(THIS IS A MULTI-AGENCY JOINT CIRCULAR)

GMAC/08-01

6 Nov 2008

To: All Researchers, Traders,
Heads of Research Institutions, Laboratories, Companies,
and all other stakeholders dealing with Genetically Modified Organisms

Dear Sir/Mdm

BIOSAFETY GUIDELINES FOR RESEARCH, RELEASE AND IMPORTATION OF GENETICALLY MODIFIED ORGANISMS

Advances in recombinant DNA technology have resulted in increasingly common use of genetically modified organisms (GMOs) in multiple fields. Heightened biosafety awareness has prompted many countries and international organizations to develop legislations and guidelines to regulate the use of recombinant DNA technology, GMOs, and GMO-derived products.

2 The Genetic Modification Advisory Committee of Singapore (GMAC) has also developed two sets of biosafety guidelines for research and commercial releases of GMOs. GMAC, together with the Ministry of Health (MOH), the Ministry of Manpower (MOM), the Ministry of the Environment and Water Resources (MEWR), the National Environment Agency (NEA), and the Agri-Food and Veterinary Authority of Singapore (AVA), encourage all researchers, traders and other stakeholders dealing with GMOs to comply with these guidelines. We also seek the support of the Heads of research institutions, laboratories, and companies in ensuring their organizations' compliance with the GMAC guidelines.

The Singapore Biosafety Guidelines for Research on GMOs (the "GMAC Research Guidelines")

3 The Singapore Biosafety Guidelines for Research on GMOs (the "GMAC Research Guidelines") was drawn up with the objective of ensuring the safe containment, handling and transport of GMOs used in research. It is the first and only set of biosafety standards designed specifically for laboratories conducting GM research in Singapore. In formulating the GMAC Research Guidelines, GMAC had closely consulted local regulatory agencies and other stakeholders and had also carried out extensive reviews of relevant guidelines, regulations, and publications including those from Australia, the United States of America, and the World Health Organization.

4 The GMAC Research Guidelines differentiates experiments involving GMOs or GMO-derived materials into three categories (Categories A, B, and C), based on their potential risks. Details on how experiments are to be classified are given under Section 4 of the GMAC Research Guidelines.

The Roles and Responsibilities of Principal Investigators and the Institutional Biosafety Committees

5 A central philosophy of the GMAC Research Guidelines is that every Principal Investigator (PI) of research projects involving GMOs and/or GMO-derived products must take responsibility in assessing the risk of his/her own work. Specifically, PIs should be thoroughly familiar with the requirements of the GMAC Research Guidelines, and should determine whether their own research proposals are within the scope of the guidelines. When research proposals fall under Category A or B of the GMAC Research Guidelines, PIs have the responsibility to submit details of these proposals for additional scrutiny and approval by their respective Institutional Biosafety Committees (IBCs). The GMAC Research Guidelines specifies that any institution, company, or organization that carries out genetic manipulation, imports organisms arising from such work, produces such organisms, or plans to sell or release such organisms into the environment, are required to establish an IBC.

6 The IBCs are vital for the day-to-day enforcement and implementation of the GMAC Research Guidelines. Among other things, each IBC is to assess proposals submitted by researchers within its host institution and determine the appropriate working and containment measures and facilities necessary. Upon its approval of each Category A or B research project, the IBC should forward the proposal, together with a summary of its recommendations or comments, to GMAC for notification or additional review. Information exchange is common between GMAC and the regulatory agencies. For experiments involving genetic manipulations of organisms controlled by the regulatory agencies, GMAC's endorsement will often be taken as a prerequisite for the regulatory agencies to consider their formal approvals.

7 The IBCs also play a very important role in the monitoring and surveillance of ongoing genetic manipulation work within the host institutions, so as to ensure that their recommendations and that of GMAC are being adhered to by the researchers.

8 The roles and responsibilities of PIs and IBCs are detailed under Section 5 of the GMAC Research Guidelines.

9 The procedure for assessment and notification of GM research work is summarized in Annex A of this circular and detailed under Section 3 of the GMAC Research Guidelines.

Importation of GMOs for Research

10 Sections 3.2 and 6 of the GMAC Research Guidelines are provisions for the importation of GMOs for research purposes. Proposals involving the importation of GMOs falling under Category A and/or B need to be supported by the IBCs. Formal import permits, where applicable, ought to be sought from the relevant regulatory agency (e.g. the MOH, AVA, or NEA). The GM nature of the organisms to be imported should be declared. In assessing the applications, the IBCs and regulatory agencies may seek advice from GMAC.

11 The approval procedure for importation of GMOs for research is summarized in Annex B of this circular.

IBC Composition

12 The calibre and experience of IBC members should be such that it can competently undertake its important duties. Section 5.2.2 of the GMAC Research Guidelines provides guidance on the recommended composition of the IBCs.

