SINGAPORE GUIDELINES ON THE RELEASE OF AGRICULTURE-RELATED GENETICALLY MODIFIED ORGANISMS (GMOs)

Genetic Modification Advisory Committee of Singapore

August 1999

1. OBJECTIVES OF GUIDELINES

1.1 These Guidelines are established to ensure the safe movement and use in Singapore of agriculture-related GMOs.

1.2 These Guidelines provide a common framework for:
(a) assessment of risks of agriculture-related GMOs to human health and the environment; and
(b) approval mechanisms for their release in Singapore.

1.2 These Guidelines address issues related to food safety based on the concept of substantial equivalence.

2. SCOPE OF GUIDELINES

Covers release of agriculture-related organisms with genetic material that has been altered in a way that is unlikely to occur naturally by mating or natural recombination.

3. DEFINITIONS

3.1 For purposes of these Guidelines, the following terms shall be defined as follows:

- "Agriculture-related organisms" refers to animals (including fish and invertebrates), plants, microorganisms and vaccines used in cultivation, farming, agronomy, husbandry and horticulture or as food.
- "GMAC" refers to the Genetic Modification Advisory Committee of Singapore.
- "Proponent" refers to any person, firm, company, institution or organisation planning to release agriculture-related GMOs into Singapore.
- "Release" means the deliberate introduction of agriculture-related GMOs into the open environment for field trials or commercial use in Singapore.
- "Risk" is defined as the magnitude and likelihood of adverse effect.

- "Substantial equivalence" embodies the concept that if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety (i.e. the food or food component can be concluded to be as safe as the conventional food or food component).

4. THE GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)

4.1 The Committee consists of representatives from national agencies:

- Agency for Science, Technology & Research (A*STAR)
- Agri-Food and Veterinary Authority of Singapore (AVA)
- Attorney General's Chambers (AG Chambers)
- Consumers Association of Singapore (CASE)
- Institute of Molecular and Cell Biology (IMCB)
- Ministry of Health (MOH)
- Ministry of Manpower (MOM)
- Nanyang Technological University (NTU)
- National Institute of Education (NIE)
- National Parks Board (NParks)
- National University of Singapore (NUS)
- Temasek Life Sciences Laboratory (TLL)

4.2 The Terms of Reference of GMAC are as follows:

- To advise and recommend for approval, or otherwise, the research and development, production, use and handling of GMOs
- To monitor the control of release of GMOs into the environment
- To review proposals related to the release of GMOs into the environment. GMAC may establish sub-committees of experts in specific areas to assess the risks involved
- To provide advice on matters related to the release of GMOs
- To inform the public, where deemed necessary, on planned release of GMOs
- To establish mechanisms for exchange of information with overseas agencies and to facilitate the harmonisation of guidelines with regional and international authorities
- To develop and approve biosafety guidelines for the research and development, production, use and handling of GMOs
- To create public awareness on GMO and GMO-related issues

5. PROCEDURES FOR NOTIFICATION

5.1 All agriculture-related GMOs brought into Singapore by the Proponent for release should comply with existing national and international regulations.

5.2 Before the release of any agriculture-related GMOs in Singapore, the Proponent is required to submit a proposal to the GMAC. The Proponent should consult GMAC to determine the appropriate approval process for the agriculture-related GMOs and the specific information necessary for an assessment.

5.3 The correspondence address of the GMAC Secretariat is as follows:

Secretariat, Genetic Modification Advisory Committee (GMAC)
20 Biopolis Way
 # 08-01 Centros
Singapore 138668
Tel: (65) 6407-0539/0362
Fax: (65) 6795-5073

5.4 The proposal should consist of information specified in Section 8.

6. PROCEDURES FOR APPROVAL

6.1 The GMAC will forward the proposal to the Sub-Committee. The Sub-Committee may either endorse/reject the proposal or appoint the relevant agency or an expert panel to evaluate the proposal within 90 days. The panel of experts will review and assess the risks associated with each stage of the release using the questionnaire and risk assessment criteria as attached as **Appendices 1 and 2.** The agency/expert panel will submit their recommendations to the Sub-Committee within 90 days.

6.2 No Proponent or any agent representing the Proponent may review his own proposal.

6.3 The GMAC will decide on the recommendations of the Sub-Committee within 60 days. The GMAC can request further information/clarification from the Proponent should the need arise.

6.4 The GMAC will decide on the release on a case-by-case basis. The GMAC will either:

i) endorse the release of the agriculture-related GMOs,
ii) endorse the release of the agriculture-related GMOs under specified conditions,
iii) require the Proponent to submit additional information which the GMAC deems necessary to complete the assessment, followed by decision (i) or (ii).

7. REGISTRATION OF APPROVED AGRICULTURE-RELATED GMOs

7.1 A register of approved agriculture-related GMOs in Singapore will be set up and updated by the GMAC Secretariat. Once the GMOs under consideration have been granted approval for release, the GMOs shall be registered with the GMAC Secretariat.

7.2 The evaluation, approval and registration in Singapore is summarised in the Flow Chart as appended in **Appendix 3.**

8. INFORMATION REQUIRED IN PROPOSAL

8.1 The Proposal should include, on the cover page, the title of the project, the address of the institution/organisation/registered company, name and telephone number of a contact person.

8.2 The Proponent is required to disclose the necessary information for risk assessment and safety as specified in **Appendix1**. **All Core Questions under Section A of Appendix 1 must be answered in detail, with relevant supporting documents included (e.g. data of field trials or laboratory tests). In addition, information on the specific agriculture-related GMOs should be given based on the classification of the GMO under Sections B-K.**

8.3 The broad classifications of information that are required include:
Section A : Core Questions

- Species of organisms
- Eventual use of GMO
- Location for release
- Habitat and ecology
- Genetics of the GMO
- Data from contained work and other studies
- Experimental procedures, monitoring and contingency planning
- Other assessments

Section B: Plants
Section C: Microorganisms living in or on animals
Section D: Microorganisms as vaccines
Section E: Microorganisms not falling into Sections C or D
Section F: Animals (vertebrates, not including fish)
Section G: Fish and aquatic organisms such as crustaceans
Section H: Invertebrates
Section I: Organisms for biological control
Section J: Organisms for bioremediation
Section K: Organisms to be consumed as food

8.4 The Risk Assessment Criteria is appended in **Appendix 2**.

9. CONFIDENTIALITY AND INTELLECTUAL PROPERTY RIGHTS (IPR)

9.1 The Proponent shall inform the GMAC of any information in their proposal which the Proponent wishes to keep confidential. The GMAC shall take steps to preserve the confidentiality of such information.

