BIOSAFETY ACT 2007

**BIOSAFETY REGULATIONS 2010**

**NBB/N/CU/22/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/22/FORM E *(at the end of the form)* *before filling out this form.***

**PROJECT TITLE:** Click here to enter text.

**NOTIFICATION CHECK LIST**

|  |  |
| --- | --- |
| 1. Form NBB/N/CU/22/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 activity involves modern biotechnology research and development).
 | [ ]  |
| 1. Any information to be treated as confidential business information (CBI) has been clearly marked “CBI” in the notification.
 | [ ]  |
| 1. One (1) original Form E and six (6) hardcopies of the completed Form E are submitted, including all supporting documents (Standard Operating Procedures, Inspection Reports, approval from other relevant authorities, training records etc.). The original Form E and hardcopies submitted must be identical.
 | [ ]  |
| 1. One (1) original and six (6) hardcopies of the IBC Assessment report (IBC/AP/20/ANNEX 2) are submitted.
 | [ ]  |
| 1. A soft copy of the Form E that is identical to the hardcopies is submitted. The softcopy should include Form E, IBC Assessment Report (IBC/AP/20/ANNEX 2) and all supporting documents (Standard Operating Procedures, Inspection Reports, approval from other relevant authorities, training records etc.).

(Information claimed to be **CBI must be excluded from the softcopy** submitted). | [ ]  |
| 1. All supporting documents/attachments required are submitted, including:
2. Most recent Inspection report(s) of the premises used (inspection done not more than two years ago from date of submission)
3. SOP for LMO transportation (if activity involves movement of LMO between premises stated in Table 3)

ii) SOP for LMO treatment and disposaliii) SOP for solid and liquid waste treatment and disposaliv) SOP for waste water treatment and disposalv) SOP for decontamination (All SOPs submitted must be **endorsed by the IBC** prior to **submission and dated not more than two years** from the date of submission). | [ ]  |
| 1. A copy of clearance documents (e.g. import permit, etc.) from the relevant Government agencies (if applicable).
 | [ ]  |
| 1. A letter of authorization from the IBC of the collaborating agency/institution/organization must be provided (If any premises outside the Applicant’s organization is used for LMO work).
 | [ ]  |
| 1. A copy of the completed notification retained for records
 |[ ]

## PRELIMINARY INFORMATION

|  |  |
| --- | --- |
| 1. Organization:
 | Click here to enter text. |
| 1. Name of Applicant (Principal Investigator):
 | Click here to enter text. |
| 1. Position in Organization:

Telephone (office):Telephone (mobile):Fax number:E-mail address:Postal address: | 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. |
| Project Title: | Click here to enter text. |
| IBC Project Identification No: | Click here to enter text. |
| Is this the first time the activity is being notified? |  |
| If this is not the first time the activity is notified, please answer the following: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?*(describe the differences or if this activity is using LMO produced through a previous notification)* | Click here to enter text.Click here to enter text.  |

**DETAILS OF IMPORTER**

***Importer refers to the Applicant as importer, or person or business importing/bringing the LMO on behalf of the Applicant. This section to be filled out only if the LMO is imported.***

|  |  |
| --- | --- |
| 1. Importing person/ company/ organization: | Click here to enter text. |
| 2. Contact Person: | Click here to enter text. |
| 1. Designation:

 Telephone (office): Telephone (mobile): Fax number: E-mail address: Postal address: | 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. |
| 1. Identification of LMO to be imported (include commercial name, if any)
 | Click here to enter text. |
| 1. Describe the form in which LMO will be imported (e.g. as seeds, cuttings, live fish, etc.)
 | Click here to enter text. |

**SUMMARY OF IBC ASSESSMENT (Refer to IBC/AP/20/ANNEX 2)**

***This section to be completed by the registered IBC of the Applicant’s organization. Please mark [X] in the appropriate box****.*

|  |  |  |
| --- | --- | --- |
| 1 | Name of Principal Investigator: | Click here to enter text. |
| 2 | Project Title: | Click here to enter text. |
| 3 | Date of the IBC Assessment: | Click here to enter text. |
| 4 | 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? |   |
| 5 | The following information related to this project has been checked and approved  |
| 1. The description of project activities
 |   |
| 1. The description and genetics of the LMO
 |   |
| 1. The emergency response plan and the specific measures to be taken in relation to a contained use activity involving LMO.
 |   |
| 1. All persons involved are appropriately trained:
 |   |
| 6 | Has the information provided in Form NBB/N/CU/22/FORM Ebeen checked by the IBC and found to be complete? |   |
| 7 | 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*

 A template of the IBC Assessment report (IBC/AP/20/ANNEX2) can be obtained at <https://www.biosafety.gov.my/wp-content/uploads/2021/08/IBC-ANNEX-2_revised-9.1.2020.pdf>) |   |

**SIGNATURES AND STATUTORY DECLARATION**

***Please mark [X] in the appropriate box***





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: Click here to enter text.

