Permohonan Penyelidikan Etika Biokeselamatan

Jargons

- GMAC-Genetic Manipulation Advisory Committee
- Biosafety/ Biokeselamatan
- LMO (Living Modified Organisms)
- GMO (Genetically Modified Organisms)
- Malaysian Biosafety Act 2007
- Biosafety (Approval and Notification) Regulations 2010

What is biosafety?

- Biosafety is used to described efforts to reduce and eliminate the potential risks resulting from modern biotechnology and its products
- It is used to protect us from harmful incidence.

What is the objective of Biosafety Act?

- Protect human, plant and animal health, the environment and biological diversity.
- Achieved through regulating the release, importation, exportation and contained use of LMOs, and the release of products of such organisms.

Activities involving LMOs that are regulated by the Act:

- Release;
- Contained use;
- Importation for release
- Importation for contained use
- exportation

What is LMO ?

Any living organism that possess a novel COMBINATION of genetic material through the use of modern biotechnology (involvement of DNA modification)

Box 1: Class of modified trait

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 resistance
16	Protein expression
17	Reporter/marker gene expression
18	Virus resistance
19	Others (please specify)

Use of modern biotechnology : DNA modification

Daffodil flowers

DNA

Rice

produce

Golden Rice

Before (wild-type/original)

After (Living modified organisms/LMO)

Why need Biosafety ethical clearance ?

- Requirement for publication acceptance
- Innovation & Invention
- Commercialization

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*.

Keperluan: Borang E

7 bahagian:

- A: Maklumat Am
- B: Pengenalan Projek
- C: Huraian tentang LMO
- D: Analisis dan pengurusan risiko
- E: Premis
- F: Maklumat Sulit Perniagaan
- G: Senarai rujukan

NBB/N/CU/15/FORM E

NBB REF.NO : **JBK (S) 602-1/2/**Click here to enter text.
(For Office Use)

BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/N/CU/15/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

Please refer to the Explanatory Notes of* NBB/N/CU/15/FORM E *before filling up this form

PROJECT TITLE: Click here to enter text.

Notification Check List

1. Form NBB/N/CU/15/FORM E is complete with the relevant signatures	☐
2. Cover letter from applicant's institute provided	☐
3. Notification has been assessed and sent through the IBC (if relevant)	☐
4. IBC Assessment Report (hardcopy and softcopy)	☐
5. A copy of clearance documents from the relevant Government agencies (if required)	☐
6. Any information to be treated as confidential business information has been clearly marked "CBI" in the notification	☐
7. One (1) original and six (6) hardcopies of the completed notification are submitted. A soft copy of the submitted notification that does not contain any CBI.	☐
8. All supporting documents/attachments required (e.g. SOPs, references)	☐
9. A copy of letter of authorization from R&D collaboration involving more than one premises (if any).	☐

Note: Please retain a copy of your completed notification.

Bahagian A: Maklumat am

Part A: General Information

1. Project team members' details.

   Information required is only for key persons involved in the project. IBC should have a record of **ALL** persons involved in the project.

Name	Address, contact number & email	Qualifications/Experience	Designation
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

Table 1: Description of team members' details

Bahagian B: Pengenalan Projek

Part B: Project Introduction

In this Part, the applicant is required to describe the proposed activities with the LMO within the context of the project.

2. General Objective:
   Click here to enter text.

   Specific Objective(s)**: (if any)**
   Click here to enter text.

3. Description of project activities (*please provide flow chart of the activities and the premises where each activity is conducted*):
   Click here to enter text.

4. Biosafety Level (BSL) of the proposed activitiy:
   (the biosafety containment level is determined by the risk assessment of the activity)
   BSL 1 ☐ BSL 2 ☐ BSL 3 ☐ BSL 4 ☐

5. Estimated duration of activity *(please provide Gantt chart):*
   Click here to enter text.

6. Intended Date of Commencement: Click here to enter text.

7. Expected Date of Completion: Click here to enter text.

8. Date of importation or intended importation (for an imported LMO)
   Click here to enter text.

9. If the experiments are successful, are there plans for an application for field experiment?

   Yes ☐ No ☐

Part C: Description of the LMO

Please refer to the Explanatory Notes on part C before filling in the specific information in a tabulated form as shown below.

