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/14/FORM E is complete with the relevant signatures |  |
| 1. Cover letter from applicant’s institute provided |  |
| 1. Notification has been assessed and sent through the IBC (if relevant) |  |
| 1. IBC Assessment Report (hardcopy and softcopy) |  |
| 1. A copy of clearance documents from the relevant Government agencies (if required) |  |
| 1. Any information to be treated as confidential business information has been clearly marked “CBI” in the notification |  |
| 1. 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. |  |
| 1. All supporting documents/attachments required (e.g. SOPs, references) |  |
| 1. 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.***

## Preliminary information

|  |  |
| --- | --- |
| 1. Organization: | Jabatan Biokeselamatan |
| 1. Name of applicant (Principal Investigator): | Dr. Upin bin Ipin |
| 1. 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](mailto:upin@jbk.gov.my)  Jabatan Biokeselamatan,  Aras 1, Wisma Sumber Asli, No. 25,  Persiaran Perdana, Presint 4, 62574 Putrajaya. |
| 1. Project Title: | PRODUCTION OF TRANSGENIC OIL PALM IN CONTAINED ENVIRONMENT CARRYING SELECTABLE AND REPORTER MARKER GENES |
| 1. IBC Project Identification No: | JBK/IBC 1 |
| 1. Is this the first time the activity is being notified? | Yes |
| 1. 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 |

**Details of Importer**

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

*Relevant only if the LMO is imported*

|  |  |
| --- | --- |
| 8. Organization: | Bio Diagnostic Sdn Bhd |
| 9. Contact Person: | Mr Yap Ah Loi |
| 10. Position in Organization:  Telephone (office):  Telephone (mobile):  Fax number:  E-mail:  Postal address: | Sales executive  03-61789090  011-50094009  [ahloi@bio\_diagnostic.com.my](mailto:ahloi@bio_diagnostic.com.my)  2, Tkt 1, Bandar Puchong Baru, 34000 Puchong, Selangor |

**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 1573 |
|  | E-mail address: | farhanan@jbk.gov.my | | |

**IBC Assessment**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 3 | Name of Principal Investigator: | Dr. Upin bin Ipin | | | |
| 4 | Project Title: | PRODUCTION OF TRANSGENIC OIL PALM IN CONTAINED ENVIRONMENT CARRYING SELECTABLE AND REPORTER MARKER GENES | | | |
| 5 | Date of the IBC Assessment: | | 10 Februari 2016 | | |
| 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? | | | Yes  No | |
| 7 | The following information related to this project has been checked and approved | | | | |
| 1. The objective(s) of the project | | | | | Yes  No |
| 1. The description and genetics of the LMO | | | | | Yes  No |
| 1. The emergency response plan and the specific measures to be taken in relation to a contained use activity involving LMO. | | | | | Yes  No |
| 1. **All persons involved are appropriately trained**: | | | | | 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?  *The risks that the IBC is required to assess are:*   1. *risks to the health and safety of human (occupational exposure) from the activities associated with genetic modification* 2. *risks to the health and safety of human and animals from an unintentional release of the LMO; and* 3. *risks to the environment from an unintentional release of the LMO*     **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/13/ANNEX2 from http://www.biosafety.nre.gov.my) | | | | 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:**

2 February 2016



Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

UPIN BIN IPIN

Name as in Identity Card/Passport: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Official Stamp: ***OFFICIAL CHOP***

**IBC Chairperson**:

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

10 February 2016



Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

FARHANAN BIN HAMDAN

Name as in Identity Card/Passport: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

DR. FARHANAN BIN HAMDAN

PENOLONG PENGARAH

JABATAN BIOKESELAMATAN

Official Stamp:

**Head of Organization/Authorized representative:**

10 February 2016



Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

A. MUTHUSAMY

Name as in Identity Card/Passport: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Official Stamp:

DR. A. MUTHUSAMY

PENGARAH

JABATAN BIOKESELAMATAN

***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 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](mailto: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](mailto:%20donald@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 |
| Dr. Jekyll Hyde | Akedemi Biologi Malaysia (ABM),  Kuala Lumpur.  Tel: 03-3456 7899  HP:012-6167546  Fax: NIL  Email: [jekyll@gmail.com](mailto:jekyll@gmail.com) | Advanced skills and knowledge in numerous areas of molecular biology. | Adjunct professor |

**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.

1. General Objective:

The overall objectiveof this contained dealing is to produce transgenic oil palmcarrying selectable and reporter marker genes. These transgenic palms will be planted and evaluated in the biosafety screen house.

