should be clearly marked "CBI" in the relevant parts of the application/notification form and justification for the request for CBI must be provided.

In the notification forms, a specific section is created for person giving notification to fill up information considered as CBI.

The information that has been identified by the applicant as CBI should then be omitted from the softcopy of the Form submitted by the applicant.

3. On what grounds may the applicant apply for treatment of information as CBI?

The Act sets out criteria that the DG must consider before the DG may grant confidentiality. The DG must be satisfied that the information specified in the application:

(a) is not known generally among, or readily accessible to, any person within the circle that normally deals with the kind of information sought to be made confidential;

(b) has commercial value because it is secret; and

(c) that reasonable steps have been taken to keep the information secret.

Subsection 59(3)

4. If the information for which the applicant is seeking for confidentiality treatment meets these criteria will the information automatically be treated as CBI?

Not necessarily. This is because the Act states that the DG *may* grant confidentiality based on the stipulated criteria. This implies that he has discretion to consider other matters such as whether the public interest in disclosure outweighs any prejudice that the disclosure would cause. If the DG considers that the public interest warrants disclosure of the information, he may refuse to grant confidentiality, even if the stipulated criteria have been met.

5. Is there any information the applicant cannot apply for treatment as CBI?

Yes. The following information cannot be considered confidential:

a. The name and address of the applicant;

b. A general description of the LMO;

c. A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

d. Any methods and plans for emergency response.

6. What about information relating to the location of field experiment sites?

The Act and the Regulations are silent on this. However administratively, the information about the location of field trial sites is treated a little bit differently to other CBI information. It is considered to be in the public interest to release the location of field experiment sites. This should only be overridden in very limited and exceptional circumstances, such as where there is clear evidence of possible vandalism. The DG can in the exercise of his discretion, grant or refuse to grant confidentiality for any information taking into account the criteria as elaborated in item 3 above.

7. What is the effect if the DG grants confidentiality?

If the DG grants confidentiality to certain information, the DG must not publicly release such information. This means that the information to which the confidentiality is granted would not:

- in the case of applications for approval for release activities and importation involving the LMO, be released for public consultation: *Subsection 59(2)*;
- be accessible by way of a request for access to information relating to any application for approval, approval granted or notification: *Subsection 60(1)*.

Even if the DG grants certain information to be CBI, the DG may disclose the information only *(Subsection 59(4))*:

- to any of the following in the course of carrying out duties or functions under the legislation:
    - the GMAC, or any of its subcommittees;
    - the NBB, or any of its committees; or
    - any relevant Government department or agency.
- for the purposes of any civil or criminal proceedings under any written law.

8. What if the CBI is disclosed?

The Act makes it an offence for any person who, during his tenure of office or during his employment or thereafter, discloses CBI. The punishments include fine and/or imprisonment: *Subsection 59(5)*.

CHAPTER 10

Review of Decisions Made Under the Legislation and Appeal

Part A: Reviewable decisions

Relevant provision of the Biosafety Act 2007: Section 18, 32 and 35.

1. What decisions are reviewable?

The following decisions are reviewable decisions for the purposes of the legislation:

1 approval granted;

2 notification approved.

2. Who can review the decisions?

The NBB in consultation with GMAC: *Subsections 18(1) and 32(1)*.

3. Can the applicant or approved person seek for review of decisions made by the NBB?

No. Any applicant or approved person aggrieved by a decision of the NBB may either appeal to the Minister, or request for variation in the case of terms and conditions imposed on the certificate of approval.

4. Under what circumstances can the NBB review its decision?

The NBB may review its decision upon obtaining new information or evidence on the LMOs or products of such LMOs. It can do so at any time.

5. What are the considerations taken into account before the NBB makes further order upon the review?

These are: when the NBB is satisfied that there is a risk posed to human, plant or animal health, the environment or biological diversity by the activity: *Subsection 18(2) and 32(2)*.

6. What order can the NBB make on its review?

In the case of a certificate of approval granted, the NBB may either:

i. revoke the approval;

ii. make a temporary cessation order;

iii. impose additional terms and conditions;

iv. order the approved person to make rectifications; or

v. make any other order as the NBB thinks fit.

In the case of a notification approved, the NBB may either:

i. make a cessation order;

ii. impose additional terms and conditions;

iii. order the approved person to make rectifications; or

iv. make any other order as the NBB thinks fit.

7. What should the approved person do if he receives a further order by the NBB?

If the certificate of approval is revoked or a cessation order for the notification is made, the approved person must:

- immediately stop all works involving LMOs and/or products of such organisms; and
- surrender to the NBB the certificate of approval or the acknowledgement of receipt of notification, as the case may be, within 7 days from the date the order is communicated.

If the NBB makes a temporary cessation order (only in the case of certificate of approval), the approved person must:

- immediately stop all works involving LMOs and/or products of such organisms; and
- surrender the certificate of approval within 7 days from the date the order is communicated, for the NBB to endorse the fact and duration of the temporary cessation.

If the NBB decides to impose additional terms and conditions for the certificate of approval, the approved person must:

- surrender the certificate of approval within 7 days from the date the notice is communicated, for the NBB to endorse such additional terms and conditions.

The law does not state what the approved person is required to do when rectifications are ordered upon a review. Presumably he has to carry out the order as otherwise it is an offence if he fails to do so. The procedure for rectifications discussed earlier (Chapter 6, Part E) only applies when the NBB orders rectifications with regard to the notification.

IMPORTANT NOTE

Any contravention of the orders of the NBB is punishable under the Act by fine and/or imprisonment.

Part B: Appeal

1. Who may appeal against a decision under the Act?

Relevant provision of the Biosafety Act 2007: Sections 20 and 34; **Biosafety Regulations 2010:** Regulation 20.

In summary, the following people may appeal against a decision made by the NBB:

- approval applicants;
- approval holders;
- notification applicants; and
- holders of acknowledgement of receipt of notification.

2. What decisions are appealable?

The following decisions are appealable:

- refusal of an approval application;
- imposition of terms or conditions;
- imposition of additional terms or conditions
- suspension of an approval;
- revocation of an approval;
- rectification to an approval;
- refusal of an application for variation to an approval;
- request for additional IPD by the NBB;
- cessation of the activity in the notification; and
- rectification to the notification.

3. How to exercise the right of appeal?

The appeal is made to the Minister of Natural Resources and Environment, by:

1 giving notice to the Minister in writing of the intention to appeal within 30 working days from the date the decision was communicated; and

2 submitting to the Minister the grounds of appeal and other relevant documents within 30 working days after giving the above notice.

Regulation 20

REPORTING, MONITORING AND ENFORCEMENT

CHAPTER 11

Part A: The NBB's powers of enforcement

1. What are the options for enforcement?

The NBB has a range of options open to it in the event of non-compliance with the law or its orders.

The options adopted by the NBB will depend on the type of non-compliance and the significance of the non-compliance.

Some of the options open to the NBB include the power to:

- Make further orders, namely:
  - Imposition of additional terms and conditions: *Subsections 19(1) and 33(1)*
  - temporary cessation: *Subsection 19(1)*
  - revocation of the approval: *Subsection 19(1)*
  - issuance of rectifications orders: *Subsections 19(1) and 33(1)*
  - cessation: *Subsection 33(1)*
- conduct investigation: *Section 39*
- search by warrant: *Section 40*
- search without warrant: *Section 41*
- access computerized data: *Section 42*
- seal premises: *Section 44*

- forfeit LMOs or products of such organisms: *Section 45*
- examine persons acquainted with case: *Section 49*
- require production of things related to offence: *Section 50*
- require supply of information on LMOs or products thereof: *Section 52*
- take samples: *Section 53*.

The course of action selected by the NBB will depend on the particular circumstances and the severity of the breach of the condition.

2. Under what circumstances can the NBB make further orders as part of the enforcement process?

The circumstances are when:

i. There is risk posed to human, plant or animal health, the environment or biological diversity;

ii. The approved person fails to comply with the terms and conditions;

iii. The approved person fails to comply with any order made by the NBB;

iv. The approved person contravenes the Act or Regulations; or

v. The approved person is convicted of an offence under the Act or Regulations.

If the approved person does not, within a specified time comply with the order issued, an enforcement officer of the NBB may apply for a warrant to conduct a search. The enforcement officer may also search without a warrant if he has reasonable cause to believe that a delay in obtaining a search warrant would adversely affect the investigation.

The enforcement officer has the power to seize any LMOs or products thereof: *Section 45* and must then provide a list of things seized: *Section 43* to the approved person.

If costs are incurred by the NBB in taking steps to bring the

activity back into compliance with the legislation, such costs may be recovered from the approved person by virtue of Section 46 of the Act.

Example:

If a LMO plant has been released in breach of a condition of containment, the DG can direct the approval holder to immediately re-contain the plant and test the surrounding areas to ensure the plant has been re-contained. If the approval holder doesn't have the necessary skills and expertise to re-contain the plant, the NBB may employ specialized persons to do so, and recover the costs associated with this from the approval holder.

3. What are the offences provided under the law?

The offences are:

- undertaking release activity or importation of LMO without prior approval of the NBB;
- undertaking exportation of LMO, contained use or importation of LMO for contained use without giving prior notification to the NBB;
- contravention of terms and conditions imposed on the approval;
- failure to furnish IPD required by the NBB after the grant of certificate of approval or authorization of the notification;
- contravention of any order made by the NBB;
- failure to take approved specific measures in relation to a contained use activity involving LMO;
- failure to implement the measures proposed in the risk management reports;
- failure to comply with the minimum risk management measures imposed by the NBB;
- failure to take the necessary measures in an emergency according to the emergency response plan;
- failure to produce any organism or product that is suspected of being a LMO or product of such organism, or other items as

required in writing by an enforcement officer;

- failure to furnish any information relating to the composition and use of the LMOs or products of such organisms as required by the NBB;
- refusal to comply with any demand made by an enforcement officer regarding samples of any organism or product suspected of being or containing LMO or products of such organisms;
- making a false entry, omits to make, alters, abstracts, conceals, destroys, forges a document;
- failure to comply with the direction of the NBB to establish an IBC when undertaking R&D with regards to genetic modification of LMO;
- assignment or transfer of certificate without the approval of the NBB; and
- undertaking release activity or importation of LMO that is not authorized by the certificate of approval.

Note: The Minister is given the power to determine offences as compoundable: section 66(1). However he has not exercised any such power.

Part B: Compliance

1. Who is responsible for compliance?

The responsibility for biosafety at an organisation conducting research involving LMOs rests with the Head of the Organisation and its PI who obtains, possesses or uses LMO/rDNA materials. This is set out in the *Guidelines for IBCs: item 2.10, p. 15*. The Guidelines, which supplement the Act and the Regulations, have been established by the DOB of the NRE.

In the case where IBC is established, the PI is accountable to the IBC and must comply with the appropriate research guidelines and all applicable laws and guidelines related to biosafety.

The IBC is responsible in providing guidance to ensure compliance

with the legislation. The BSO is designated to assist the IBC in assuring compliance with the Act and the Regulations pertaining to LMO/rDNA research conducted at an organisation.

On IBCs generally, see Chapter 1, Part C, item 4.2.

The practice is that in all other cases, where there has been no direction for the establishment of an IBC, the responsibility to ensure compliance is borne by the applicant, Head of the Organisation and the relevant biosafety officer.

Part C: Reporting requirements

1. Who is responsible for reporting?

There is nothing in the Act or the regulations as yet that provide for periodic reporting as part of the risk management. However the *Guidelines for IBCs* require reporting by institutions carrying out R&D involving LMOs.

The IBCs are assigned the responsibility for reporting. They are required to review and report to the Head of the organisation and to the NBB any significant problems with non-compliance of the Act and the Regulations as well as any significant research-related accidents or illnesses.

The IBCs are also required to submit an annual report to the NBB on behalf of the organisation, through its BSO. The PI is responsible for ensuring that the reporting requirements under the Act Part V (Risk Assessment and Risk Management Reports and Emergency Response Plan) are fulfilled.

In the case of contained use activities not involving R&D and release activities not involving R&D, where no IBC is established, the practice of the NBB is to impose the obligation of reporting on the applicant when approving the activity.

2. What to report?

The *Guidelines for IBCs* require reporting of incidents or spills. There are three categories of reporting, namely:

- internal reporting,

- external reporting, and
- other external reporting.

The categorization of the reporting is based on the authority to which the report is sent.

For internal reporting, the *Guidelines for IBCs* provide that the PI/laboratory personnel must report any laboratory research incident to the IBC through the BSO using the Incident Reporting Form (IBC/IR/10/ANEX3) within 24 hours. Laboratory personnel include technician, technologist, student, and post-doctorate candidate.

Incidents include:

- non-compliance of the Act, or
- any significant research-related accidents and illnesses, for example,
  - exposure to any uncontained LMO/rDNA materials,
  - any overt exposure in a BSL-2 lab such as a needle-stick injury, splash, or contamination from equipment failure or
  - a potential or overt exposure in the BSL-3 or BSL-4.
- a significant event may also occur from a containment breach in the GM facility or at the field experiment location, which may be subsequently determined to pose both an overt or potential exposure to individuals and the environment.

If necessary, the BSO will activate the RRT to respond to the incident.

If there is any occupational exposure to LMO/rDNA materials, the PI/laboratory personnel will use the Occupational Disease/ Exposure Investigation Form (IBC/OD/10/ANEX4) to make a formal report within 24 hours **to**:

- The OHSC established under the guidelines of the Occupational Safety and Health Act 1994,
- The Head of the Organisation, and
- The IBC.

For external reporting, the PI is responsible for reporting any incident by submitting the Incident Reporting Form (IBC/IR/10/ANEX3) **to NBB** within 48 hours from the incident. This form should be reviewed by BSO before submission. If there is any occupational exposure to LMO/rDNA materials, the Occupational Disease/Exposure Investigation Form (IBC/OD/10ANEX4) should be submitted to NBB within 24 hours from the incident. These form(s) should be sent to the DG of the DOB.

For other external reporting, the NBB may, if deemed necessary, recommend that the IBC inform the incident **to external agencies** such as the local public health departments, state agencies, and the relevant funding bodies.

Note: The NBB may, in granting the certificate of approval, or approving the notification, impose terms requiring auditing and reporting including condition for entry into premises where the activity is being undertaken.

In the case of contained use activities not involving R&D and release activities not involving R&D, it would depend on the terms and conditions imposed by the NBB. This is on a case by case basis.

Part D: Monitoring

1. Who is responsible for monitoring?

The IBC is responsible. It is tasked to:

- monitor activities dealing with modern biotechnology; and
- monitor the implementation of policies and procedures for the purpose of handling LMOs.

Where no IBC is established, based on practice, in the case of contained use activities not involving R&D and release activities not involving R&D, it would depend on the terms and conditions imposed by the NBB. This is on a case by case basis.

2. What does the IBC do to monitor?

The IBC is required to, among others:

- Periodically review research projects that are recommended for approval;

- Assess and monitor the facilities, procedures, practices, training and expertise of personnel involved in research;
- Assess and set containment levels and modify them as necessary;
- Assess field experiments to ensure that the proposed risk assessment, risk management and emergency response plans are sufficient;
- Adopt and implement emergency response plans covering accidental spills and personnel contamination, resulting from LMO/rDNA research;
- Review and report to the head of organisation and the NBB any significant problems with non-compliance of the Act or Regulations and any significant research-related accidents or illness;
- Recommend suspension of project approval or use of LMO/rDNA materials where there is non-compliance or that the use or possession poses a threat to the health and safety of the community; and
- Routinely review the policies and procedures of the IBC and modify as necessary to ensure appropriate biosafety measures and compliance with the Act and Regulations.

3. Who assists the IBC in carrying out its functions to monitor?

The BSO and the PI.

4. What will happen in the case of an emergency?

The approved person must take all necessary measures to deal with an emergency involving any LMO or product of such organism. If the approved person fails to do so, or is incompetent to do so, the DG may seek the assistance and co-operation of the relevant agencies in implementing any emergency measure including those measures provided in the emergency response plan. Any costs incurred in implementing the emergency measures must be borne by the approved person.

Part E: Reporting of non-compliance with the legislation

1. Is the NBB obliged to publicly report cases of non-compliance?

No, there is no obligation imposed by the Act or the Regulations to do so.

THE MALAYSIAN BIOSAFETY WEBSITE

CHAPTER 12

1. Is there a website address for biosafety in Malaysia?

Yes. The website address is www.biosafety.nre.gov.my.

It is called the Malaysia Biosafety Website. It is under the management of the DOB, NRE.

