

BIOSAFETY ACT 2007**BIOSAFETY REGULATIONS 2010****NBB/A/ER/10/FORM B****APPROVAL FOR RELEASE ACTIVITIES OF LIVING MODIFIED ORGANISM (LMO)
(SCRESEARCH AND DEVELOPMENT PURPOSES IN ALL FIELD EXPERIMENTS) OR
IMPORTATION OF LMO OTHER THAN HIGHER PLANTS**

NBB/A/ER/10/FORM B shall be submitted to the Director General as an application for certificate of approval of release of LMO [Research and development purposes in all field experiments - Second Schedule of the Act - 1] or importation of living modified organism (LMO) other than a higher plant (not for contained use activities). Any organization undertaking modern biotechnology research and development shall submit the form through its registered Institutional Biosafety Committee (IBC). The IBC should assess the information in the form prior to submission. 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.

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 forms 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)

APPLICATION CHECK LIST

1. Form NBB/A/ER/10/FORM B is completed with relevant signatures obtained	<input type="checkbox"/>
2. Application assessed and to be sent through the IBC	<input type="checkbox"/>
3. A copy of clearance documents from the relevant Government agencies included (if required)	<input type="checkbox"/>
4. A copy of the clearance document from the state office where the release is to take place	<input type="checkbox"/>
5. Any information to be treated as confidential business information should be clearly marked "CBI" in the application	<input type="checkbox"/>
6. 1 original copy and 6 copies of the completed application submitted. A soft copy of the submitted application (including all supporting documents/attachments, if any) that do not contain any CBI.	<input type="checkbox"/>
7. 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"/>

Preliminary information

1. Organization:	
2. Name of Applicant:	
3. Position in Organization: Telephone (office): Telephone (mobile): Fax number: Email: Postal Address:	
4. Project Title/Unique Identification Code:	
5. IBC Project Identification No:	
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 notification/application submitted for this activity? (please provide an attachment if additional space is required)	

NBB REF.NO : (For Office Use)

Details of Agent / Importer

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

Institutional Biosafety Committee (IBC) Assessment Report for release of LMO (Research and development purposes in all field experiments) or importation of LMO other than a higher plant (not for contained use activities).

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

Section A – IBC Details

1	Name of organization:			
2	Name of IBC Chairperson:			
	Telephone number:		Fax:	
	Email address:			

Section B – IBC Assessment

3	Name of principal investigator:	
4	Project Title:	
5	Date of the IBC Assessment:	
6	Does the IBC consider that the principal investigator and every other person(s) authorized to be involved in the field experiment with the LMO have adequate training and experience for the task?	<input type="checkbox"/> Yes <input type="checkbox"/> No
7	The following information related to this project has been checked and approved	
	a) The objective of the project	<input type="checkbox"/> Yes <input type="checkbox"/> No
	b) The description and genetics of the LMO	<input type="checkbox"/> Yes <input type="checkbox"/> No
	c) The risk assessment and risk management, taking into account the risks to the health and safety of people and the environment from the release of the LMO.	<input type="checkbox"/> Yes <input type="checkbox"/> No
	d) The emergency response plan	<input type="checkbox"/> Yes <input type="checkbox"/> No
8	Has the information been checked by the IBC and found to be complete?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9	Has the IBC assessed the proposed project? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please append a copy of the IBC's assessment report and indicate the attachment in which details are provided.	

Signatures and Statutory Declaration

The proposed release of LMO (Research and development purposes in all field experiments) or importation of LMO that is a higher plant (not for contained use activities) has been assessed as above and endorsed by the IBC. 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:

IBC Chairperson:

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 Risk Assessment**A1 General Information**

1. Project Title:
2. Rationale of Project:
3. Project objectives:
 - a) Overall Objective
 - b) Specific Objective
4. Details of the LMO to be released:
 - a) Genus and species
 - b) Common name
 - c) Modified trait(s)
5. Release site(s):

(If more than one site is involved, then the information required in numbers 5, 6, 7, 8 & 9 should be repeated for each site(s) of release)

