

**BIOSAFETY ACT 2007****BIOSAFETY REGULATIONS 2010****NBB/A/ER/10/FORM C****APPROVAL FOR RELEASE ACTIVITIES (SECOND SCHEDULE 2-6) OR IMPORTATION OF LIVING MODIFIED ORGANISM (LMO) THAT IS A HIGHER PLANT AND PRODUCT OF SUCH ORGANISM**

NBB/A/ER/10 FORM C shall be submitted as an application for certificate of approval for release activities (SECOND SCHEDULE 2-6) or importation for release of living modified organism (LMO) that is a higher plant and product of such organism(not for contained use activities) . Application must be accompanied by the prescribed fees as found in Third Schedule of the Biosafety (Approval and Notification) Regulations 2010. 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.

If the application is for release activities of an LMO or importation for release of an LMO that is a higher plant, please fill up Part A – D.

If the application is for release activities of a product of such organism or importation for release of a product of such organism, please fill up Part E.

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 issuance of the certificate of approval by the National Biosafety Board (NBB).

The applicant shall submit 1 original and 6 copies of the application to the Director General. A soft copy of the submitted application (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.

**Accuracy of information**

The application 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 application without prejudice to the submission of a fresh

application. 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.

### **Confidentiality**

Any information within this application 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 application 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 application is being completed on behalf of the proposed user, that the person completing this application holds proper authority to submit this application for the proposed user. Please provide written proof of authorization.

### **For further information**

Please contact the Director General by:

Telephone: 603-8886 1579

E-mail: biosafety@nre.gov.my

### **The completed form 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.

***Please retain a copy of your completed form***

NBB REF.NO : (For office use)
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**APPLICATION CHECK LIST**

1. Form NBB/A/ER/10/FORM C is completed with relevant signatures obtained	<input type="checkbox"/>
2. A copy of the clearance documents from the Department of Agriculture included. (If required)	<input type="checkbox"/>
3. Any information to be treated as confidential business information should be clearly marked "CBI" in the application	<input type="checkbox"/>
4. 1 original and 6 copies of the completed applications submitted. A soft copy of the submitted application (including all supporting documents/attachments, if any) that do not contain any CBI.	<input type="checkbox"/>
5. Fees as prescribed in the regulation: RM _____ Money order/ Bank draft No: _____ Made payable to the Secretary General of the Ministry of Natural Resources and environment.	<input type="checkbox"/>

NBB REF.NO : (For office use)
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**Preliminary information**

1. Organization:	
2. Name of Applicant:	
3. Position in Organization Telephone (office) Telephone (mobile) Fax number Email Postal Address	
4. Product Name (commercial and other names)/Unique Identification Code:	
5. Type of release activity	<input type="checkbox"/> Supply or offer to supply for sale/ placing on the market <input type="checkbox"/> Offer as gift, prize or free item <input type="checkbox"/> Disposal <input type="checkbox"/> Remediation purposes <input type="checkbox"/> Commercial planting <input type="checkbox"/> Any other activity which does not amount to contained use (please specify)
6. Is this the first time an approval is being applied for this activity?	Yes <input type="checkbox"/> No <input type="checkbox"/> if no, please provide information in no 7 below
7. I) Please provide the NBB reference no. for your previous notification /application. II) How is this application different from the previous application submitted for this activity? (please provide an attachment if additional space is required)	

NBB REF.NO : (For office use)
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**Details of Agent / Importer**

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

**Signatures and Statutory Declaration**

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

**Applicant:**

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

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

Official Stamp:

**Head of organization/Authorized representative:**

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

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

Official Stamp:

**PART A - Living Modified Organism (LMO) that is a Higher Plant****Risk Assessment****A1 General Information**

1. Details of the LMO to be released:
  - a) Genus and species
  - b) Common name
  - c) Modified trait (s)
  
2. Objective(s) of the release.
  
3. Release site(s):

(If more than one site is involved, then the information required in numbers 3, 4, 5, 6, 7 & 8 should be repeated for each release site)

  - a) District(s),
  - b) State(s) in which the release(s) will take place.
  