2. What is included on the website?

The website includes:

- contact details for the DOB;
- information about the vision, mission, objective and functions of the DOB and its organisation chart;
- information about the functions of NBB and its chairperson and members;
- information about the functions of GMAC and its chairperson and members;
- Malaysian biosafety laws: the *Biosafety Act 2007* and the *Biosafety (Approval and Notification) Regulations 2010*;
- the *Guidelines for IBCs*;
- the *Biosafety Guidelines for Contained Use Activity of LMO*;
- forms relating to:
    - registration of IBC,
    - assessment of project proposal,

    - incident reporting,
    - occupational disease/exposure investigation, and
    - project extension and notice of termination;
- briefing on the approval process with a flow chart and downloadable approval application forms;
- briefing on the notification process with a flow chart and downloadable forms for notification;
- the approved events, products and field experiments involving LMOs;
- on-going bilingual public consultation containing fact sheet on the activity proposed and public announcement;
- public consultation archives;
- up-coming and past events;
- press releases;
- response to letters;
- publications; and
- links to:
    - the Biosafety Clearing House Central Portal;
    - the Cartagena Protocol on Biosafety; and
    - the Convention on Biological Diversity.

The website will be updated regularly so as to provide the visitors up-to-date information on biosafety-related issues in Malaysia.

CHAPTER 13

FEES AND CHARGES

Relevant schedule of the Biosafety Regulations 2010: 3rd Schedule

1. Are there any fees or charges associated with applications made under the legislation?

Yes. The Regulations levy fees only for the approval application for release activities although the Regulations provide for the application for contained use to be accompanied by a prescribed fee.

For release activities, the Regulations prescribe the fees as follows:

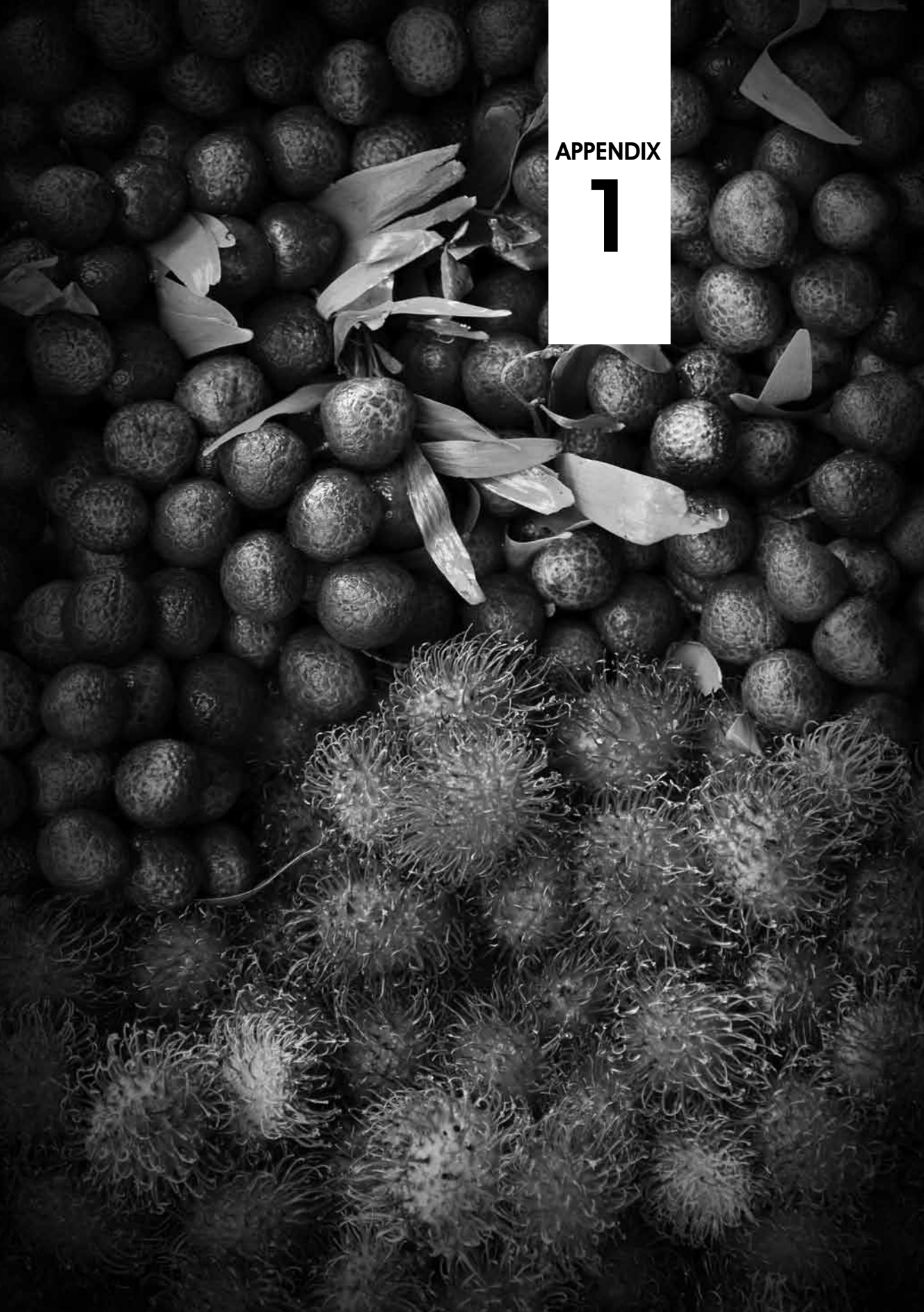
- For R&D purposes in all field experiments per release site:
  - less than 5 hectares – RM100;
  - 5 hectares to 10 hectares – RM250;
  - More than 10 hectares – RM500; and
- All release activities other than above – RM5000.

2. How to make the payment?

The fees must be paid by money order or bank draft in the name of the Secretary General of the Ministry of Natural Resources and Environment.

IMPORTANT NOTE

The fees submitted are not refundable. Any fresh application must be accompanied by the prescribed fee.



APPENDIX 1

NBB REF NO :
(For Office Use)

BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/A/ER/10/FORM A

APPROVAL FOR RELEASE ACTIVITIES OF LIVING MODIFIED ORGANISM (LMO) (RESEARCH AND DEVELOPMENT PURPOSES IN ALL FIELD EXPERIMENTS) OR IMPORTATION OF LMO THAT IS HIGHER PLANT

NBB/A/ER/10/FORM A shall be submitted to the Director General as an application for certificate of approval of release of LMO [Research and development purposes in all field experiments - Second Schedule of the Act - 1] or importation of living modified organism (LMO) that is a higher plant (not for contained use activities). Any organization undertaking modern biotechnology research and development shall submit the form through its registered Institutional Biosafety Committee (IBC). The IBC should assess the information in the form prior to submission. Application must be accompanied by the prescribed fees as found in Third Schedule of the Biosafety (Approval and Notification) Regulations 2010. Not all parts in this form will apply to every case. Therefore, applicants will only address the specific questions/parameters that are appropriate to individual applications.

In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated. The risk assessment, risk management plan, emergency response plan and the fulfillment of any other requirements under the Biosafety Act 2007 will be the basis of the issuance of the certificate of approval by the National Biosafety Board (NBB).

The applicant shall submit 1 original and 6 copies of the application to the Director General. A soft copy of the submitted application (including all supporting documents/ attachments, if any) shall also be provided in the form of a CD by the applicant. However, all information that has been declared as Confidential Business Information (CBI) should be omitted from the CD.

Accuracy of information

The application should also be carefully checked before submission to ensure that all the information is accurate. If the information provided is incorrect, incomplete or misleading, the NBB may issue a withdrawal of the acknowledgement of receipt of application without prejudice to the submission of a fresh application. Thus, it is important to provide accurate and timely information that is as comprehensive as existing scientific knowledge would permit, and supported by whatever data available.

NBB REF NO :
(For Office Use)

Confidentiality

Any information within this application which is to be treated as CBI, as described in the Biosafety Act 2007 in section 59(3) should be clearly marked "CBI" in the relevant parts of the application by providing the justification for the request for CBI. The following information shall not be considered confidential:

a) The name and address of the applicant
b) A general description of the LMO
c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
d) Any methods and plans for emergency response

Authorization

Please ensure that if this application is being completed on behalf of the proposed user, that the person completing this application holds proper authority to submit this application for the proposed user. Please provide written proof of authorization.

For further information

Please contact the Director General by:
Telephone: 603-8886 1579
E-mail: biosafety@nre.gov.my

The completed forms to be submitted as follows:

The Director General
Department of Biosafety
Ministry of Natural Resources and Environment Malaysia,
Level 1, Podium 2
Wisma Sumber Asli, No. 25, Persiaran Perdana
Precinct 4, Federal Government Administrative Centre
62574 Putrajaya, Malaysia

Please retain a copy of your completed form.

NBB REF NO :
(For Office Use)

APPLICATION CHECK LIST

1. Form NBB/A/ER/10/FORM A is completed with relevant signatures obtained	☐
2. Application assessed and to be sent through the IBC	☐
3. A copy of clearance documents from the Department of Agriculture included (if required)	☐
4. A copy of the clearance document from the state office where the release is to take place	☐
5. Any information to be treated as confidential business information should be clearly marked “CBI” in the application	☐
6. 1 original copy and 6 copies of the completed application submitted. A soft copy of the submitted application (including all supporting documents/attachments, if any) that do not contain any CBI.	☐
7. Fees as prescribed in the regulation: RM_____ Money order/ Bank draft No: _____ Made payable to the Secretary General of the Ministry of Natural Resources and Environment	☐

NBB REF NO :
(For Office Use)

Preliminary information

1. Organization:	
2. Name of Applicant:	
3. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	
4. Project Title/ Unique Identification Code:	
5. IBC Project Identification No:	
6. Is this the first time an approval is being applied for this activity?	Yes ☐ No ☐ if no, please provide information in no 7 below
7. I) Please provide the NBB reference no. for your previous notification/ application. II) How is this application different from the previous notification/application submitted for this activity? (please provide an attachment if additional space is required)	

Details of Agent / Importer

8. Organization name:	
9. Contact Person:	
10. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	

NBB REF NO :
(For Office Use)

Institutional Biosafety Committee (IBC) Assessment Report for release of LMO (Research and development purposes in all field experiments) or importation of LMO that is a higher plant (not for contained use activities).

This must be completed by the registered IBC of the Applicant's organization

Section A – IBC Details

1.	Name of organization:			
2.	Name of IBC Chairperson:			
	Telephone number:		Fax:	
	Email address:			

Section B – IBC Assessment

3.	Name of principal investigator:	
4.	Project Title:	
5.	Date of the IBC Assessment:	
6.	Does the IBC consider that the principal investigator and every other person(s) authorized to be involved in the field experiment with the LMO have adequate training and experience for the task?	☐ Yes ☐ No
7.	The following information related to this project has been checked and approved	
	a) The objective of the project	☐ Yes ☐ No
	b) The description and genetics of the LMO	☐ Yes ☐ No
	c) The risk assessment and risk management, taking into account the risks to the health and safety of people and the environment from the release of the LMO.	☐ Yes ☐ No
	d) The emergency response plan	☐ Yes ☐ No
8.	Has the information been checked by the IBC and found to be complete?	☐ Yes ☐ No
9.	Has the IBC assessed the proposed project? ☐ Yes ☐ No If yes, please append a copy of the IBC's assessment report and indicate the attachment in which details are provided.	

NBB REF NO :
(For Office Use)

Signatures and Statutory Declaration

The proposed release of LMO (Research and development purposes in all field experiments) or importation of LMO that is a higher plant (not for contained use activities) has been assessed as above and endorsed by the IBC. We declare that all information and documents herein is true and correct. We understand that providing misleading information to the NBB, deliberately or otherwise, is an offence under the Biosafety Act 2007.

Applicant:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

IBC Chairperson:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

Head of organization/Authorized representative:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

NBB REF NO :
(For Office Use)

Part A Risk Assessment

A1 General Information

1. Project Title.
2. Rationale of Project.
3. Project objectives:
   a) Overall Objective
   b) Specific Objective
4. Details of the LMO to be released:
   a) Genus and species
   b) Common name
   c) Modified trait(s)
5. Release site(s) :
   (If more than one location is involved, then the information required in numbers 5, 6, 7, 8 & 9, 10, 11) should be repeated for each location(s) of release)
   a) District(s)
   b) State(s) in which the release(s) will take place
6. Scale of release per release site.
   (Number of LMO involved, size of plot/site etc)
7. Date when the release(s) is expected to commence.
8. Frequency of releases.
9. Date when release(s) is expected to end.
10. For an imported LMO – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA).
11. Description of the proposed activities with the LMO.
12. Name of person(s) authorized to undertake activities with the LMO.

NBB REF NO :
(For Office Use)

A2 Risk Assessment Information - Parent Organism

(If more than one parent organism of the same species is involved then the information required in this part should be repeated for each parent organism)

13. Details of the parent organism
    If the LMO is the result of a crossing event between more than one species/ cultivar/breeding line/variety please include relevant information (for example, LMO crossed with non-LMO or 2 LMOs crossed)
    a) Family name
    b) Genus
    c) Species
    d) Subspecies
    e) Cultivar/Breeding line/Variety
    f) Common name

14. A statement about whether the parent organism has an extended history of safe use in agriculture or in other industries.

15. Information concerning the reproduction of the parent organism:
    a) The mode or modes of reproduction
    b) Any specific factors affecting reproduction
    c) Generation time

16 Information regarding the sexual compatibility of the parent organism with other cultivated or wild plant species.

17. Information concerning the survivability of the parent organism:
    a) Ability to form structures for survival or dormancy including seeds, spores and sclerotia
    b) Any specific factors affecting survivability, for example seasonability

18. Information concerning the dissemination of the parent organism:
    a) The means and extent of dissemination
    b) Any specific factors affecting dissemination

19. Details of the natural habitat of the parent organism and its range.

20. Is the parent organism exotic in Malaysia?

    ☐ Yes ☐ No

21. Is the parent organism naturalized in Malaysia?

    ☐ Yes ☐ No

22. Is the parent organism, or a closely related organism, present at, or near, the site of the proposed release(s)?
(If more than one location is involved, then the information required in numbers 22 & 23 should be repeated for each location(s) of release)

☐ Yes ☐ No

23. If yes, please provide details of the population(s) and the estimated distances between them from the proposed release(s).

24. The potentially significant interactions of the parent organism with organisms other than plants in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.

25. An assessment of whether the parent organism is capable of causing disease or other ill-health in human, plants or animals and, if so, the details of the possible effects.

26. Details of any known predators, parasites, pests or diseases of the parent organism in Malaysia.

27. Details of pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses) and ability to colonize other organisms.

28. Is the parent organism resistant to any known antibiotic and if yes, what is the potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy?

29. Is the parent organism involved in environmental processes including primary production, nutrient turnover, decomposition of organic matter and respiration?

A3 Risk Assessment Information - LMO

30. Details of the modified trait(s) and how the genetic modification will change the phenotype of the LMO to be released.

31. What are the gene(s) responsible for the modified trait(s)?

32. Give details of the organism(s) from which the gene(s) of interest is derived:
(If more than one gene is involved then the information required in numbers 32, 33, 34, 35, 36 and 37 should be repeated for each gene)
    a) Family name
    b) Genus
    c) Species

d) Subspecies
e) Cultivar/Breeding line/Variety
f) Common name

33. Indicate whether it is a:
    a) viroid
    b) RNA virus
    c) DNA virus
    d) bacterium
    e) fungus
    f) animal
    g) plant
    h) other (please specify)

34. Does the gene(s) of interest come from an organism that causes disease or other ill-health in humans, plants or animals? Provide details of the possible effects.

35. Please provide the following information about the gene(s) of interest(s):
    a) Size of sequence of the gene(s) of interest inserted
    b) Sequence of the gene(s)of interest inserted
    c) Intended function of the gene(s) of interest
    d) Number of copies of the gene(s) of interest in the construct
    e) Details of the steps involved in the construction
    f) Provide the map(s) of construct(s) indicating the gene(s) of interests and all other regulatory elements that will finally be inserted in the LMO

36. Please provide the following information about the deleted sequence(s):
    a) Size of the deleted sequence(s)
    b) Function of the deleted sequence(s)
    c) Details of the steps involved in the deletion of sequences from the parental organism
    d) Provide the map(s) of construct(s)

37. The following information is on the expression of the gene(s) of interest:
    a) Level of expression of the gene(s) of interest and methods used for its characterization
    b) The parts of the plant where the gene(s) of interest is expressed, such as roots, stem or pollen
    c) Indicate the part(s) of the vector(s) that remains in the LMO
    d) The genetic stability of the gene(s) of interest

38. A description of the methods used for the genetic modification:
    a) How gene(s) of interest was introduced into the parent organism, or
    b) How a sequence of a gene was deleted from the parent organism

39. If no vector was used for the genetic modification please provide details of how the gene(s) of interest is introduced.

