

BIOLOGICAL AGENTS AND TOXINS ACT 2005
(SECTIONS 61 AND 63)

BIOLOGICAL AGENTS AND TOXINS
(PROFICIENCY TESTING) REGULATIONS 2008

ARRANGEMENT OF REGULATIONS

Regulation

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[1 March 2008]

Citation

1. These Regulations are the Biological Agents and Toxins (Proficiency Testing) Regulations 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 Fifth Schedule toxin, as part of an examination to determine the proficiency of that person in respect of such analysis;
- “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 Fifth Schedule toxin in that specimen.

Prepared and Published by

THE LAW REVISION COMMISSION UNDER THE AUTHORITY
OF THE REVISED EDITION OF THE LAWS ACT 1983

18.12.2024

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 5 and 6 (with the exception of section 41(e)) of the Act do not apply in relation to the handling of any biological agent or Fifth Schedule toxin in the course of carrying out proficiency testing.

(2) Despite paragraph (1), a person must not 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) Despite paragraph (1), where any biological agent or Fifth Schedule toxin is provided to any person for proficiency testing and the person uses the biological agent or Fifth Schedule 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 5 and 6 of the Act apply in relation to the possession and use of the biological agent or Fifth Schedule toxin by that person.

(4) Despite paragraph (1), where any biological agent or Fifth Schedule toxin is provided to any person for proficiency testing and the person transfers the biological agent or Fifth Schedule 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 5 and 6 of the Act apply in relation to the transfer of the biological agent or Fifth Schedule toxin to, and the possession and use of the biological agent or Fifth Schedule 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 must immediately notify the Director, in such form and manner as the Director may require, in the event that the holder fails to receive the consignment of the proficiency testing sample to which the permit to import relates.

(2) For the purposes of paragraph (1), the holder of the permit to import is deemed to have failed to receive the consignment of the

proficiency testing sample to which the permit to import relates if the holder does not receive the consignment within 24 hours of such time as may be reasonably estimated by the holder for the receipt.

Biological agent or Fifth Schedule toxin when present in proficiency testing sample

5.—(1) Where a biological agent or Fifth Schedule 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 must 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;
 - (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 5 and 6 of the Act apply in relation to the possession, use and transfer of the proficiency testing sample.

(2) To avoid 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 1) 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 First Schedule (Part 1) biological agent) or Fifth Schedule 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.