Genetic Modification Advisory Committee

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Notice to Adopt the Revised Singapore Biosafety Guidelines on the Research on GMOs 2020

Background

1 In 2020, the Genetic Modification Advisory Committee (GMAC) invited regulatory agencies and stakeholders to give feedback on the proposed amendments to the Singapore Biosafety Guidelines for Research on Genetically Modified Organisms (GMOs) (henceforth referred to as Guidelines). The proposed amendments sought to update the Guidelines. GMAC would like to thank all agencies and stakeholders who participated in the public consultation process.

Summary of Responses

2 Respondents from the consultation exercise suggested refinements to the proposed amendments and also proposed other amendments to the Guidelines. GMAC has considered and incorporated some of these suggestions in finalizing the amendments. GMAC has taken into account the need to uphold the objectives of the Guidelines to ensure safe containment, handling and transport of GMOs used in research and at the same time to provide a common framework for assessment and notification of research on GMOs.

3 A list of major changes made to the revised Guidelines can be found in Annex A of this document.

How to obtain a copy of the Singapore Biosafety Guidelines for Research on GMOs (2020)

4 The Singapore Biosafety Guidelines for Research on GMOs (2020) is now available from the GMAC Website (as PDF).

For more info, kindly contact:

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NOTICE PERTINENT TO THE 2020 REVISIONS OF THE SINGAPORE BIOSAFETY GUIDELINES FOR RESEARCH ON GENETICALLY MODIFIED ORGANISMS (GMOs)

Summary of Amendments [Major Actions]

Annex A

Section	Original	Revised
2.2 Exemption	"If further manipulations are performed on any of the above described transgenic organisms, they may not be automatically exempted from the guidelines…"	"If further manipulations (e.g. breeding with genetic crossing) are performed on any of the above described genetically modified organisms, they may not be automatically exempted from the guidelines…"
3.2 Flow Chart for Importation of GMOs for Research	Flow chart indicated that the IBC and regulatory agency may require further assessment from GMAC for import applications and approvals. To make it clear that PI would not be required to submit GMAC proposal for importation purposes unless instructed by the agency/IBC, the section was revised.	The flowchart was removed and replaced with the paragraph, "Principal investigators intending to import GMOs for research should approach the IBC for assessment and the relevant regulatory agency for import approval. If necessary, the IBC and/or regulatory agency may seek GMAC's advice".
3.5 Category C	Cat C proposals no longer need to be submitted by GMAC and will be filed independently by the IBC: "Experiments in this category are exempt from the guidelines and therefore, the 'Proposal Form for Assessment of Genetic Manipulation Work' does not need to be submitted to GMAC. However, experiments in this category still require assessment by the IBC before commencement. Principal Investigators are to inform IBC of their projects by forwarding the duly-signed proposal form and relevant documents. Principal investigators who are unsure if their work falls under the exemptions in Sections 2.2.1 (i) – 2.2.1 (vii) should submit a proposal form to their respective IBCs for assessment. The IBC shall assess the proposal and determine the appropriate categorisation. Principal investigators **should not** start Category C experiments until advised by the IBC.	

5.2.7 Reporting requirements	IBCs are no longer required to submit annual reports.
6 Import, export and transport for GMOs	Contact details from relevant regulatory agencies were updated with inputs from NParks divisions: Plant Science and Health – For plants; and Animal & Veterinary Service – Industry & Biosecurity Management Division.
Appendix 2 List of approved host, vector systems	The updated list is now found on GMAC's webpage as the following link: https://www.gmac.sg/pdf/Research/List%20of%20GMAC-approved%20host,%20vector%20systems%202020.pdf
Appendix 3 Instructions for completing GMAC proposal forms	New paragraph inserted to clarify on the validity period of GMAC's endorsement: "GMAC's endorsement will be valid from the date of receipt of the endorsement for the total number of years corresponding to project duration as indicated in question 9 of the GMAC proposal form. For example, if the PI indicates that the duration of experiment is 3 years, the expiration would occur in 3 years' time from the date on which IBC receives the endorsement from GMAC." Removal of GMAC's extension form; proposals will be extended administratively via email correspondence and renewed proposals will observe the following naming convention indicating the number of extensions for the specific proposal, e.g. Res-16-252-E1, Res-16-252-E2. Cat C renewals now fall under IBC records and do not have to be notified to GMAC.

	New section added to clarify the intent of question 8 regarding the DURC checklist: **Assessment on DURC** Researchers will find in the GMAC proposal form a question on DURC for experiments involving microorganism/virus/toxins. The purpose of the question is to screen for possible dual use research of concern for the research project. According to the WHO[1], dual use research of concern (DURC) is life sciences research that is intended for benefit, but which might easily be misapplied to do harm. The possibility that dual use research might result in misuse, either intentionally or accidentally, is a long-standing concern of science. The issues are broad and encompass not only research and public health, but also security, scientific publishing and public communications, biotechnology and ethics and wider societal issues. As GMAC has an established review process, it is appropriate to include a screen for such concerns within its proposal form. As such, this question serves as a checklist for DURC that is relevant to research work involving GMOs. Please also find a relevant document for more information on DURC, "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern": https://www.phe.gov/s3/dualuse/Documents/oversight-durc.pdf

[1] Definition of DURC available on WHO website: https://www.who.int/csr/durc/en/

Appendix 8 Biosafety requirements for biosafety level 2	Removed sections of this appendix which listed general guidelines on BSL 2 as appendix 7 had already made reference to the WHO Biosafety Manual, as the references are good for the purpose of providing users info pertaining to general operational requirements of BSL2 facilities. Requirements specific for GM microorganisms, animals, arthropods, aquatic animals and plants remain.