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	RISK ASSESSMENT AND RISK MANAGEMENT PLAN		Page 1 of 3

PROJECT INTRODUCTION

In this part, the applicant is required to describe the proposed activities with the GMO within the context of the project.

1. Project Title: _____
2. Biosafety Level (BSL) :
BSL 1 ☐ BSL2 ☐ BSL3 ☐ BSL4 ☐
3. Rationale of activity: _____
4. Overall Project/Programme Objective: _____
5. Specific Objective(s): _____
6. Intended Date of Commencement: _____
7. Expected Date of Completion: _____
8. For an imported GMO– 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, etc.
9. Categories of people (Research staff, technicians, students etc) authorized to undertake activities with the GMO: _____

RISK ASSESSMENT

1. In order to prepare the Emergency Response Plan, an assessment of any possible risks or potential harm that may be posed by the GMO(s) and the level of risk posed by such hazards based on an assessment of the likelihood and consequence of the hazard occurring must be carried out. The risks that are required to assess are:

a) risks to the health and safety of humans from the activities associated with genetic modification

b) risks to the health and safety of humans from an unintentional release of the GMO(s);
and

c) risks to the environment from an unintentional release of the GMO(s)

The risk management plan details show that any risks posed by the GMO(s) will be managed to ensure that unacceptable risks are not realized. Summaries of any protocols and/or standard operating procedures can be included to specifically answer the individual questions.

BASIC INFORMATION

1. Is there any risk to health and safety of humans and/ or environments occurring from the proposed activity over and above those posed by the donor/parent organism?

No known hazard ☐

Not relevant ☐

Yes ☐

If yes, please provide information in question below.

2. What are the possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (i.e. the risk) from the proposed genetic modification(s)?

3. In regard to the health and safety of humans, what are the possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (i.e. the risk) from an unintentional release of the GMO(s) into the environment?

4. In regard to the environment, what are the possible hazard(s) and the likelihood and consequence of the hazard(s) occurring (i.e. the risk) from an unintentional release of the GMO(s) into the environment?

RISK MANAGEMENT

5. Do you propose to transport the GMO(s) outside the premises? If yes, describe the precautions to be taken.

6. How will the GMO(s) be disposed of?

7. What are the procedures for decontaminating equipment used during the proposed activities in order to render any GMO(s) unviable?

EMERGENCY RESPONSE PLAN

8. Plans for protecting human health and the environment in case of the occurrence of an undesirable effect observed during contained use activities.

9. Methods for removal of the GMO(s) in the affected areas in the case of an unintentional release.

10. Methods for disposal of other plants, animals and any other organisms exposed during the unintentional release.

11. Methods for isolation of the area affected by the unintentional release.

12. Details of any other contingency measure that will be in place to rectify any unintended consequences if an adverse effect becomes evident during the contained use activities or when an unintentional release occur (Please include attachment if more space needed)

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Date received			
Name		Signature	
Remarks			