4. Scale of release per release site.

*(Number of LMO involved, size of plot/ site etc)*
  
5. Date when the release(s) is expected to commence.

(Frequency of releases)
  
6. For an imported LMO – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA), Ministry of Health, Malaysia.
  
7. Description of the proposed activities with the LMO.
  
8. Name of person(s) authorized to undertake activities with the LMO.

**A2 Risk Assessment Information - Parent Organism**

**(If more than one parent organism of the same species is involved then the information required in this part should be repeated for each parent organism)**

## 9. Details of the parent organism:

If the LMO is the result of a crossing event between more than one species/cultivar/ breeding line/variety, please include relevant information (for example, LMO crossed with non-LMO or 2 LMOs crossed)

- a) Family name
- b) Genus
- c) Species
- d) Subspecies
- e) Cultivar/Breeding line/Variety
- f) Common name

## 10. A statement about whether the parent organism has an extended history of safe use in agriculture or in other industries.

## 11. Information concerning the reproduction of the parent organism:

- a) The mode or modes of reproduction
- b) Any specific factors affecting reproduction
- c) Generation time

## 12. Information regarding the sexual compatibility of the parent organism with other cultivated or wild plant species.

## 13. Information concerning the survivability of the parent organism:

- a) Ability to form structures for survival or dormancy including seeds, spores and sclerotia,
- b) Any specific factors affecting survivability (e.g. seasonability).

## 14. Information concerning the dissemination of the parent organism:

- a) The means and extent of dissemination
- b) Any specific factors affecting dissemination.

## 15. Details of the natural habitat of the parent organism and its range.

## 16. Is the parent organism exotic in Malaysia?

Yes     No

## 17. Is the parent organism naturalized in Malaysia?

Yes     No

18. Is the parent organism, or a closely related organism, present at, or near, the site of the proposed release?

(If more than one location is involved, then the information required in numbers 18 & 19 should be repeated for each location(s) of release)

Yes     No

19. If yes, please provide details of the population or populations and the estimated distances between them from the proposed release(s).

20. The potentially significant interactions of the parent organism with organism other than plant in ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.

21. An assessment of whether the parent organism is capable of causing disease or other ill-health in human, plants or animals and, if so, the details of the possible effects.

22. Details of any known predators, parasites, pests or diseases of the parent organism in Malaysia.

23. Details of pathogenicity, including infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms and possible activation of latent viruses (proviruses) and ability to colonize other organisms.

24. Is the parent organism resistant to any known antibiotic and if yes, what is the potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy?

25. Is the parent organism involved in environmental processes including primary production, nutrient turnover, decomposition of organic matter and respiration?

### **A3 Risk Assessment Information - LMO**

26. Details of the modified trait(s) and how the genetic modification will change the phenotype of the LMO to be released.

27. What are the gene(s) responsible for the modified trait(s)?

28. Give details of the organism(s) from which the gene(s) of interest is derived :

(If more than one gene is involved then the information required in numbers 28, 29, 30, 31, 32 & 33 should be repeated for each gene)

- a) Family name
- b) Genus
- c) Species
- d) Subspecies
- e) Cultivar/Breeding line/Variety
- f) Common name

29. Indicate whether it is a:

- a) viroid
- b) RNA virus
- c) DNA virus
- d) bacterium
- e) fungus
- f) animal
- g) plant
- h) other (please specify)

30. Does the gene(s) of interest come from an organism that causes disease or other ill-health in humans, plants or animals? Provide details of the possible effects.

31. Please provide the following information about the gene(s) of interest:

- a) Size of sequence of the gene(s) of interest inserted
- b) Sequence of the gene(s) of interest inserted
- c) Intended function of the gene(s) of interest
- d) Number of copies of the gene(s) of interest in the construct
- e) Details of the steps involved in the construction
- f) Provide the map(s) of construct(s) indicating the gene(s) of interests and all other regulatory elements that will finally be inserted in the LMO