9.2 It is the responsibility of the Proponent to obtain the necessary patents for the Proponent's agriculture-related GMOs for the protection of the Proponent's intellectual property.

10. RESPONSIBILITY OF PROPONENT

10.1 The Proponent is responsible for ensuring that GMAC's requirements are complied with in the release of agriculture-related GMOs. The Proponent shall appoint/designate a qualified project supervisor familiar with the requirements and ensure that all persons or agents involved in the release are made aware of and directed to comply with the requirements and recommendations made by the GMAC.

10.2 The Proponent is required to disclose all relevant information to the GMAC, including all previous approvals or refusals for release in other countries.

10.3 The Proponent shall proceed with the release only when the proponent has received official approval from the GMAC.

10.4 The Proponent shall continually collect information and perform post-release monitoring relating to the agriculture-related GMOs and their application(s). The Proponent shall report to the GMAC immediately if new information regarding risks to environment or human health is found. The GMAC reserves the right to recall any agriculture-related GMOs approved for release in its respective country based on its assessment of new information.

10.5 Upon completion of the field trials or the commercial release of the GMO, the proponent is required to submit a report.

11. REVIEW AND UPDATE

11.1 Due to the rapid changes in technology and the range of agriculture-related GMOs being developed, these Guidelines shall be periodically reviewed and updated as deemed necessary.

APPENDIX 1:
QUESTIONNAIRE FOR RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS (GMOs) RELATED TO AGRICULTURE

A. CORE QUESTIONS

		Risk Assessment Criteria **(See Appendix 2)**
Species of organisms		
1	What is the species of GMO? Where relevant, give information on the strain, cultivar etc.	A2
2	Is the GMO capable of causing disease or other ill-health in humans, plants or animals? If so, what are the possible effects?	C2
3	What is the origin of the inserted DNA? Does the inserted DNA come from an organism that causes disease or other ill-health in humans, plants or animals? If so, what are the possible effects?	A3, B1
Eventual use of GMOs		
1	What is the aim of the proposal and the intended eventual use of the GMO?	General Information
2	What are the advantages and disadvantages of the chosen strategy compared with other methods?	General Information
Location (for the release of GMO)		
1.	Describe the size of the release, and, where relevant, the area of land to be used, and its location. Include a map, where relevant	D5
2.	What are the reasons for the choice of location?	D1, D5
3.	Describe in detail the relevant features of the physical environment, particularly those which may minimize or exacerbate any undesirable effects.	D1, D5
4.	How close is the site to population centres, of agricultural activity, or the habitat of biota that might affect, or be affected by the release?	D3, D5
Habitat and ecology		
1.	What is the natural habitat of the parent organism and its range?	A5
2.	Where was the parent organism originally isolated?	A2, A5
3.	What is the distribution of the parent organism in Singapore ?	A5
4.	Is the parent organism already present at or near the site of the release? If so, provide available data on populations (for field trial).	A5
5.	Is the parent organism exotic to Singapore ?	A2, A5

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		Risk Assessment Criteria **(See Appendix 2)**
6.	Are there any known predators or parasites of the organism in Singapore ? If so, describe.	C6
7.	Could the release of the GMO prejudice any beneficial function of the parent organism in the environment?	D4
8.	Describe any anticipated direct or indirect ecological effects of the release which are not covered in subsequent sections (B, C, D etc.)	C5 , D8, D4
	Genetics of the GMO	
1.	What genetic modification has been made? Give a detailed description of the steps undertaken.	B1
2.	Does the GMO have a potentially unstable genotype?	B5
3.	To what extent is the genetic modification characterized? Provide data to show the extent of characterization.	B2
4.	What is the location of the inserted DNA in the final construct, and how many copies are present?	B2
5.	What markers or sequences will enable the GMO to be identified in the laboratory and under field conditions?	B2
6.	What type of vector was used in the transfer? Provide a description of the vector, showing the position of the inserted DNA and any other control sequences or markers in the vector.	B3
7.	Can the vector transfer to other hosts? If so, provide information on its host range.	B3, C3
8.	Is the recombinant vector present in the final construct? If not, how was it removed?	B4
9.	If no vector was involved: how was the DNA introduced and how many copies of the gene were inserted?	B3
10.	How does the modification change the phenotype of the organism? Present data to demonstrate the effect of the modification, including level of expression and regulation of the genetic insert. What secondary genetic effects may be anticipated?	General Information, C7, C8
11.	What intrinsic genetic features, if any, of the GMO regulate its survival in the environment if it is release? How stable are these features?	D1, B5

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	Risk Assessment Criteria **(See Appendix 2)**
12. What genetic changes, if any, have been included in the GMO to limit or eliminate its capacity to reproduce or transfer its genes to other organisms?	C5

Data from contained work and other studies on stability, survival and transfer

1. On the basis of contained experiments, provide data on: i) the survival times of the GMO in habitats relevant to the release; ii) the growth rate (or generation time) of the parent organism and GMO in the ranges of environmental conditions characteristic for the place and date of release; iii) the frequency of reversion or loss of the genetic change.	Supporting Data
2. What is the capability of the GMO to disperse from the release area? What are the dispersal mechanisms in air, water and soil?	Supporting Data
3. Can the parent organism form long-term survival structures such as seeds or spores?	Supporting Data
4. Is there any evidence that the inserted genetic trait can be transferred to other organisms found at the release site and surrounding environment? If so: i)to what organisms and at what frequencies? List the species that have been tested for transfer and explain the rationale for this choice. ii)what transfer mechanisms are involved? iii)what techniques have been used to demonstrate transfer? iv)what are the possible adverse effects of the transfer?	Supporting Data
5. Does the modified trait confer a selective advantage on the GMO under certain conditions?	Supporting Data
6. If so, what are these conditions? Provide data on growth rates with and without selection pressure.	Supporting Data
7. Would you expect the GMO to show any competitive advantages over its unmodified parent in mixed populations under the conditions in the test site? If so, what are the advantages?	Supporting Data