Name as in Identity Card/Passport: Click here to enter text.

Official Stamp:

**IBC Chairperson**:

*This section is applicable to organizations involved in modern biotechnology research and development.*

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: Click here to enter text.

Name as in Identity Card/Passport: Click here to enter text.

Official Stamp:

**Head of Organization/Authorized representative:**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: Click here to enter text.

Name as in Identity Card/Passport: Click here to enter text.

Official Stamp:

***PART A: DETAILS OF TEAM MEMBERS***

1. Project team members’ details.

*Note 1: Information required is for ALL persons involved in the project and IBC should have their records.*

*Note 2: All persons listed here should be assessed and approved by IBC.*

| **Name** | **Address, contact number & e-mail** | **Qualifications & Relevant Experience** | **Designation in Organisation** |
| --- | --- | --- | --- |
| 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**

***PART B: PROJECT DESCRIPTION***

Applicant is required to describe the proposed activities with the LMO within the context of the project.

1. General Objective:

Click here to enter text.

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

Click here to enter text.

1. Description of project activities

*Note 1: Please provide a brief description that clearly shows the involvement of handling LMO materials and a flow chart of the activities that accurately reflects the narrative provided.*

 *Note 2: In the flowchart, state all premises where each activity is conducted.*

 *Note 3: A separate attachment may be provided for the flowchart or incorporated into the text box below*:

Click here to enter text.

1. Biosafety Level (BSL) of the proposed activity:

*Note: 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

*Note 1: Please indicate the duration of this activity*

*Note 2: Please provide a Gantt chart that itemizes the sequence of the activity within the time period stipulated.*

*Note 3: Separate attachment may be provided for the Gantt chart or incorporated into the text box below:*

Click here to enter text.

1. Intended Date of Commencement:

*Note: Please provide an estimate of a feasible date that takes into account the documents processing time period of IBC (if relevant) and documents processing time period of the Department of Biosafety.*

Click here to enter text.

1. Expected Date of Completion:

*Note: Please ensure that the information provided here is consistent with what is provided in the Gantt Chart.*

Click here to enter text.

1. Date of importation or expected importation of LMO (if relevant)

***Note: Import of LMO is not allowed until Applicant receives the Letter of Acknowledgement from the Director General of the Department of Biosafety.***

Click here to enter text.

1. If the experiments are successful, are there plans for an application for field experiment / large scale production /commercialization?



***PART C: DESCRIPTION OF THE LMO***

1. Please refer to the Explanatory Notes of NBB/N/CU/22/FORM E (at the end of the form)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** **recipient organism**  | **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 and protein(s) expressed** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 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. |
| 4. | 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. |
| 5. | 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 D: THE PREMISES***

1. Please provide information for **all of the premises** being used for the contained use activities in the table below. This includes premises for production/ handling of LMO materials, treatment of LMO materials and storage of LMO materials.

*Note 1: For notifications with more than one premises, use additional columns provided.*

*Note 2: For a Research and Development collaboration involving more than one organization (premises is under the oversight of a different IBC), please provide proof of collaboration (such as letter of authorization) to use the premises.*

**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: *Note 1: Example of premises type includes. animal containment premises, laboratory, insect containment premises, greenhouse, etc.)**Note 2: 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. Purpose of using the premises *Note: Please indicate which step(s) of the activity the premises is used for, e.g. genetic manipulation or the organism, feeding study on mice, treatment of LMO materials, or for storage.* | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| 5. Who undertook the most recent inspection of the premises?*Note: Please indicate which IBC, if more than one IBC is involved in the premises used or if it the most recent inspection was done by the Department of Biosafety enforcement.* | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| 6. Date of the most recent inspection :*Note: Provide the most recent inspection report which is NOT MORE than two years from the commencement date of the activity and include a record of any corrective actions as recommended by the report.* | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| 7. Fill the following if premises is BSL 3 or BSL 4:a) Date of certification by competent authorityb) Certificate reference no:*Note: Provide the latest inspection report and a record of any corrective actions as recommended by the report.* | 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. |
| 8. Full address of premises:*Note: Includes floor level, if relevant, and name of building.* | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| 9. Name of contact person in charge of premises/*Note: This could be the Biosafety Officer or Laboratory Manager or any other person in charge of the premises*  | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| 10. Office/ Premises phone number:*Note: Please provide a number that the person in charge will be accessible to take the call.*  | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| 11. Mobile phone number: | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| 12. Fax number: | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| 13. E-mail address: | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

***PART E: RISK ASSESSMENT AND MANAGEMENT***

***E1 Risk Assessment (Basic information)***

1. You are required to fill in the matrix below. Consider what are the possible hazard(s), and the likelihood and consequences of the hazard(s) occurring (i.e. the risk) from the genetic modification(s) and proposed activity to the health and safety of human, plant and animals and the environment (including unintentional release).