 - a) District(s)
 - b) State(s) in which the release(s) will take place
6. Scale of release per release site.
(number of LMO involved, size of plot/site, etc)
7. Date when the release(s) is expected to commence.
8. Frequency of releases.
9. Date when release is expected to end.
10. 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.
11. Description of the proposed activities with the LMO.
12. 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 organism)

13. Details of the parent organism:
If the LMO is the result of a crossing event between more than one species/strain, 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/strain
 - f) Common name
14. A statement about whether the parent organism has an extended history of safe use in agriculture or in other industries.
15. Information concerning the reproduction of the organism:
 - a) The mode or modes of reproduction
 - b) Any specific factors affecting reproduction
 - c) Generation time
16. Information regarding the sexual compatibility of the organism with other common/ domesticated or wild types.
17. Information concerning the survivability of the parent organism:
 - a) Ability to form structures for survival or dormancy including spores and sclerotia
 - b) Any specific factors affecting survivability, for example seasonability
18. Information concerning the dissemination of the parent organism:
 - a) The means and extent of dissemination
 - b) Any specific factors affecting dissemination
19. Details of the natural habitat of the parent organism and its range.

20. Is the parent organism exotic in Malaysia?
 Yes No
21. Is the parent organism naturalized in Malaysia?
 Yes No
22. Is the parent organism, or a closely related organism, present at, or near, the site of the proposed release(s)?
(If more than one location is involved, then the information required in numbers 23 & 24 should be repeated for each site of release)
 Yes No
23. If yes, please provide details of the population(s) and the estimated distances between them from the proposed release(s).
24. The potentially significant interactions of the parent organism with other organisms (including plants) in the ecosystem where it is usually found, including information on toxic effects on humans, plants, animals and other organisms.
25. An assessment of whether the parent organism is capable of causing disease or other ill-health in human, plants, animals and other organisms and, if so, the details of the possible effects.
26. Details of any known predators, parasites, pests or diseases of the parent organism in Malaysia.
27. 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.
28. 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?
29. Is the parent organism involved in environmental processes including primary production, nutrient turnover, decomposition of organic matter and respiration?

A3 Risk Assessment Information - LMO

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

31. What are the gene(s) responsible for the modified trait(s)?
32. Give the name of the organism from which the gene(s) of insert is derived:
- (If more than one source is involved then the information required in numbers 32, 33, 34, 35, 36 and 37 should be repeated for each organism)
- a) Family name
 - b) Genus
 - c) Species
 - d) Subspecies
 - e) Breeding line /Strain
 - f) Common name
33. 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)
34. 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.
35. Please provide the following information about the gene(s) of interest:
- a) Size of the 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

36. 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)
37. 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
 - c) Indicate the part(s) of the vector that remains in the LMO
 - c) The genetic stability of the gene(s) of interest
38. A description of the methods used for the genetic modification:
- a) How the gene(s) of interest was introduced into the parent organism, or
 - b) How a sequence of a gene was deleted from the parent organism
39. If no vector was used for the genetic modification please provide details of how the gene(s) of interest is introduced.
40. If vector(s) was used, please provide the following information:

(If more than one vector was used, then the information required in 40 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
41. 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).
42. Information (biological features) on how the LMO differs from the parent organism in the following respects:
- a) Mode(s) and/or the rate of reproduction
 - b) Dissemination
43. If there is any possibility that the inserted gene(s) 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
44. The identification and description of the target organism(s), if any.
45. The anticipated mechanism and result of interaction between the released LMO and the target organism(s).
46. 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.
47. 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.

48. Details of any other possible adverse consequences.
49. Details whether the LMO compared to the parent organism that will confer a selective advantage, if any, of the LMO(s) that can impact on survival in the release site(s) and if so the nature of the advantages including a statement on how stable those features are.
50. Details of whether the modified trait(s) will confer a selective advantage on the LMO under certain conditions, if so the conditions, including data on the growth rate with and without the selection pressure.
51. 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.
52. 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
53. 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.

54. The description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed.
55. 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.

