



## **Notice to Adopt the Revised Singapore Biosafety Guidelines on the Research on GMOs**

### Background

1 In March 2012, 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 amendments 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 (2013)

4 The Singapore Biosafety Guidelines for Research on GMOs (2013) is now available from the GMAC Website (as PDF). Should you require a printed copy of the Guidelines, please submit your request to the GMAC Secretariat.

### Contact Details

5 Genetic Modification Advisory Committee (GMAC) Secretariat  
20 Biopolis Way  
#08-01, Centros  
Singapore 138668  
Tel: (65) 64070515  
Email: [info@gmac.gov.sg](mailto:info@gmac.gov.sg)

**NOTICE PERTINENT TO THE 2013 REVISIONS OF THE SINGAPORE BIOSAFETY GUIDELINES FOR RESEARCH ON  
GENETICALLY MODIFIED ORGANISMS (GMOs)  
GENETIC MODIFICATION ADVISORY COMMITTEE (GMAC)**

**Summary of Amendments [Major Actions]**

Page 5	Section 2.3: New Sub-section: Work Subjected to Other and/or Additional Regulatory Requirements.
Page 23 - 24	Section 6.2: New Section on Transport of Genetically Modified Microorganisms
Appendix - Page 5	Appendix 1: New Relevant Guidelines: Arthropod Containment Guidelines (Version 3.1)
Appendix - Page 7	Appendix 2: New GMAC - Approved Host/Vector Systems ( <i>Advanced Generation of lentiviral vector (3<sup>rd</sup> generation and later</i> )).
Appendix - Page 8	Appendix 3: New Instructions for GMAC Proposal Form for Extension of Endorsement.
Proposal Form for Extension of GMAC Endorsement - Page 1 of 1	Appendix 3: New GMAC Proposal Form for Extension of Endorsement.
Appendix - Page 10	Appendix 4: New Toxins ( <i>T-2 Toxin, HT-2 Toxin and Tetanus Toxin</i> ).
	Appendix 19: Removed Appendix 19 Regulated Organisms
Appendix - Page 38- 41	Appendix 19: New Appendix: Disposal.
Appendix - Page 42- 43	Appendix 20: New Appendix: Preclinical Research Involving HIV-1 Based Lentiviral Vectors.

## Summary of Amendments [Minor Actions] - Additions/Corrections/Updates

	Table of Contents: Renumbered.
Page 1	Section 1.1: Updated GMAC Secretariat contact details.
Page 4	Section 1.4: Added definition of GMMs.
Page 3	Section 2.1: Exclusion of work involving human subjects.
Page 3	Section 2.1: Removed paragraphs 2.1.4, 2.1.5 and 2.1.6.
Page 4	Section 2.2: Added new class of experiments to be exempted ( <i>iv</i> ).
Page 5	Section 2.3.1: Removed “Section 2(c)” from first sentence; replaced “are” with “may be” in second sentence.
Page 5	Section 2.3.2: Removed reference to the Ministry of Health (MOH) in the first sentence.
Page 6	Section 2.4: previously Section 2.3, renumbered; Added “( <i>The requirements of the regulatory bodies should be met; See Appendix 1 for relevant local Acts</i> )”; Updated the MOH and Ministry of Manpower (MOM) scope of work.
Page 7	Section 3.1: Updated Workflow for Cat B and C Proposals.
Page 8	Section 3.2: Updated link to Tradenet via Singapore Customs URL.
Page 10	Section 3.4: Added “ <i>review and forward comments/recommendations to IBC and if necessary, to relevant regulatory authorities.</i> ” to Category B experiments.
Page 10	Section 3.5: Added “ <i>Principal Investigators are encouraged to inform IBC of their decision by forwarding a duly-signed proposal form and relevant documents.</i> ” in 2 <sup>nd</sup> paragraph.
Page 13	Section 4.2: Added “ <i>usually</i> ” in B(iii)(a).
Page 18	Sub-section 5.2.8: Title changed to “ <i>Medical Surveillance of Workers</i> ”
Page 18	Sub-section 5.2.9: Added “ <i>Under the WSHA, it may be required for such incidents to be reported to the MOM and/or relevant regulatory agencies.</i> ”
Page 20	Section 6: Title changed to “ <i>Import, Export and Transport of GMOs and/or GMO-derived Materials</i> ”
Page 20 - 23	Section 6.1: Updated Section; added new sub-section 6.1.3 Risk Classification and 6.1.5 Labelling
Page 24 - 25	Section 6.3: New titles - “6.3.1 General Considerations” and “6.3.2 Packaging and Transport Requirements”
Page 25 - 26	Section 6.4: Replacement of the term “ <i>insects</i> ” with “ <i>arthropod</i> ”; New sub-sections- “6.4.1 General Considerations”, “6.4.2 Packaging and Transport Requirements”, “6.4.3 Labelling”, “6.4.4 Treatment of containment after transportation”
Page 26	Section 6.5: New titles - “6.5.1 Packaging and Transport Requirements”, “6.5.2 Labelling”, “6.5.3 Documentation”
Page 27	Section 6.6.1: Added “ <i>If the genetically manipulated materials fall under the First, Second and Fifth</i>

