NBB REF.NO :
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BIOSAFETY ACT 2007

BIOSAFETY REGULATIONS 2010

NBB/A/ER/10/FORM D

APPROVAL FOR RELEASE ACTIVITIES (SECOND SCHEDULE 2-6) OF LIVING MODIFIED ORGANISM (LMO) OTHER THAN A HIGHER PLANT AND PRODUCT OF SUCH ORGANISM

NBB/A/ER/FORM D shall be submitted as an application for certificate of approval of release activities (SECOND SCHEDULE 2-6) or importation of LMO and product of such organism and 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 other than 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 should be omitted from the CD.

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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 Confidential Business Information (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 living modified organism
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.

For further information

Please contact the Director General by:
Telephone: 603-8886 1579
E-mail: biosafety@nre.gov.my

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The completed 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

APPLICATION CHECK LIST

1. Form NBB/A/ER/10/FORM D is completed with relevant signatures obtained	☐
2. A copy of the clearance document from the Department of Agriculture included (If required)	☐
3. Any information to be treated as confidential business information should be clearly marked “CBI” in the application	☐
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.	☐
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	☐

Preliminary information

1. Organization:	
2. Name of Applicant:	
3. Position in Organization Telephone (office) Telephone (mobile) Fax number Email Postal Address	

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4. Product Name (commercial and other names) Unique Identification Code/:	
5. Type of release activity	☐ Supply or offer to supply for sale/ placing on the market ☐ Offer as gift, prize or free item ☐ Disposal ☐ Remediation purposes ☐ Commercial planting ☐ 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 ☐ No ☐ if no, please provide information in no 7 below
7. I) Please provide the NBB reference no. for your previous notification/application if any II) How is this application different from the previous application submitted for this activity? (please provide an attachment if additional space is required)	

Details of Agent / Importer

8. Organization name:	
9. Contact Person:	
10. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	

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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:

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PART A 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 location is involved, then the information in numbers 3, 4, 5, 6, 7 & 8 should be repeated for each location(s) of release)
   a) District(s)
   b) State(s) in which the release(s) will take place

4. Scale of release per release site.
   (No 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/ product of such organism.

8. Name of person(s) authorized to undertake activities.

A2 Risk Assessment Information – The 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)

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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) Breeding line/ Strains
f) Common name

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

11. Information concerning the reproduction of the 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 organism with other common/ domesticated or wild types.

13. Information concerning the survivability of the organism:

a) Ability to form structures, including spores, sclerotia for survival or dormancy
b) Any specific factors affecting survivability like seasonability

14. Information concerning the dissemination of the 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

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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(s) 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 modifications 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 organism is involved then the information required in numbers 28, 29 & 30, should be repeated for each organism)

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a) Family name
b) Genus
c) Species
d) Subspecies
e) Breeding line/ Strain
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(s)

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 organism where the gene(s) of interest is expressed

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c) 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 vector(s) was used, please provide the following information:
(If more than one vector was used, then the information required in 35 should be repeated for each vector)

a) Type of vector

ii. plasmid
iii. bacteriophage
iv. virus
v. cosmid
vi. phasmid
vii. transposable element
viii. 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 pathogenecity 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

36. If no vector was used for the genetic modification please provide the detail of how the gene(s) of interest is introduced.

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 gene(s) including marker gene(s).

38. Information on how the LMO(s) differs from the parent organism in the following respects:

a) Mode(s) and/or the rate of reproduction

b) Dissemination

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39. If there is any possibility that the inserted gene(s) in the LMO(s) 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 if so, 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. The location of the gene(s) of interest in the cells (whether it is integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form) and the methods for its determination.

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48. Details of the genetic changes, if any, which will be included in the LMO(s) to limit or eliminate any capacity to reproduce or transfer genes to other organisms.

49. 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

50. Details of unintended pleiotropic effects (if any), including undesirable effects on characteristics of the organism which may result from the expression of the gene(s) of interest in the LMO(s) (for example, reduced fertility, increased prevalence, production losses), including an indication of the likelihood of these events.

51. The description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.

A4 Characteristics affecting survival of LMO(s)

52. The predicted habitat of the LMO(s).

53. The biological features which affect survival, multiplication and dispersal.

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54. The known or predicted environmental conditions which may affect survival, multiplication and dispersal, including wind, water, soil, temperature, pH.

55. The sensitivity to specific agents (e.g. Disinfectant, pesticides, fertilizers, wind, water).

56. Survivability

a) Ability to form structures enhancing survival or dormancy

i. endospores
ii. cysts
iii. sclerotia
iv. asexual spores (fungi)
v. sexual spores (fungi)
vi. eggs
vii. pupae
viii. larvae
ix. other, please specify

A5 Information about any secondary ecological effects that might result from the release

57. An assessment of possible effects of the proposed release on:

a) Native species
b) Resistance of insect populations to an insecticide
c) Abundance of prey or parasites

A6 Information about resistance of the LMO(s) to a chemical agent (other than selective agents, such as antibiotics, used in strain construction)

58. Details of any environmental risks related specifically to the resistance of the LMO(s) 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 modification.