A4 Characteristics affecting survival of LMO(s)

56. The predicted habitat of the LMO.
57. The biological features which affect survival, multiplication and dispersal.
58. The known or predicted environmental conditions which may affect survival, multiplication and dispersal, including wind, water, soil, temperature, pH.
59. The sensitivity to specific agents (e.g. Disinfectant, pesticides, fertilizers, wind, water).
60. 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

61. 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 to a chemical agent (other than selective agents, such as antibiotics, used in strain construction)

62. 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 modification.

A7 Information about resistance of the LMO to a biological agent

63. 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.

A 8. 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.

64. The size of the proposed release site(s).
65. The site(s) of the proposed release or releases. Provide site map(s) with national grid reference(s).
66. Details of the reasons for the choice of the release site(s).
67. Details of the arrangements for conducting any other activities in association with the proposed release(s), such as importation of a LMO and transportation of a LMO, to or from the release site(s).
68. The preparation of the release site(s) before the release(s).
69. The methods to be used for the release(s).
70. The quantity of LMO(s) to be released.
71. 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.

72. The physical or biological proximity of the release site(s) to humans and other significant biota or protected areas.
73. The size of local human population.
74. The local economic activities which are based on the natural resources of the area.
75. The distance to the nearest drinking water supply zone areas and/or areas protected for environmental purposes.
76. The flora and fauna, including crops, livestock and migratory species in the release site(s).
77. The description of target and non-target ecosystems likely to be affected.
78. The comparison of the natural habitat of the parent organisms with the proposed site or sites of release.
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 genetic trait(s) to other organisms.
81. Details of proposed site 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 site(s) of the applicant.
82. A description of post-release treatment methods for the LMO.
83. 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 of interest to other species
 - d) Any other hazards or deleterious effect
84. Details of proposed procedures for auditing, monitoring and reporting on compliance with any conditions imposed by the NBB.
85. Details of ongoing monitoring to be undertaken after the release(s) are completed.
86. Details of proposed measures to minimize the possible adverse consequences. If no measures have been taken, please give reasons.
87. 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 plans

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

Part C Emergency Response Plan

92. Methods and procedures for controlling the LMO(s) in case of unintentional release.
93. Methods for removal of the LMO(s) in the affected areas.
94. Methods for disposal of other plants, animals and any other thing exposed during the unintentional release.
95. Methods for isolation of the area affected by the unintentional release.

96. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.
97. 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

98. 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
 - e) Relevant data if the previous release is on a different scale or into a different ecosystem
 - f) Any other relevant details
99. Details of results of any applications made for approval of the LMO(s), in other countries, including information about conditions (if any) attaching to the approval.
100. Details of any previous notifications for contained use activities according to the Biosafety Act 2007 from which the work in the present application has been developed.
101. If the LMO has been previously released overseas, details of any adverse consequences of the release, including identifying references and reports of assessments if any.
102. Give details of data or results from any previous releases 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 LMO(s) that is a Microorganism Associated with Plants

You must only respond to this Part if your application deals with a LMO(s) that is associated with plants.

E1 Information about Modified Microorganism Associated with Plants

103. Details of the plant species, including information about the specificity of the interaction and the range of plant species with which the LMO(s) can interact.
104. An assessment of the effect of the LMO(s) on the plant species, and details of how it will be monitored.
105. An assessment of any secondary effects that the LMO(s) might have on the plant species.
106. An assessment of whether the modification is likely to cause any change to the range of host plant species susceptible to infection by the organism.
107. An assessment of the effect, if any, of the LMO(s) on the distribution and abundance of host plant species or other species with which the LMO(s) can interact.
108. An assessment of the effect the LMO(s) might have on insects, birds, animals or humans that may eat the plant.

E2 Information if the Parent Organism has an Extended History of Use in Agriculture

109. If the parent organism has an extended history of use in agriculture, a description of the use.

E3 Information if the LMO(s) is a Microorganism Associated with Plant Species that are Food Crops

110. If the LMO(s) is associated with plant species that are food crops, an assessment of whether the LMO(s) could affect the suitability of the resultant produce for consumption by animals or human beings and, if so, details of the effect.

E4 Information about the Impact of the LMO(s) on Soil and Water

111. Details of the expected effects of the LMO(s) on local soil chemistry.
(For example, pH, mineral leaching and nutrient levels)
112. Details of the possible effects of the LMO(s) on local water quality.