13 ***All research institutions, companies, or organizations that carries out genetic manipulation, imports organisms arising from such work, produces such organisms, or plans to sell or release such organisms into the environment are urged to submit details on their IBC compositions to GMAC by filling up the form in Annex C of this circular, if they have not already done so within the past 12 months.***

The Singapore Guidelines on the Release of Agriculture-Related GMOs (the "GMAC Release Guidelines")

14 The GMAC Research Guidelines covers the use of GMOs and GMO-derived products under contained conditions. A second set of guidelines – the Singapore Guidelines on the Release of Agriculture-Related GMOs (the "GMAC Release Guidelines") – becomes applicable when there are intentions to release GMOs into the environment.

15 The GMAC Release Guidelines provide a common framework for the risk assessment and approval of proposed releases of agriculture-related GMOs in Singapore. It covers intentional releases of the following types of agriculture-related GMOs:

i) GM plants
ii) GM microorganisms living in or on animals
iii) GM microorganisms as vaccines
iv) GM microorganisms not falling under (ii) or (iii)
v) GM animals (invertebrates, not including fish)
vi) GM fish and aquatic organisms such as crustaceans
vii) GM invertebrates
viii) GMOs for biological control
ix) GMOs for bioremediation
x) GMOs to be consumed as food

16 Under the GMAC Release Guidelines, before the release of any agriculture-related GMOs in Singapore, the proponent is required to submit a proposal and relevant experimental data to GMAC for a scientific risk assessment. As GMAC is an advisory committee, formal approvals for the release of GMOs in Singapore will be granted by the relevant regulatory agency. GMAC, at the conclusion of its assessment of each application, will forward its recommendations to the appropriate regulatory agency. GMAC's endorsement will be a key consideration of regulatory agencies when they decide on their formal approval of GM-related applications.

17 The procedure for the evaluation and approval of proposals to release agriculture-related GMOs in Singapore is summarized in Annex D of this circular.

Important Note

18 The two sets of GMAC guidelines are designed to supplement existing rules, legislations and regulations by the various regulatory agencies. Exemptions from the

GMAC guidelines do not confer exemptions from existing rules, legislations and regulations.

19 Copies of the GMAC guidelines, relevant application forms, and further details can be viewed and downloaded from http://www.gmac.gov.sg/Index_Guidelines_Overview_on_GMAC_Guidelines.html.

20 For enquiries or clarifications please contact GMAC Secretariat at Tel: 6826-6355 or Email: info@gmac.gov.sg. We will also appreciate your feedback and suggestions on how we may further improve the GMAC guidelines.

Thank you

This is a joint message from the Genetic Modification Advisory Committee of Singapore (GMAC), the Ministry of Health (MOH), the Ministry of Manpower (MOM), the Ministry of the Environment and Water Resources (MEWR), the National Environment Agency (NEA), and the Agri-Food and Veterinary Authority of Singapore (AVA).

(This is a computer-generated circular and requires no signature.)