Experimental procedures, monitoring and contingency planning

1. Describe in detail the overall experimental protocol for the release , including the protocol for control, test, and challenge organisms, if appropriate.	Supporting Data
2. How many organisms are to be released?	Supporting Data
3. How many releases of the GMO are proposed?	Supporting Data

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		Risk Assessment Criteria **(See Appendix 2)**
4.	What are the arrangements for producing the GMO in quantity, transporting it to the site and accounting for the transported organisms?	Supporting Data
5.	How will the GMO be released?	Supporting Data
6.	What methods are to be used to test for batch to batch consistency if large scale production is required to produce GMOs for release?	Supporting Data
7.	What specific measures have been taken or will be taken in the production process to ensure the quality/purity of the GMO to be released?	Supporting Data
8.	How will the survival of the GMO be monitored? Provide a description of techniques for monitoring the presence of GMOs or transferred genetic material beyond the primary site, including specificity, sensitivity and reliability of detection methods.	Supporting Data
9.	If the release is likely to affect the characteristics or abundance of other species, how will this be monitored?	Supporting Data
10.	How will transfer of the introduced gene to other species be monitored?	Supporting Data
11.	What potential hazards or deleterious effects can be postulated and how are these to be evaluated during the release?	Supporting Data
12	Describe any structures or procedures that will be in place to reduce dissemination of the GMO.	Supporting Data
13.	If transfer of the inserted genetic trait to other organisms with adverse consequences is possible, what methods will be used to minimize these effects?	Supporting Data
14.	Will the GMO remain in the environment after the release? If so, (a) for what period of time, and (b) what might be the consequences?	Supporting Data
15.	Will measures be taken to reduce populations or dispose of the GMO once the release is completed? If so, provide details.	Supporting Data
16.	What monitoring is to be undertaken after the release is completed?	Supporting Data
17.	What contingency measures will be in place to remove the GMOs if a hazard becomes evident during the course of the release?	Supporting Data
18.	Describe site supervision procedures and any safety procedures undertaken by staff.	Supporting Data

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Other assessments

		Risk Assessment Criteria **(See Appendix 2)**
1.	Have the same or similar GMO been used or released before, either within or outside SINGAPORE ? If so, what were the beneficial or adverse consequences? Provide references or reports of previous assessments.	General Information
2.	Has an overseas country refused an application for the use or release of this organism?	General Information
3.	What factors might suggest greater or less risk with the proposed use or release in SINGAPORE ?	General Information
4.	Has the GMO been imported? If so, provide documentation of quarantine clearance or assessment.	General Information
5.	Is there any reason to think that the GMO, if used or released in SINGAPORE, could constitute a hazard, not discussed elsewhere in the proposal? If so, please explain.	General Information
6.	Provide any other information you may have that could assist with the assessment of this proposal.	General Information

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B. PLANTS

If the plant is intended for human or animal consumption, answer also the questions in Section K.

		Risk Assessment Criteria **(See Appendix 2)**
1.	Has the parent plant an extended history of cultivation and of safe use? If not, explain.	A1
2.	What, if any, unintended pleiotropic effects, including undesirable effects on agronomic characteristics of the plant, may result from the expression of the transgene in the GMO (e.g. reduced fertility, increased disease prevalence, production losses, grain shedding)? Indicate the likelihood of these events.	C8, C10
3.	Describe the mechanism of pollen spread (by insect vectors or by other means) in the plant.	D3
4.	Provide any available data on pollen viability for the plant.	C9, D2
5.	Indicate any potential pollinators and their range and distribution in Singapore.	D3
6.	Are any members of the genus of unmodified parent plants known to be weeds in any environment? If so, specify.	A3
7.	Are there any literature reports on cross-pollination between the species to which the GMO belongs and wild relatives known to be weeds? If so, please list.	D2, A6
8.	Provide quantitative data on successful cross-pollination between the plant and its wild relatives.	D2, A6
9.	If you know that sexually compatible plants live near the site of the release, give details and quantify the chances for cross-pollination.	D2
10.	If cross-pollination occurred, would the resulting plants survive/compete well? If not, why not?	D1
11.	Will the plants in this release be allowed to set seed? If not, is this planned for later releases?	D2
12.	If plants are allowed to set seed, does the mature seed normally remain contained within an ear, capsule, pod etc. so that practically all of the seed can readily be harvested, or is the seed shed soon after it matures?	D2
13.	Can the seed be dispersed by natural mechanisms? If so, describe.	D3
14.	Are the seeds capable of being dormant for a long time? If so, how long?	C9, D2

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		Risk Assessment Criteria **(See Appendix 2)**
15.	Can the plant be dispersed by vegetative propagation? If so, describe the possible mechanisms.	D3
16.	What is the likelihood that the imparted characteristic could be integrated into other species, with adverse consequences?	D2
17.	If there is any possibility of such integration, would it have the potential to affect the distribution and abundance of the other species? If so, specify. Data on the factors which normally control populations of these other species in the natural environment (e.g. pathogens, herbivory, physiological stress) may be relevant.	C6, D1, D8, D4
18.	If there is any possibility of such integration, has any attempt been made to minimize the risk (e.g. by imparting male sterility or other means of reproductive isolation)? If not, why not?	C5, D7
19	How might the plant's competitive advantages (fitness) be changed (i) in the agricultural setting; (ii) in the natural environment? Explain	D1
20.	Does the novel characteristic change the capacity of the plant to add substances to or subtract substances from the soil (e.g. nitrogen, toxic compounds)? If so, describe the change.	C4, D4
21.	Is there any likelihood that the introduced gene could cause an increase in toxicity of the plant for animals and humans? If so, provide available data.	C2, E2
22.	Could any products of the plant concentrate in the natural or human food chain to level which become toxic? If so, explain.	C2, E3
23.	Is the biodegradability of the plant changed? If so, how?	D4
24.	What secondary ecological effects might result from release of the GMO (e.g. effect on endangered native species, resistance of insect populations to an insecticide, reduction or increases in numbers of prey or parasites)?	D4, D8
25.	If the construct involves resistance to a chemical agent (other than selective agents, such as antibiotics, used in strain construction): i) provide data on the degradability, selectivity and toxicity of the chemical concerned; ii) what is the agronomic significance of the chemical? iii) what is the biological activity of the chemical? iv) how is the chemical applied and used?	General Information, C6