40. If vector(s) was used, please provide the following information:
(If more than one vector was used, then the information required in 40 should be repeated for each vector).
    a) Type of vector
        i. plasmid
        ii. bacteriophage
        iii. virus
        iv. cosmid
        v. phasmid
        vi. transposable element
        vii. other, please specify
    b) Identity of the vector(s)
    c) Information on the degree of which the vector(s) contains sequences whose product or function is not known
    d) Host range of the vector(s)
    e) Potential pathogenicity of the vector(s)
    f) The sequence of transposons and other non-coding genetic segments used to construct the LMO and to make the introduced vector(s) and insert(s) function in those organisms

41. Details of the markers or sequences that will enable the LMO to be identified in the laboratory and under field conditions. Provide appropriate evidence for the identification and detection techniques including primer sequences of the detection of the inserted gene(s) including marker gene(s).

42. Information (biological features) on how the LMO differs from the parent organism in the following respects:
    a) Mode(s) and/or the rate of reproduction
    b) Dissemination

43. If there is any possibility that the inserted gene(s) in the LMO could be integrated into other species at the release site(s) and the surrounding environment and if so, please provide the following details:
    a) The organism(s) to which the modified trait(s) can be transferred to and the frequency at which it can be transferred
    b) The transfer mechanism involved and the techniques that have been used to demonstrate transfer
    c) Any possible adverse effects of the transfer including
        i. Any advantages the affected organism(s) are likely to have over the number of the species that do not contain the inserted gene(s)

ii. Environmental risks posed by such an advantage

44. The identification and description of the target organism(s), if any.

45. The anticipated mechanism and result of interaction between the released LMO and the target organism(s).

46. The known or predicted interaction on non-target organisms in the release site(s) and the impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

47. A statement on whether the modified trait(s) of the LMO will change the capacity of the plant to add substances to, or subtract substances from, soil (for example, nitrogen or toxic compounds) and, if so, details of all such changes.

48. Details of any other possible adverse consequences.

49. Details whether the LMO compared to the parent organism that will confer a selective advantage that can impact on survival in the release site(s), including a statement on how stable those features are.

50. Details of whether the modified trait(s) will confer a selective advantage on the LMO compared to the parent organism and if so, the nature of the advantages including a statement on how stable those features are and under what conditions.

51. Details of whether the gene(s) of interest or any part of the vector(s) has the ability to reproduce or transfer to other hosts and, if so, details of the host range.

52. In relation to human health:
    a) The toxic or allergenic effects of the non-viable organisms and/or their metabolic products
    b) The comparison of the organisms to the donor, or (where appropriate) parent organism regarding pathogenicity
    c) The capacity of the organisms for colonization
    d) If the organisms are pathogenic to immunocompetent persons:
        i. diseases caused and mechanisms of pathogenicity including invasiveness and virulence,
        ii. communicability,
        iii. infective dose,
        iv. host range and possibility of alteration,
        v. possibility of survival outside of human host,
        vi. presence of vectors or means of dissemination,
        vii. biological stability,
        viii. antibiotic-resistance patterns,
        ix. allergenicity, and
        x. availability of appropriate therapies.

53. Details of unintended pleiotropic effects (if any), including undesirable effects on agronomic characteristics of the plant which may result from the expression of the gene of interest(s) in the LMO (for example, reduced fertility, increased prevalence, production losses, grain shedding), including an indication of the likelihood of these events.

54. The description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

55. Details of how the genetic modification will change the phenotype of the LMO to be released, including information to demonstrate the effect of the genetic modification.

56. Details of the mechanism of pollen spread (by insect vectors or by other means) in the plant population:
    a) Details of pollen viability for the parent organism and of the LMO
    b) Details of any potential pollinators and their range and distribution in Malaysia
    c) Quantitative data on successful cross-pollination between the parent organism, the LMO and its wild relatives, if available

A4 Information about weeds

57. Details of the members of the family of parent organism that are known to be weeds in any environment.

58. Details of cross-pollination between the species to which the LMO belongs and wild relatives known to be weeds, including a copy of any literature reports that support the information.

A5 Information about the seeds of the LMO

59. A statement on whether the LMO proposed to be released will be allowed to set seed and, if not, whether setting seed is planned for a later release.

60. If the LMO is to be allowed to set seed, will the mature seed normally remain contained within an ear, capsule or pod, so that practically all of the seed can be readily harvested, or is the seed shed soon after it matures?
    If the latter, provide an indication of the proportion of seed likely to remain in the release site(s) following harvest.

61. Details of the length of time that the seeds are capable of being dormant and whether it differs from the parent organism.

A6 Characteristics affecting survival of LMO

62. The predicted habitat of the LMO.

63. The biological features which affect survival, multiplication and dispersal.

64. The known or predicted environmental conditions which may affect survival, multiplication and dispersal, including wind, water, soil, temperature, pH.

65. The sensitivity to specific agents (e.g. disinfectant, pesticides, fertilizers, wind, water).

A7 Information about any secondary ecological effects that might result from the release

66. An assessment of possible effects of the proposed release on:
    a) Native species
    b) Resistance of insect populations to an insecticide
    c) Abundance of parasites

A8 Information about resistance of the LMO to a chemical agent (other than selective agents, such as antibiotics, used in strain construction)

67. Details of any environmental risks related specifically to the resistance of the LMO to a chemical agent (for example, a herbicide, but not a selective agent, such as an antibiotic, used in strain construction), where the resistance is a result of the genetic modification.

A9 Information about resistance of the LMO to a biological agent

68. Details of any environmental risks related specifically to the resistance of the LMO to a biological agent (for example, an insect or a fungal disease), where the resistance is a result of the genetic modification.

A10 Information relating to the release site(s)

(If more than one release site is involved, then the information required in this part should be repeated for each release site)

69. The size of the proposed release site(s).

70. The location of the proposed release site(s). Provide site map(s) with national grid reference(s).

71. Details of the reasons for the choice of the release site(s).

72. Details of the arrangements for conducting any other activities in association with the proposed release(s), such as importation of the LMO and transportation of the LMO, to or from the release site(s).

73. The preparation of the release site(s) before the release(s).

74. The methods to be used for the release(s).

75. The quantity of the LMO to be released.

76. The physical or biological proximity of the release site(s) to humans and other significant biota or protected areas.

77. The size of local human population.

78. The local economic activities which are based on the natural resources of the area.

79. The distance to the nearest drinking water supply zone areas and/or areas protected for environmental purposes.

80. The flora and fauna, including crops, livestock and migratory species in the release site(s).

81. The comparison of the natural habitat of the parent organism(s) with the proposed release site(s).

82. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

Part B Risk Management

B1 Information on control, monitoring, post-release plans

83. A description of measures (if any) to minimize the effects of any transfer of the modified genetic trait(s) to other organisms.

84. Details of the proposed release site(s) supervision procedures and if necessary any relevant safety procedures designed to protect staff, including a description of procedures for onsite supervision of the release if the release site(s) is located at some distance from the location of the applicant.

85. Details of proposed measures (if any) for monitoring any risks posed by the LMO(s), including monitoring for:
    a) The survival or presence of the LMO, or transferred genetic material, beyond the proposed release site(s), including specificity, sensitivity and reliability of detection methods
    b) Impacts on the characteristics, or abundance, of other species
    c) Transfer of the gene(s) of interest to other species
    d) Any other hazards or deleterious effect

86. Details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the NBB.

87. Details of ongoing monitoring to be undertaken after the release(s) are completed.

88. Details of proposed measures to minimize the possible adverse consequences. If no measures have been taken, please give reasons.

89. The methods for elimination or inactivation of the organisms at the end of the experiment and the measures proposed for restricting the persistence of the LMO or its genetic material in the release site(s).

B2 Waste treatment plans

90. Type of waste generated.

91. Expected amount of waste.

92. Possible risks resulting from the waste.

93. Description of waste treatment envisaged and its disposal.

Part C Emergency response plan

94. Methods and procedures for controlling/removing the LMO in case of unintentional release or any adverse effects being realized.

95. Methods for isolation of the area affected.

96. Methods for disposal of other plants, animals and any other thing exposed to the adverse effects

Part D Data or results from any previous release(s) of the LMO

97. Give the following information from the previous applications and releases of the LMO for which the applicant is seeking an approval:
    i. Reference number of each application
    ii. Date of the certificate of approval issued
    iii. Terms and conditions (if any) attached to the approval
    iv. Data and results of post-release monitoring methods and effectiveness of any risk management procedures, terms and conditions and other relevant details
    v. Relevant data if the previous release is on a different scale or into a different ecosystem
    vi. Any other relevant details

98. Details of results of any applications made for approval of the LMO in other countries, including information about conditions (if any) attached to the approval.

99. Details of any previous notifications for contained use activities according to the Biosafety Act 2007 from which the work in this present application has been developed.

100. If the LMO has been previously released overseas, details of any adverse consequences of the release, including identifying references and reports of assessments if any.

APPENDIX 2

NBB REF NO :
(For Office Use)

BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/A/ER/10/FORM B

APPROVAL FOR RELEASE ACTIVITIES OF LIVING MODIIFED ORGANISM (LMO) (SCRESEARCH AND DEVELOPMENT PURPOSES IN ALL FIELD EXPERIMENTS) OR IMPORTATION OF LMO OTHER THAN HIGHER PLANTS

NBB/A/ER/10/FORM B shall be submitted to the Director General as an application for certificate of approval of release of LMO [Research and development purposes in all field experiments - Second Schedule of the Act - 1] or importation of living modified organism (LMO) other than a higher plant (not for contained use activities). Any organization undertaking modern biotechnology research and development shall submit the form through its registered Institutional Biosafety Committee (IBC). The IBC should assess the information in the form prior to submission. Application must be accompanied by the prescribed fees as found in Third Schedule of the Biosafety (Approval and Notification) Regulations 2010. Not all parts in this form will apply to every case. Therefore, applicants will only address the specific questions/parameters that are appropriate to individual applications.

In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated. The risk assessment, risk management plan, emergency response plan and the fulfillment of any other requirements under the Biosafety Act 2007 will be the basis of the issuance of the certificate of approval by the National Biosafety Board (NBB).

The applicant shall submit 1 original and 6 copies of the application to the Director General. A soft copy of the submitted application (including all supporting documents/ attachments, if any) shall also be provided in the form of a CD by the applicant. However, all information that has been declared as Confidential Business Information (CBI) should be omitted from the CD.

Accuracy of information

The application should also be carefully checked before submission to ensure that all the information is accurate. If the information provided is incorrect, incomplete or misleading, the NBB may issue a withdrawal of the acknowledgement of receipt of application without prejudice to the submission of a fresh application. Thus, it is important to provide accurate and timely information that is as comprehensive as existing scientific knowledge would permit, and supported by whatever data available.

NBB REF NO :
(For Office Use)

Confidentiality

Any information within this application which is to be treated as CBI, as described in the Biosafety Act 2007 in section 59(3) should be clearly marked "CBI" in the relevant parts of the application by providing the justification for the request for CBI. The following information shall not be considered confidential:

a) The name and address of the applicant
b) A general description of the LMO
c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
d) Any methods and plans for emergency response

Authorization

Please ensure that if this application is being completed on behalf of the proposed user, that the person completing this application holds proper authority to submit this application for the proposed user. Please provide written proof of authorization.

For further information

Please contact the Director General by:
Telephone: 603-8886 1579
E-mail: biosafety@nre.gov.my

The completed forms to be submitted as follows:

The Director General
Department of Biosafety
Ministry of Natural Resources and Environment Malaysia,
Level 1, Podium 2
Wisma Sumber Asli, No. 25, Persiaran Perdana
Precinct 4, Federal Government Administrative Centre
62574 Putrajaya, Malaysia

Please retain a copy of your completed form.

NBB REF NO :
(For Office Use)

APPLICATION CHECK LIST

1. Form NBB/A/ER/10/FORM B is completed with relevant signatures obtained	☐
2. Application assessed and to be sent through the IBC	☐
3. A copy of clearance documents from the relevant Government agencies included (if required)	☐
4. A copy of the clearance document from the state office where the release is to take place	☐
5. Any information to be treated as confidential business information should be clearly marked “CBI” in the application	☐
6. 1 original copy and 6 copies of the completed application submitted. A soft copy of the submitted application (including all supporting documents/attachments, if any) that do not contain any CBI.	☐
7. Fees as prescribed in the regulation: RM_____ Money order/ Bank draft No: _____ Made payable to the Secretary General of the Ministry of Natural Resources and Environment	☐

NBB REF NO :
(For Office Use)

Preliminary information

1. Organization:	
2. Name of Applicant:	
3. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	
4. Project Title/ Unique Identification Code:	
5. IBC Project Identification No:	
6. Is this the first time an approval is being applied for this activity?	Yes ☐ No ☐ if no, please provide information in no 7 below
7. I) Please provide the NBB reference no. for your previous notification/ application. II) How is this application different from the previous notification/application submitted for this activity? (please provide an attachment if additional space is required)	

Details of Agent / Importer

8. Organization name:	
9. Contact Person:	
10. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	

NBB REF NO :
(For Office Use)

Institutional Biosafety Committee (IBC) Assessment Report for release of LMO (Research and development purposes in all field experiments) or importation of LMO that is a higher plant (not for contained use activities).

This must be completed by the registered IBC of the Applicant's organization

Section A – IBC Details

1.	Name of organization:			
2.	Name of IBC Chairperson:			
	Telephone number:		Fax:	
	Email address:			

Section B – IBC Assessment

3.	Name of principal investigator:	
4.	Project Title:	
5.	Date of the IBC Assessment:	
6.	Does the IBC consider that the principal investigator and every other person(s) authorized to be involved in the field experiment with the LMO have adequate training and experience for the task?	☐ Yes ☐ No
7.	The following information related to this project has been checked and approved	
	a) The objective of the project	☐ Yes ☐ No
	b) The description and genetics of the LMO	☐ Yes ☐ No
	c) The risk assessment and risk management, taking into account the risks to the health and safety of people and the environment from the release of the LMO.	☐ Yes ☐ No
	d) The emergency response plan	☐ Yes ☐ No
8.	Has the information been checked by the IBC and found to be complete?	☐ Yes ☐ No
9.	Has the IBC assessed the proposed project? ☐ Yes ☐ No If yes, please append a copy of the IBC's assessment report and indicate the attachment in which details are provided.	

NBB REF NO :
(For Office Use)

Signatures and Statutory Declaration

The proposed release of LMO (Research and development purposes in all field experiments) or importation of LMO that is a higher plant (not for contained use activities) has been assessed as above and endorsed by the IBC. We declare that all information and documents herein is true and correct. We understand that providing misleading information to the NBB, deliberately or otherwise, is an offence under the Biosafety Act 2007.

Applicant:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

IBC Chairperson:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

Head of organization/Authorized representative:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

NBB REF NO :
(For Office Use)

Part A Risk Assessment

A1 General Information

1. Project Title.
2. Rationale of Project.
3. Project objectives:
   a) Overall Objective
   b) Specific Objective
4. Details of the LMO to be released:
   a) Genus and species
   b) Common name
   c) Modified trait(s)
5. Release site(s) :
   (If more than one location is involved, then the information required in numbers 5, 6, 7, 8 & 9, 10, 11) should be repeated for each location(s) of release)
   a) District(s)
   b) State(s) in which the release(s) will take place
6. Scale of release per release site.
   (Number of LMO involved, size of plot/site etc)
7. Date when the release(s) is expected to commence.
8. Frequency of releases.
9. Date when release(s) is expected to end.
10. For an imported LMO – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA).
11. Description of the proposed activities with the LMO.
12. Name of person(s) authorized to undertake activities with the LMO.

NBB REF NO :
(For Office Use)

A2 Risk Assessment Information - Parent Organism

(If more than one parent organism of the same species is involved then the information required in this part should be repeated for each parent organism)

13. Details of the parent organism:
    If the LMO is the result of a crossing event between more than one species/strain, please include relevant information (for example, LMO crossed with non-LMO or 2 LMOs crossed)
    a) Family name
    b) Genus
    c) Species
    d) Subspecies
    e) Cultivar/Breeding line/Variety
    f) Common name

14. A statement about whether the parent organism has an extended history of safe use in agriculture or in other industries.

15. Information concerning the reproduction of the organism:
    a) The mode or modes of reproduction
    b) Any specific factors affecting reproduction
    c) Generation time

16 Information regarding the sexual compatibility of the organism with other common/ domesticated or wild types.

17. Information concerning the survivability of the parent organism:
    a) Ability to form structures for survival or dormancy including spores and sclerotia
    b) Any specific factors affecting survivability, for example seasonability

18. Information concerning the dissemination of the parent organism:
    a) The means and extent of dissemination
    b) Any specific factors affecting dissemination

19. Details of the natural habitat of the parent organism and its range.

20. Is the parent organism exotic in Malaysia?

    ☐ Yes ☐ No

21. Is the parent organism naturalized in Malaysia?

    ☐ Yes ☐ No

22. Is the parent organism, or a closely related organism, present at, or near, the site of the proposed release(s)?
(If more than one location is involved, then the information required in numbers 23 & 24 should be repeated for each site of release)

☐ Yes ☐ No

23. If yes, please provide details of the population(s) and the estimated distances between them from the proposed release(s).

