

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: PRODUCTION OF TRANSGENIC OIL PALM IN CONTAINED ENVIRONMENT CARRYING SELECTABLE AND REPORTER MARKER GENES

Notification Check List

1. Form NBB/N/CU/15/FORM E is complete with the relevant signatures	<input checked="" type="checkbox"/>
2. Cover letter from applicant's institute provided	<input checked="" type="checkbox"/>
3. Notification has been assessed and sent through the IBC (if relevant)	<input checked="" type="checkbox"/>
4. IBC Assessment Report (hardcopy and softcopy)	<input type="checkbox"/>
5. A copy of clearance documents from the relevant Government agencies (if required)	<input type="checkbox"/>
6. Any information to be treated as confidential business information has been clearly marked "CBI" in the notification	<input type="checkbox"/>
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.	<input checked="" type="checkbox"/>
8. All supporting documents/attachments required (e.g. SOPs, references)	<input checked="" type="checkbox"/>
9. A copy of letter of authorization from R&D collaboration involving more than one premises (if any).	<input type="checkbox"/>

Note: Please retain a copy of your completed notification.

Preliminary information

1. Organization:	Jabatan Biokeselamatan
2. Name of applicant (Principal Investigator):	Dr. Upin bin Ipin
3. Position in Organization: Telephone (office): Telephone (mobile): Fax number: E-mail: Postal address:	Senior Research Officer 03-8888 1776 012-3456789 03-8888 1775 upin@jbk.gov.my Jabatan Biokeselamatan, Aras 1, Wisma Sumber Asli, No. 25, Persiaran Perdana, Presint 4, 62574 Putrajaya.
4. Project Title:	Production of transgenic oil palm carrying selectable and reporter marker genes
5. IBC Project Identification No:	JBK/IBC 1
6. Is this the first time the activity is being notified?	Yes
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)	Not relevant Not relevant

Details of Importer

Importer: person or business bringing the LMO on behalf of the applicant

Relevant only if the LMO is imported

8. Organization:	Not relevant
9. Contact Person:	Not relevant
10. Position in Organization: Telephone (office): Telephone (mobile): Fax number: E-mail: Postal address:	Not relevant 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.

Institutional Biosafety Committee (IBC) Assessment for the contained use and import for contained use of LMO

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

This section is not relevant to organizations not involved in modern biotechnology research and development.

IBC Details

1	Name of Organization:	Jabatan Biokeselamatan		
2	Name of IBC Chairperson:	Dr. Farhanan bin Hamdan		
	Telephone number:	03-8888 1572	Fax:	03-8888 1572
	E-mail address:	farhanan@jbk.gov.my		

IBC Assessment

3	Name of Principal Investigator:	Dr. Upin bin Ipin
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4	Project Title:	Production of transgenic oil palm carrying selectable and reporter marker genes	
5	Date of the IBC Assessment:	7 August 2014	
6	Does the IBC consider that the Principal Investigator and every other person authorized to be involved in the contained use of the LMO have adequate training and experience for the task?		<input type="checkbox"/> Yes <input type="checkbox"/> No
7	The following information related to this project has been checked and approved		
	a)	Description of project activities	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	b)	The description and genetics of the LMO	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	c)	The emergency response plan and the specific measures to be taken in relation to a contained use activity involving LMO.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	d)	All persons involved are appropriately trained:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
8	Has the information provided in Form NBB/N/CU/15/FORM E been checked by the IBC and found to be complete?		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
9	<p>Has the IBC assessed the biosafety of the proposed project? <i>The risks that the IBC is required to assess are:</i></p> <p>a) <i>risks to the health and safety of human (occupational exposure) from the activities associated with genetic modification</i></p> <p>b) <i>risks to the health and safety of human and animals from an unintentional release of the LMO; and</i></p> <p>c) <i>risks to the environment from an unintentional release of the LMO</i></p> <p>Please append a copy of the IBC's assessment report and indicate the attachment in which details are provided. (For the IBC Assessment report, please use IBC/AP/15/ANNEX2 from http://www.biosafety.nre.gov.my/)</p>		<input checked="" type="checkbox"/> Yes

Signatures and Statutory Declaration

Please mark [X] in chosen box

- The contained use of LMO within this project has been assessed as above and endorsed by the IBC.*
- Applicant is not involved in modern biotechnology research and development.*

We declare that all information and documents herein are true and correct. We understand that providing misleading information to the NBB, deliberately or otherwise, is an offence under the Biosafety Act 2007.