32. Please provide the following information about the deleted sequence(s):

- a) Size of the deleted sequence(s)
  - b) Function of the deleted sequence(s)
  - c) Details of the steps involved in the deletion of sequences from the parental organism
  - d) Provide the map(s) of construct
33. The following information is on the expression of the gene(s) of interest:
- a) Level of expression of the gene(s) of interest and methods used for its characterization,
  - b) The parts of the LMO where the gene(s) of interest is expressed, such as roots, stem or pollen
  - c) Indicate the part(s) of the vector(s) that remains in the LMO
  - d) The genetic stability of the gene(s) of interest.
34. A description of the methods used for the genetic modification:
- a) How gene(s) of interest was introduced into the parent organism, or
  - b) How a sequence of a gene was deleted from the parent organism
35. If no vector was used for the genetic modification, please provide the detail of how the gene(s) of interest is introduced.
36. If vector(s) was used, please provide the following information:  
(If more than one vector was used, then the information required in 36 should be repeated for each vector)
- a) Type of vector:
    - i. plasmid
    - ii. bacteriophage
    - iii. virus
    - iv. cosmid
    - v. phasmid
    - vi. transposable element
    - vii. other, please specify
  - b) Identity of the vector (s)
  - c) Information on the degree of which the vector (s) contains sequences whose product or function is not known
  - d) Host range of the vector(s)
  - e) Potential pathogenicity of the vector(s)

- f) The sequence of transposons, and other non-coding genetic segments used to construct the LMO and to make the introduced vector(s) and insert(s) function in those organisms
37. Details of the markers or sequences that will enable the LMO to be identified in the laboratory and under field conditions. Provide appropriate evidence for the identification and detection techniques including primer sequences for the detection of the inserted genes including marker genes.
38. Information (biological features) on how the LMO differs from the parent organism in the following respects:
- g) Mode(s) and/or the rate of reproduction
- a) Dissemination
39. If there is any possibility that the inserted genes in the LMO could be integrated into other species at the release site(s) and the surrounding environment, and if so, please provide the following details:
- a) The organism(s) to which the modified trait(s) can be transferred to and the frequency at which it can be transferred
- b) The transfer mechanism involved and the techniques that have been used to demonstrate transfer
- c) Any possible adverse effects of the transfer including
- i. Any advantages the affected organism(s) are likely to have over the number of the species that do not contain the inserted gene(s)
- ii. Environmental risks posed by such an advantage
40. The identification and description of the target organism(s), if any.
41. The anticipated mechanism and result of interaction between the released LMO and the target organism(s).
42. The known or predicted interaction on non-target organisms in the release site(s) and the impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens.
43. A statement on whether the modified trait(s) of the LMO will change the capacity of the plant to add substances to, or subtract substances from, soil (for example, nitrogen or toxic compounds) and, if so, details of all such changes.

44. Details of any other possible adverse consequences.
45. Details of whether the modified trait(s) will confer a selective advantage on the LMO compare to the parent organism and if so, the conditions including data on the growth rate with and without the selection pressure and the nature of the advantages including a statement on how stable those features are.
46. Details of the genetic changes, if any, which will be included in the LMO to limit or eliminate any capacity to reproduce or transfer genes to other organism.
47. In relation to human health:
- a) The toxic or allergenic effects of the non-viable organisms and/or their metabolic products
  - b) The comparison of the organisms to the donor, or (where appropriate) parent organism regarding pathogenicity
  - c) The capacity of the organisms for colonization
  - d) If the organisms are pathogenic to immunocompetent persons:
    - i. diseases caused and mechanisms of pathogenicity including invasiveness and virulence
    - ii. communicability
    - iii. infective dose
    - iv. host range and possibility of alteration
    - v. possibility of survival outside of human host
    - vi. presence of vectors or means of dissemination
    - vii. biological stability
    - viii. antibiotic-resistance patterns
    - ix. allergenicity, and
    - x. availability of appropriate therapies
48. Details of unintended pleiotropic effects (if any), including undesirable effects on agronomic characteristics of the plant which may result from the expression of the gene of interest(s) in the LMO (for example, reduced fertility, increased prevalence, production losses, grain shedding), including an indication of the likelihood of these events.
49. The description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

50. Details of how the genetic modification will change the phenotype of the LMO to be released, including information to demonstrate the effect of the genetic modification.
51. Details of the mechanism of pollen spread (by insect vectors or by other means) in the plant population:
- a) Details of pollen viability for the parent organism and of the LMO
  - b) Details of any potential pollinators and their range and distribution in Malaysia
  - c) Quantitative data on successful cross-pollination between the parent organism, the LMO and its wild relatives, if available

**A4 Information about weeds**

52. Details of the members of the family of parent organism that are known to be weeds in any environment.
53. Details of cross-pollination between the species to which the LMO belongs and wild relatives known to be weeds, including a copy of any literature reports that support the information.

