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

**BIOLOGICAL AGENTS AND TOXINS (EXEMPTION)
REGULATIONS 2009**

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 (Exemption) Regulations 2009 and shall come into operation on 1st November 2009.

Exemption for excluded purposes

2.—(1) Subject to paragraph (3) and regulation 3(2), sections 31, 35 and 36 of the Act shall not apply to a person when possessing or handling any Fifth Schedule toxin (referred to in these Regulations as the exempted Fifth Schedule toxin) for carrying out any activity undertaken solely with the intention of analysing any specimen from another person, an animal, the environment or any other source (including but not limited to a food sample) in which a Fifth Schedule toxin is, or is suspected of being, present for any of the following purposes:

- (a) determining the cause 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;
- (d) determining the cause of death of any person or animal in an autopsy;
- (e) identifying, or determining the nature of, the toxin that is, or that is suspected of being, present in the specimen for public health purposes.

(2) Regulation 6 of the Biological Agents and Toxins (Transportation) Regulations (Rg 1) shall not apply to a transferor in relation to the transportation in Singapore of any exempted Fifth Schedule toxin, and regulations 7 and 8 of those Regulations shall not apply to a carrier in relation to such transportation.

(3) For the avoidance of doubt, paragraph (1) does not apply in a case where the person who possesses or handles any exempted Fifth Schedule toxin for any purpose specified in that paragraph —

- (a) uses the exempted Fifth Schedule toxin for any other purpose; or
- (b) transfers the exempted Fifth Schedule toxin to any other person for any other purpose.

Duties of exemptee

3.—(1) Every person who possesses or handles any exempted Fifth Schedule toxin in accordance with regulation 2(1) shall —

- (a) ensure that the exempted Fifth Schedule toxin is kept or stored in a facility which is safe and secure, and which is accessible only to persons authorised by the operator of the facility;
- (b) report immediately to the Director, in such form and manner as the Director may require —
 - (i) all adverse incidents involving the exempted Fifth Schedule toxin; and
 - (ii) any loss, whether through theft or otherwise, of the exempted Fifth Schedule toxin;
- (c) maintain an inventory of all the exempted Fifth Schedule toxins in his possession, in such form as the Director may require, which shall include records of the following:
 - (i) the place at which each exempted Fifth Schedule toxin is kept or used;

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- (ii) the use to which each exempted Fifth Schedule toxin is to be put and has been put;
 - (iii) the manner of disposal of each exempted Fifth Schedule toxin (where applicable); and
 - (iv) the particulars of the transfer of each exempted Fifth Schedule toxin (where applicable), whether within the facility or between the facility and any other facility; and
- (d) submit to the Director, in such form and manner as the Director may require —
- (i) a report, before the 30th day of June of the current year, on all the exempted Fifth Schedule toxins in his possession between the 1st day of December of the preceding year and the 31st day of May of the current year (both dates inclusive); and
 - (ii) a report, before the 31st day of December of the current year, on all the exempted Fifth Schedule toxins in his possession between the 1st day of June and the 30th day of November of the current year (both dates inclusive).

(2) In every case in which a Fifth Schedule toxin is found to be present in any specimen analysed by a person under regulation 2(1), the person shall immediately —

- (a) destroy the specimen in the facility referred to in paragraph (1)(a); or
- (b) if he wishes to retain, transfer or transport the Fifth Schedule toxin, comply with the requirements of the Act relating to the possession, transfer or transportation of Fifth Schedule toxin, respectively.

(3) For the purposes of a report to be submitted to the Director before the 31st day of December 2009 under paragraph (1)(d)(ii), the reference to the 1st day of June in that paragraph shall be read as a reference to the 1st day of November 2009.

Offences

4. Any person who contravenes any requirement specified in regulation 3(1) shall be guilty of an offence and shall 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 18th day of September 2009.

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

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