113. Details of the effect the LMO(s) might have on soil organisms that are known to be beneficial to plants (for example, *Rhizobium*, *Azopirillum*, *Frankia* and mycorrhizal fungi) and that are likely to be in a release site.

E5 Information about any Interactions between LMO(s) and Closely Related Microorganisms

114. Details of any known interaction between the LMO(s) and closely related microorganisms in any partner plant (if applicable) and in the environment of the release site.

E6 Information about Known Genetic Exchange between Parent Organism and Plant Pathogens

115. Details of any known exchange of genetic material between the parent organism and plant pathogens.

E7 Other Information

116. Information about the expected survival and dispersal of the LMO(s), including dispersal in natural waters, soil and on other natural surfaces.
117. A statement about whether the LMO(s) will produce spores.
118. A statement about whether the LMO(s) will be resistant to desiccation.
119. A list of sterilising and anti-microbial agents (if any) that are expected to be active against the LMO(s).
120. A statement about whether the LMO(s) will be susceptible to ultraviolet or ionizing radiation.

PART F LMO(s) that is a Microorganism that Lives in or on Animals

You must only respond to this Part if your application deals with the release of a LMO(s) that is a microorganism that lives in or on animals, including an organism such as gut biota living in larger hosts, and a microorganism applied externally to an animal (for example, bacteria to prevent fleece rot).

F1 Information about the Impact of the LMO(s) on the Host

121. Identification of the animal host species.
122. A statement about whether the parent organism has an extended history of use in agriculture and, if so, details of the use.
123. An assessment of any new capacity the LMO(s) will provide for the host species (for example, ability to degrade plant or pasture toxins).
124. An assessment of whether the competitive advantage, ecological fitness, biology or distribution, of the host will be altered, and relevant data (if any) on the subject.
125. Details of any secondary effect expected to result from the introduction of the LMO(s) into or onto the host (for example, information about any possibility of the genetic insert being transferred to other organisms in the host, or to host cells).

F2 Information about the Impact of the LMO(s) on the Environment (particularly the impact on other animals, plants, soil and water)

126. Any evidence that the LMO(s) might be capable of establishing in, or on, other animals, including feral animals.
127. Any evidence of other likely effects (including secondary effects) on other plants or animals in the agricultural and natural environments.
128. If the LMO(s) will establish in an animal, information about whether the LMO(s) will be excreted or otherwise leave the animal and, if so, the time period that is expected the LMO(s) can survive outside the animal.
129. An assessment of the possible effects of the LMO(s) on local water quality.

F3 Other Information

130. A statement about whether the LMO(s) will produce spores.
131. A statement about whether the LMO(s) will be resistant to desiccation.
132. A list of sterilising and anti-microbial agents (if any) that are expected to be active against the LMO(s).
133. An statement about whether the LMO(s) will be susceptible to ultraviolet or ionizing radiation.

Part G LMO(s) that is a Vertebrate Animal

You must only respond to this Part if your proposal deals with a LMO(s) that is a vertebrate animal (other than aquatic organisms).

G1 Information about the effects of the LMO(s) on the environment

134. Information about the likelihood of any unintended effect on an animal resulting from the release.
135. Information about any intended gains that are directly linked to changes in other characteristics of the subject species.

G2 Information about Any Effects the Expression of the Modified Trait might have on the Animal

136. Information about the expected effects on the physiology, behaviour and reproduction of the animal or animals.

G3 Information about future LMO activities

137. A statement on whether an animal in the experiment is intended to be allowed to breed and, if not, whether breeding is planned in the future.
138. A statement on whether the proposed arrangements for handling any offspring are the same as those for the experimental animal or animals, and, if not, the proposed different arrangements.