24. The potentially significant interactions of the parent organism with other organisms (including plants) in the ecosystem where it is usually found, including information on toxic effects on humans, plants, animals and other organisms.

25. An assessment of whether the parent organism is capable of causing disease or other ill-health in human, plants, animals and other organisms and, if so, the details of the possible effects.

26. Details of any known predators, parasites, pests or diseases of the parent organism in Malaysia.

27. Details of pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses) and ability to colonize other organisms.

28. Is the parent organism resistant to any known antibiotic and if yes, what is the potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy?

29. Is the parent organism involved in environmental processes including primary production, nutrient turnover, decomposition of organic matter and respiration?

A3 Risk Assessment Information - LMO

30. Details of the modified trait(s) and how the genetic modifications will change the phenotype of the LMO to be released.

31. What are the gene(s) responsible for the modified trait(s)?

32. Give the name of the organism from which the gene(s) of insert is derived:
(If more than one gene is involved then the information required in numbers 32, 33, 34, 35, 36 and 37 should be repeated for each gene)
    a) Family name
    b) Genus
    c) Species

d) Subspecies
e) Cultivar/Breeding line/Variety
f) Common name

33. Indicate whether it is a:
    a) viroid
    b) RNA virus
    c) DNA virus
    d) bacterium
    e) fungus
    f) animal
    g) plant
    h) other (please specify)

34. Does the gene(s) of interest come from an organism that causes disease or other ill-health in humans, plants or animals? Provide details of the possible effects.

35. Please provide the following information about the gene(s) of interest(s):
    a) Size of sequence of the gene(s) of interest inserted
    b) Sequence of the gene(s)of interest inserted
    c) Intended function of the gene(s) of interest
    d) Number of copies of the gene(s) of interest in the construct
    e) Details of the steps involved in the construction
    f) Provide the map(s) of construct(s) indicating the gene(s) of interests and all other regulatory elements that will finally be inserted in the LMO

36. Please provide the following information about the deleted sequence(s):
    a) Size of the deleted sequence(s)
    b) Function of the deleted sequence(s)
    c) Details of the steps involved in the deletion of sequences from the parental organism
    d) Provide the map(s) of construct(s)

37. The following information is on the expression of the gene(s) of interest:
    a) Level of expression of the gene(s) of interest and methods used for its characterization
    b) The parts of the plant where the gene(s) of interest is expressed, such as roots, stem or pollen
    c) Indicate the part(s) of the vector(s) that remains in the LMO
    d) The genetic stability of the gene(s) of interest

38. A description of the methods used for the genetic modification:
    a) How gene(s) of interest was introduced into the parent organism, or
    b) How a sequence of a gene was deleted from the parent organism

39. If no vector was used for the genetic modification please provide details of how the gene(s) of interest is introduced.

40. If vector(s) was used, please provide the following information:
(If more than one vector was used, then the information required in 40 should be repeated for each vector).
    a) Type of vector
        i. plasmid
        ii. bacteriophage
        iii. virus
        iv. cosmid
        v. phasmid
        vi. transposable element
        vii. other, please specify
    b) Identity of the vector(s)
    c) Information on the degree of which the vector(s) contains sequences whose product or function is not known
    d) Host range of the vector(s)
    e) Potential pathogenicity of the vector(s)
    f) The sequence of transposons and other non-coding genetic segments used to construct the LMO and to make the introduced vector(s) and insert(s) function in those organisms

41. Details of the markers or sequences that will enable the LMO to be identified in the laboratory and under field conditions. Provide appropriate evidence for the identification and detection techniques including primer sequences for the detection of the inserted gene(s) including marker gene(s).

42. Information (biological features) on how the LMO differs from the parent organism in the following respects:
    a) Mode(s) and/or the rate of reproduction
    b) Dissemination

43. If there is any possibility that the inserted gene(s) in the LMO could be integrated into other species at the release site(s) and the surrounding environment and if so, please provide the following details:
    a) The organism(s) to which the modified trait(s) can be transferred to and the frequency at which it can be transferred
    b) The transfer mechanism involved and the techniques that have been used to demonstrate transfer
    c) Any possible adverse effects of the transfer including
        i. Any advantages the affected organism(s) are likely to have over the number of the species that do not contain the inserted gene(s)

ii. Environmental risks posed by such an advantage

44. The identification and description of the target organism(s), if any.

45. The anticipated mechanism and result of interaction between the released LMO and the target organism(s).

46. The known or predicted interaction on non-target organisms in the release site(s) and the impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

47. A statement on whether the modified trait(s) of the LMO will change the capacity of the plant to add substances to, or subtract substances from, soil (for example, nitrogen or toxic compounds) and, if so, details of all such changes.

48. Details of any other possible adverse consequences.

49. Details whether the LMO compared to the parent organism that will confer a selective advantage, if any, of the LMO(s) that can impact on survival in the release site(s) and if so the nature of the advantages including a statement on how stable those features are.

50. Details of whether the modified trait(s) will confer a selective advantage on the LMO under certain conditions, if so the conditions, including data on the growth rate with and without the selection pressure.

51. Details of the genetic changes, if any, which will be included in the LMO(s) to limit or eliminate any capacity to reproduce or transfer genes to other organisms.

52. In relation to human health:
    a) The toxic or allergenic effects of the non-viable organisms and/or their metabolic products
    b) The comparison of the organisms to the donor, or (where appropriate) parent organism regarding pathogenicity
    c) The capacity of the organisms for colonization
    d) If the organisms are pathogenic to immunocompetent persons:
        i. diseases caused and mechanisms of pathogenicity including invasiveness and virulence
        ii. communicability
        iii. infective dose
        iv. host range and possibility of alteration
        v. possibility of survival outside of human host
        vi. presence of vectors or means of dissemination
        vii. biological stability
        viii. antibiotic-resistance patterns

ix. allergenicity, and
x. availability of appropriate therapies.

53. Details of unintended pleiotropic effects (if any), including undesirable effects on characteristics of the organism which may result from the expression of the gene(s) of interest in the LMO(s) (for example, reduced fertility, increased prevalence, production losses), including an indication of the likelihood of these events.

54. The description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

55. Details of how the genetic modification will change the phenotype of the LMO to be released, including information to demonstrate the effect of the genetic modification.

A4 Characteristics affecting survival of LMO(s)

56. The predicted habitat of the LMO.

57. The biological features which affect survival, multiplication and dispersal.

58. The known or predicted environmental conditions which may affect survival, multiplication and dispersal, including wind, water, soil, temperature, pH.

59. The sensitivity to specific agents (e.g. Disinfectant, pesticides, fertilizers, wind, water).

60. Survivability
    a) Ability to form structures enhancing survival or dormancy
        i. endospores
        ii. cysts
        iii. sclerotia
        iv. asexual spores (fungi)
        v. sexual spores (fungi)
        vi. eggs
        vii. pupae
        viii. larvae
        ix. other, please specify

A5 Information about any secondary ecological effects that might result from the release

61. An assessment of possible effects of the proposed release on:
    a) Native species
    b) Resistance of insect populations to an insecticide
    c) Abundance of prey or parasites.

A6 Information about resistance of the LMO to a chemical agent (other than selective agents, such as antibiotics, used in strain construction)

62. Details of any environmental risks related specifically to the resistance of the LMO to a chemical agent (for example, a herbicide, but not a selective agent, such as an antibiotic, used in strain construction), where the resistance is a result of the modification.

A7 Information about resistance of the LMO to a biological agent

63. Details of any environmental risks related specifically to the resistance of the LMO to a biological agent (for example, an insect or a fungal disease), where the resistance is a result of the genetic modification.

A8 Information relating to the release site(s)

If more than one release site is involved, then the information required in this part should be repeated for each release site.

64. The size of the proposed release site(s).

65. The site(s) of the proposed release or releases. Provide site map(s) with national grid reference(s).

66. Details of the reasons for the choice of the release site(s).

67. Details of the arrangements for conducting any other activities in association with the proposed release(s), such as importation of a LMO and transportation of a LMO, to or from the release site(s).

68 The preparation of the release site(s) before the release(s).

69. The methods to be used for the release(s).

70. The quantity of LMO(s) to be released.

71. Details of features of the physical environment of the release site(s) particularly features that may minimize or exacerbate any undesirable effects of the LMO.

72. The physical or biological proximity of the release site(s) to humans and other significant biota or protected areas.

73. The size of local human population.

74. The local economic activities which are based on the natural resources of the area.

75. The distance to the nearest drinking water supply zone areas and/or areas protected for environmental purposes.

76. The flora and fauna, including crops, livestock and migratory species in the release site(s).

77. The description of target and non-target ecosystems likely to be affected.

78. The comparison of the natural habitat of the parent organisms with the proposed site or sites of release.

79. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

Part B Risk Management

B1 Information on control, monitoring, post-release plans

80. A description of measures (if any) to minimize the effects of any transfer of the modified genetic trait(s) to other organisms.

81. Details of proposed site supervision procedures and if necessary any relevant safety procedures designed to protect staff, including a description of procedures for onsite supervision of the release if the release site(s) is located at some distance from the site(s) of the applicant.

82. A description of post-release treatment methods for the LMO.

83. Details of proposed measures (if any) for monitoring any risks posed by the LMO(s), including monitoring for:
    a) The survival or presence of the LMO(s), or transferred genetic material, beyond the proposed release site or sites, including specificity, sensitivity and reliability of detection methods
    b) Impacts on the characteristics, or abundance, of other species
    c) Transfer of the gene of interest to other species
    d) Any other hazards or deleterious effect

84. Details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the NBB.

85. Details of ongoing monitoring to be undertaken after the release(s) are completed.

86. Details of proposed measures to minimize the possible adverse consequences. If no measures have been taken, please give reasons.

87. The methods for elimination or inactivation of the organisms at the end of the experiment and measures proposed for restricting the persistence of the LMO or its genetic material in the release site(s).

B2 Waste treatment plans

88. Type of waste generated.

89. Expected amount of waste.

90 Possible risks resulting from the waste.

91. Description of waste treatment envisaged, and its disposal.

Part C Emergency Response Plan

92. Methods and procedures for controlling the LMO(s) in case of unintentional release.

93. Methods for removal of the LMO(s) in the affected areas.

94. Methods for disposal of other plants, animals and any other thing exposed during the unintentional release.

95. Methods for isolation of the area affected by the unintentional release.

96. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

97. Details of any other contingency measures that will be in place to rectify any unintended consequences if an adverse effect becomes evident during the course of the release.

Part D Data or results from any previous release(s) of the LMO

98. Give the following information from the previous applications (successful or unsuccessful) and releases of the LMO for which the applicant is seeking an approval:
    a) Reference number of each application
    b) Date of the certificate of approval issued
    c) Terms and conditions (if any) attached to the approval
    d) Data and results of post-release monitoring methods and effectiveness of any risk management procedures
    e) Relevant data if the previous release is on a different scale or into a different ecosystem
    f) Any other relevant details

99. Details of results of any applications made for approval of the LMO(s), in other countries, including information about conditions (if any) attaching to the approval.

100. Details of any previous notifications for contained use activities according to the Biosafety Act 2007 from which the work in the present application has been developed.

101. If the LMO has been previously released overseas, details of any adverse consequences of the release, including identifying references and reports of assessments if any.

102. Give details of data or results from any previous releases of the LMO(s) for which the applicant is seeking an approval, especially the results of monitoring and the effectiveness of any risk management procedures, terms and conditions and any other relevant details.

PART E LMO(s) that is a Microorganism Associated with Plants

You must only respond to this Part if your application deals with a LMO(s) that is associated with plants.

E1 Information about Modified Microorganism Associated with Plants

103. Details of the plant species, including information about the specificity of the interaction and the range of plant species with which the LMO(s) can interact.

104. An assessment of the effect of the LMO(s) on the plant species, and details of how it will be monitored.

105. An assessment of any secondary effects that the LMO(s) might have on the plant species.

106. An assessment of whether the modification is likely to cause any change to the range of host plant species susceptible to infection by the organism.

107. An assessment of the effect, if any, of the LMO(s) on the distribution and abundance of host plant species or other species with which the LMO(s) can interact.

108. An assessment of the effect the LMO(s) might have on insects, birds, animals or humans that may eat the plant.

E2 Information if the Parent Organism has an Extended History of Use in Agriculture

109. If the parent organism has an extended history of use in agriculture, a description of the use.

E3 Information if the LMO(s) is a Microorganism Associated with Plant Species that are Food Crops

110. If the LMO(s) is associated with plant species that are food crops, an assessment of whether the LMO(s) could affect the suitability of the resultant produce for consumption by animals or human beings and, if so, details of the effect.

E4 Information about the Impact of the LMO(s) on Soil and Water

111. Details of the expected effects of the LMO(s) on local soil chemistry.
(For example, pH, mineral leaching and nutrient levels)

112. Details of the possible effects of the LMO(s) on local water quality.

113. Details of the effect the LMO(s) might have on soil organisms that are known to be beneficial to plants (for example, *Rhizobium, Azopirillum, Frankia* and mycorrhizal fungi) and that are likely to be in a release site.

E5 Information about any Interactions between LMO(s) and Closely Related Microorganisms

114. Details of any known interaction between the LMO(s) and closely related microorganisms in any partner plant (if applicable) and in the environment of the release site.

E6 Information about Known Genetic Exchange between Parent Organism and Plant Pathogens

115. Details of any known exchange of genetic material between the parent organism and plant pathogens.

E7 Other Information

116. Information about the expected survival and dispersal of the LMO(s), including dispersal in natural waters, soil and on other natural surfaces.

117. A statement about whether the LMO(s) will produce spores.

118. A statement about whether the LMO(s) will be resistant to desiccation.

119. A list of sterilising and anti-microbial agents (if any) that are expected to be active against the LMO(s).

120. A statement about whether the LMO(s) will be susceptible to ultraviolet or ionizing radiation.

PART F LMO(s) that is a Microorganism that Lives in or on Animals

You must only respond to this Part if your application deals with the release of a LMO(s) that is a microorganism that lives in or on animals, including an organism such as gut biota living in larger hosts, and a microorganism applied externally to an animal (for example, bacteria to prevent fleece rot).

F1 Information about the Impact of the LMO(s) on the Host

121. Identification of the animal host species.

122. A statement about whether the parent organism has an extended history of use in agriculture and, if so, details of the use.

123. An assessment of any new capacity the LMO(s) will provide for the host species (for example, ability to degrade plant or pasture toxins).

124. An assessment of whether the competitive advantage, ecological fitness, biology or distribution, of the host will be altered, and relevant data (if any) on the subject.

125. Details of any secondary effect expected to result from the introduction of the LMO(s) into or onto the host (for example, information about any possibility of the genetic insert being transferred to other organisms in the host, or to host cells).

F2 Information about the Impact of the LMO(s) on the Environment (particularly the impact on other animals, plants, soil and water)

126. Any evidence that the LMO(s) might be capable of establishing in, or on, other animals, including feral animals.

127. Any evidence of other likely effects (including secondary effects) on other plants or animals in the agricultural and natural environments.

128. If the LMO(s) will establish in an animal, information about whether the LMO(s) will be excreted or otherwise leave the animal and, if so, the time period that is expected the LMO(s) can survive outside the animal.

129. An assessment of the possible effects of the LMO(s) on local water quality.

F3 Other Information

130. A statement about whether the LMO(s) will produce spores.

131. A statement about whether the LMO(s) will be resistant to desiccation.

132. A list of sterilising and anti-microbial agents (if any) that are expected to be active against the LMO(s).

133. An statement about whether the LMO(s) will be susceptible to ultraviolet or ionizing radiation.

Part G LMO(s) that is a Vertebrate Animal

You must only respond to this Part if your proposal deals with a LMO(s) that is a vertebrate animal (other than aquatic organisms).

G1 Information about the effects of the LMO(s) on the environment

134. Information about the likelihood of any unintended effect on an animal resulting from the release.

135. Information about any intended gains that are directly linked to changes in other characteristics of the subject species.

G2 Information about Any Effects the Expression of the Modified Trait might have on the Animal

136. Information about the expected effects on the physiology, behaviour and reproduction of the animal or animals.

G3 Information about future LMO activities

137. A statement on whether an animal in the experiment is intended to be allowed to breed and, if not, whether breeding is planned in the future.

138. A statement on whether the proposed arrangements for handling any offspring are the same as those for the experimental animal or animals, and, if not, the proposed different arrangements.

G4 Information about Feral Populations of Subject Species, if any, that Exist In Malaysia or that may be established

139. Details of any agricultural, environmental or disease-control problems caused by feral populations of the subject species.