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

1. To test several protocols for oil palm transformation, i.e. biolistic, *Agrobacterium*-mediated and microinjection-mediated.
2. To produce transgenic oil palms by transforming either embryogenic calli or immature embryos, selecting transformed cells and regenerating transgenic plants.
3. To grow transgenic oil palm carrying selectable and reporter genes in the biosafety nursery and screen house.
4. To produce progenies (T1) of transgenic oil palms (T0) for confirmation of transgene transmission into the progenies.
5. 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. The recombinant *Agrobacterium* used for this activity will initially be imported from Marker Genes Technologies Inc., USA.

In summary, the project involves research activities in the laboratory, planting in polybags and, later on soil until the plants reach maturity. Hence, 3 facilities will be used to conduct these activities, i.e. genetic modification lab, tissue culture lab, and plant nursery. As Jabatan Biokeselamatan does not have a screen house of its own, we will be using the screen house of Institut Penyelidikan Pertanian Khas GMO (IPPKG). Crosses will be carried out to ensure successful transmission of the desired traits to the next generation.

1. Biosafety Level (BSL) : *(the biosafety containment level is determined by the risk assessment of the activity)*

BSL 1  BSL 2 ⬜ BSL 3 ⬜ BSL 4 ⬜

1. Estimated duration of activity *(please provide Gantt chart ):*

The above activities will be continuous, therefore there is no specific time frame when all the objectives will be achieved. However, as an estimation, the whole process will take 8 years as listed below. Estimated timeframe for each activity:

Gantt chart

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Activity | 2016  (Feb-Dec) | 2017  (Jan-Dec) | 2018  (Jan-Dec) | 2019  (Jan-Dec) | 2020  (Jan-Dec) | 2021  (Jan-Dec) | 2022  (Jan-Dec) | 2023  (Jan-Dec) |
| 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 |  |  |  |  |  |  |  |  |

1. Intended Date of Commencement:

12 February 2016

1. Expected Date of Completion:

December 2023

1. Date of importation or intended importation (for an imported LMO).  
    3April 2016
2. 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, *Elaeis guineensis* | *Streptomyces viridochromogenes* | *Agrobacterium tumefaciens* mediated system | 13 | Herbicide tolerance | 4, Refer Appendix I | *bar* functions to detoxify  glufosinate, the active  ingredient of herbicide Basta |
| Maize, *Zea mays* |  |  |  | *Ubiquitin* promoter |
| *Agrobacterium tumefaciens* |  |  |  | *nos* (napoline synthase)  terminator |
| *E. coli* | 17 | Reporter gene |  | *β-*glucuronidase (*gusA*) gene –  visible marker gene after  adding a substrate |
| *E. coli* | 6 | Antibiotic resistance |  | Hygromycin  phosphotransferase (*hptII*) gene for resistance  against antibiotic hygromycin |
| Cauliflower mosaic virus |  |  |  | 35S promoter |