Table 2: Description of the LMO for contained use activities

LMO	Common and scientific name(s) of parent organism (recipient)	Common and scientific name(s) of donor organism	Vector(s) and method of genetic modification	Class of modified trait (Refer to Box 1 of the Explanatory Notes)	Modified trait	Number of genes involved (Please provide the gene construct(s) map)	Identity and function of the gene(s) involved
1.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
2.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
3.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

Bahagian C:
Huraian tentang LMO

Bahagian D1: Analisis risiko

Part D: Risk assessment and management

D1 Risk Assessment (Basic information)

10. 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) including unintentional release to the health and safety of human and animals and the environment?

    You are required to fill in the matrix below. Please refer to Chapter 4 of Biosafety Guidelines: Contained use activity of Living Modified Organism (www.biosafety.nre.gov.my/guideline.shtml)

Risk assessment matrix

Hazard from	Identification of Potential hazard	Comments on risk	Risk Management by applicant	Residual risk
Science of Genetic modification	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Admin. Policy, People and Practice	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

Bahagian D2: Pengurusan risiko

D2 Risk Management

11. Do you propose to transport the LMO outside the premises or between premises?

    If yes, provide specific Standard Operating Procedures (SOPs) which are compliant with the Biosafety Guidelines. Please ensure all the premises used are included in Part E of this form.

    Click here to enter text.

12. How will the LMO be disposed of?

    Provide specific Standard Operating Procedures (SOPs) which are compliant with the Biosafety Guidelines. If the activity involves LMO at various growth stages (seedlings, trees), the SOP should cover the disposal of LMO at each growth stage.

    Click here to enter text.

13. How will the solid and liquid wastes from the activities (e.g. media, disposable gloves, planting materials, plant parts, etc.) be treated and disposed of?

    Provide specific Standard Operating Procedures (SOPs) which are compliant with the Biosafety Guidelines.

    Click here to enter text.

14. How will the wastewater from the activities be disposed of? (e.g. water used for cleaning equipment, watering the plants, etc.)

    Provide specific Standard Operating Procedures (SOPs) which are compliant with the Biosafety Guidelines.

    Click here to enter text.

15. How will the equipment/tools/surfaces used during the activities be decontaminated? (e.g. sharps, pipette, decontaminated glassware, etc.)

    Provide specific Standard Operating Procedures (SOPs) which are compliant with the Biosafety Guidelines.

    Click here to enter text.

Bahagian D3: Pelan Tindakan kecemasan

D3 Emergency Response Plan

16. Provide plans for protecting human and animal health and the environment in case of the occurrence of an undesirable effect observed during contained use activities.
(e.g. medical management which includes first aid and hospitalization, line of communication both within and outside the organization).
Click here to enter text.

17. Provide plans for removal of the LMO in the affected areas in the case of an unintentional release (*e.g. to contain and treat spillage*).
Click here to enter text.

18. Provide plans for disposal of plants, animals and any other organisms exposed during the unintentional release.
Click here to enter text.

19. Provide plans for isolation of the area affected by the unintentional release *(e.g. evacuation and quarantine).*
Click here to enter text.

20. Provide 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.
Click here to enter text.

Bahagian E: Premis

Part E: The Premises

21. Please provide information for all of the facilities being used for the contained use activities in the table below.

Note 1: For a Research and Development collaboration involving more than one IBC, please provide proof of collaboration (such as letter of authorization) to use the premises.
*Note 2: * For notifications with more than one premises, use additional columns provided.*

Table 3: Details of premises

Information required	Premises 1	Premises 2*	Premises 3*	Premises 4*
1. Name of premises:	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
2. Premises type: *(e.g. animal containment premises, laboratory, insect containment premises, greenhouse, etc,)* *(Please specify if it is a large scale facility involving culture volume greater than or equal to 10L of culture of any LMO)*	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
3. Biosafety level (BSL):	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
4. Who undertook the inspection of the premises? *(please indicate which* IBC*)*	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
5. Date of the most recent inspection : Attach latest inspection report.	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

NBB/N/CU/15/FORM E

Part F: Confidential Business Information

Enter in this section any information required in Part A - E for which confidentiality is claimed together with full justification for that claim.

Criteria for confidentiality are as follows (section 59 of Biosafety Act 2007):

a) that the information 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) that the information has commercial value because it is secret; and
c) those reasonable steps have been taken to keep the information secret.

Click here to enter text.

Part G: List of references

Click here to enter text.

Bahagian F & G:
Maklumat Sulit Perniagaan & Senarai Rujukan

Rujukan JKEPU (Biokeselamatan)

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