	Risk Assessment Criteria **(See Appendix 2)**
26. If the construct involves resistance to a herbicide, explain: i) what impact the release will have on use of that herbicide (provide forecasts on areas to be sprayed and volumes to be applied); ii) what impact the release will have on total use of other herbicides and insecticides; iii) what impact the release will have on weed control; iv) what effect the release will have on the overall farming system; v) how the release will affect programs designed to involve environmentally friendly chemicals or practices; vi) the role that the release will have in future pest management strategies.	General Information, C6

C. MICROORGANISMS LIVING IN OR ON ANIMALS

Questions here relate to organisms such as gut biota living in larger hosts, and microorganisms applied externally to animals (e.g. bacteria to prevent fleece rot). Issues included here should also take into account the ecological interactions and behavior of host organisms which could have environmental impacts.

		Risk Assessment Criteria **(See Appendix 2)**
1.	What is the animal host species?	C3
2.	Has the parent organism an extended history of use in agriculture? If so, please elaborate.	A1, C7
3.	Is there any evidence that the GMO might be capable of establishing in or on other animals, including feral animals? If so, what are these animals and what are the effects?	C3, D2
4.	What new capacity will the GMO provide for the host species? (e.g. ability to degrade plant or pasture toxins)?	C10
5.	What secondary effects can be postulated from conferring that capacity on the host?	C10
6.	Will the competitive advantage or ecological fitness of the host be altered? Explain, providing data to support your answer.	C10, D4
7.	What effects (including secondary effects) are likely on other plants or animals in the agricultural and natural environments? (Please include in your answer any likely effect on non-host animals or feral populations.)	D4, D8
8.	What secondary effects can be postulated from the introduction of the GMO into or onto the host? (For example, is there a possibility of the genetic insert being transferred to other organisms in the host, or to host cells?)	C10, D2
9.	For GMOs living in animals, will the GMO be excreted or otherwise leave the animal? If so, for how long does it survive outside the animal?	C5, C9
10.	What is the survival and dispersal of the GMO in natural waters and soil?	C1, C9 D2
11.	What could be the effects of the GMO on water quality?	D4
12.	Does the GMO produce spores?	C9
13.	Is the GMO resistant to desiccation?	C9
14.	What sterilizing and anti-microbial agents are active against the GMO?	C6, D7
15.	Is the GMO susceptible to UV and ionizing radiation?	C6, D7

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D. MICROORGANISMS AS VACCINES

		Risk Assessment Criteria **(See Appendix 2)**
1.	What disease is to be controlled by the use of this vaccine?	General Information
2.	On what host species is the vaccine to be used?	General Information, C3
3.	What is the host range of the parent organism from which the vaccine was constructed?	A7
4.	If the vaccine is intended for animals, what are the proposed target species/breeds for the vaccine? Specify age range, risk factor groups, and geographic area, if applicable.	General Information, C3
5.	Provide data regarding level and duration of immunity produced in the host species after vaccination with the GMO.	General Information, C10
6.	Over what period can the vaccine organism be detected in the vaccinated animals or their excretions? Provide supporting data.	General Information, C9
7.	Can the vaccine organism spread from vaccinated to non-vaccinated animals or to other species (including humans)? If so, what is the mechanism and frequency? Provide data, if available.	C3, D2
8.	Is there any evidence to indicate whether the susceptibility of the host to the vaccine organism could be affected by the current state of the host (e.g. immunosuppression or superimposition of other disease) or by other treatments (e.g. drugs)? If so, elaborate.	C10
9.	Does the genetic material of the vaccine organism have the potential to become incorporated in whole or in part into the genome of any cells of the vaccinated host?	D2
10.	If this is a viral vaccine, can the nucleic acid of the virus in the vaccine be rescued, or be restored to wild type, by recombination or complementation with intracellular viruses?	B3, B5, D2
11.	In trials, is it proposed to dispose of waste which contains vaccine organisms? If so. describe the arrangements.	D7
12.	What is the fate of the vaccinated animals at the conclusion of the trial (in the case of an experiment)?	D7

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		Risk Assessment Criteria **(See Appendix 2)**
13.	Will the vaccinated animals carry vaccine organisms at the end of the trial? If so: i) will they be likely to disseminate the vaccine organisms to their family contacts or to the general population? ii) what measures, if any, will be taken to minimize this possibility? iii) will the organisms be able to cross the placenta?	D2 D7 D2
14.	Is the use of this vaccine organism likely to preclude its use for vaccination against other diseases subsequently? Will its usefulness for other vaccinations be affected?	C8
15.	Is the vaccine likely to have any deleterious effects on pregnant humans or animals? If so, specify. For humans, provide data from animal models.	C2
16.	Is the vaccine teratogenic (i.e. causing developmental defects) for the foetus at any stage of gestation? If so, elaborate.	C2
17.	Does the GMO produce spores?	C9
18.	Is the GMO resistant to desiccation?	C9
19.	What sterilizing and anti-microbial agents are active against the GMO?	C6, D7
20.	Is the GMO susceptible to UV and ionizing radiation?	C6, D7

E. MICROORGANISMS NOT FALLING INTO SECTIONS C OR D

Questions here relate to microorganisms associated with plants and microorganisms which might be applied to modify the physical or chemical environment (e.g. microorganisms to modify soil properties).