140. Details of any experimental work that has been done on expression of the novel genetic material in feral animals (such as cross-breeding of LMO(s) with captive feral animals), and the results of such work.

141. An assessment of the likelihood of the novel genetic material entering the feral gene pool (for example, by interbreeding with modified farm animals).

142. An assessment of the effect that the entry of novel genetic material into a feral gene pool might have:
    a) On the distribution and abundance of the feral population

b) On the ability of the feral population to cause agricultural or environmental problems
c) In contributing to the spread of infectious disease

143. If no feral population exists in Malaysia, information about:
a) The likelihood of the imparted characteristic enhancing the ability of the species to establish feral populations
b) If there is a likelihood, the arrangements in place to prevent this from occurring

G5 Information about the capacity of the LMO(s) to Interbreed

144. Details of the capacity of the LMO(s) to interbreed with any species native to, or currently present in, Malaysia.

G6 Information about requirements for optimal expression of the introduced modified trait(s)

145. Details of the management procedures and environmental factors, if any, which would be required for optimal expression of the introduced trait(s).

Part H LMO(s) that is an Aquatic Organism

You must only respond to this Part if your application deals with a LMO(s) that is an aquatic organism, for example, fish, crustaceans and molluscs not included aquatic plants.

H1 Information about Effects of the LMO(s) on the Environment

146. Information about the effect that the LMO(s) might have on the food chain.

147. A statement on whether the LMO(s) could produce any novel metabolites, or toxins, that are likely to have deleterious effects on parasites or predators and, if so, the likely effect.

148. Details of any unintended effects that may result from the release.

149. A statement on whether the expression of the modified gene is expected to be directly linked to undesirable changes in other characteristics of the subject organisms (for example, a decrease in nutritional value).

150. Information about:
a) Whether the modified genetic material can be transmitted to any other species
b) If so, the expected mechanism of transfer, the likely affected species and any likely consequences

H2 Information About Any Impact On Natural Populations

151. Information about whether natural populations of parent organism, or a closely related species, exist in Malaysia (including in rivers, lakes, dams or coastal waters) and, if so, details about any problems the natural populations cause with other organisms.

152. If no natural populations of the organism to be modified exist in Malaysia, information about the potential for the modified traits to enhance the ability of the species to establish populations in aquatic habitats.

153. Information about the results of any experimental work that has been done on phenotypic expression of the modified genetic material in naturally occurring organisms (such as cross-breeding of LMO(s) with wild or farmed stocks).

154. An assessment of the likelihood of the modified genetic material entering the gene pool of natural populations.

155. Information about any impact the entry of the modified genetic material into the gene pool of a natural organism could have on:
    a) The distribution and abundance of the organism
    b) Associated aquatic farms
    c) The environment
    d) Public health

156. Information about mechanisms intended to be used to prevent dispersal of the LMO(s) into other ecosystems.

H3 Information about Future Activities in Relation to the LMO(s)

157. A statement about whether the LMO(s) is intended to be allowed to breed or whether breeding is planned in the future.

158. A statement about whether the proposed arrangements for handling any offspring are the same as those for the experimental LMO(s) and, if not, the proposed different arrangements.

Part I LMO(s) that is an Invertebrate Animal

You must only respond to this Part if your application deals with a LMO(s) that is an invertebrate animal.

159. Information about the effect that the LMO(s) might have on the food chain.

160. Information about the potential for the LMO(s) to produce any novel metabolites, or toxins, that is likely to have deleterious effects on parasites or predators.

161. Information about other unintended effects that may result from the release.

162. A statement on whether the LMO(s) will be fertile and, if not, whether it is intended to use fertile organisms in later releases.

163. Information about whether populations of the parent organism, or a closely related species, exist in Malaysia and, if so, any environmental or public health problems, or benefits, caused by the populations.

164. Information about:
    a) Whether the modified genetic material can be transmitted by means other than by normal reproduction for the species
    b) If so, the likelihood of that genetic material entering gene pools or natural populations

165. Information about:
    a) Whether the modified genetic material can be transmitted to any other species
    b) If so, the expected mechanism of transfer and the likely affected species

166. Information about any experimental work that has been done on the phenotypic expression of the novel genetic material in other genetic backgrounds (such as cross-breeding of modified strains with wild or caught stock).

167. Information about the effect on the distribution and abundance of the natural populations of the organism, of the entry of the novel genetic material into the gene pool of those populations.

168. Details of the mechanisms proposed to be used to prevent dispersal of the LMO(s) into other ecosystems.

Part J LMO(s) that is to be used for Biological Control

You must only respond to this Part if your proposal deals with a LMO(s) that is to be used for biological control.

J1 Information about the Expected Interaction between the LMO(s) and the Species Targeted for Biological Control

169. The name of the species targeted for biological control.

170. Details of any direct effects the parent organism has on the target.

171. Details of any direct effects the LMO(s) is expected to have on the target species.

172. Details of how the LMO(s) is intended to be transferred from one target species to another and what factors affect the transferability.

173. Details of the genetic response that may be invoked in populations of the target organism as a result of the use of the LMO(s) (for example, increased resistance to the modified organism), and the expected evidence for the response.

J2 Information on the Possible Effects of the LMO(s) on Non-Target Organisms

174. Details of the host range of the LMO(s), and details of any difference between that host range and the host range of the parent organism.

175. A list of the non-target organisms that have been tested for susceptibility to the LMO(s), and the rationale for the choice of species tested.

176. If the modified traits can be transmitted to other organisms that are likely to be in the environment, details of any effects those other organisms are likely to have on non-target species.

J3 Information on Other Possible Effects of the LMO(s) on the Environment

177. A statement about the secondary effects that can be envisaged on competitors, predators, prey or parasites of the target species.

178. An assessment of the consequence of the removal, or reduction, of the target species on the management of agriculturally significant plants or farm animals.

179. Details of any predicted change in the ecosystem resulting from a reduction in the population of the target organism.

180. Information about:
    a) Whether the LMO(s) produces metabolites that may have deleterious effects directly or indirectly (through concentration in the food chain) on other organisms, including human beings
    b) If so, the likely effect

PART K LMO(s) that is to be Used for Bioremediation

You must only respond to this Part if your application deals with a LMO(s) that is to be used for bioremediation

K1 Information about the Expected Interaction between the LMO(s) and the Target Substrate for Bioremediation

181. Identification of the target substrate for bioremediation.

182. Details of the effect the parent organism has on the target substrate.

183. Details of the effect the LMO(s) is expected to have on the target substrate.

184. A list of the substances other than the target substrate that can be metabolized by the LMO(s) and that cannot be metabolized by the parent organism.

K2 Information about the LMO(s) and its impact on the Environment

185. A statement about whether the LMO(s) will be self-sufficient if added to the contaminated site or whether additional measures may be required.
(For example, provision of supplementary nutrients and growth factors, or other environmental modifications)

186. A list of any metabolites produced by the LMO(s) that may have deleterious effects, either directly or indirectly (through concentration in the food chain), on other organisms.

187. Details of effects the LMO(s) might have on water, air or soil quality.

188. Details of effects the LMO(s) might have on organisms that ingest it.

189. A statement on whether the LMO(s) will be dispersed from the site of application and, if so, the proposed mechanisms involved and the likely consequences.

PART L LMO(s) Intended to be Used as Food for Human or Vertebrate Animal Consumption

You must only respond to this Part if your application deals with a LMO(s) intended to be used as food for human or vertebrate animal consumption.

190. Details of:
    a) Whether the parent organism or the donor organism is of a kind already in use as a food for consumption by human beings or animals, or used in the production of such a food
    b) Whether any processing is needed, or is commonly applied, before consumption

191. Details of any metabolites produced by the LMO(s) that may have adverse effects on the consumer (human or animal), including available data on toxicology, allergenicity and other possible adverse effects.

192. Details of any products of the LMO(s) that are expected to concentrate in the food chain to levels which may become toxic.

193. Details of any expected changes to the nutritional quality of such food as a result of the genetic modification.

194. A statement on whether the LMO(s) is a major component of such food as consumed, or a minor component (for example, yeast cells in beer).

Note: For a food for human consumption that contains LMO(s) or GM products, see also the assessment requirements under the Malaysia Food Safety Act 1983

APPENDIX 3

NBB REF NO :
(For Office Use)

BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/A/ER/10/FORM C

APPROVAL FOR RELEASE ACTIVITIES (SECOND SCHEDULE 2-6) OR IMPORTATION OF LIVING MODIFIED ORGANISM (LMO) THAT IS A HIGHER PLANT AND PRODUCT OF SUCH ORGANISM

NBB/A/ER/10 FORM C shall be submitted as an application for certificate of approval for release activities (SECOND SCHEDULE 2-6) or importation for release of living modified organism (LMO) that is a higher plant and product of such organism(not for contained use activities) . Application must be accompanied by the prescribed fees as found in Third Schedule of the Biosafety (Approval and Notification) Regulations 2010. Not all parts in this form will apply to every case. Therefore, applicants will only address the specific questions/parameters that are appropriate to individual applications.

If the application is for release activities of an LMO or importation for release of an LMO that is a higher plant, please fill up Part A – D.
If the application is for release activities of a product of such organism or importation for release of a product of such organism, please fill up Part E.

In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated. The risk assessment, risk management plan, emergency response plan and the fulfillment of any other requirements under the Biosafety Act 2007 will be the basis of the issuance of the certificate of approval by the National Biosafety Board (NBB).

The applicant shall submit 1 original and 6 copies of the application to the Director General. A soft copy of the submitted application (including all supporting documents/ attachments, if any) shall also be provided in the form of a CD by the applicant. However, all information that has been declared as Confidential Business Information (CBI) should be omitted from the CD.

Accuracy of information
The application should also be carefully checked before submission to ensure that all the information is accurate. If the information provided is incorrect, incomplete or misleading, the NBB may issue a withdrawal of the acknowledgement of receipt of application without prejudice to the submission of a fresh application. Thus, it is important to provide accurate and timely information that is as comprehensive as existing scientific knowledge would permit, and supported by whatever data available.

NBB REF NO :
(For Office Use)

Confidentiality

Any information within this application which is to be treated as CBI , as described in the Biosafety Act 2007 in section 59(3) should be clearly marked “CBI” in the relevant parts of the application by providing the justification for the request for CBI. The following information shall not be considered confidential:

a) The name and address of the applicant
b) A general description of the LMO
c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
d) Any methods and plans for emergency response

Authorization

Please ensure that if this application is being completed on behalf of the proposed user, that the person completing this application holds proper authority to submit this application for the proposed user. Please provide written proof of authorization.

For further information

Please contact the Director General by:
Telephone: 603-8886 1579
E-mail: biosafety@nre.gov.my

The completed forms to be submitted as follows:

The Director General
Department of Biosafety
Ministry of Natural Resources and Environment Malaysia,
Level 1, Podium 2
Wisma Sumber Asli, No. 25, Persiaran Perdana
Precinct 4, Federal Government Administrative Centre
62574 Putrajaya, Malaysia.

Please retain a copy of your completed form.

NBB REF NO :
(For Office Use)

APPLICATION CHECK LIST

1. Form NBB/A/ER/10/FORM B is completed with relevant signatures obtained	☐
2. A copy of the clearance documents from the Department of Agriculture included. (If required)	☐
3. Any information to be treated as confidential business information should be clearly marked “CBI” in the application	☐
4. 1 original and 6 copies of the completed applications submitted. A soft copy of the submitted application (including all supporting documents/attachments, if any) that do not contain any CBI.	☐
5. Fees as prescribed in the regulation: RM_____ Money order/ Bank draft No: _____ Made payable to the Secretary General of the Ministry of Natural Resources and Environment	☐

Preliminary information

1. Organization:	
2. Name of Applicant:	
3. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	
4. Product Name (commercial and other names) Unique Identification Code:	

NBB REF NO :
(For Office Use)

5. Type of release activity:	☐ Supply or offer to supply for sale/ placing on the market ☐ Offer as gift, prize or free item ☐ Disposal ☐ Remediation purposes ☐ Commercial planting ☐ Any other activity which does not amount to contained use (please specify)
6. Is this the first time an approval is being applied for this activity?	Yes ☐ No ☐ if no, please provide information in no 7 below
7. I) Please provide the NBB reference no. for your previous notification/application II) How is this application different from the previous application submitted for this activity? (please provide an attachment if additional space is required)	

Details of Agent / Importer

8. Organization name:	
9. Contact Person:	
10. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	

NBB REF NO :
(For Office Use)

Signatures and Statutory Declaration

We declare that all information and documents herein is true and correct. We understand that providing misleading information to the NBB, deliberately or otherwise, is an offence under the Biosafety Act 2007.

Applicant:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

Head of organization/Authorized representative:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

NBB REF NO :
(For Office Use)

Part A Living Modified Organism (LMO) that is a Higher Plant

Risk Assessment

A1 General Information

1. Details of the LMO to be released:
   a) Genus and species
   b) Common name
   c) Modified trait (s)

2. Objective(s) of the release.

3. Release site(s):
   (If more than one site is involved, then the information required in numbers 3, 4, 5, 6, 7 & 8 should be repeated for each release site)
   a) District(s),
   b) State(s) in which the release(s) will take place.

4. Scale of release per release site.
   (Number of LMO involved, size of plot/ site etc)

5. Date when the release(s) is expected to commence.
   (Frequency of releases)

6. For an imported LMO – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA), Ministry of Health, Malaysia.

7. Description of the proposed activities with the LMO.

8. Name of person(s) authorized to undertake activities with the LMO.

A2 Risk Assessment Information - Parent Organism

(If more than one parent organism of the same species is involved then the information required in this part should be repeated for each parent organism)

9. Details of the parent organism:
   If the LMO is the result of a crossing event between more than one species/ cultivar/ breeding line/variety, please include relevant information (for example, LMO crossed with non-LMO or 2 LMOs crossed)
   a) Family name
   b) Genus
   c) Species
   d) Subspecies
   e) Cultivar/Breeding line/Variety
   f) Common name

10. A statement about whether the parent organism has an extended history of safe use in agriculture or in other industries.

11. Information concerning the reproduction of the parent organism:
    a) The mode or modes of reproduction
    b) Any specific factors affecting reproduction
    c) Generation time

12. Information regarding the sexual compatibility of the parent organism with other cultivated or wild plant species.

13. Information concerning the survivability of the parent organism:
    a) Ability to form structures for survival or dormancy including seeds, spores and scloretia,
    b) Any specific factors affecting survivability (e.g. seasonability).

14. Information concerning the dissemination of the parent organism:
    a) The means and extent of dissemination
    b) Any specific factors affecting dissemination.

15. Details of the natural habitat of the parent organism and its range.

16. Is the parent organism exotic in Malaysia?

    ☐ Yes ☐ No

17. Is the parent organism naturalized in Malaysia?

    ☐ Yes ☐ No

18. Is the parent organism, or a closely related organism, present at, or near, the site of the proposed release?
    (If more than one location is involved, then the information required in numbers 18 & 19 should be repeated for each location(s) of release)

    ☐ Yes ☐ No

19. If yes, please provide details of the population or populations and the estimated distances between them from the proposed release(s).

20. The potentially significant interactions of the parent organism with organism other than plant in ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.

21. An assessment of whether the parent organism is capable of causing disease or other ill-health in human, plants or animals and, if so, the details of the possible effects.

22. Details of any known predators, parasites, pests or diseases of the parent organism in Malaysia.

23. Details of pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses) and ability to colonize other organisms.

24. Is the parent organism resistant to any known antibiotic and if yes, what is the potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy?

25. Is the parent organism involved in environmental processes including primary production, nutrient turnover, decomposition of organic matter and respiration?

A3 Risk Assessment Information - LMO

26. Details of the modified trait(s) and how the genetic modification will change the phenotype of the LMO to be released.

27. What are the gene(s) responsible for the modified trait(s)?

28. Give details of the organism(s) from which the gene(s) of interest is derived :
(If more than one gene is involved then the information required in numbers 28, 29, 30, 31, 32 & 33 should be repeated for each gene)
    a) Family name
    b) Genus
    c) Species
    d) Subspecies
    e) Cultivar/Breeding line/Variety
    f) Common name

29. Indicate whether it is a:
    a) viroid
    b) RNA virus
    c) DNA virus
    d) bacterium
    e) fungus
    f) animal
    g) plant
    h) other (please specify)

30. Does the gene(s) of interest come from an organism that causes disease or other ill-health in humans, plants or animals? Provide details of the possible effects.