*Please refer to Chapter 4 of Biosafety Guidelines: Contained use activity of Living Modified Organism (*[*https://www.biosafety.gov.my/wp-content/uploads/2021/08/Garis-Panduan-Aktiviti-Kegunaan-Terkawal-LMO.pdf*](https://www.biosafety.gov.my/wp-content/uploads/2021/08/Garis-Panduan-Aktiviti-Kegunaan-Terkawal-LMO.pdf)*).*

**RISK ASSESSMENT MATRIX**

| **Assessment category** | **Identification of Potential hazard** | **Comments on risk** | **Risk Management by Applicant** |
| --- | --- | --- | --- |
| **Potential risk from the science of genetic modification** *Points for consideration*1. *Hazards from gene(s), protein(s), change in virulence /pathogenicity of LMO*
2. *Risk from vector used (e.g. retroviral vector, etc)*
 | 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. |
| **Risk to human health (occupational exposure)** *Points for consideration*1. *Activities with LMO (e.g. large volume, handling sharps, competency of* *personnel, use of PPE, compliance to SOPs)*
2. *Equipment used (e.g. BSC)*
 | 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. |
| **Containment integrity (risk of unintentional release of the LMO to the environment)***Points for consideration*1. *Maintenance of the facility and equipment*
2. *Transfer of LMO between premises*
3. *Waste decontamination*
 | 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. |
| **Special risks unique to notification***Points for consideration*1. *Long term duration*
2. *Use of animals/ arthropods/ exotic species*
3. *Immunocompromised personnel*
4. *Techniques used (e.g. synthetic biology, genome editing)*
5. *Large scale volume of LMO*
 | 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. |
|

***E2 Risk Management***

*For questions 13-17, an activity specific SOP endorsed by the IBC must be provided. The date that the SOP has been developed/approved or reviewed/revised should not exceed more than two years from the date of submission to this form.*

1. Do you propose to transfer/transport the LMO between premises?

*Note 1: Please ensure all the premises used are included in Part D of this form and are stated in the activity flowchart provided.*

*Note 2:* *If yes, please give statement(s) and identify/ state the relevant SOP provided for this.*

Click here to enter text.

1. What is the treatment method and how will the LMO and related wastes be disposed of?

 *Note 1: If the activity involves LMO at various growth stages (seedlings, trees), the SOP should cover the disposal of LMO at each growth stage.*

*Note 2: Please give statement(s) and identify/ state the relevant SOP provided for this.*

*Note 3: Please refer to Chapter 12 and 13 of Biosafety Guidelines: Contained use activity of Living Modified Organism (*[*https://www.biosafety.gov.my/wp-content/uploads/2021/08/Garis-Panduan-Aktiviti-Kegunaan-Terkawal-LMO.pdf*](https://www.biosafety.gov.my/wp-content/uploads/2021/08/Garis-Panduan-Aktiviti-Kegunaan-Terkawal-LMO.pdf)*)*

 Click here to enter text.

1. How will the solid and liquid wastes from the activities be treated/decontaminated and disposed of?

 *Note 1: Examples of wastes include media, disposable gloves, planting materials, plant parts, etc.*

 *Note 2: Please give statement(s) and identify/ state the relevant SOP provided for this.*

 Click here to enter text.

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

*Note 1: Examples of wastewater include water used for cleaning equipment, watering the plants, keeping fish, etc.*

 *Note 2: Please give statement(s) and identify/ state the relevant SOP provided for this.*

 *.*

 Click here to enter text.

1. How will the equipment/tools/surfaces used during the activities be decontaminated?

*Note 1: Examples of equipment/tools/surfaces include sharps, pipette, decontaminated glassware, etc.*

 *Note 2: Please give statement(s) and identify/ state the relevant SOP provided for this.*

 Click here to enter text.