		Risk Assessment Criteria **(See Appendix 2)**
1.	For microorganisms associated with plants, what is the partner species of plant? Describe the specificity of the interaction and indicate the range of plant species with which the GMO can interact.	C3, C10
2.	Has the parent organism an extended history of use in agriculture? If so, please elaborate.	A1
3.	For microorganisms associated with plants:	
	i) what is the effect of the GMO on the partner plant species and how will this be monitored?	C10
	ii) what other secondary effects might the GMO have on the plant?	C10
	iii) does the modification cause any change to the range of host plant species available to the organism?	C3 C10
	iv) what effect of the GMO, if any, is anticipated on the distribution and abundance of the host plant species and other species with which the organism can interact?	C10, D8
4.	If the GMO is associated with plant species which are food crops, could it affect the suitability of the resultant produce for human or animal consumption? If so, explain.	E1, E2, E3, E4
5.	What are the effects expected on soil chemistry (e.g. pH, mineral leaching, chelation, nutrient levels)?	C4, D4
6.	What is the survival and dispersal of the GMO in natural waters and soil?	C1, C9, D2
7.	What could be the effects of the GMO on water quality?	D4
8.	Does the GMO produce spores?	C9
9.	Is the GMO resistant to desiccation?	C9
10.	What effects might the GMO have on soil organisms which are known to be beneficial to plants (e.g. *Rhizobium*, *Azospirillum*, *Frankia* and mycorrhizal fungi) and are likely to be in the test area?	D4, D8
11.	What is known about interactions between the GMO and closely related microorganisms in the partner plant (if applicable) or the environment of the release site?	D2, D4

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	Risk Assessment Criteria **(See Appendix 2)**
12. For GMOs associated with plants, what effect might the GMO have on insects, birds and animals (including humans) which may eat the plant?	C2
13. Does the GMO exchange genetic material with known plant pathogens? If so, elaborate.	D2
14. What sterilizing and anti-microbial agents are active against the GMO?	C6, D7
15. Is the GMO susceptible to UV and ionizing radiation?	C6, D7

F. ANIMALS (VERTEBRATES, NOT INCLUDING FISH)

If the organism is to be consumed as a food, answer also the questions in Section K.

		Risk Assessment Criteria **(See Appendix 2)**
1.	What unintended effects (environmental, animal welfare or economic) may result from the release, and what is their likelihood?	C8
2.	Are any of the intended gains directly linked to changes in other characteristics of the species? If so, specify.	C10
3.	What effects might the expression of the modified trait have on the physiology, behavior and reproduction of the animal? Explain, with data (e.g. studies from model animals).	C1, C10
4.	Will the animals in this experiment be allowed to breed? If not, is breeding planned for later experiments or in the commercial phase?	D2
5.	Are the arrangements for handling any offspring the same as those for the experimental animals? If not, please specify the arrangements.	D7
6.	Do feral populations of the species exist in Singapore ? If so:	
	i) do the feral populations cause agricultural, environmental or disease-control problems? Specify the problems.	A3
	ii) has any experimental work been done on the expression of the novel genetic material in feral animals (e.g. cross-breeding of GMOs with captive feral animals)? If so, what were the results?	A6, D2
	iii) what is the likelihood of the novel genetic material entering the feral gene pool (e.g. by interbreeding with modified farm animals)?	D2
	iv) what effect might the entry of the novel genetic material into a feral gene pool have on the distribution and abundance of the feral population or on its ability to cause agricultural or environmental problems, or to contribute to the spread of infectious disease? Provide data to support your answer.	D4
7.	If no feral populations exist in Singapore, comment on the likelihood that the imparted characteristic may enhance the ability of the species to establish feral populations.	C1, D1
8.	Can the GMO interbreed with any species native to Singapore?	D2
9.	What management procedures and environmental factors, if any, are required for optimal expression of the introduced trait? Provide data to support your answer.	D7

G. FISH AND AQUATIC ORGANISMS SUCH AS CRUSTACEANS

If the organism is to be consumed as a food, answer also the questions in Section K.

		Risk Assessment Criteria **(See Appendix 2)**
1.	Could the GMO produce any 'new' metabolites or toxins likely to have deleterious effects on parasites or predators? If so, elaborate.	C2 C6
2.	What other unintended effects may result from the release? Please include consideration of the effect of the GMO on the community ecology at the release site.	C3,D4 , C8
3.	Are any of the likely gains directly linked to losses in other characteristics of the organisms?	General Information
4.	Will the GMOs in this release be allowed to breed? If not, is breeding planned for later releases or commercial use?	D2
5.	Are the arrangements for handling any offspring the same as those for the experimental organisms? If not, please specify the arrangements.	D7
6.	Can the changed or added genetic material be transmitted by means other than by reproduction normal for the species or to any other species? If so, specify, and elaborate its effects.	D2, D3
7.	Do natural populations of the parental organism exist in Singapore (including water bodies such as reservoirs, rivers, lakes, or coastal waters)? If so, do the natural populations cause problems with other organisms? Specify the organisms and the problems.	A3, A5
8.	If no natural populations of the organism to be modified exist in Singapore, could the modified characteristics enhance the ability of the species to establish populations in aquatic habitats?	C1, D1
9.	Has any experimental work been done on phenotypic expression of the novel genetic material in naturally occurring organisms (e.g. cross-breeding of GMOs with wild/farmed stocks)? If so, what were the results?	A6, D2
10.	What is the likelihood of the novel genetic material entering the gene pool of natural populations?	A6, D2
11.	Could the entry of the novel genetic material into the gene pool of a natural organism have any effect on the distribution and abundance of the organism or on associated fisheries, the environment or public health? If so, please explain.	C8, D8, D4
12.	What mechanisms will be used to prevent dispersal of the GMO into other ecosystems?	D7

H. INVERTEBRATES

If the organism is to be consumed as a food, answer also the questions in Section K.