G4 Information about Feral Populations of Subject Species, if any, that Exist In Malaysia or that may be established

139. Details of any agricultural, environmental or disease-control problems caused by feral populations of the subject species.
140. Details of any experimental work that has been done on expression of the novel genetic material in feral animals (such as cross-breeding of LMO(s) with captive feral animals), and the results of such work.
141. An assessment of the likelihood of the novel genetic material entering the feral gene pool (for example, by interbreeding with modified farm animals).
142. An assessment of the effect that the entry of novel genetic material into a feral gene pool might have:
- a) On the distribution and abundance of the feral population
 - b) On the ability of the feral population to cause agricultural or environmental problems
 - c) In contributing to the spread of infectious disease
143. If no feral population exists in Malaysia, information about:
- a) The likelihood of the imparted characteristic enhancing the ability of the species to establish feral populations
 - b) If there is a likelihood, the arrangements in place to prevent this from occurring

G5 Information about the capacity of the LMO(s) to Interbreed

144. Details of the capacity of the LMO(s) to interbreed with any species native to, or currently present in, Malaysia.

G6 Information about requirements for optimal expression of the introduced modified trait(s)

145. Details of the management procedures and environmental factors, if any, which would be required for optimal expression of the introduced trait(s).

Part H LMO(s) that is an Aquatic Organism

You must only respond to this Part if your application deals with a LMO(s) that is an aquatic organism, for example, fish, crustaceans and molluscs not included aquatic plants.

H1 Information about Effects of the LMO(s) on the Environment

146. Information about the effect that the LMO(s) might have on the food chain.
147. A statement on whether the LMO(s) could produce any novel metabolites, or toxins, that are likely to have deleterious effects on parasites or predators and, if so, the likely effect.
148. Details of any unintended effects that may result from the release.
149. A statement on whether the expression of the modified gene is expected to be directly linked to undesirable changes in other characteristics of the subject organisms (for example, a decrease in nutritional value).
150. Information about:
- a) Whether the modified genetic material can be transmitted to any other species
 - b) If so, the expected mechanism of transfer, the likely affected species and any likely consequences

H2 Information About Any Impact On Natural Populations

151. Information about whether natural populations of parent organism, or a closely related species, exist in Malaysia (including in rivers, lakes, dams or coastal waters) and, if so, details about any problems the natural populations cause with other organisms.
152. If no natural populations of the organism to be modified exist in Malaysia, information about the potential for the modified traits to enhance the ability of the species to establish populations in aquatic habitats.
153. Information about the results of any experimental work that has been done on phenotypic expression of the modified genetic material in naturally occurring organisms (such as cross-breeding of LMO(s) with wild or farmed stocks).

154. An assessment of the likelihood of the modified genetic material entering the gene pool of natural populations.
155. Information about any impact the entry of the modified genetic material into the gene pool of a natural organism could have on:
- a) The distribution and abundance of the organism
 - b) Associated aquatic farms
 - c) The environment
 - d) Public health
156. Information about mechanisms intended to be used to prevent dispersal of the LMO(s) into other ecosystems.

H3 Information about Future Activities in Relation to the LMO(s)

157. A statement about whether the LMO(s) is intended to be allowed to breed or whether breeding is planned in the future.
158. A statement about whether the proposed arrangements for handling any offspring are the same as those for the experimental LMO(s) and, if not, the proposed different arrangements.

Part I LMO(s) that is an Invertebrate Animal

You must only respond to this Part if your application deals with a LMO(s) that is an invertebrate animal.

159. Information about the effect that the LMO(s) might have on the food chain.
160. Information about the potential for the LMO(s) to produce any novel metabolites, or toxins, that is likely to have deleterious effects on parasites or predators.
161. Information about other unintended effects that may result from the release.
162. A statement on whether the LMO(s) will be fertile and, if not, whether it is intended to use fertile organisms in later releases.

163. Information about whether populations of the parent organism, or a closely related species, exist in Malaysia and, if so, any environmental or public health problems, or benefits, caused by the populations.
164. Information about:
- a) Whether the modified genetic material can be transmitted by means other than by normal reproduction for the species
 - b) If so, the likelihood of that genetic material entering gene pools or natural populations
165. Information about:
- a) Whether the modified genetic material can be transmitted to any other species
 - b) If so, the expected mechanism of transfer and the likely affected species
166. Information about any experimental work that has been done on the phenotypic expression of the novel genetic material in other genetic backgrounds (such as cross-breeding of modified strains with wild or caught stock).
167. Information about the effect on the distribution and abundance of the natural populations of the organism, of the entry of the novel genetic material into the gene pool of those populations.
168. Details of the mechanisms proposed to be used to prevent dispersal of the LMO(s) into other ecosystems.