Applicant/Principal Investigator:



Signature: _____ Date: **27 JULY 2014**

Name as in Identity Card/Passport: **UPIN BIN IPIN**

Official Stamp:

**DR. UPIN BIN IPIN
PEGAWAI PENYELIDIK
JABATAN
BIOKESELAMATAN**

IBC Chairperson:

This section is not relevant to organizations not involved in modern biotechnology research and development.



Signature: _____ Date: **7 AUGUST 2014**

Name as in Identity Card/Passport: **FARHANAN BIN HAMDAN**

Official Stamp:

**DR. FARHANAN BIN
HAMDAN
PENOLONG PENGARAH
JABATAN BIOKESELAMATAN**

Head of Organization/Authorized representative:



Signature: _____ Date: **7 AUGUST 2014**

Name as in Identity Card/Passport: **A. MUTHUSAMY**

Official Stamp:



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.)

Table 1 Description of team members' details

Name	Address, contact number & email	Qualifications/Experience	Designation
Dr. Upin bin Ipin	Jabatan BiokeSELAMATAN, Aras 1, Wisma Sumber Asli, No. 25, Persiaran Perdana, Presint 4, 62574 Putrajaya. Tel:03-8888 1776 HP:012-3456789 Fax:03-8888 1775 Email: upin@jbk.gov.my	PhD in Plant Genetic Engineering, UPM 1998. 10 years of experience in plant molecular biology and genetic engineering. Trained in Agrobacterium-mediated plant transformation and regeneration.	Research Officer

Dr. Donald Dee	Jabatan Biokeselamatan, Aras 1, Wisma Sumber Asli, No. 25, Persiaran Perdana, Presint 4, 62574 Putrajaya. Tel:03-8888 1778 HP:012-4147584 Fax:03-8888 1775 Email: donald@jbk.gov.my	PhD in Plant Genetic Engineering, UPM 1999. 10 years of experience in plant molecular biology and genetic engineering. Trained in plant and fatty acid and bioplastic analyses	Research Officer
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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.

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:

The overall objective of this contained dealing is to produce transgenic oil palm carrying selectable and reporter marker genes. These transgenic palms will be planted and evaluated in the biosafety screenhouse.

Specific Objective(s): **(if any)**

- a. To test several protocols for oil palm transformation, i.e. biolistic, *Agrobacterium*-mediated and microinjection-mediated.
- b. To produce transgenic oil palms by transforming either embryogenic calli or immature embryos, selecting transformed cells and regenerating transgenic plants.

- c. To grow transgenic oil palm carrying selectable and reporter genes in the biosafety nursery and screenhouse.
- d. To produce progenies (T1) of transgenic oil palms (T0) for confirmation of transgene transmission into the progenies.

