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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

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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 If the applicant fails to provide the additional information requested, the notification shall be deemed to have been withdrawn but it shall not affect the right of the applicant to make a fresh notification.

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

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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.

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 notification.

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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 number 7

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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)	

Details of Agent / Importer

Organization:	
Contact Person:	
Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	

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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

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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.

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:

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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:

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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).

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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 Table 2)**	**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								

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Table 2 Various Classes or Types of Traits

Class (type) of trait
Abiotic stress resistance
Altered agronomic characteristics
Altered nutritional characteristics
Altered pharmaceutical characteristics
Altered physical product characteristics
Antibiotic resistance
Foreign antigen expression
Attenuation
Bacterial resistance
Disease resistance
Flower colour
Fungal resistance
Herbicide tolerance
Immuno-modulatory protein expression
Pest resistance *e.g.* insect
Protein expression
Reporter/marker gene expression
Virus resistance
Other (provide details)
Unknown

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)

14. 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.

15. 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)?

16. 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?

17. 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

18. Do you propose to transport the LMO outside the premises? If yes, describe the precautions taken.

19. How will the LMO be disposed of?

20. What are the procedures for decontaminating equipments used during the proposed activities in order to render any LMO unviable?

A4.3 Emergency Response Plan

21. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect observed during contained use activities.

22. 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.

A5 The Premises

Please provide information for all of the facilities being used for the confined activities in the table below.

Information required	**Premise 1**	**Premise 2***	**Premise 3***
Name of premises:			
Premises type: *(e.g. animal containment premise, laboratory, insect containment premise, etc)*			
Biosafety level (BSL):			
Who undertook the inspection: *(indicate whether it was* NBB, IBC *or its representative)*			
Date of most-recent inspection			
Fill the following if the BSL level is 3 or 4: Date of certification by competent authority (If any) Certificate reference no			
Premises address:			
Premises contact			

person details/ Biosafety Officer Name:			
Business phone number:			
Mobile phone number:			
Fax number:			
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.