		Risk Assessment Criteria **(See Appendix 2)**
1.	What effects might the GMO have on the food chain?	D4, E3
2.	Could the GMO produce any 'new' metabolites or toxins likely to have deleterious effects on parasites or predators? If so, elaborate.	C2, C6
3.	What other unintended effects may result from the release? Your answer should include consideration of the effect of the GMO on the community ecology at the release site.	C8
4.	Will the GMOs in this release be fertile? If not, is it intended to use fertile organisms in later releases?	D2
5.	Are the genotype and phenotype of the offspring the same as those of the GMOs to be released? If not, please specify the differences.	General Information
6.	Do populations of the parental organism exist in Singapore? If so, do these populations cause agricultural, environmental or public health problems or benefits? Specify the problems or benefits.	A3, A5
7.	Can the changed or added genetic material be transmitted by means other than reproduction normal for the species? If so, specify, and elaborate its effects.	D2, D3
8.	What is the likelihood of the novel genetic material entering gene pools of natural populations?	A 6, D2
9.	Can the changed or added genetic material be transmitted to any other species? If so, specify the mechanism of transfer and list the species.	D2
10.	Has any experimental work been done on the phenotypic expression of the novel genetic material in other genetic backgrounds (e.g. cross-breeding of modified strains with wild/caught stock)? If so, what were the results?	A6, D2
11.	Could the entry of the novel genetic material into the gene pool of natural populations of the organism have any effect on the distribution and abundance of the natural populations? What would be the effect of this change?	D4, C8,D8
12.	What mechanisms will be used to prevent dispersal of the GMO into other ecosystems?	D7

APPENDIX 1:
QUESTIONNAIRE FOR RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS (GMOs) RELATED TO AGRICULTURE

I. ORGANISMS FOR BIOLOGICAL CONTROL

		Risk Assessment Criteria **(See Appendix 2)**
1.	What is the species targeted for biological control?	C3
2.	What direct effects does the parent organism have on the target species?	General Information
3.	What direct effects does the GMO have on the target species?	C10
4.	What is the host range of the GMO? If the host range of the GMO is likely to be different from that of the parent organism, explain why.	C3
5.	What non-target organisms have been tested for susceptibility to the GMO?	D8
6.	What is the rationale for the choice of species tested?	General Information
7.	How is the GMO transferred from one target individual to another and what factors affect this transferability?	D2, D3
8.	What secondary effects can be envisaged on predators, prey or parasites of the target species?	D4, D8
9.	Explain the consequence of the removal or reduction of the target species on the management of agriculturally significant plants or farm animals.	D4
10.	Predict any change in the ecosystem resulting from a reduction in the population of the target organism.	D4
11.	Does the GMO produce metabolites which may have deleterious effects directly on other organisms or indirectly through concentration in the food chain? If so, elaborate.	C2, E3
12.	If the modified genetic traits can be transmitted to other organisms which are likely to be in the environment, are these other organisms likely to affect non-target species?	D2, D3, D8
13.	What genetic response might be invoked in populations of the target organism as a result of the use of the GMO (e.g. increased resistance to the modified organism)? What evidence is there for this response?	C3,C10, C8

APPENDIX 1:
QUESTIONNAIRE FOR RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS (GMOs) RELATED TO AGRICULTURE

J. ORGANISMS FOR BIOREMEDIATION

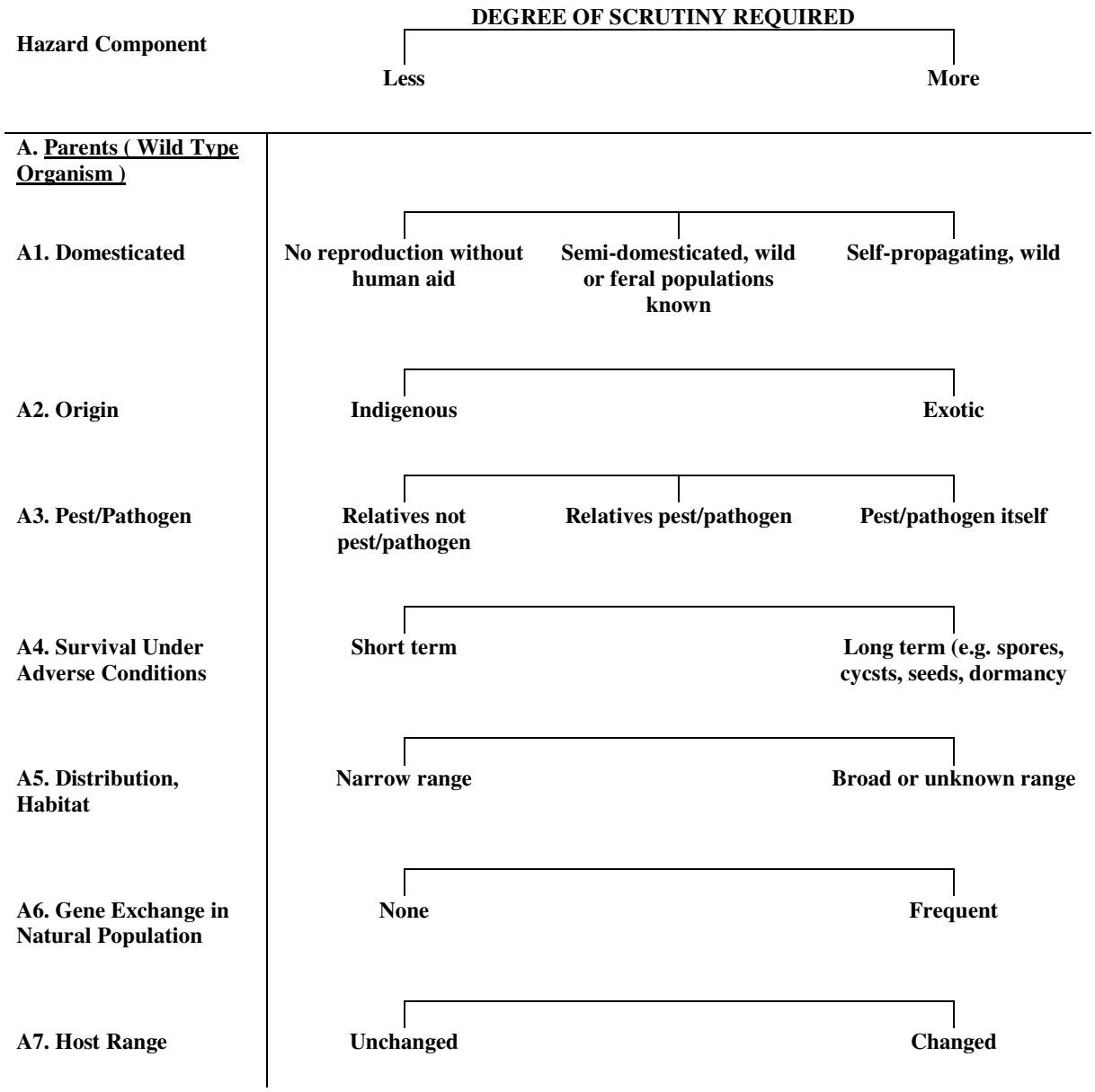
		Risk Assessment Criteria **(See Appendix 2)**
1.	What is the target substrate for bioremediation?	General Information
2.	What effect does the parent organism have on the target substrate?	General Information
3.	What effect does the GMO have on the target substrate?	General Information
4.	What other substances can be metabolized by the GMO which cannot be metabolized by the parent organism?	C4
5.	Will the GMO be self-sufficient once exposed to the target substrate or will additional measures be required (e.g. provision of supplementary nutrients and growth factors or other environmental modifications)?	C5
6.	Does the GMO produce metabolites which may have deleterious effects directly on other organisms or indirectly through concentration in the food chain? If so, specify.	C2, E3, C8
7.	What effects might the GMO have on water, air or soil quality?	D4
8.	What effects might the GMO have on organisms which ingest it?	D8, E2
9.	Will the GMO be dispersed from the site of application? If so, describe the mechanisms involved and the consequences.	D2, D3