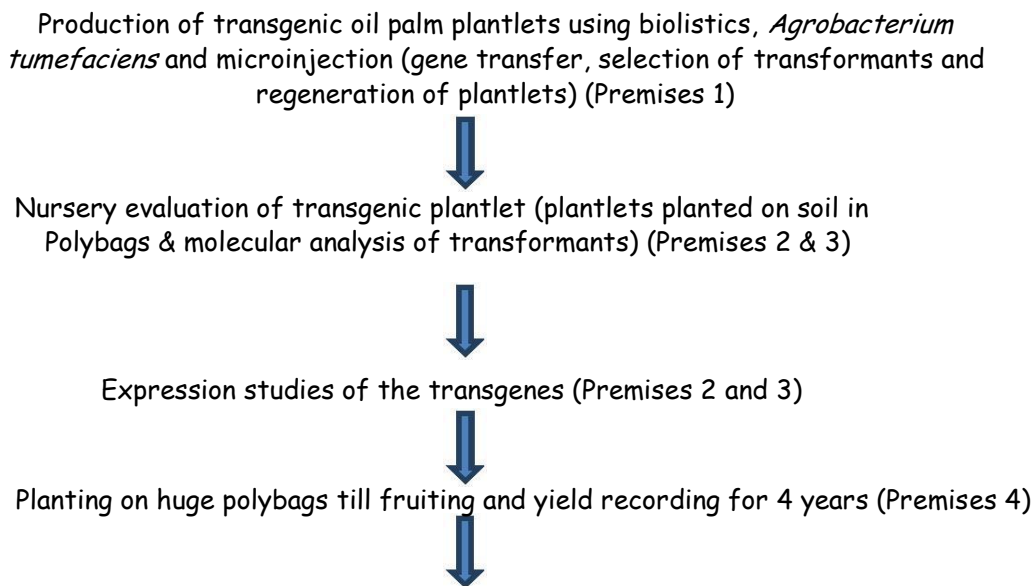
3. Description of project activities (please provide flow chart of the activities and the premises where each activity is conducted):

Oil palm is a major economic crop for Malaysia and in order to maintain sustainability of the industry, it is important to increase the yield and quality of palm oil at a rate faster than that has been achieved by conventional breeding. JBK has identified genetic engineering as an approach to overcome the above challenges. Taking into account the requirement of back-crossing in conventional breeding, genetic engineering could save 80 - 90% of the time required for introducing a new trait into oil palm. The use of selectable and reporter marker genes are required to identify the optimum selection scheme for effective transformation of oil palm as well as to monitor the expression of the novel gene introduced into oil palm.

This project involves the production of genetically modified (transgenic) oil palms carrying selectable and reporter marker genes, planting of the palms in the biosafety screenhouse and producing their progenies.

In summary, the project involves research activities in the laboratory, planting in polybags and, later on soil until the plants reach maturity. Crosses will be carried out to ensure successful transmission of the desired traits to the next generation.

A simplified flowchart of activities is as follows:



Production of T1 and confirmation of transgene transmission
 (crossing or selfing and molecular analysis of progenies to detect
 the presence of transgene) (Premises 2,3 and 4)

List of constructs: Appendix 1

4. Biosafety Level (BSL) : *(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):*

Activity	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Production of transgenic oil palm plantlets											
Nursery evaluation of transgenic plantlet											
Planting on soil till fruiting and yield recording for 4 years											
Production of T1 and confirmation of transgene transmission											

6. Intended Date of Commencement: 20 October 2014

7. Expected Date of Completion: October 2024

8. Date of importation or intended importation (for an imported LMO).

Not relevant

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.	Oil palm, <i>Elaeis guineensis</i>	<i>Streptomyces viridochromogenes</i>	pAH25 transformed using biolistic device and <i>Agrobacterium tumefaciens</i>	13	Herbicide tolerance	4	<i>bar</i> functions to detoxify glufosinate, the active ingredient of herbicide Basta

2.	Oil palm, <i>Elaeis guineensis</i>	<i>Agrobacterium tumefaciens</i>	pAH25 transformed using biolistic device and <i>Agrobacterium tumefaciens</i>	Click here to enter text.	Click here to enter text.	Click here to enter text.	<i>nos</i> (napoline synthase) terminator
3.	Oil palm, <i>Elaeis guineensis</i>	<i>E. coli</i>	pAH25 transformed using biolistic device and <i>Agrobacterium tumefaciens</i>	17	Reporter gene	Click here to enter text.	β -glucuronidase (<i>gusA</i>) gene - visible marker gene after adding a substrate