31. Please provide the following information about the gene(s) of interest:
    a) Size of sequence of the gene(s) of interest inserted
    b) Sequence of the gene(s) of interest inserted
    c) Intended function of the gene(s) of interest
    d) Number of copies of the gene(s) of interest in the construct
    e) Details of the steps involved in the construction
    f) Provide the map(s) of construct(s) indicating the gene(s) of interests and all other regulatory elements that will finally be inserted in the LMO

32. Please provide the following information about the deleted sequence(s):
    a) Size of the deleted sequence(s)
    b) Function of the deleted sequence(s)
    c) Details of the steps involved in the deletion of sequences from the parental organism
    d) Provide the map(s) of construct

33. The following information is on the expression of the gene(s) of interest:
    a) Level of expression of the gene(s) of interest and methods used for its characterization,
    b) The parts of the LMO where the gene(s) of interest is expressed, such as roots, stem or pollen
    c) Indicate the part(s) of the vector(s) that remains in the LMO
    d) The genetic stability of the gene(s) of interest.

34. A description of the methods used for the genetic modification:
    a) How gene(s) of interest was introduced into the parent organism, or
    b) How a sequence of a gene was deleted from the parent organism

35. If no vector was used for the genetic modification, please provide the detail of how the gene(s) of interest is introduced.

36. If vector(s) was used, please provide the following information:
    (If more than one vector was used, then the information required in 36 should be repeated for each vector)
    a) Type of vector:
        i. plasmid
        ii. bacteriophage
        iii. virus
        iv. cosmid
        v. phasmid
        vi. transposable element
        vii. other, please specify
    b) Identity of the vector (s)

c) Information on the degree of which the vector (s) contains sequences whose product or function is not known
d) Host range of the vector(s)
e) Potential pathogenicity of the vector(s)
f) The sequence of transposons, and other non-coding genetic segments used to construct the LMO and to make the introduced vector(s) and insert(s) function in those organisms

37. Details of the markers or sequences that will enable the LMO to be identified in the laboratory and under field conditions. Provide appropriate evidence for the identification and detection techniques including primer sequences for the detection of the inserted genes including marker genes.

38. Information (biological features) on how the LMO differs from the parent organism in the following respects:
g) Mode(s) and/or the rate of reproduction
a) Dissemination

39. If there is any possibility that the inserted genes in the LMO could be integrated into other species at the release site(s) and the surrounding environment, and if so, please provide the following details:
a) The organism(s) to which the modified trait(s) can be transferred to and the frequency at which it can be transferred
b) The transfer mechanism involved and the techniques that have been used to demonstrate transfer
c) Any possible adverse effects of the transfer including
i. Any advantages the affected organism(s) are likely to have over the number of the species that do not contain the inserted gene(s)
ii. Environmental risks posed by such an advantage

40. The identification and description of the target organism(s), if any.

41. The anticipated mechanism and result of interaction between the released LMO and the target organism(s).

42. The known or predicted interaction on non-target organisms in the release site(s) and the impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

43 A statement on whether the modified trait(s) of the LMO will change the capacity of the plant to add substances to, or subtract substances from, soil (for example, nitrogen or toxic compounds) and, if so, details of all such changes.

44. Details of any other possible adverse consequences.

45. Details of whether the modified trait(s) will confer a selective advantage on the LMO compare to the parent organism and if so, the conditions including data on the growth rate with and without the selection pressure and the nature of the advantages including a statement on how stable those features are.

46. Details of the genetic changes, if any, which will be included in the LMO to limit or eliminate any capacity to reproduce or transfer genes to other organism.

47. In relation to human health:
    a) The toxic or allergenic effects of the non-viable organisms and/or their metabolic products
    b) The comparison of the organisms to the donor, or (where appropriate) parent organism regarding pathogenicity
    c) The capacity of the organisms for colonization
    d) If the organisms are pathogenic to immunocompetent persons:
        i. diseases caused and mechanisms of pathogenicity including invasiveness and virulence
        ii. communicability
        iii. infective dose
        iv. host range and possibility of alteration
        v. possibility of survival outside of human host
        vi. presence of vectors or means of dissemination
        vii. biological stability
        viii. antibiotic-resistance patterns
        ix. allergenicity, and
        x. availability of appropriate therapies

48. Details of unintended pleiotropic effects (if any), including undesirable effects on agronomic characteristics of the plant which may result from the expression of the gene of interest(s) in the LMO (for example, reduced fertility, increased prevalence, production losses, grain shedding), including an indication of the likelihood of these events.

49. The description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

50. Details of how the genetic modification will change the phenotype of the LMO to be released, including information to demonstrate the effect of the genetic modification.

51. Details of the mechanism of pollen spread (by insect vectors or by other means) in the plant population:
    a) Details of pollen viability for the parent organism and of the LMO
    b) Details of any potential pollinators and their range and distribution in Malaysia

c) Quantitative data on successful cross-pollination between the parent organism, the LMO and its wild relatives, if available

A4 Information about weeds

52. Details of the members of the family of parent organism that are known to be weeds in any environment.

53. Details of cross-pollination between the species to which the LMO belongs and wild relatives known to be weeds, including a copy of any literature reports that support the information.

A5 Information about the seeds of the LMO

54. A statement on whether the LMO proposed to be released will be allowed to set seed and, if not, whether setting seed is planned for a later release.

55. If the LMO is to be allowed to set seed, will the mature seed normally remain contained within an ear, capsule or pod, so that practically all of the seed can be readily harvested, or is the seed shed soon after it matures?
If the latter, provide an indication of the proportion of seed likely to remain in the environment following harvest.

56. Details of the length of time that the seeds are capable of being dormant and whether it differs from the parent organism.

A6 Characteristics affecting survival of LMO

57. The predicted habitat of the LMO.

58. The biological features which affect survival, multiplication and dispersal.

59. The known or predicted environmental conditions which may affect survival, multiplication and dispersal, including wind, water, soil, temperature, pH.

60. The sensitivity to specific agents (e.g. disinfectant, pesticides, fertilizers, wind, water).

A7 Information about any secondary ecological effects that might result from the release

61. An assessment of possible effects of the proposed release on:
    a) Native species
    b) Resistance of insect populations to an insecticide
    c) Abundance of parasites

A8 Information about resistance of the LMO to a chemical agent (other than selective agents, such as antibiotics, used in strain construction)

62. Details of any environmental risks related specifically to the resistance of the LMO to a chemical agent (for example, a herbicide, but not a selective agent, such as an antibiotic, used in strain construction), where the resistance is a result of the genetic modification.

A9 Information about resistance of the LMO to a biological agent

63. Details of any environmental risks related specifically to the resistance of the LMO to a biological agent (for example, an insect or a fungal disease), where the resistance is a result of the genetic modification.

A10 Information relating to the release site(s)
(If more than one release site is involved, then the information required in this part should be repeated for each release site)

64. The size of the proposed release site(s).

65. The location of the proposed release site(s). Provide site map(s) with national grid reference(s).

66. Details of the reasons for the choice of the release site(s).

67. Details of the arrangements for conducting any other activities in association with the proposed release(s), such as importation of the LMO and transportation of the LMO, to or from the release site(s).

68. The preparation of the release site(s) before the release(s).

69. The methods to be used for the release(s).

70. The quantity of LMO to be released.

71. The physical or biological proximity of the release site(s) to humans and other significant biota or protected areas.

72. The size of local human population.

73. The local economic activities which are based on the natural resources of the area.

74. The distance to the nearest drinking water supply zone areas and/or areas protected for environmental purposes.

75. The flora and fauna, including crops, livestock and migratory species in the release site(s).

76. The comparison of the natural habitat of the parent organism with the proposed release site(s).

77. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

Part B Risk Management

B1 Information on control, monitoring, post-release plans

78. A description of measures (if any) to minimize the effects of any transfer of the modified trait(s) to other organisms.

79. Details of the proposed release site(s) supervision procedures and if necessary any relevant safety procedures designed to protect staff, including a description of procedures for onsite supervision of the release if the release site(s) is located at some distance from the location of the applicant.

80. Details of proposed measures (if any) for monitoring any risks posed by the LMO, including monitoring for:
    a) The survival or presence of the LMO, or transferred genetic material, beyond the proposed release site(s), including specificity, sensitivity and reliability of detection methods
    b) Impacts on the characteristics, or abundance, of other species
    c) Transfer of the gene(s) of interest to other species.
    d) Any other hazards or deleterious effect

81. Details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the NBB.

82. Details of ongoing monitoring to be undertaken after the release(s) are completed.

83. Details of proposed measures to minimize the possible adverse consequences. If no measures have been taken, please give reasons.

84. The methods for elimination or inactivation of the organisms at the end of the release and measures proposed for restricting the persistence of the LMO or its genetic material in the release site(s).

B2 Waste treatment plans

85. Type of waste generated.

86. Expected amount of waste.

87. Possible risks resulting from the waste.

88. Description of waste treatment envisaged and its disposal.

Part C Emergency Response Plan

89. Methods and procedures for controlling the LMO in case of any unintentional release and adverse effects being realized.

90. Methods for isolation of affected area.

91. Methods for disposal of other plants, animals and any other thing exposed to the adverse effects during the unintentional release.

Part D Data or results from any previous release(s) of the LMO

92. Give the following information from the previous applications (successful or unsuccessful) and releases of the LMO for which the applicant is seeking an approval:
    a. Reference number of each application
    b. Date of the certificate of approval issued
    c. Terms and conditions (if any) attached to the approval
    d. Data and results of post-release monitoring methods and effectiveness of any risk management procedures, terms and conditions and other relevant details
    e. Relevant data if the previous release is on a different scale or into a different ecosystem
    f. Any other relevant details

93. Details of results of any applications made for approval of the LMO in other countries, including information about conditions (if any) attached to the approval.

94. Details of any previous notifications for contained use activities according to the Biosafety Act 2007 from which the work in this present application has been developed.

95. Give details of data or results from any previous release of the LMO(s) for which the applicant is seeking an approval, especially the results of monitoring and the effectiveness of any risk management procedures, terms and conditions and any other relevant details.

PART E - Product of Such Organism

E1 General Information

96. The name and address of the manufacturer or distributor of the product.

97. General description of the product:
    a) Type of product
    b) Composition of the product
    c) Physical state of the product

98. For an imported product – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA), Ministry Of Health, Malaysia.

99. The type of environment and/or the geographical areas within Malaysia for which the product is suited.

100. The type of expected use of the product and the description of the persons who are expected to use the product.

E2 Information regarding proposed labeling of the product (according to Malaysian regulations on the labeling of genetically modified food)

101. Is the product being simultaneously notified to another country?

☐ Yes ☐ No

If yes, please specify.

102. Is the same product marketed in a country outside Malaysia?

☐ Yes ☐ No

If yes, please supply the following information:

a) Name of country
b) Authority which granted consent (if applicable)
c) Conditions under which consent was given (if applicable)

103. Has the product ever been withdrawn from the market of a country?

☐ Yes ☐ No

If yes, please supply the following information:

a) Name of country or countries
b) Reasons for withdrawing the product, if known

104. Has the product been rejected by authorities of a country?

☐ Yes ☐ No

If yes, please supply the following information:

a) Name of country or countries
b) Authority which rejected the product
c) Reasons for rejecting the product, if known

105. Description of identification and detection techniques for the LMO(s) in the product.

E3 Description of the LMO from which the product was derived from

(If the product is derived from more than one LMO, then the information required in numbers 106,107,108,109 & 110 should be repeated for each LMO)

106. Description of the LMO:
    a) Genus and species
    b) Common name
    c) Modified trait(s)
    d) Gene(s) responsible for the modified trait(s)

107. Details of the parent organism:
    a) Genus and species
    b) Common name

108. A statement about whether the parent organism has an extended history of safe use in agriculture and other industries.

109. Give the name of the organism from which the gene(s) of interest is derived from:
    a) Genus and species
    b) Common name

110. Indicate whether the organism from which the gene(s) of interest is derived from is a:
    a) virus
    b) bacterium
    c) fungus
    d) animal
    e) plant
    f) other (please specify)

E4 Risk Management of the Product

111. Specific instructions or recommendations for storage and handling of the product.

112. Measures for waste disposal and treatment of the product.

E5 Emergency Response Plan

113. Details of proposed measures to be taken in the event of adverse consequences/ misuse of the product.

APPENDIX 4

NBB REF NO :
(For Office Use)

BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/A/ER/10/FORM D

APPROVAL FOR RELEASE ACTIVITIES (SECOND SCHEDULE 2-6) OF LIVING MODIFIED ORGANISM (LMO) OTHER THAN A HIGHER PLANT AND PRODUCT OF SUCH ORGANISM

NBB/A/ER/FORM D shall be submitted as an application for certificate of approval of release activities (SECOND SCHEDULE 2-6) or importation of LMO and product of such organism and accompanied by the prescribed fees as found in Third Schedule of the Biosafety (Approval and Notification) Regulations 2010. Not all parts in this form will apply to every case. Therefore, applicants will only address the specific questions/ parameters that are appropriate to individual applications.

If the application is for release activities of an LMO or importation for release of an LMO other than a higher plant, please fill up Part A – D.
If the application is for release activities of a product of such organism or importation for release of a product of such organism, please fill up Part E.

In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated. The risk assessment, risk management plan, emergency response plan and the fulfillment of any other requirements under the Biosafety Act 2007 will be the basis of the issuance of the certificate of approval by the National Biosafety Board (NBB).

The applicant shall submit 1 original and 6 copies of the application to the Director General. A soft copy of the submitted application (including all supporting documents/ attachments, if any) shall also be provided in the form of a CD by the applicant. However, all information that has been declared as Confidential Business Information should be omitted from the CD.

Accuracy of information
The application should also be carefully checked before submission to ensure that all the information is accurate. If the information provided is incorrect, incomplete or misleading, the NBB may issue a withdrawal of the acknowledgement of receipt of application without prejudice to the submission of a fresh application.

Thus, it is important to provide accurate and timely information that is as comprehensive as existing scientific knowledge would permit, and supported by whatever data available.

NBB REF NO :
(For Office Use)

Confidentiality

Any information within this application which is to be treated as Confidential Business Information (CBI), as described in the Biosafety Act 2007 in section 59(3) should be clearly marked "CBI" in the relevant parts of the application by providing the justification for the request for CBI. The following information shall not be considered confidential:

a) The name and address of the applicant
b) A general description of the living modified organism
c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
d) Any methods and plans for emergency response

Authorization

Please ensure that if this application is being completed on behalf of the proposed user, that the person completing this application holds proper authority to submit this application for the proposed user.

For further information

Please contact the Director General by:
Telephone: 603-8886 1579
E-mail: biosafety@nre.gov.my

The completed forms to be submitted as follows:

The Director General
Department of Biosafety
Ministry of Natural Resources and Environment Malaysia,
Level 1, Podium 2,
Wisma Sumber Asli, No. 25, Persiaran Perdana
Precinct 4, Federal Government Administrative Centre
62574 Putrajaya, Malaysia.

Please retain a copy of your completed form.

NBB REF NO :
(For Office Use)

APPLICATION CHECK LIST

1. Form NBB/A/ER/10/FORM D is completed with relevant signatures obtained	☐
2. A copy of the clearance document from the Department of Agriculture included (if required)	☐
3. Any information to be treated as confidential business information should be clearly marked "CBI" in the application	☐
4. 1 original and 6 copies of the completed applications submitted. A soft copy of the submitted application (including all supporting documents/attachments, if any) that do not contain any CBI.	☐
5. Fees as prescribed in the regulation: RM_____ Money order/ Bank draft No: _____ Made payable to the Secretary General of the Ministry of Natural Resources and Environment	☐

Preliminary information

1. Organization:	
2. Name of Applicant:	
3. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	
4. Product Name (commercial and other names) Unique Identification Code:	

NBB REF NO :
(For Office Use)

5. Type of release activity:	☐ Supply or offer to supply for sale/ placing on the market ☐ Offer as gift, prize or free item ☐ Disposal ☐ Remediation purposes ☐ Commercial planting ☐ Any other activity which does not amount to contained use (please specify)
6. Is this the first time an approval is being applied for this activity?	Yes ☐ No ☐ if no, please provide information in no 7 below
7. I) Please provide the NBB reference no. for your previous notification/application II) How is this application different from the previous application submitted for this activity? (please provide an attachment if additional space is required)	

Details of Agent / Importer

8. Organization name:	
9. Contact Person:	
10. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	

NBB REF NO :
(For Office Use)

Signatures and Statutory Declaration

We declare that all information and documents herein is true and correct. We understand that providing misleading information to the NBB, deliberately or otherwise, is an offence under the Biosafety Act 2007.