APPENDIX 1:
QUESTIONNAIRE FOR RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS (GMOs) RELATED TO AGRICULTURE

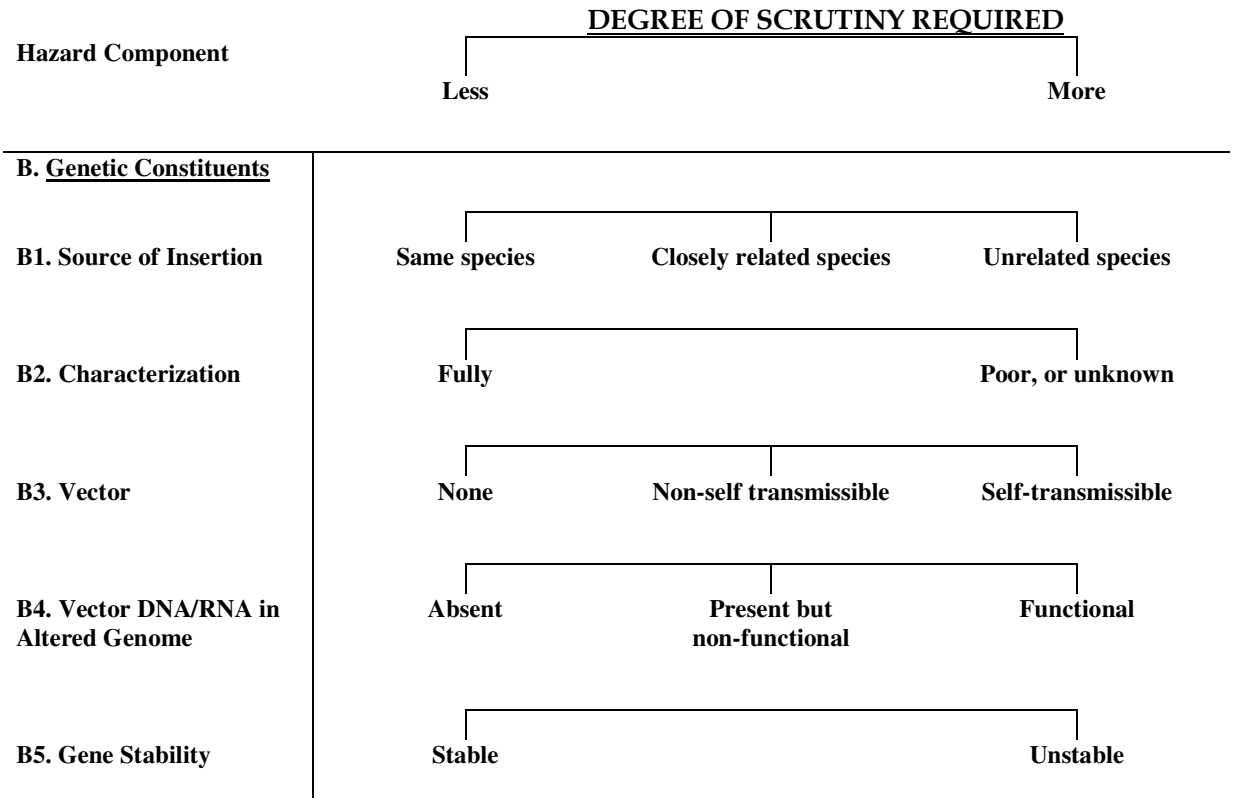
K. ORGANISMS TO BE CONSUMED AS FOOD

		Risk Assessment Criteria **(See Appendix 2)**
1.	Is the parent organism or the donor organism already used in food production or eaten as food? If so, (i) at what level of daily/weekly intake, and (ii) is any processing needed or commonly used before consumption?	E1
2.	Does the GMO produce metabolites which may have adverse effects on the consumer (humans or animals)? If so, elaborate. Provide available data on toxicology, allergenicity and other possible adverse effects.	E2, E3
3.	Can any products of the GMO concentrate in the food chain to levels which may become toxic? If so, elaborate.	E3
4.	Will the nutritional quality of the food be changed by the genetic modification? If so, how?	E1
5.	Is the GMO to be processed during the production of the food? If so, elaborate.	General Information
6.	Is the GMO the major component of the food as eaten, or is it in small numbers in the final product	E4