**A5 Information about the seeds of the LMO**

56. A statement on whether the LMO proposed to be released will be allowed to set seed and, if not, whether setting seed is planned for a later release.
57. If the LMO is to be allowed to set seed, will the mature seed normally remain contained within an ear, capsule or pod, so that practically all of the seed can be readily harvested, or is the seed shed soon after it matures?  
If the latter, provide an indication of the proportion of seed likely to remain in the environment following harvest.
58. Details of the length of time that the seeds are capable of being dormant and whether it differs from the parent organism.

**A6 Characteristics affecting survival of LMO**

59. The predicted habitat of the LMO.

- 60 The biological features which affect survival, multiplication and dispersal.
- 61 The known or predicted environmental conditions which may affect survival, multiplication and dispersal, including wind, water, soil, temperature, pH.
- 62 The sensitivity to specific agents (e.g. disinfectant, pesticides, fertilizers, wind, water).

**A7 Information about any secondary ecological effects that might result from the release**

63. An assessment of possible effects of the proposed release on:
- a) Native species
  - b) Resistance of insect populations to an insecticide
  - c) Abundance of parasites

**A8 Information about resistance of the LMO to a chemical agent (other than selective agents, such as antibiotics, used in strain construction)**

64. Details of any environmental risks related specifically to the resistance of the LMO to a chemical agent (for example, a herbicide, but not a selective agent, such as an antibiotic, used in strain construction), where the resistance is a result of the genetic modification.

**A9 Information about resistance of the LMO to a biological agent**

65. Details of any environmental risks related specifically to the resistance of the LMO to a biological agent (for example, an insect or a fungal disease), where the resistance is a result of the genetic modification.

**A10 Information relating to the release site(s)**

(If more than one release site is involved, then the information required in this part should be repeated for each release site)

66. The size of the proposed release site(s).
67. The location of the proposed release site(s). Provide site map(s) with national grid reference(s).
68. Details of the reasons for the choice of the release site(s).

69. Details of the arrangements for conducting any other activities in association with the proposed release(s), such as importation of the LMO and transportation of the LMO, to or from the release site(s).
70. The preparation of the release site(s) before the release(s).
71. The methods to be used for the release(s).
72. The quantity of LMO to be released.
73. The physical or biological proximity of the release site(s) to humans and other significant biota or protected areas.
74. The size of local human population.
75. The local economic activities which are based on the natural resources of the area.
76. The distance to the nearest drinking water supply zone areas and/or areas protected for environmental purposes.
77. The flora and fauna, including crops, livestock and migratory species in the release site(s).
78. The comparison of the natural habitat of the parent organism with the proposed release site(s).
79. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

## **Part B Risk Management**

### **B1 Information on control, monitoring, post-release plans**

80. A description of measures (if any) to minimize the effects of any transfer of the modified trait(s) to other organisms.
81. Details of the proposed release site(s) supervision procedures and if necessary any relevant safety procedures designed to protect staff, including a description of procedures for onsite supervision of the release if the release site(s) is located at some distance from the location of the applicant.

82. Details of proposed measures (if any) for monitoring any risks posed by the LMO, including monitoring for:
- a) The survival or presence of the LMO, or transferred genetic material, beyond the proposed release site(s), including specificity, sensitivity and reliability of detection methods
  - b) Impacts on the characteristics, or abundance, of other species
  - c) Transfer of the gene(s) of interest to other species.
  - d) Any other hazards or deleterious effect
83. Details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the NBB.
84. Details of ongoing monitoring to be undertaken after the release(s) are completed.
85. Details of proposed measures to minimize the possible adverse consequences. If no measures have been taken, please give reasons.
86. The methods for elimination or inactivation of the organisms at the end of the release and measures proposed for restricting the persistence of the LMO or its genetic material in the release site(s).

