

MH 78:70 V14



**MINISTRY OF HEALTH
SINGAPORE**

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All Heads,
Departments of Microbiology of Hospitals/Diagnostic Laboratories

**MOH CIRCULAR 34/2006
“DIAGNOSIS” UNDER SECTION 4(1)(B) OF THE BIOLOGICAL AGENTS AND
TOXINS ACT 2005 (‘BATA’)**

This administrative circular addresses the interpretation of diagnosis as applied to the Biological Agents and Toxins Act 2005 (BATA). It does not purport to be a full and binding statement of law. This circular does not constitute guidance or advice. Anyone in doubt about how they may be affected by BATA may wish to seek legal advice.

2 Section 4(1)(b) of the Biological Agents and Toxins Act 2005 (‘BATA’) states that Parts III to IV of the Act, with the exception of section 41(e), shall not apply in relation to the handling of any biological agent or toxin in the course of carrying out a diagnosis or autopsy (hereafter “the Exclusion”). “Diagnosis” is in turn defined in section 2 of the Act to mean any activity undertaken solely with the intention of analyzing any specimen from a person or an animal in which a biological agent is or is suspected of being present for the purpose of (a) determining the cause of death of any disease suffered by any person or animal; (b) assessing the clinical progress of any person or animal; (c) carrying out the clinical management of any person or animal; or (d) determining the cause of death of any person or animal in an autopsy.

3 The Exclusion provided for in section 4(1)(b) of BATA will not cover activities such as, but not limited to, the importation, production and storage of specimens known to contain biological agents or toxins regulated under the Act. The Act also does not distinguish between the types of laboratory, diagnostic or otherwise, where such activities are carried out.

4 The Exclusion will, however, cover the handling of positive samples of biological agents or toxins in order to carry out diagnosis of unknown clinical samples taken from persons or animals. This is provided that the positive samples, together with any biological agents and toxins positively identified in any clinical samples, are destroyed or are transferred to a facility that has been granted the requisite approvals to possess such biological agents or toxins as soon as possible after confirmation of diagnostic test results. Approval under BATA will have to be obtained if diagnostic laboratories intend to possess biological agents or toxins beyond the Exclusion.

5 Please contact the following officer at the Biosafety Branch for further clarifications:
Se Thoe Su Yun: Se_Thoe_Su_Yun@moh.gov.sg

A handwritten signature in black ink, appearing to be 'K Satku', written on a light-colored background.

PROF K SATKU
DIRECTOR OF MEDICAL SERVICES