Applicant:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

Head of organization/Authorized representative:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

NBB REF NO :
(For Office Use)

Part A Risk Assessment

A1 General Information

1. Details of the LMO to be released:
   a) Genus and species
   b) Common name
   c) Modified trait(s)

2. Objective(s) of the release.

3. Release site(s):
   (If more than one location is involved, then the information in numbers 3, 4, 5, 6, 7 & 8 should be repeated for each location(s) of release)
   a) District(s)
   b) State(s) in which the release(s) will take place

4. Scale of release per release site.
   (No of LMO involved, size of plot/site etc)

5. Date when the release(s) is expected to commence.
   (Frequency of releases)

6. For an imported LMO – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA), Ministry of Health, Malaysia.

7. Description of the proposed activities with the LMO/ product of such organism.

8. Name of person(s) authorized to undertake activities.

A2 Risk Assessment Information – The Parent Organism

(If more than one parent organism of the same species is involved then the information required in this part should be repeated for each parent organism)

9. Details of the parent organism:
   If the LMO is the result of a crossing event between more than one species/ cultivar/ breeding line/variety, please include relevant information (for example, LMO crossed with non-LMO or 2 LMOs crossed)
   a) Family name
   b) Genus
   c) Species
   d) Subspecies
   e) Breeding line/ Strains
   f) Common name

10. A statement about whether the parent organism has an extended history of safe use in agriculture and other industries.

11. Information concerning the reproduction of the organism:
    a) The mode or modes of reproduction
    b) Any specific factors affecting reproduction
    c) Generation time

12. Information regarding the sexual compatibility of the organism with other common/ domesticated or wild types.

13. Information concerning the survivability of the organism:
    a) Ability to form structures, including spores, sclerotia for survival or dormancy
    b) Any specific factors affecting survivability like seasonability

14. Information concerning the dissemination of the organism:
    a) The means and extent of dissemination
    b) Any specific factors affecting dissemination

15. Details of the natural habitat of the parent organism and its range.

16. Is the parent organism exotic in Malaysia?

    ☐ Yes ☐ No

17. Is the parent organism naturalized in Malaysia?

    ☐ Yes ☐ No

18. Is the parent organism, or a closely related organism, present at, or near, the site of the proposed release?
    (If more than one location is involved, then the information required in numbers 18 & 19 should be repeated for each location(s) of release)

    ☐ Yes ☐ No

19. If yes, please provide details of the population(s) and the estimated distances between them from the proposed release(s).

20. The potentially significant interactions of the parent organism with organism other than plant in ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.

21. An assessment of whether the parent organism is capable of causing disease or other ill-health in human, plants or animals and, if so, the details of the possible effects.

22. Details of any known predators, parasites, pests or diseases of the parent organism in Malaysia.

23. Details of pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses) and ability to colonize other organisms.

24. Is the parent organism resistant to any known antibiotic and if yes, what is the potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy?

25. Is the parent organism involved in environmental processes including primary production, nutrient turnover, decomposition of organic matter and respiration?

A3 Risk Assessment Information – LMO

26. Details of the modified trait (s) and how the genetic modifications will change the phenotype of the LMO to be released.

27. What are the gene(s) responsible for the modified trait(s)?

28. Give details of the organism(s) from which the gene(s) of interest is derived:
(If more than one organism is involved then the information required in numbers 28, 29 & 30, should be repeated for each organism)
    a) Family name
    b) Genus
    c) Species
    d) Subspecies
    e) Breeding line/ Strain
    f) Common name

29. Indicate whether it is a:
    a) viroid
    b) RNA virus
    c) DNA virus
    d) bacterium
    e) fungus
    f) animal
    g) plant
    h) other (please specify)

30. Does the gene(s) of interest come from an organism that causes disease or other ill-health in humans, plants or animals? Provide details of the possible effects.

31. Please provide the following information about the gene(s) of interest:
    a) Size of sequence of the gene(s) of interest inserted
    b) Sequence of the gene(s) of interest inserted
    c) Intended function of the gene(s) of interest
    d) Number of copies of the gene(s) of interest in the construct
    e) Details of the steps involved in the construction
    f) Provide the map(s) of construct(s) indicating the gene(s) of interests and all other regulatory elements that will finally be inserted in the LMO

32. Please provide the following information about the deleted sequence(s):
    a) Size of the deleted sequence(s)
    b) Function of the deleted sequence(s)
    c) Details of the steps involved in the deletion of sequences from the parental organism
    d) Provide the map(s) of construct(s)

33. The following information is on the expression of the gene(s) of interest:
    a) Level of expression of the gene(s) of interest and methods used for its characterization
    b) The parts of the organism where the gene(s) of interest is expressed
    c) The genetic stability of the gene(s) of interest

34. A description of the methods used for the genetic modification:
    a) How gene(s) of interest was introduced into the parent organism, or
    b) How a sequence of a gene was deleted from the parent organism

35. If vector(s) was used, please provide the following information:
    (If more than one vector was used, then the information required in 35 should be repeated for each vector)
    a) Type of vector
        ii. plasmid
        iii. bacteriophage
        iv. virus
        v. cosmid
        vi. phasmid
        vii. transposable element
        viii. other, please specify
    b) Identity of the vector(s)
    c) Information on the degree of which the vector(s) contains sequences whose product or function is not known
    d) Host range of the vector (s)
    e) Potential pathogenecity of the vector(s)

f) The sequence of transposons, and other non-coding genetic segments used to construct the LMO and to make the introduced vector(s) and insert(s) function in those organisms

36. If no vector was used for the genetic modification please provide the detail of how the gene(s) of interest is introduced.

37. Details of the markers or sequences that will enable the LMO to be identified in the laboratory and under field conditions. Provide appropriate evidence for the identification and detection techniques including primer sequences for the detection of the inserted gene(s) including marker gene(s).

38. Information on how the LMO(s) differs from the parent organism in the following respects:
    a) Mode(s) and/or the rate of reproduction
    b) Dissemination

39. If there is any possibility that the inserted gene(s) in the LMO(s) could be integrated into other species at the release site(s) and the surrounding environment, and if so please provide the following details:
    a) The organism(s) to which the modified trait(s) can be transferred to and the frequency at which it can be transferred
    b) The transfer mechanism involved and the techniques that have been used to demonstrate transfer
    c) Any possible adverse effects of the transfer including:
        i. Any advantages the affected organism(s) are likely to have over the number of the species that do not contain the inserted gene(s)
        ii. Environmental risks posed by such an advantage

40. The identification and description of the target organism(s), if any.

41. The anticipated mechanism and result of interaction between the released LMO and the target organism(s).

42. The known or predicted interaction on non-target organisms in the release site(s) and the impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.

43. A statement on whether the modified trait(s) of the LMO will change the capacity of the plant to add substances to, or subtract substances from, soil (for example, nitrogen or toxic compounds) and, if so, details of all such changes.

44. Details of any other possible adverse consequences.

45. Details of whether the modified trait(s) will confer a selective advantage on the LMO compare to the parent organism and if so, the conditions including data on the growth rate with and without the selection pressure and if so, the nature of the advantages including a statement on how stable those features are.

46. Details of the genetic changes, if any, which will be included in the LMO to limit or eliminate any capacity to reproduce or transfer genes to other organism.

47. The location of the gene(s) of interest in the cells (whether it is integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form) and the methods for its determination.

48. Details of the genetic changes, if any, which will be included in the LMO(s) to limit or eliminate any capacity to reproduce or transfer genes to other organisms.

49. In relation to human health:
    a) The toxic or allergenic effects of the non-viable organisms and/or their metabolic products
    b) The comparison of the organisms to the donor, or (where appropriate) parent organism regarding pathogenicity
    c) The capacity of the organisms for colonization
    d) If the organisms are pathogenic to immunocompetent persons:
        i. diseases caused and mechanisms of pathogenicity including invasiveness and virulence
        ii. communicability
        iii. infective dose
        iv. host range and possibility of alteration
        v. possibility of survival outside of human host
        vi. presence of vectors or means of dissemination
        vii. biological stability
        viii. antibiotic-resistance patterns
        ix. allergenicity, and
        x. availability of appropriate therapies

50. Details of unintended pleiotropic effects (if any), including undesirable effects on characteristics of the organism which may result from the expression of the gene(s) of interest in the LMO(s) (for example, reduced fertility, increased prevalence, production losses), including an indication of the likelihood of these events.

51. The description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

A4 Characteristics affecting survival of LMO(s)

52. The predicted habitat of the LMO(s).

53. The biological features which affect survival, multiplication and dispersal.

54. The known or predicted environmental conditions which may affect survival, multiplication and dispersal, including wind, water, soil, temperature, pH.

55. The sensitivity to specific agents (e.g. Disinfectant, pesticides, fertilizers, wind, water).

56. Survivability
    a) Ability to form structures enhancing survival or dormancy
        i. endospores
        ii. cysts
        iii. sclerotia
        iv. asexual spores (fungi)
        v. sexual spores (fungi)
        vi. eggs
        vii. pupae
        viii. larvae
        ix. other, please specify

A5 Information about any secondary ecological effects that might result from the release

57. An assessment of possible effects of the proposed release on:
    a) Native species
    b) Resistance of insect populations to an insecticide
    c) Abundance of prey or parasites

A6 Information about resistance of the LMO(s) to a chemical agent (other than selective agents, such as antibiotics, used in strain construction)

58. Details of any environmental risks related specifically to the resistance of the LMO(s) to a chemical agent (for example, a herbicide, but not a selective agent, such as an antibiotic, used in strain construction), where the resistance is a result of the modification.

A7 Information about resistance of the LMO(s) to a biological agent

59. Details of any environmental risks related specifically to the resistance of the LMO(s) to a biological agent (for example, an insect or a fungal disease), where the resistance is a result of the genetic modification.

A8 Information relating to the site of release

(If more than one release site is involved, then the information required in this part should be repeated for each release site)

60. The size of the release site(s).

61. The location of the proposed release site(s). Provide site map(s) with national grid reference.

62. Details of the reasons for the choice of release site(s).

63. Details of the arrangements for conducting any other activities in association with the proposed release(s), such as importation of a LMO(s) and transportation of a LMO(s), to or from the release site(s).

64. The preparation of the release site(s) before the release(s).

65. The methods to be used for the release(s).

66. The quantity of LMO to be released.

67. The physical or biological proximity of the release site(s) to humans and other significant biota or protected areas.

68. The size of the local human population.

69 The local economic activities which are based on the natural resources of the area.

70. The distance to the nearest drinking water supply zone areas and/or area protected for environmental purposes.

71. The flora and fauna including crops, livestock and migratory species in the release site(s).

72. The comparison of the natural habitat of the parent organism with the proposed release site(s).

73. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

74. Details of features of the physical environment of the release site(s) particularly features that may minimize or exacerbate any undesirable effects of the LMO.

Part B Risk Management

B1 Information on control, monitoring, post-release plans and waste treatment plans

75. A description of measures (if any) to minimize the effects of any transfer of the modified genetic trait(s) to other organisms.

76. Details of proposed release site(s) supervision procedures and if necessary any relevant safety procedures designed to protect staff, including a description of procedures for onsite supervision of the release if the release site(s) is located at some distance from the location of the applicant.

77. A description of post-release treatment methods for the LMO(s), e.g. the techniques for elimination or inactivation of the organisms at the end of the experiment.

78. Details of proposed measures (if any) for monitoring any risks posed by the LMO(s), including monitoring for:
    a) The survival or presence of the LMO(s), or transferred genetic material, beyond the proposed release site or sites, including specificity, sensitivity and reliability of detection methods
    b) Impacts on the characteristics, or abundance, of other species
    c) Transfer of the gene(s) of interest to other species
    d) Any other hazards or deleterious effect

79. Details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the NBB.

80. Details of ongoing monitoring to be undertaken after the release is completed.

81. Details of proposed measures to minimize the possible adverse consequences. If no measures have been taken, please give reasons.

82. The methods for elimination or inactivation of the organisms at the end of the experiment and measures proposed for restricting the persistence of the LMO or its genetic material in the release site(s).

B2 Waste treatment

83. Type of waste generated.

84. Expected amount of waste.

85. Possible risks resulting from the waste.

86. Description of waste treatment envisaged and its disposal.

Part C Emergency Response Plan

87. Methods and procedures for controlling the LMO(s) in case of any adverse effects being realized.

88. Methods for isolation of the affected area.

89. Methods for disposal of other plants, animals and any other thing exposed to the adverse effects.

90. Details of any other contingency measures that will be in place to rectify any unintended consequences if an adverse effect becomes evident during the course of the release.

Part D Data or results from any previous release(s) of the LMO

91. Give the following details/data/results from the previous application of releases of the LMO for which the applicant is seeking an approval:
    a. Reference number of each application
    b. Date of the certificate of approval issued
    c. Terms and conditions (if any) attached to the approval
    d. Data and results of post-release monitoring methods and effectiveness of any risk management procedures, terms and conditions and other relevant details
    e. Relevant data if the previous release is on a different scale or into a different ecosystem
    f. Any other relevant details

92. Details of results of any applications made for approval of the LMO(s), or any derived GM products in other countries, including information about conditions (if any) attaching to the approval.

93. Details of any previous notifications contained use activities according to the Biosafety Act 2007 from which the work in the present application has been developed.

94. If the LMO has been previously released in overseas, details of any adverse consequences of the release, including identifying references and reports of assessments if any.

PART E Product of Such Organism

E1 General Information

95. The name and address of the manufacturer or distributor of the product.

96. General description of the product:
    a) Type of product

b) Composition of the product
c) Physical state of the product

97. For an imported product – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA), Ministry Of Health, Malaysia.

98. The type of environment and/or the geographical areas within Malaysia for which the product is suited.

99. The type of expected use of the product and the description of the persons who are expected to use the product.

100. Information regarding proposed labeling of the product (if product is genetically modified food, then according to Malaysian regulations on the labeling)

101. Is the product being simultaneously notified to another country?

☐ Yes ☐ No

If yes, please specify.

102. Is the same product marketed in a country outside Malaysia?

☐ Yes ☐ No

If yes, please supply the following information:

a) Name of country
b) Authority which granted consent (if applicable)
c) Conditions under which consent was given (if applicable)

103. Has the product ever been withdrawn from the market of a country?

☐ Yes ☐ No

If yes, please supply the following information:

a) Name of country or countries
b) Reasons for withdrawing the product, if known

104. Has the product been rejected by authorities of a country?

☐ Yes ☐ No

If yes, please supply the following information:

a) Name of country or countries

b) Authority which rejected the product
c) Reasons for rejecting the product, if known

105. Description of identification and detection techniques for the LMO(s) in the product.

E2 Description of the LMO from which the product was derived from

(If the product is derived from more than one LMO, then the information required in numbers 106,107, 108,109 &110 should be repeated for each LMO)

106. Description of the LMO:
    a) Genus and species of the LMO
    b) Common name
    c) Modified trait(s)
    d) Gene(s) responsible for the modified trait(s)

107. Details of the parent organism:
    a) Genus and species
    b) Common name

108. A statement about whether the parent organism has an extended history of safe use in agriculture and other industries.

109. Give the name of the organism from which the gene(s) of interest is derived from:
    a) Genus and species
    b) Common name

110. Indicate whether the organism from which the gene of interest is derived from is a:
    a) virus
    b) bacterium
    c) fungus
    d) animal
    e) plant
    f) other (please specify)

E3 Description of the LMO contained in the product

(If more than one LMO contained in the product, then the information required in numbers 111, 112, 113, 114, 115 & 116 should be repeated for each LMO).

111. Description of the LMO:
    a) The genus and species of the LMO
    e) Modified trait(s)
    f) Gene(s) responsible for the modified trait(s)

112. Details of the parent organism:
    a) Genus and species
    b) Common name

113. A statement about whether the parent organism has an extended history of safe use in agriculture and other industries.

114. Give the name of the organism from which the gene(s) of interest is derived from:
    a) Genus and species
    b) Common name
    c) Indicate whether the organism from which the gene of interest is derived from is a:
    d) i. bacterium
        ii. Virus
        iii. fungus
        iv. animal
        v. plant
        vi. other (please specify)

115. Information concerning reproduction of LMO in the product.

116. Information on survival and factors affecting the LMO.

E4 Risk Management for the product

117. Specific instructions or recommendations for storage and handling of the product.

118. Measures for waste disposal and treatment of the product.

E5 Emergency Response Plan

119. Details of proposed measures to be taken in the event of adverse consequences/ misuse of the product.

APPENDIX 5

NBB REF NO :
(For Office Use)

BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/N/CU/10/FORM E

NOTIFICATION FOR CONTAINED USE AND IMPORT FOR CONTAINED USE ACTIVITIES INVOLVING LIVING MODIFIED ORGANISM (LMO) FOR BIOSAFETY LEVELS 1, 2, 3 AND 4

NBB/N/CU/10/FORM E shall be submitted to the Director General as a notification for contained use and import for contained use (not involving release into the environment of Living Modified Organism (LMO) as specified in Second Schedule of the Act). Any organization undertaking modern biotechnology research and development shall submit the notification through its Institutional Biosafety Committee (IBC) that is registered with the National Biosafety Board (NBB). The IBC should do an assessment prior to submission. Not all parts in this form will apply to every case. Therefore, applicants will only address the specific questions/parameters that are appropriate to individual applications.