## **B2 Waste treatment plans**

87. Type of waste generated.
88. Expected amount of waste.
89. Possible risks resulting from the waste.
90. Description of waste treatment envisaged and its disposal.

## **Part C Emergency Response Plan**

91. Methods and procedures for controlling the LMO in case of any unintentional release and adverse effects being realized.
92. Methods for isolation of affected area.

93. Methods for disposal of other plants, animals and any other thing exposed to the adverse effects during the unintentional release.

#### **Part D Data or results from any previous release(s) of the LMO**

94. Give the following information from the previous applications (successful or unsuccessful) and releases of the LMO for which the applicant is seeking an approval:
- a. Reference number of each application
  - b. Date of the certificate of approval issued
  - c. Terms and conditions (if any) attached to the approval
  - d. Data and results of post-release monitoring methods and effectiveness of any risk management procedures, terms and conditions and other relevant details
  - e. Relevant data if the previous release is on a different scale or into a different ecosystem
  - f. Any other relevant details
95. Details of results of any applications made for approval of the LMO in other countries, including information about conditions (if any) attached to the approval.
96. Details of any previous notifications for contained use activities according to the Biosafety Act 2007 from which the work in this present application has been developed.
97. Give details of data or results from any previous release of the LMO(s) for which the applicant is seeking an approval, especially the results of monitoring and the effectiveness of any risk management procedures, terms and conditions and any other relevant details.

#### **PART E - Product of Such Organism**

##### **E1 General Information**

98. The name and address of the manufacturer or distributor of the product.
99. General description of the product:
- a) Type of product
  - b) Composition of the product
  - c) Physical state of the product

100. For an imported product – the date of importation or intended importation, including, if possible, a copy of documentation of clearance or assessment from the relevant authorities like Department of Agriculture (DOA), Ministry Of Health, Malaysia.
101. The type of environment and/or the geographical areas within Malaysia for which the product is suited.
102. The type of expected use of the product and the description of the persons who are expected to use the product.

**E2 Information regarding proposed labeling of the product (according to Malaysian regulations on the labeling of genetically modified food)**

103. Is the product being simultaneously notified to another country?  
 Yes  No  
If yes, please specify.
104. Is the same product marketed in a country outside Malaysia?  
 Yes  No  
If yes, please supply the following information:  
a) Name of country  
b) Authority which granted consent (if applicable)  
c) Conditions under which consent was given (if applicable)
105. Has the product ever been withdrawn from the market of a country?  
 Yes  No  
If yes, please supply the following information:  
a) Name of country or countries  
b) Reasons for withdrawing the product, if known
106. Has the product been rejected by authorities of a country?  
 Yes  No  
If yes, please supply the following information:  
a) Name of country or countries  
b) Authority which rejected the product  
c) Reasons for rejecting the product, if known

107. Description of identification and detection techniques for the LMO(s) in the product.

**E3 Description of the LMO from which the product was derived from**

(If the product is derived from more than one LMO, then the information required in numbers 110, 111, 112, 113 & 114 should be repeated for each LMO)

108. Description of the LMO:

- a) Genus and species
- b) Common name
- c) Modified trait(s)
- d) Gene(s) responsible for the modified trait(s)

109. Details of the parent organism:

- a) Genus and species
- b) Common name

110. A statement about whether the parent organism has an extended history of safe use in agriculture and other industries.

111. Give the name of the organism from which the gene(s) of interest is derived from:

- a) Genus and species
- b) Common name

112. Indicate whether the organism from which the gene(s) of interest is derived from is a:

- a) virus
- b) bacterium
- c) fungus
- d) animal
- e) plant
- f) other (please specify)

**E4 Risk Management of the Product**

113. Specific instructions or recommendations for storage and handling of the product.

114. Measures for waste disposal and treatment of the product.

**E5 Emergency Response Plan**

115. Details of proposed measures to be taken in the event of adverse consequences/ misuse of the product.