About GMAC

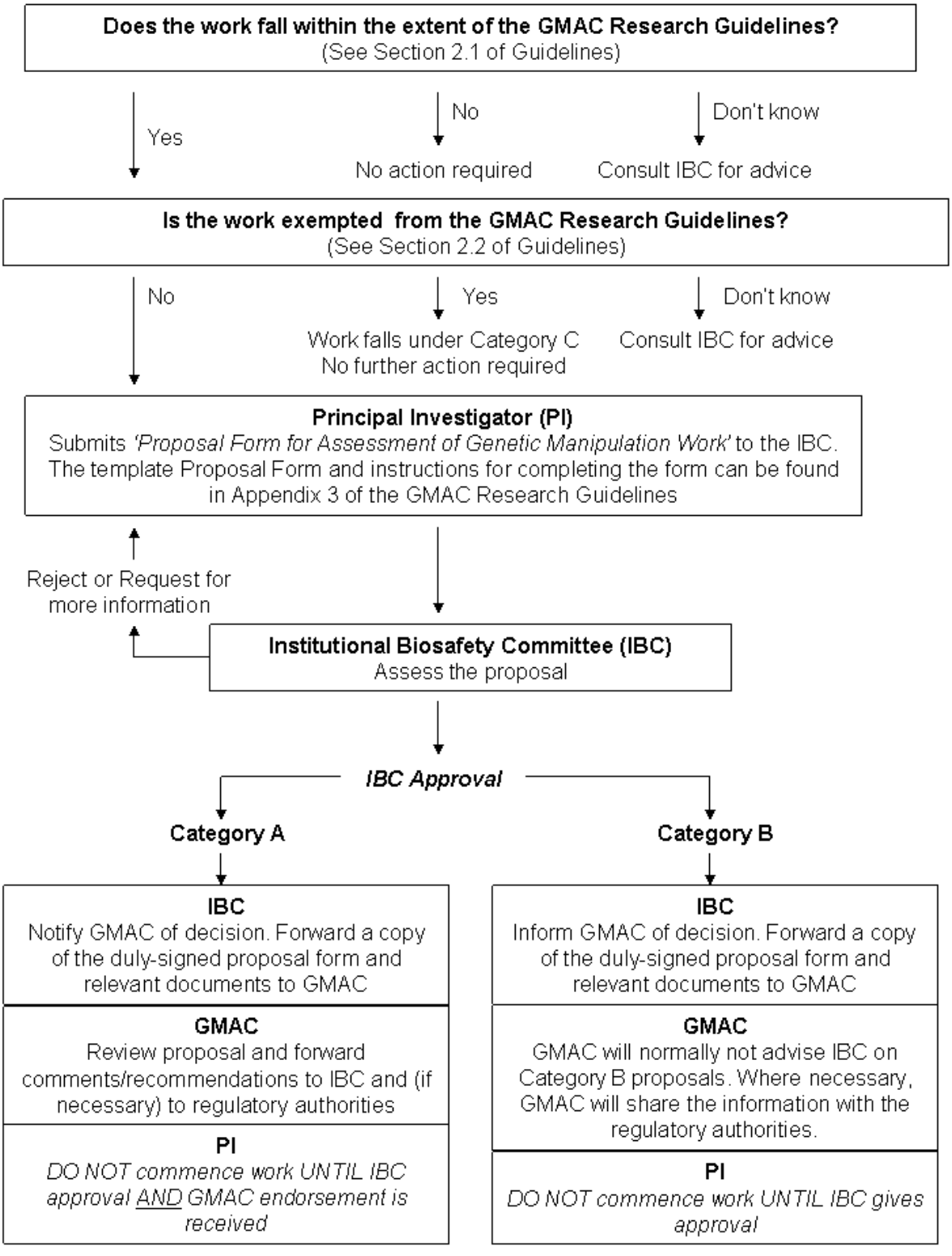
Established under the purview of the Ministry of Trade and Industry in 1999, GMAC is the national committee tasked to oversee and advise on the research and development, production, use and handling of GMOs in Singapore. GMAC is a multi-agency committee comprising senior designates drawn from various regulatory agencies, statutory boards, research and academic institutions, and consumer interest groups.

GMAC's objective is to ensure public safety while allowing for the commercial use of GMOs and GMO-derived products by companies and research institutions, in compliance with international standards. In this regard, GMAC has published the Singapore Guidelines on the Release of Agriculture-Related GMOs and the Singapore Biosafety Guidelines for Research on GMOs.

GMAC has and will continue to work closely with the regulatory agencies in implementing its guidelines.

ANNEX A

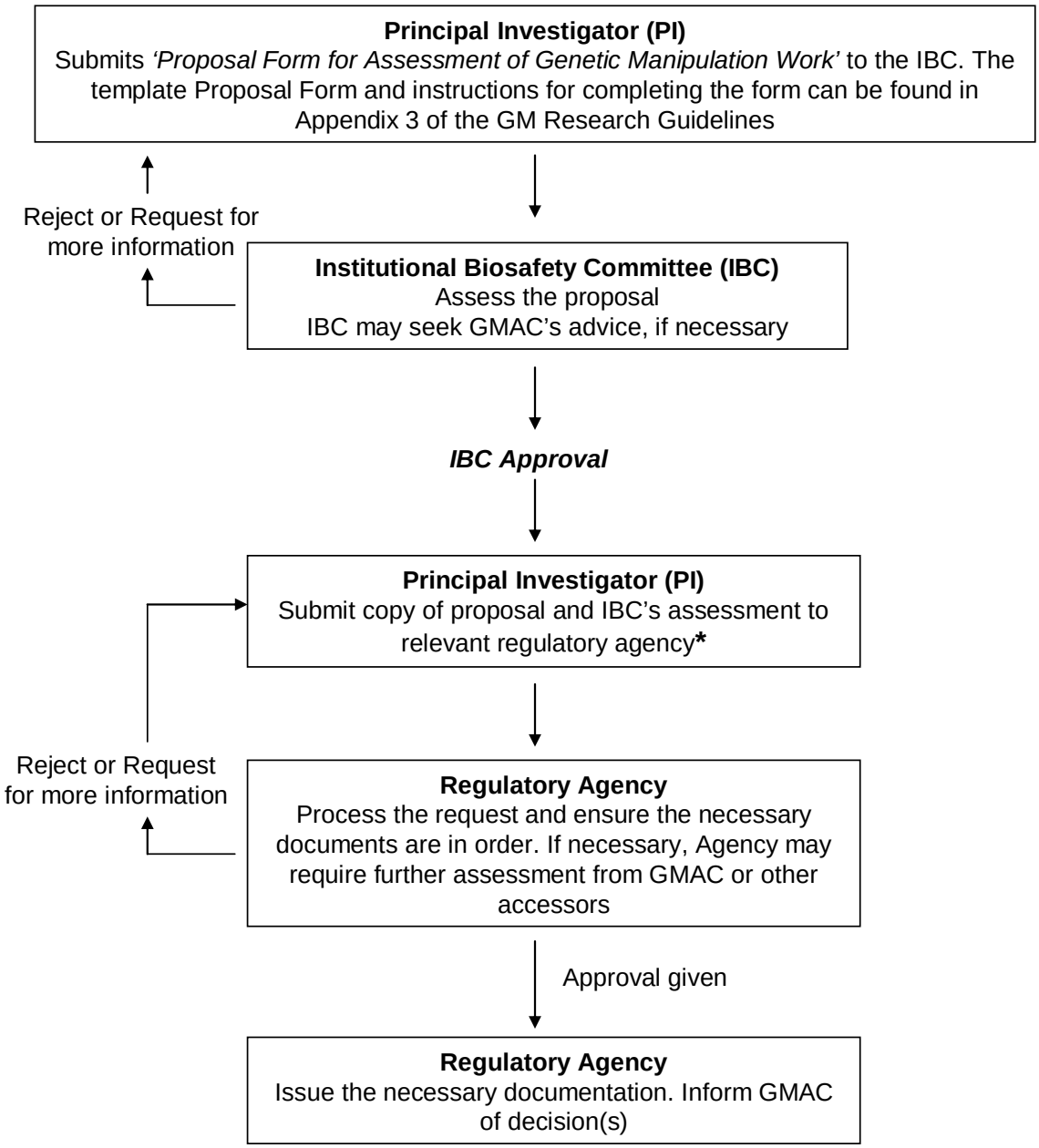
DECISION FLOW CHART FOR THE ASSESSMENT AND NOTIFICATION OF RESEARCH WORK INVOLVING GMOs OR GMO-DERIVED MATERIALS