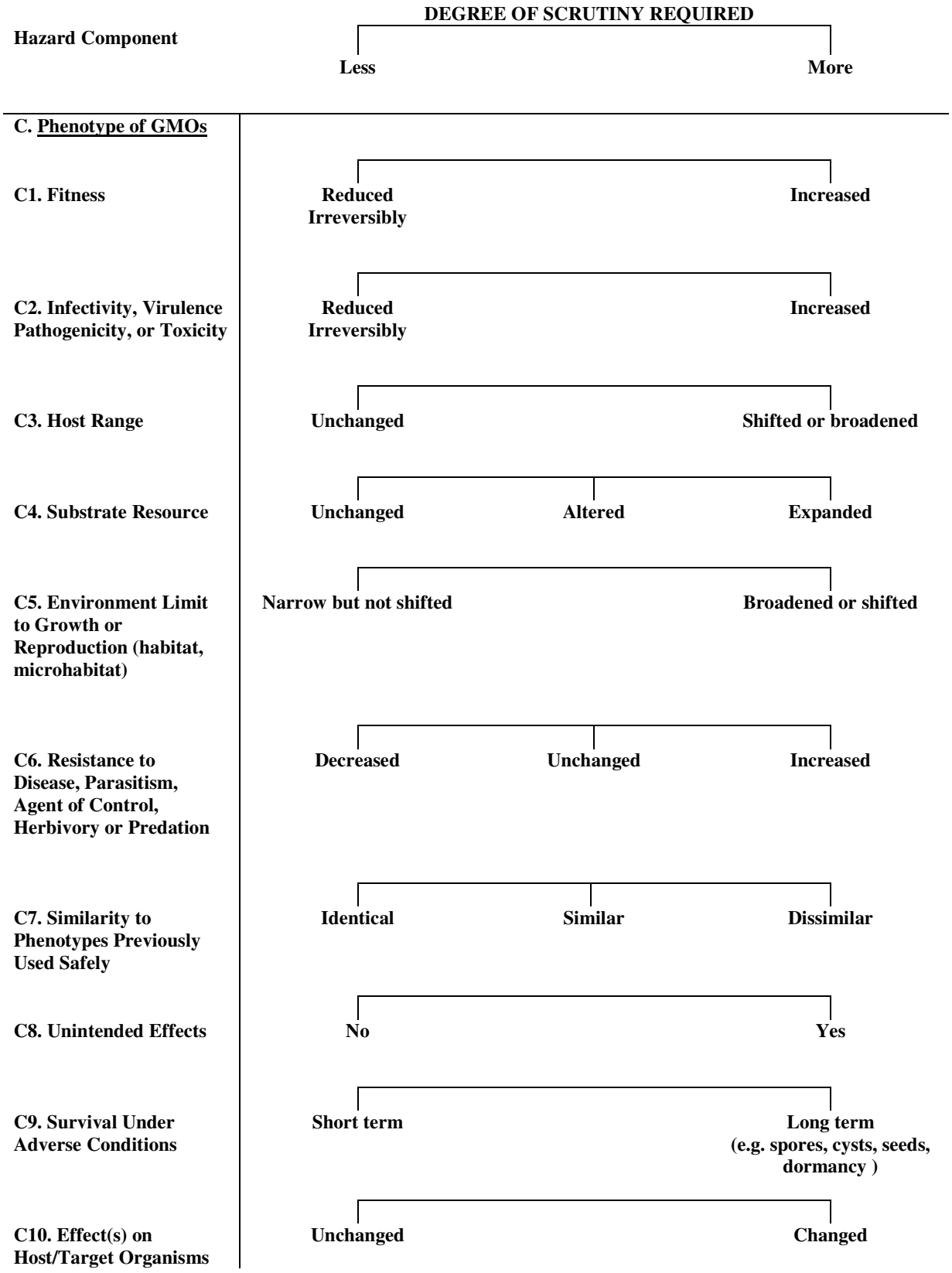
APPENDIX 2:
RISK ASSESSMENT CRITERIA



APPENDIX 2:
RISK ASSESSMENT CRITERIA



APPENDIX 2:
RISK ASSESSMENT CRITERIA



APPENDIX 2:
RISK ASSESSMENT CRITERIA

Hazard Component	DEGREE OF SCRUTINY REQUIRED Less ⟷ More
D. Attributes of the Environment	
D1. Positive Selection for GMO	Absent ⟷ Present
D2. Dispersal Possible to Wild, Weedy, or Feral Relatives/Gene Transfer to Other Organisms	No ⟷ Yes
D3. Vectors or Agents of Dissemination or Dispersal (mites, insects, rodents, birds, humans, machines, wind, water etc.	Absent or Controllable ⟷ Present or uncontrollable
D4. Effects on Ecosystem	No ⟷ Marginal ⟷ Yes
D5. Range of Environments For Testing or Use: Potential Geographical Range	Very restricted ⟷ Broad, Widespread
D6. Simulation of Test Conditions	Can simulate Realistically ⟷ Very difficult to simulate realistically
D7. Effectiveness of Monitoring and Mitigation Plans	Proven Effective ⟷ Untested or Unlikely to be effective
D8. Effect on Non-Target Organism	Known ⟷ Unknown

APPENDIX 2:
RISK ASSESSMENT CRITERIA

Hazard Component	DEGREE OF SCRUTINY REQUIRED Less — More
E. Food Safety	
E1. Substantial Equivalence	Yes — No
E2. Toxicity and Allergenicity	No — Yes
E3. Concentration of GMO/its Products in Food Chain	No — Yes
E4. Quantity of GMO/its Products to be Consumed	Low — High

APPENDIX 3:
FLOW CHART FOR EVALUATION, APPROVAL AND REGISTRATION OF AGRICULTURE-RELATED GENETICALLY MODIFIED ORGANISMS (GMOs)