	<i>Schedule of the BATA, MOH shall be notified of the transfer of the materials.”</i>
Page 27	Section 6.6.2: Replaced Article 19.4 of the Convention on Biological Diversity with exportation legislation in Singapore and contact details of the relevant regulatory agencies.
Page 28	Section 6.7.1: Added <i>“Part IV of the Control of Vectors and Pesticides Act (Cap 59)”</i>
Page 28	Section 6.7.3: Added <i>“arthropod”</i> to the list of GM organisms under the purview of the Guidelines.  In view of the removal of Appendix 19 Regulated Organisms, references of regulated organisms in Singapore were added <i>“Regulated organisms are stated in the Bio-security Assurance Arrangement Guidelines and the Notifiable Diseases list of the Animal and Birds Act of the Agri-food and Veterinary Authority (AVA). The import of any arthropod vectors capable of transmitting infectious diseases regulated in the Infectious Diseases Act (Cap 137) of the National Environmental Agency (NEA).”</i>
Page 28	Section 6.7.4: Added <i>“After obtaining the permission from the relevant agencies, the importer should apply for an import permit through TradeNet® (Link can be found on URL: <a href="http://www.customs.gov.sg/">http://www.customs.gov.sg/</a>).”</i>  Updated contact details of the Agri-Food & Veterinary Authority (AVA) and National Environmental Agency (NEA).
Page 29	Section 6.7.5: The term <i>“form”</i> was replaced by <i>“information provided”</i>
Appendix - Page 1	1. Relevant Local Legislation: Added <i>“The requirements of the regulatory bodies should be met”</i>
Appendix - Page 1	2.3 Guidelines on the Care and Use of Animals for Scientific Purposes, NACLAR: Updated contact details of NACLAR and added <i>“as a downloadable PDF from <a href="http://www.ava.gov.sg/AnimalsPetSector/CareAndUseAnimalsForScientificPurp/">http://www.ava.gov.sg/AnimalsPetSector/CareAndUseAnimalsForScientificPurp/</a>”</i>
Proposal Form for Assessment of Genetic Manipulation - Page 2 of 3	Added New Section 5a: Nature of transgene(s)
Appendix - Page 12	Appendix 5: Added <i>“as appropriate PPE”</i> in 4(a) and <i>“decontaminated with an efficacious chemical disinfectant or autoclaved before disposal, taking into considerations sharps disposal requirements”</i> in 4(d).
Appendix - Page 13	Appendix 5: Amended <i>“hood”</i> to <i>“biosafety cabinet/laminar flow hood”</i> in 4(k).
Appendix - Page 28	Appendix 13: Added <i>“provisions set out in Appendix 19 of the Guidelines”</i> in paragraph 7.
Appendix - Page 34	Appendix 16: Added <i>“Arthropod Containment Guidelines (American Society of Tropical Medicine and Hygiene) in the construction and operation of a Arthropod Containment Level (ACL)-2 insectary.... These standards may also be applicable for work with insects and/or their pathogens where a higher level of biological containment is usually necessary, provided that only non-flying stages of insects</i>

	<p><i>(eggs and larvae), and genetically crippled strains of the pathogen is used, such that transmission is not possible. Genetically manipulated insects (GMI) infected with pathogens shall be housed in a separate facility or in different rooms.</i>" in Paragraph 1.</p> <p>Amended "BSL-2" to "ACL-2" in Paragraph 2.</p> <p>Added "<i>These materials should be disposed of by waste disposal contractors licensed by NEA and in accordance to NEA guidelines on disposal of such waste.</i>" as Paragraph 3.</p> <p>Removed sections on Construction and Operating Procedures.</p>
Appendix - Page 35	<p>Replaced "BSL" to "ACL".</p> <p>Added "<i>The standards specified in Arthropod Containment Guidelines (American Society of Tropical Medicine and Hygiene) in the construction and operation of a ACL-3 insectary are regarded as suitable minima for genetic manipulation work involving insects which falls under Category A in Section 3 of these Guidelines.</i>" in Paragraph 1.</p> <p>Added "<i>(See Appendix 16)</i>" in Paragraph 3.</p> <p>Added "<i>These materials should be disposed of by waste disposal contractors licensed by NEA and in accordance to NEA guidelines on disposal of such waste.</i>" in Paragraph 4.</p> <p>Removed sections on Construction and Operating Procedures.</p>
Appendix - Page 44 and 46	Appendix 20: New definition of the terms - ACL, BATA and GMM.
Various Locations	References to OSH Guidelines were changed to Laboratory Biosafety Manual, 3 <sup>rd</sup> Edition, World Health Organization, 2004