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**BIOLOGICAL AGENTS AND TOXINS ACT  
(CHAPTER 24A)**

**BIOLOGICAL AGENTS AND TOXINS  
(PROFICIENCY TESTING)  
REGULATIONS 2008**

**ARRANGEMENT OF REGULATIONS**

Regulation

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In exercise of the powers conferred by sections 61 and 63 of the Biological Agents and Toxins Act, the Minister for Health hereby makes the following Regulations:

**Citation and commencement**

**1.** These Regulations may be cited as the Biological Agents and Toxins (Proficiency Testing) Regulations 2008 and shall come into operation on 1st March 2008.

**Definitions**

- 2.** In these Regulations, unless the context otherwise requires —
- “biological agent” means any First Schedule biological agent;
- “proficiency test” means the analysis of a proficiency testing sample by a person for the presence of a biological agent or toxin, as part of an examination to determine the proficiency of that person in respect of such analysis;

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“proficiency testing sample” means a specimen, whether or not obtained from any person or animal, used in the conduct of a proficiency test to simulate the presence or absence of a biological agent or toxin in that specimen;

“toxin” means any Fifth Schedule toxin.

### **Exemption for proficiency testing**

**3.—**(1) Subject to these Regulations, sections 6, 8(1), 9, 11, 12, 27, 31, 32(1), 33, 35 and 36 and Parts V and VI (with the exception of section 41(e)) of the Act shall not apply in relation to the handling of any biological agent or toxin in the course of carrying out proficiency testing.

(2) Notwithstanding paragraph (1), no person shall import or procure the import of any proficiency testing sample unless the import of the proficiency testing sample is authorised by and is carried out in accordance with the conditions of a permit granted by the Director.

(3) Notwithstanding paragraph (1), where any biological agent or toxin is provided to any person for proficiency testing and the person uses the biological agent or toxin for any purpose other than for proficiency testing, sections 6, 8(1), 9, 11, 12, 27, 31, 32(1), 33, 35 and 36 and Parts V and VI of the Act shall apply in relation to the possession and use of the biological agent or toxin by that person.

(4) Notwithstanding paragraph (1), where any biological agent or toxin is provided to any person for proficiency testing and the person transfers the biological agent or toxin to any other person for any purpose other than for proficiency testing, sections 6, 8(1), 9, 11, 12, 27, 31, 32(1), 33, 35 and 36 and Parts V and VI of the Act shall apply in relation to the transfer of the biological agent or toxin to, and the possession and use of the biological agent or toxin by, that other person.

### **Notification of failure of receipt of import**

**4.—**(1) Every holder of a permit granted by the Director under regulation 3(2) to import a proficiency testing sample shall immediately notify the Director, in such form and manner as the Director may require, in the event that he fails to receive the consignment of the proficiency testing sample to which the permit to import relates.

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(2) For the purposes of paragraph (1), the holder of the permit to import shall be deemed to have failed to receive the consignment of the proficiency testing sample to which the permit to import relates if he does not receive the consignment within 24 hours of such time as may be reasonably estimated by him for the receipt.

### **Biological agent or toxin when present in proficiency testing sample**

5.—(1) Where a biological agent or toxin is confirmed to be present in a proficiency testing sample, whether as a result of a proficiency test or otherwise —

- (a) the person who has possession or control of, or is otherwise responsible for, the proficiency testing sample shall immediately take one of the following steps in respect of the proficiency testing sample:
  - (i) destroy the sample;
  - (ii) transfer the sample to a transferee in accordance with the provisions of the Act; or
  - (iii) store the sample in accordance with the provisions of the Act; and
- (b) sections 6, 8(1), 9, 11, 12, 27, 31, 32(1), 33, 35 and 36 and Parts V and VI of the Act shall apply in relation to the possession, use and transfer of the proficiency testing sample.

(2) For the avoidance of doubt —

- (a) paragraph (1) may at any one time impose the same duty on 2 or more other persons, whether in the same capacity or in different capacities; and
- (b) a duty imposed by paragraph (1) on any person is not diminished or affected by the fact that it is imposed on one or more other persons, whether in the same capacity or in different capacities.

### **Offences**

6. Any person who contravenes regulation 3(2), 4(1) or 5(1)(a) shall be guilty of an offence and shall —

- (a) where the offence relates to any First Schedule (Part I) biological agent, be liable on conviction to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both; and

(b) where the offence relates to any biological agent (other than a biological agent referred to in paragraph (a)) or toxin, be liable on conviction to a fine not exceeding \$100,000 or to imprisonment for a term not exceeding 10 years or to both.

Made this 5th day of February 2008.

YONG YING-I  
*Permanent Secretary,  
Ministry of Health,  
Singapore.*

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