

Biological Agents and Toxins (Proficiency Testing) Regulations 2008

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BIOLOGICAL AGENTS AND TOXINS ACT (CHAPTER 24A)

BIOLOGICAL AGENTS AND TOXINS (PROFICIENCY TESTING) REGULATIONS 2008

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;

“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.

(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