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A7 Information about resistance of the LMO(s) to a biological agent

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

A8 Information relating to the site of release

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

60. The size of the release site(s).

61. The location of the proposed release site(s). Provide site map(s) with national grid reference.

62. Details of the reasons for the choice of release site(s).

63. Details of the arrangements for conducting any other activities in association with the proposed release(s), such as importation of a LMO(s) and transportation of a LMO(s), to or from the release site(s).

64. The preparation of the release site(s) before the release(s).

65. The methods to be used for the release(s).

66. The quantity of LMO to be released.

67. The physical or biological proximity of the release site(s) to humans and other significant biota or protected areas.

68. The size of the local human population.

69 The local economic activities which are based on the natural resources of the area.

70. The distance to the nearest drinking water supply zone areas and/or area protected for environmental purposes.

71. The flora and fauna including crops, livestock and migratory species in the release site(s).

72. The comparison of the natural habitat of the parent organism with the proposed release site(s).

73. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

74. Details of features of the physical environment of the release site(s) particularly features that may minimize or exacerbate any undesirable effects of the LMO.

Part B Risk Management

B1 Information on control, monitoring, post-release plans and waste treatment plans

75. A description of measures (if any) to minimize the effects of any transfer of the modified genetic trait(s) to other organisms.

76. Details of 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.

77. A description of post-release treatment methods for the LMO(s), e.g. the techniques for elimination or inactivation of the organisms at the end of the experiment.

78. Details of proposed measures (if any) for monitoring any risks posed by the LMO(s), including monitoring for:

a) The survival or presence of the LMO(s), or transferred genetic material, beyond the proposed release site or sites, 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

79. Details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the NBB.

80. Details of ongoing monitoring to be undertaken after the release is completed.

81. Details of proposed measures to minimize the possible adverse consequences. If no measures have been taken, please give reasons.

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82. The methods for elimination or inactivation of the organisms at the end of the experiment and measures proposed for restricting the persistence of the LMO or its genetic material in the release site(s).

B2 Waste treatment

83. Type of waste generated.

84. Expected amount of waste.

85. Possible risks resulting from the waste.

86. Description of waste treatment envisaged and its disposal.

Part C Emergency Response Plan

87. Methods and procedures for controlling the LMO(s) in case of any adverse effects being realized.

88. Methods for isolation of the affected area.

89. Methods for disposal of other plants, animals and any other thing exposed to the adverse effects.

90. Details of any other contingency measures that will be in place to rectify any unintended consequences if an adverse effect becomes evident during the course of the release.

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

91. Give the following details/data/results from the previous application of 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

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92. Details of results of any applications made for approval of the LMO(s), or any derived GM products in other countries, including information about conditions (if any) attaching to the approval.

93. Details of any previous notifications contained use activities according to the Biosafety Act 2007 from which the work in the present application has been developed.

94. If the LMO has been previously released in overseas, details of any adverse consequences of the release, including identifying references and reports of assessments if any.

PART E Product of Such Organism

E1 General Information

95. The name and address of the manufacturer or distributor of the product.

96. General description of the product:
    a) Type of product
    b) Composition of the product
    c) Physical state of the product

97. 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.

98. The type of environment and/or the geographical areas within Malaysia for which the product is suited.

99. The type of expected use of the product and the description of the persons who are expected to use the product.

100. Information regarding proposed labeling of the product (if product is genetically modified food, then according to Malaysian regulations on the labeling)

101. Is the product being simultaneously notified to another country?
    ☐ Yes ☐ No
    If yes, please specify.

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102. 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)

103. 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

104. 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

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

E2 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 106,107, 108,109 &110 should be repeated for each LMO)

106. Description of the LMO:

a) Genus and species of the LMO

b) Common name

c) Modified trait(s)

d) Gene(s) responsible for the modified trait(s)

107. Details of the parent organism:

a) Genus and species

b) Common name

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

109. Give the name of the organism from which the gene(s) of interest is derived from:
   a) Genus and species
   b) Common name

110. Indicate whether the organism from which the gene of interest is derived from is a:
   a) virus
   b) bacterium
   c) fungus
   d) animal
   e) plant
   f) other (please specify)

E3 Description of the LMO contained in the product

(If more than one LMO contained in the product, then the information required in numbers 111, 112, 113, 114, 115 & 116 should be repeated for each LMO).

111. Description of the LMO:
   a) The genus and species of the LMO
   e) Modified trait(s)
   f) Gene(s) responsible for the modified trait(s)

112. Details of the parent organism:
   a) Genus and species
   b) Common name

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

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

   a) Genus and species
   b) Common name
   c) Indicate whether the organism from which the gene of interest is derived from is a:
   d)
      i. bacterium
      ii. Virus

iii. fungus
iv. animal
v. plant
vi. other (please specify)

115. Information concerning reproduction of LMO in the product.

116. Information on survival and factors affecting the LMO.

E4 Risk Management for the product

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

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

E5 Emergency Response Plan

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