ANNEX B

FLOW CHART FOR IMPORTATION OF GMOs FOR RESEARCH

(Applicable to GMOs falling under Category A and/or B)



***Relevant Regulatory Agencies Controlling the Importation of Different Types of Organisms/Materials[1]:**

Type of Organism/ Material to be Imported[1]	**Regulatory Agency Involved[2]**	**Relevant Legislation[3]**	**Relevant Contact(s)**
Biological agents and toxins capable of causing death, disease or malfunctions in humans, as those specified under the First, Second, Fourth and Fifth Schedules of the Biological Agents and Toxins Act	MOH	Biological Agents and Toxins Act (Cap 24A)	Email: MOH_Biosafety@moh.gov.sg Website: www.biosafety.moh.gov.sg
Plants, animals, and plant-related or animal-related pathogens and pests	AVA	Control of Plants Act (Cap 57A) Animals and Birds Act (Cap 7, Part II, Section 9)	*For plants and plant-related pests:* Email: ava_phytosanitary@ava.gov.sg *For animals and animal-related pathogens:* Email: ava_import&export_animals@ava.gov.sg
Vectors capable of transmitting diseases	NEA	Infectious Diseases Act (Cap 137, Part V, Section 40) Control of Vectors and Pesticides Act (Cap 59, Part IV, Section 16)	Environmental Health Department Email: Contact_NEA@nea.gov.sg

[1] Applicable for both GMOs and non-GMOs. Where GMOs are concerned, the GMAC guidelines should be adhered to in addition to relevant legislation.

[2] Certain organisms/materials are jointly controlled by two or more agencies. When importers are unclear of which regulatory agencies they should approach, they could approach GMAC for guidance.

[3] Relevant legislation (with provisions on the penalties for non-compliance), can be viewed from Singapore Statutes Online at http://statutes.agc.gov.sg.

ANNEX C

REPORT ON THE COMPOSITION OF THE INSTITUTIONAL BIOSAFETY COMMITTEE

Name of Institution: _____

Address of Institution: _____

_____

_____

Name of Contact Person: _____

Email Address of Contact Person: _____

Telephone No. of Contact Person: _____

Submitted by: _____ Date: _____

Name and Signature

Composition of IBC

IBC APPOINTMENT	NAME	DESIGNATION
Chairman		
Biological Safety Officer		
Committee Members		

(Attach separate sheet if necessary)

Please submit this form to:

Secretariat, Genetic Modification Advisory Committee (GMAC)
20 Biopolis Way, #08-01 Centros, Singapore 138668
Tel: 68266-355
Fax: 6478-9581
Email: info@gmac.gov.sg | Website: www.gmac.gov.sg

ANNEX D

FLOW CHART FOR THE EVALUATION AND APPROVAL OF PROPOSED RELEASES OF AGRICULTURE-RELATED GMOs