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	Basta resistant gene from bacterium <i>Streptomyces viridochromogenes</i>	<i>Streptomyces viridochromogenes</i> is a soil bacterium, widely present in the environment and is harmless to humans and animals. In this study, the bar gene which confers resistance to herbicide 'Basta' is only used as a selectable marker.	Experiments and planting are done in BSL2 facilities. SOPs for decontamination, disposal, transportation, and weed & pest control are available. Use of dedicated facility & equipment.	Click here to enter text.
	<i>gusA</i> and <i>hptII</i> genes from <i>E. coli</i> .	<i>E. coli</i> K12 used is non-pathogenic. <i>gusA</i> gene has been commonly used as a reporter gene in plant	Experiments and planting are done in BSL2 facilities. SOPs for decontamination, disposal, transportation,	Click here to enter text.

Hazard from	Identification of Potential hazard	Comments on risk	Risk Management by applicant	Residual risk
		transformation work and has a long history of safe use. <i>hptII gene isolated from E. coli K12 confers resistance to antibiotic hygromycin and is a commonly used selectable marker in plant transformation work. It also has a long history of safe use.</i>	and weed & pest control are available. Use of dedicated facility & equipment.	
	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	Occupational health hazard to worker due to possible exposure to GM plants, particularly to the pollen (allergenicity).	There should not be any occupational hazard related the handling of the GM palm. Furthermore, there is no evidence of allergenicity related to use of the transgenes	Experiments and planting are done in BSL2 facilities	1. Lack of knowledge / evidence of allergenicity related to pollen from GM palm. 2. Workers with allergic and respiratory problems (asthmatic) may be affected by pollen from GM palms.
	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.

Hazard from	Identification of Potential hazard	Comments on risk	Risk Management by applicant	Residual risk
Containment integrity	Containment integrity of the facilities in premises 1 & 2.	Click here to enter text.	These are BSL 2 facilities, not accessible to public, and entry is limited to authorised personnel only.	None
	Facilities in premises 3 & 4 are screenhouses of stainless steel mesh with polycarbonate roof. In premises 4, to ensure it is not penetrable by animals, the facility is also surrounded by wall both above and below ground.	These facilities are huge with height 5 - 6 m, and are made of stainless steel mesh and polycarbonate roof. The nylon mesh may be torn and the polycarbonate roof crack due to strong physical impact.	These facilities are not accessible to public and entry is limited to authorised personnel only. They are inspected regularly (normally once a month) to check for the intactness and integrity. Immediate corrective action will be taken if tear is detected.	1. Facilities are huge with the upper part 5 - 6 m high.
	LMOs are transported outside the premises. Plantlets are transferred from premises 2 to the nursery in premises 3. (same location). Plantlets from premises 3 are transferred to the	Standard operating procedure for transfer of plantlets from premises 2 to premises 3 and for transfer of fruits from premises 4 to Laboratory for analysis are provided.	Plants from premises 3 transported to premises 4 in a fully covered lorry straight to the screenhouse. Follow SOP provided on Transportation of LMO.	Click here to enter text.

Hazard from	Identification of Potential hazard	Comments on risk	Risk Management by applicant	Residual risk
	screenhouse in premises 4, few km away. Fruits collected are transferred to the laboratory for analysis.			
Special risks unique to notification	Unintentional release of the LMOs into the environment: in the form of pollen, plant parts or fruits	Pollen can pollinate untransformed oil palm and the fruits develop into maturity. However, there is a very small or negligible chance for such fruits or any parts of the palm to be consumed or used for commercial application. It is standard industry practice that all commercial plantings and breeding trials are derived from specific crosses.	Chances of pollen flow through pollinating weevil are minimal as the facility is surrounded by stainless steel mesh. Furthermore, all male flowers will either be bagged if needed for pollination or will be removed before maturity. Another protection is that the facility is locked and fenced. SOPs available for disposal.	Click here to enter text.
	This is a long-term continuous project, for 10 years.	Researchers / personnel involved in the project would change; activities and facilities may be affected.	SOPs are in place.	Click here to enter text.