Part J LMO(s) that is to be used for Biological Control

You must only respond to this Part if your proposal deals with a LMO(s) that is to be used for biological control.

J1 Information about the Expected Interaction between the LMO(s) and the Species Targeted for Biological Control

169. The name of the species targeted for biological control.
170. Details of any direct effects the parent organism has on the target.
171. Details of any direct effects the LMO(s) is expected to have on the target species.

172. Details of how the LMO(s) is intended to be transferred from one target species to another and what factors affect the transferability.
173. Details of the genetic response that may be invoked in populations of the target organism as a result of the use of the LMO(s) (for example, increased resistance to the modified organism), and the expected evidence for the response.

J2 Information on the Possible Effects of the LMO(s) on Non-Target Organisms

174. Details of the host range of the LMO(s), and details of any difference between that host range and the host range of the parent organism.
175. A list of the non-target organisms that have been tested for susceptibility to the LMO(s), and the rationale for the choice of species tested.
176. If the modified traits can be transmitted to other organisms that are likely to be in the environment, details of any effects those other organisms are likely to have on non-target species.

J3 Information on Other Possible Effects of the LMO(s) on the Environment

177. A statement about the secondary effects that can be envisaged on competitors, predators, prey or parasites of the target species.
178. An assessment of the consequence of the removal, or reduction, of the target species on the management of agriculturally significant plants or farm animals.
179. Details of any predicted change in the ecosystem resulting from a reduction in the population of the target organism.
180. Information about:
- a) Whether the LMO(s) produces metabolites that may have deleterious effects directly or indirectly (through concentration in the food chain) on other organisms, including human beings
 - b) If so, the likely effect

PART K LMO(s) that is to be Used for Bioremediation

You must only respond to this Part if your application deals with a LMO(s) that is to be used for bioremediation

K1 Information about the Expected Interaction between the LMO(s) and the Target Substrate for Bioremediation

- 181. Identification of the target substrate for bioremediation.
- 182. Details of the effect the parent organism has on the target substrate.
- 183. Details of the effect the LMO(s) is expected to have on the target substrate.
- 184. A list of the substances other than the target substrate that can be metabolized by the LMO(s) and that cannot be metabolized by the parent organism.

K2 Information about the LMO(s) and its impact on the Environment

- 185. A statement about whether the LMO(s) will be self-sufficient if added to the contaminated site or whether additional measures may be required.
(For example, provision of supplementary nutrients and growth factors, or other environmental modifications)
- 186. A list of any metabolites produced by the LMO(s) that may have deleterious effects, either directly or indirectly (through concentration in the food chain), on other organisms.
- 187. Details of effects the LMO(s) might have on water, air or soil quality.
- 188. Details of effects the LMO(s) might have on organisms that ingest it.
- 189. A statement on whether the LMO(s) will be dispersed from the site of application and, if so, the proposed mechanisms involved and the likely consequences.

PART L LMO(s) Intended to be Used as Food for Human or Vertebrate Animal Consumption

You must only respond to this Part if your application deals with a LMO(s) intended to be used as food for human or vertebrate animal consumption.

190. Details of:
- a) Whether the parent organism or the donor organism is of a kind already in use as a food for consumption by human beings or animals, or used in the production of such a food
 - b) Whether any processing is needed, or is commonly applied, before consumption
191. Details of any metabolites produced by the LMO(s) that may have adverse effects on the consumer (human or animal), including available data on toxicology, allergenicity and other possible adverse effects.
192. Details of any products of the LMO(s) that are expected to concentrate in the food chain to levels which may become toxic.
193. Details of any expected changes to the nutritional quality of such food as a result of the genetic modification.
194. A statement on whether the LMO(s) is a major component of such food as consumed, or a minor component (for example, yeast cells in beer).

Note: For a food for human consumption that contains LMO(s) or GM products, see also the assessment requirements under the Malaysia Food Safety Act 1983