***Part D: Risk assessment and management***

***D1 Risk Assessment (Basic information)***

1. 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 *Streptomyces viridochromogenes* | *Streptomyces viridochromogenes* 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 a selectable marker. | Experiments and planting are done in BSL1 facilities. SOPs for decontamination, disposal, transportation, and weed & pest control are available. Use of dedicated facility & equipment. |  |
| gusA and hptII genes from *E. coli* . | *E. coli* K12 used is non-pathogenic. gusA gene has been commonly used as a reporter gene in plant transformation work and has a long history of safe use. *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. | Experiments and planting are done in BSL1 facilities. SOPs for decontamination, disposal, transportation, and weed & pest control are available. Use of dedicated facility & equipment. |  |
| **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. Furthemore, there is no evidence of allergenicity related to use of the transgenes. | Experiments and planting are done in BSL1 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. |
| **Containment integrity** | Failure of HEPA filter of clean bench hood thus expose to bacteria used in this study. | Bacteria used in this study are non-pathogenic. | Yearly maintenance by lab manager to all clean bench hood. |  |
| **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. |  |
| This is a long-term continuous project, for 8 years. | Researchers / personnel involved in the project would change; activities and facilities may be affected. | SOPs are in place. |  |
| Plants in the screen house will be planted on soil in huge polybags for 6 years (to maturation, production of fruit bunches for yield recording). | Genes in GM palm are already present in the soil microbes; no additional hazard is posed to the environment. Horizontal gene transfer from one bacteria to another has been reported but not from plant to microbes. | None |  |
| Ants and other small insects which can become passive pollinators. |  | Pest management to prevent access of insects in and out of the containment facility are in place. |  |

***D2 Risk Management***

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

*If yes, provide specific Standard Operating Procedures (SOPs) which are in compliant with the Biosafety Guidelines.*

Please refer to SOP on LMO transportation as provided in Appendix II

1. How will the LMO be disposed of?

*Provide specific Standard Operating Procedures (SOPs) which are in 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.*

Please refer to SOP on LMO disposal as provided in Appendix III

1. 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 in compliant with the Biosafety Guidelines.*

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

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1. How will the wastewater from the activities be disposed of?

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

Please refer to SOP on wastewater disposal as provided inAppendix IVb

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

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

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

***D3 Emergency Response Plan***

1. 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 screenhouse 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.

The detailed SOP is provided in Appendix VI.

1. 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 screen house, 18-22 weeks after the unintentional release, and autoclave them as done with the leaves. The detailed SOP is provided in Appendix VII.

1. 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. The detailed plan is provided in Appendix VIII.

1. 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***

20. 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 IBCs, 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** | **Premises** | **Premises** |
| 1.Name of premises: | Lab GM 01 | Lab TC 01 | Plant Nursery |
| 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)* | Genetic Modification Laboratory | Tissue Culture Laboratory | Plant nursery |
| 3.Biosafety level (BSL): | 1 | 1 | 1 |
| 4. Who undertook the inspection of the premises?  *(please indicate which* IBC*)* | IBC Jabatan Biokeselamatan | IBC Jabatan Biokeselamatan | IBC Jabatan Biokeselamatan |
| 5.Date of the most-recent inspection : | October 2015 | October 2015 | January 2016 |
| 6.Fill the following if the BSL level is 3 or 4:  Date of certification by competent authority  Certificate reference no:  Attach latest inspection report. |  |  |  |
| 7. Address of premises: | Lab GM 01,  Jabatan Biokeselamatan,  Aras 1, Wisma Sumber Asli, No. 25,  Persiaran Perdana, Presint 4, 62574 Putrajaya. | Lab TC 01,  Jabatan Biokeselamatan,  Aras 1, Wisma Sumber Asli, No. 25,  Persiaran Perdana, Presint 4, 62574 Putrajaya. | Plant Nursery Jabatan Biokeselamatan, Rooftop, Wisma Sumber Asli, No. 25,Persiaran Perdana, Presint 4, 62574 Putrajaya. |
| 8.Name of contact person for premises/ Biosafety Officer Name: | Dr. Upin b. Ipin | Dr. Daniel Dee | Dr. Daniel Dee |
| 9.Business phone number: | 03-8888 1776 | 03-8888 1778 | 03-8888 1778 |
| 10.Mobile phone number: | 012-3456789 | 012-4147584 | 012-4147584 |
| 11.Fax number: | 03-8888 1775 | 03-8888 1775 | 03-8888 1775 |
| 12.Email address: | [upin@jbk.gov.my](mailto:upin@jbk.gov.my) | [donald@jbk.gov.my](mailto:donald@jbk.gov.my) | [donald@jbk.gov.my](mailto:donald@jbk.gov.my) |

***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):

1. 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;
2. That the information has commercial value because it is secret; and
3. Those reasonable steps have been taken to keep the information secret.

No CBI declared.

**List of references.**

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/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.

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:

1. The name and address of the applicant
2. A general description of the LMO
3. 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
4. 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.***