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.

Yes. The plants will be transported in a fully covered lorry and sent straight to the screenhouse. No parts of the plants were left exposed and released into the environment during transportation as the palms were trimmed prior to transportation. All plant parts left behind in the screenhouse as well as inside the lorry, will be collected and autoclaved prior to disposal.

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.

All plant parts (after leaf pruning or flower removal) will be collected from the nursery and screenhouse and placed in biohazard autoclave bags, autoclaved and disposed as normal waste. Flowers from the screenhouse will be collected in autoclave bags and autoclaved prior to disposal. After analysis, all fruits and oil will be autoclaved prior to disposal.

At the conclusion of the trial, all plants will be cut down and all parts, including roots and all debris, will be chipped into small pieces and autoclave/dispose within the screenhouse.

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.

Please refer to SOP on solid and liquid wastes disposal as provided in Appendix 1

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.

Please refer to SOP on wastewater disposal as provided in Appendix 2

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.

Please refer to SOP on decontamination of equipment as provided in Appendix 3

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).

Red and white caution plastic tape will be used to mark off the perimeter of the greenhouse and no entry signs will be put up to stop any unauthorized personnel from entering the site. All plants will be uprooted, placed in autoclave bags and autoclaved prior to disposal.

The flowers, fruits and loose fruits will be collected in biohazard bags and autoclaved prior to disposal. If involving LMO during regeneration, all the cultures (while still in petri dish, beakers or test tubes) will be collected in autoclave bags and autoclaved prior to disposal

The PI/laboratory personnel will report any incident to the IBC through the BSO using the Incident Reporting Form (IBC/IR/10/ANNEX3) within 24 hours.

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).

LMO in tissue culture stages will be collected in biohazard bags and autoclaved prior to disposal. Any spillage will be wiped and the waste will be collected in autoclave bags and autoclaved prior to disposal. If the release involves plant parts or fruits, it will be handpicked and will be collected in autoclave bags and autoclaved prior to disposal. All of these activities will be carried out under the supervision of JBK's IBC.

18. Provide plans for disposal of plants, animals and any other organisms exposed during the unintentional release.

In the case of pollen release i.e. the worst-case scenario, is to harvest any oil palm fruits produced within a 50 meter radius of the greenhouse, 18-22 weeks after the unintentional release, and autoclave them as done with the leaves.

19. Provide plans for isolation of the area affected by the unintentional release (e.g. evacuation and quarantine).

The area will be cordoned off with the white and red caution tape and "No Entry" signs will be put up to prevent any unauthorized entry. In the case of laboratory spillage, the area will be immediately evacuated and "No Entry" signs will be put up. Workers in the surrounding areas will be notified to prevent any entry into the release area. A staff will be on standby until cleaning and disposal are completed under the supervision of the IBC.

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.

The area will be cordoned off with the white and red caution tape and "No Entry" signs will be put up to prevent any unauthorized entry. BSO and IBC will be immediately notified and followed by NBB. Staff will be advised to stay calm and not to enter the designated area. Under the supervision of IBC, staff will use proper PPE to collect all the LMO materials, autoclave and dispose. Pest management practices will be carried out at the premises to minimize potential exposure of the LMO material to insects or animals such as squirrels or rats. Traps for rats and squirrels will be placed inside the facilities. Baits will also be placed both inside and outside the facilities to prevent rats and squirrels from entering the facility.