In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated. The risk assessment, risk management plan, emergency response plan and the fulfillment of any other requirements under the Biosafety Act 2007 will be the basis of the decision by the NBB.

The applicant shall submit 1 original and 6 copies of the notification to the Director General. A soft copy of the submitted notification (including all supporting documents/ attachments, if any) shall also be provided in the form of a CD by the applicant. However, all information that has been declared as Confidential Business Information (CBI) should be omitted from the CD.

Providing information

The information provided in this notification will be used to evaluate the emergency response plan as specified in section 37 of the Biosafety Act 2007 and specific measures to be taken in relation to a contained use activity involving LMO. Thus it is important to provide accurate and timely information that is as comprehensive as existing scientific knowledge would permit, and supported by whatever data available.

The NBB may require additional information, and the applicant will be notified should this be the case. If the applicant fails to provide the additional information requested, the notification shall be deemed to have been withdrawn but it shall not affect the right of the applicant to make a fresh notification.

NBB REF NO :
(For Office Use)

Accuracy of information

The notification should also be carefully checked before submission to ensure that all the information is accurate. If the information provided is incorrect, incomplete or misleading, the NBB may issue a withdrawal of the acknowledgement of receipt of notification without prejudice to the submission of a fresh notification.

Confidentiality

Any information within this notification which is to be treated as CBI, as described in the Biosafety Act 2007 in section 59(3) should be clearly marked "CBI" in the relevant parts of the notification by providing the justification for the request for CBI. The following information shall not be considered confidential:

a) The name and address of the applicant
b) A general description of the LMO
c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
d) Any methods and plans for emergency response

Authorization

Please ensure that if this notification is being completed on behalf of the proposed user, that the person completing this notification holds proper authority to submit this notification for the proposed user. Please provide written proof of authorization.

For further information

Please contact the Director General by:
Telephone: 603-8886 1579
E-mail: biosafety@nre.gov.my

The completed forms to be submitted as follows:

The Director General
Department of Biosafety
Ministry of Natural Resources and Environment Malaysia
Level 1, Podium 2
Wisma Sumber Asli, No. 25, Persiaran Perdana
Precinct 4, Federal Government Administrative Centre
62574 Putrajaya, Malaysia.

Acknowledgment of Receipt:

Upon receipt of the notification, the Director General shall send to the applicant an acknowledgement of receipt with an assigned reference number. The reference number should be used in all correspondence with respect to the notification.

NBB REF NO :
(For Office Use)

Exemption:

The First Schedule of the Biosafety (Approval and Notification) Regulations 2010 allows exemptions for some types of techniques and contained use activities in relation to LMO posing a very low risk (i.e. contained research activities involving very well understood organisms and processes for creating and studying LMO). Exempted activities should be carried out under conditions of standard laboratory practice. Appropriate biosafety levels as according to Second Schedule of the Biosafety (Approval and Notification) Regulations 2010 should be used for the exempted activities and personnel should have appropriate training. Principal Investigators who believe that the work falls into any of the exemptions should nevertheless notify their IBC of the proposed project. The IBC may review all submitted research projects to determine their exemption or non-exemption status.

Please retain a copy of your completed form.

NBB REF NO :
(For Office Use)

NOTIFICATION CHECK LIST

1. Form NBB/N/CU/10/FORM E is completed with relevant signatures obtained	☐
2. Notification assessed and to be sent through the IBC (if relevant)	☐
3. A copy of clearance documents from the relevant Government agencies (if required)	☐
4. Any information to be treated as confidential business information should be clearly marked “CBI” in the notification	☐
5. 1 original and 6 copies of the completed notification submitted. A soft copy of the submitted notification (including all supporting documents/attachments, if any) that do not contain any CBI.	☐

Preliminary information

1. Organization:	
2. Name of Applicant:	
3. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	
4. Project Title:	
5. IBC Project Identification No:	
6. Is this the first time the activity is being notified?	Yes ☐ No ☐ if no, please provide information in no 7 below
7. I) Please provide the NBB reference number of your previous notification. II) How is this notification different from the previous notification submitted for this activity? (please provide an attachment if additional space is required)	

NBB REF NO :
(For Office Use)

Details of Agent / Importer

8. Organization name:	
9. Contact Person:	
10. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	

NBB REF NO :
(For Office Use)

Institutional Biosafety Committee (IBC) Assessment Report for the contained use and import for contained use of LMO

This must be completed by the registered IBC of the Applicant's organization

Section A – IBC Details

1.	Name of organization:			
2.	Name of IBC Chairperson:			
	Telephone number:		Fax:	
	Email address:			

Section B – IBC Assessment

3.	Name of principal investigator:	
4.	Project Title:	
5.	Date of the IBC Assessment:	
6.	Does the IBC consider that the principal investigator and every other person(s) authorized to be involved in contained use of the LMO have adequate training and experience for the task?	☐ Yes ☐ No
7.	The following information related to this project has been checked and approved	
	a) The objective of the project	☐ Yes ☐ No
	b) The description and genetics of the LMO	☐ Yes ☐ No
	c) The emergency response plan and the specific measures to be taken in relation to a contained use activity involving LMO.	☐ Yes ☐ No
8.	Has the information been checked by the IBC and found to be complete?	☐ Yes ☐ No
9.	Has the IBC assessed the biosafety of the proposed project? ☐ Yes ☐ No If yes, please append a copy of the IBC's assessment report and indicate the attachment in which details are provided.	

NBB REF NO :
(For Office Use)

Signatures and Statutory Declaration

The contained use of LMO within this project has been assessed as above and endorsed by the IBC. We declare that all information and documents herein is true and correct. We understand that providing misleading information to the NBB, deliberately or otherwise, is an offence under the Biosafety Act 2007.

Applicant:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

IBC Chairperson:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

Head of organization/Authorized representative:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

NBB REF NO :
(For Office Use)

Part A General Information

A1 Information

1. The name and address of the applicant and the name, qualifications and experience of the scientist and of every other person who will be responsible for planning and carrying out the contained use activities and for the supervision, monitoring and safety of the activity.

A2 Project Introduction

In this Part, the applicant is required to describe the proposed activities with the LMO within the context of the project.

2. Project Title:

3. Biosafety Level (BSL) :

   BSL 1 ☐ BSL2 ☐ BSL3 ☐ BSL4 ☐

4. Rationale of activity:

5. Overall Project/Programme Objective:
   Specific Objective(s):

6. Include an estimated time schedule to achieve the objectives:

7. Intended Date of Commencement:

8. Expected Date of Completion:

9. For an imported LMO– the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA), Ministry of Health, Malaysia, etc...

10. Categories of people (Research staff, technicians, students etc) authorised to undertake activities with the LMO:

11. Briefly describe the project using non-technical terms:

12. If the experiments are successful are there plans for an application for field experiment?

    ☐ Yes ☐ No

13. If yes, where would the proposed field experiment take place?

14. Who will undertake the unconfined release?

A3 Description of the LMO

The information requested in the following section is required to help identify any possible hazards associated with the proposed activities with the LMO. Some questions in this section may also relate to risk assessment and risk management, which are addressed in A4.

(If more than one LMO is involved, then the information required in A3 should be repeated for each LMO).

Please fill the specific information in a tabulated form as below

Table 1 Description of the LMO for contained use activities

LMO	Common and scientific name of donor organism	Common and scientific name of parent organism	Vector(s) or method of genetic modification	Class of modified trait (Refer to Box 1)	Modified trait	Identity and function of gene(s)of donor organism responsible for the modified trait	Target organism(s) of the LMO	Target tissues for genetic modification
1.								
2.								

NBB REF NO :
(For Office Use)

Box 1 : Various Classes or Types of Traits

NO	Class (type) of trait
1	Abiotic stress resistance
2	Altered agronomic characteristics
3	Altered nutritional characteristics
4	Altered pharmaceutical characteristics
5	Altered physical product characteristics
6	Antibiotic resistance
7	Foreign antigen expression
8	Attenuation
9	Bacterial resistance
10	Disease resistance
11	Flower colour
12	Fungal resistance
13	Herbicide tolerance
14	Immuno-modulatory protein expression
15	Pest resistance e.g. insect
16	Protein expression
17	Reporter/marker gene expression
18	Virus resistance
19	Other (provide details)
20	Unknown

NOTE:

1. If the LMO has more than one modified trait please list all, as according to the list in the Box 1.

2. If the modified trait is not listed in the Box 1, please list it as “other” and provide details of the modified trait.

A4 Risk assessment and management

(If more than one LMO is involved, then the information required in A4.1, A4.2 & A4.3 should be repeated for each LMO)

In order to prepare the Emergency Response Plan, an assessment of any possible risks or potential harm that may be posed by the LMO and the level of risk posed by such hazards based on an assessment of the likelihood and consequence of the hazard occurring must be carried out.

The risks that the IBC is required to assess are:

a) risks to the health and safety of humans from the activities associated with genetic modification
b) risks to the health and safety of humans from an unintentional release of the LMO; and
c) risks to the environment from an unintentional release of the LMO

The risk management plan details how any risks posed by the LMO will be managed to ensure that unacceptable risks are not realised.

Summaries of any protocols and/or standard operating procedures can be included to specifically answer the individual questions.

A4.1 Risk Assessment (Basic information)

15. Is there any risk to health and safety of humans occurring from the proposed activity over and above those posed by the donor/parent organism?

    No known hazard ☐ Not relevant ☐ Yes ☐

    If yes, please provide information in question below.

16. What are the possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (i.e. the risk) from the proposed genetic modification(s)?

17. In regard to the health and safety of humans, what are the possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (i.e. the risk) from an unintentional release of the LMO into the environment?

18. In regard to the environment, what are the possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (i.e. the risk) from an unintentional release of the LMO into the environment?

A4.2 Risk Management

19. Do you propose to transport the LMO outside the premises? If yes, describe the precautions taken.

20. How will the LMO be disposed of?

21. What are the procedures for decontaminating equipments used during the proposed activities in order to render any LMO unviable?

A4.3 Emergency Response Plan

22. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect observed during contained use activities.

23. Methods for removal of the LMO in the affected areas in the case of an unintentional release.

24. Methods for disposal of other plants, animals and any other organisms exposed during the unintentional release.

25. Methods for isolation of the area affected by the unintentional release.

26. Details of any other contingency measure that will be in place to rectify any unintended consequences if an adverse effect becomes evident during the contained use activities or when an unintentional release occurs.

A3 The Premises

Please provide information for all of the facilities being used for the confined activities in the table below.

Table 1 Description of the LMO for contained use activities

Information required	Premise 1	Premise 2*	Premise 3*
1. Name of premises:			
2. Premises type: *(e.g. animal containment premise, laboratory, insect containment premise, etc)*			
3. Biosafety level (BSL):			
4.Who undertook the inspection: *(indicate whether it was NBB, IBC or its representative)*			
5. Date of most-recent inspection:			
6. Fill the following if the BSL level is 3 or 4: Date of certification by competent authority (If any) Certificate reference no:			
7. Premises address:			
8. Premises contact person details/ Biosafety Officer Name:			
9. Business phone number:			
10. Mobile phone number:			
11. Fax number:			
12. Email address:			

Note:

* For notifications with more than one premise; use additional columns if necessary.

A6 Confidential Business Information

Enter in this section any information required in Part A 1 - A 5 for which confidentiality is claimed together with full justification for that claim.

APPENDIX 6

NBB REF NO :
(For Office Use)

BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/N/Ex/10/FORM F

NOTIFICATION FOR EXPORT OF LIVING MODIFIED ORGANISM (LMO)

NBB/N/Ex/10/FORM F shall be submitted to the Director General as a notification for export of LMO under the Biosafety Act 2007. The applicant shall submit 1 original and 6 copies of the notification to the Director General. A soft copy of the submitted notification (including all supporting documents/attachments, if any) shall also be provided in the form of a CD by the applicant. However, all information that has been declared as Confidential Business Information (CBI) should be omitted from the CD.

Accuracy of Information

The notification should be carefully checked before submission to ensure that all the information is accurate. If the information provided is incorrect or incomplete or misleading, the Director General may issue a withdrawal of the acknowledgement of submission of notification without prejudice to the submission of a fresh notification.

Compliance with Requirements of Importing Country

The applicant is required to comply with all the requirements of the importing country to export LMO. Evidence of compliance should be submitted with this notification.

Confidentiality

Any information within this application which is to be treated as Confidential Business Information (CBI), as described in the Biosafety Act 2007 in section 59(3) should be clearly marked “CBI” in the relevant parts of the application by providing the justification for the request for CBI. The following information shall not be considered confidential:

a) The name and address of the applicant
b) Description of the LMO

NBB REF NO :
(For Office Use)

For further information
Please contact the Director General by:
Telephone: 03-8886 1579
Email: biosafety@nre.gov.my

The completed form to be submitted as follows
Director General
Department of Biosafety
Ministry of Natural Resources and Environment Malaysia
Level 1, Podium 2
Wisma Sumber Asli, No. 25, Persiaran Perdana
Precinct 4, Federal Government Administrative Centre
62574 Putrajaya, Malaysia

Acknowledgement of Receipt
Upon receipt of the notification, the Director General shall send to the applicant an acknowledgement of receipt with an assigned reference number. The reference number should be used in all correspondence with respect to the notification.

Exemption
An applicant who has submitted a Notification for export of LMO and has received an Acknowledgement of Receipt from the Director General is exempt from making any subsequent Notifications for the same LMO, to the same country for the same purpose (as specified in the Acknowledgement of Receipt). However, there is no exemption for compliance with all the requirements of the importing country to export LMO for each subsequent export.

Please retain a copy of your completed form.

NOTIFICATION CHECK LIST

1. Form NBB/N/Ex/10/FORM F is completed with relevant signatures obtained	☐
2. Any information to be treated as confidential business information should be clearly marked “CBI” in the notification	☐
3. 1 original and 6 copies of the complete notification submitted. A soft copy of the submitted notification (including all supporting documents/attachments, if any) that do not contain any CBI.	☐

NBB REF NO :
(For Office Use)

Part 1 Details of the Applicant (Exporter)

1. Organization:	
2. Name of Applicant:	
3. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	

Part 2 Details of LMO to be exported

1. Description of LMO to be exported	
a. Plant b. Fish/shellfish c. Virus d. Animal e. Micro-organism (bacterium/fungus etc.) f. Animal cell g. Others (Please specify)	
2. Identification of LMO:	
3. Common name(s) Scientific name	
4. Introduced Trait(s)	
5. Intended use of LMO	
6. Describe the form in which LMO will be exported e.g. as seeds, cuttings, live fish, etc.	
7. Mode of export: Sea Rail Road Air Others (Please specify)	
8. Point of exit:	
9. Suggested methods for safe handling, storage, transport and use (if available)	

NBB REF NO :
(For Office Use)

Part 3 Importing Country

1) Name of importing country

2) Evidence of compliance with importing country's requirements (e.g. Copy of Import permit, copy of approval from competent authority, etc.)

Part 4 Confidential Business Information

Enter in this section any information required in Part 1-3 for which you are claiming confidentiality, together with full justification for that claim.

Part 5 Signatures and Statutory Declaration

We declare that all information and documents provided to the importing country are accurate and true and in compliance with the requirements of the importing country.

We also understand that providing misleading information to the National Biosafety Board (NBB), deliberately or otherwise, is an offence under the Biosafety Act 2007.

Applicant:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

Head of organization/Authorized representative:

Signature: _____ Date: _____

Name as in Identity Card/Passport: _____

Official Stamp:

Malaysia ratified the Cartagena Protocol on Biosafety in September 2003. In 2007, a Biosafety Act was approved to regulate the release, importation and contained use of living modified organisms (LMOs) and the products of such organisms. The Biosafety Act 2007 (the Act) is drafted to be in line with the National Biological Diversity Policy (1998) and the National Biotechnology Policy (2005) and covers only modern biotechnology activities. This Act will ensure the potential adverse impact of modern biotechnology is minimized and managed in a manner that does not have a negative impact on biodiversity and human health. The Act is an enabling law where most of the operational issues will be spelt out within the regulations. After series of negotiations with stakeholders, the Act entered into force on 1 December 2009. This was later followed by the entry into force of the Biosafety (Approval and Notifications) Regulations in November 2010. With this User's Guide, it is hoped that any organisation that conduct work with LMOs will understand and comply with the requirements of the new regulatory system for LMOs.

Ministry of Natural Resources and Environment

Department of Biosafety
Level 1, Podium 2
Wisma Sumber Asli, Precinct 4
62574 Putrajaya, Malaysia

Tel : + 603 8886 1580
+ 603 8886 1579

Fax : + 603 8890 4935

www.biosafety.nre.gov.my

For more information or clarification, please send your queries to biosafety@nre.gov.my

GEF

UNDP