***E3 Emergency Response Plan***

*For questions 18-22, form* [*IBC/IR/10/ANNEX3 or IBCOD/10/ANNEX4*](https://www.biosafety.gov.my/perkhidmatan/tadbir-urus-ibc/senarai-borang-berkaitan-ibc/) *shall to be used to report all incidents or occupational exposure to LMO materials to IBC and Department of Biosafety in addition to any internal administrative procedures in place. This requirement must be included in the SOP provided.*

1. Provide plans for protecting human and animal health and the environment in case of the occurrence of an adverse effect observed during contained use activities.

*Note 1: Examples include medical management which includes first aid and hospitalization, line of communication both within and outside the organization.*

 *Note 2: Please give statement(s) and identify/ state the relevant SOP provided for this.*

Click here to enter text.

1. Provide plans for removal of the LMO in the affected areas in the case of an unintentional release
 *Note 1: Examples include to contain and treat spillage.
 Note 2: Please give statement(s) and identify/ state the relevant SOP provided for this.*

 Click here to enter text.

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

*Note: Please give statement(s) and identify/ state the relevant SOP provided for this.*

 Click here to enter text.

1. Provide plans for isolation of the area affected by the unintentional release

*Note 1: Examples include evacuation and quarantine.*

*Note 2: Please give statement(s) and identify/ state the relevant SOP provided for this.*

 Click here to enter text.

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.

 *Note: Please give statement(s) and identify/ state the relevant SOP provided for this.*

Click here to enter text.

***PART F: CONFIDENTIAL BUSINESS INFORMATION***

*Enter in this section any information required in Parts 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
3. that reasonable steps have been taken to keep the information secret.

Click here to enter text.

***PART G: REFERENCES***

*Please include references mentioned in the Project Description, supporting documents for any statements in the Risk Assessment matrix or any other relevant references associated with this activity.*

Click here to enter text.

**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/20/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 Biosafety Act 2007]. 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 and submit the result of the assessment via the [IBC Assessment Form (IBC/AP/20/ANNEX 2](https://www.biosafety.gov.my/wp-content/uploads/2021/08/IBC-ANNEX-2_revised-9.1.2020.pdf)). 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. If there are other related documents (example If a comprehensive description of the activity is provided in the Research Project proposal, please provide a summary in in Form E but you may provide a reference to the proposal document for more details). 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. The six copies submitted should be identical to the original form. Please ensure that the information provided can be clearly read/seen. 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 by the Applicant. However, **all information that has been declared as Confidential Business Information (CBI) should be omitted from the softcopy**. You may collate documents related to one notification into one document/ softcopy (do not combine with any other notification that you may submit concurrently).

**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. Therefore 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, details of importer, date of intended importation and approval from relevant authorities like Department of Agriculture (DOA), Ministry of Health, Malaysia, etc. should be provided.

If the activity involves work with animals (example of feeding studies involving LMO products), please provide the status of approval from the Institutional Animal Care and Use.

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 – Table 2 (Part C)**

1. ‘Recipient organism’ refers to the final recipient of the intended genetic modification.
2. ‘Donor organism’ refers to the source of the genetic sequences used for modification. If more than one gene is used and the source is different for each gene, ensure that the donor organism for each gene used is stated.
3. ‘Vector’ should include all vectors and method (s) used.
4. ‘Modified trait’ can be stated as “unknown” if for example building a genomic library.
5. 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.

**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 (please specify) |
| 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 Confidential Business Information (CBI), as described in section 59(3) of the Biosafety Act 2007 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 jbksnp@biosafety.gov.my

**The completed form, cover letter and relevant documents shall be submitted to:**

The Director General

Department of Biosafety

Ministry of Environment and Water

Level 4, Block F11, Complex F

Lebuh Perdana Timur, Precinct 1

Federal Government Administrative Centre

62000 Putrajaya, Malaysia

**Acknowledgement of Receipt**

Upon receipt of the notification, the Director General of the Department of Biosafety shall send to the applicant a Letter of Acknowledgement of receipt with an assigned reference number. The reference number should be used in all correspondence with respect to the notification. The activity (contained use activity and import of any LMO) can start only after the Letter of Acknowledgement is issued. The Principal Investigator is still required to be complaint to any decisions made by the NBB (as described in section 30(3) of the Biosafety Act 2007 and is required to comply with other written laws governing LMO.

**Exemption**

[The First Schedule of the Biosafety (Approval and Notification) Regulations 2010](https://www.biosafety.gov.my/wp-content/uploads/2021/09/exemption-first-schedule-english.pdf) 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 shall review all submitted research projects to determine their exemption or non-exemption status. The IBC will provide oversight of the exempted activities and report to the Department of Biosafety through the IBC Annual Report.

***Please retain a copy of your completed notification.***