Part E: The Premises

21. Please provide information for all of the facilities being used for the confined 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 if necessary.*

Table 3: Details of premises

Information required	Premises 1	Premises 2*	Premises 3*	Premises 4*
1.Name of premises:	Jabatan Biokeselamatan	Jabatan Biokeselamatan	Jabatan Biokeselamatan	Jabatan Biokeselamatan
2.Premises type: <i>(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)</i>	Genetic Modification Laboratory	Tissue Culture Laboratory	Nursery	Screenhouse IBC
3.Biosafety level (BSL):	2	2	2	2
4. Who undertook the inspection of the premises? <i>(please indicate which IBC)</i>	IBC	IBC	IBC	IBC
5.Date of the most-recent inspection :	May 2013	May 2013	May 2013	May 2013
6.Fill the following if premises is BSL 3 or BSL 4:	Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

<p>Date of certification by competent authority</p> <p>Certificate reference no:</p> <p>Attach latest inspection report.</p>	<p>Click here to enter text.</p> <p>Click here to enter text.</p>	<p>Click here to enter text.</p> <p>Click here to enter text.</p>	<p>Click here to enter text.</p> <p>Click here to enter text.</p>	<p>Click here to enter text.</p> <p>Click here to enter text.</p>
<p>7. Address of premises:</p>	<p>Jabatan Biokeselamatan, Aras 1, Wisma Sumber Asli, No. 25, Persiaran Perdana, Presint 4, 62574 Putrajaya.</p>	<p>Jabatan Biokeselamatan, Aras 1, Wisma Sumber Asli, No. 25, Persiaran Perdana, Presint 4, 62574 Putrajaya.</p>	<p>Screenhouse HQ, Jabatan Biokeselamatan, Bangunan Penyelidikan NRE, Jalan Diplomatik 2/4, Presint Diplomatik,62576 Putrajaya.</p>	<p>Screenhouse HQ, Jabatan Biokeselamatan, Bangunan Penyelidikan NRE, Jalan Diplomatik 2/4, Presint Diplomatik,62576 Putrajaya.</p>
<p>8.Name of contact person for premises/ Biosafety Officer Name:</p>	<p>Dr. Upin b. Ipin</p>	<p>Dr. Daniel Dee</p>	<p>Dr. Upin b. Ipin</p>	<p>Dr. Daniel Dee</p>
<p>9.Business phone number:</p>	<p>03-8888 1776</p>	<p>03-8888 1778</p>	<p>03-8888 1776</p>	<p>03-8888 1778</p>
<p>10.Mobile phone number:</p>	<p>012-3456789</p>	<p>012-4147584</p>	<p>012-3456789</p>	<p>012-4147584 03-8888 1775</p>
<p>11.Fax number:</p>	<p>03-8888 1775</p>	<p>03-8888 1775</p>	<p>03-8888 1775</p>	<p>03-8888 1775</p>
<p>12.Email address:</p>	<p>upin@jbk.gov.my</p>	<p>donald@jbk.gov.my</p>	<p>upin@jbk.gov.my</p>	<p>donald@jbk.gov.my</p>

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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.

No CBI declared.

Part G: List of references

1. Sambanthamurthi, R., Siti Nor Akmar, A., and Parveez, G.K.A. (2002) *Genetic manipulation of the oil palm - Challenges and prospects. The Planter* 78, 547-562.

EXPLANATORY NOTES FOR 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/15/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. This submission should be accompanied by a cover letter from the applicant's institution. 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.

If the LMO is imported, detail of importer, date of intended importation and approval from relevant authorities like Department of Agriculture (DOA), Ministry of Health, Malaysia, etc. should be provided.

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.

Description of LMO (Part C)

Parent organism refers to the final recipient of the intended genetic modification

Donor organism refers to the source of the genetic sequences used for modification.

Vector should include all vectors and method (s) used.

Modified trait can be stated as “unknown” if for example building a genomic library,

Identity and function of gene(s) of donor organism responsible for the modified trait can be stated as “unknown” if for example building a genomic library.

Target organism(s) of the LMO refers to the organism (s) that is expected to be affected or to interact with the LMO

Class of modified trait, please refer box below.

If the LMO has more than one modified trait please list all. If the modified trait is not listed in the Box 1, please list it as “other” and provide details of the modified traits

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)

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 or any queries related to filling up this form

Please contact the office of the Director General by:

Telephone: 603-8886 1580

E-mail: biosafety@nre.gov.my

The completed form and cover letter 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.

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

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.