(Unofficial Translation)

NOTIFICATION OF MINISTRY OF PUBLIC HEALTH
RE: CRITERIA, PROCEDURES AND CONDITIONS TO BE ABIDED BY AGENCIES UNDER SECTION 28, AND ESTABLISHMENT OF A BIOSAFETY CONTROL COMMITTEE
B.E.2560 (2017)

Whereas it is expedient to define the criteria, procedures, and conditions to be abided by agencies under section 28, and establishment of a biosafety control committee;

By virtue of section 5 paragraph one and section 6 (9) of the Pathogens and Animal Toxins Act B.E.2558 (2015), the Minister of Public Health by the advice of the Pathogens and Animal Toxins Committee, hereby issues the Notification as follows:

Clause 1 This Notification is called the "Notification of Ministry of Public Health Re: Criteria, Procedures and Conditions to be abided by agencies under section 28, and establishment of a biosafety control committee B.E.2560 (2017)".

Clause 2 This Notification shall come into force as from the day following the date of its publication in the Government Gazette.

Clause 3 In this Notification:

"agency" means Ministries, Ta-buangs, Departments, educational institutes or infirmaries of the State, public organisations or other State agencies, the Government Pharmaceutical Organisation and the Thai Red Cross Society;

"studies and research" means studies, research, analysis or systematic experiment by using pathogens or animal toxins as objects of experiment to find the facts, knowledge, or principles as applied to formulate rules, theories, guidelines, or inventions specifically for disease control, disease prevention and therapy.

CHAPTER I
CRITERIA, PROCEDURES AND CONDITIONS TO BE ABIDED BY AGENCIES

Clause 4 An agency conducting studies and research for the purpose of disease control, disease prevention and therapy, which intends to produce or possess Group 2 Pathogens, Group 3 Pathogens, Group 1 Animal Toxins, or Group 2 Animal Toxins shall operate as follows:

(1) to arrange to have an operator and operation personnel for such agency in accordance with the Notifications issued under section 6 (5);

(2) to arrange to have a biosafety control committee in accordance with chapter 2 of this Notification;

(3) to comply with the Notifications relating to criteria, procedures and conditions in relation to studies and research for disease control, disease prevention and therapy issued under section 6 (10).

Clause 5 After the requirements under Clause 4 have been complied with, an agency shall notify in writing details of operations and information of pathogens or animal toxins which are to be produced or possess to the Director-General, enclosed with documents or evidence in support of consideration in accordance with the form prescribed by the Director-General as published in the Government Gazette.

After the notification has been made on details of operations and information of pathogens or animal toxins which are to be produced or possess to the Director-General, such agency shall be deemed to have become a person receiving a certificate of notification under section 21 or a licensee under section 22 until the Director-General notifies an order of non-issuance of a certificate of notification or a license, as the case may be.

Clause 6 Upon receipt of the notification, the Director-General shall inspect the notification with supporting documents or evidence for accuracy and completeness; in case where a notification, a document or evidence is inaccurate and incomplete, the Director-General shall notify an agency to make amendments to the notification or to send documents or evidence to meet the requirements within five days from the date of notification.

In the case where an agency makes no amendment to the notification or sends no other documents or evidence to meet the requirements within the period of time prescribed by the Director-General under paragraph one, such agency shall be deemed to have abandoned the notification, and the Director-General shall remove such notification from the directory and notify the agency in writing.

Clause 7 In the case where the Director-General has already inspected and deemed a notification, documents and evidence as accurate and complete, the Director-General shall issue an order of receipt of notification for consideration and shall issue a receipt of notification to such agency within two days from the date of receipt of notification.

Clause 8 Upon having issued an order of receipt of notification under Clause 7, the Director-General is to issue a certificate of notification or a license to an agency on condition that such agency has arranged to have an operator and operation personnel in accordance with the Notifications issued under section 6 (5) and to have a biosafety control committee in accordance with chapter 2 of this Notification as well as having the place and equipment used in production and possession of pathogens and animal toxins in accordance with the Notifications relating to criteria, procedures and conditions in relation to studies and research for disease control, disease prevention and therapy issued under section 6 (10).

The Director-General shall notify the result of the consideration in writing to an agency within thirty days from the date of receipt of notification.

A certificate of notification or a license shall be valid for 1 year from the date of issuance of a certificate of notification or a license, as the case may be.

Clause 9 An agency who produces and has in possession of pathogens and animal toxins shall arrange to have a pathogen and animal toxin account and send the original of such account to the Director-General quarterly and shall keep a copy of such account at the agency as evidence in the investigation in accordance with the form prescribed by the Director-General as published in the Government Gazette.

CHAPTER II
BIOSAFETY CONTROL COMMITTEE

Clause 10. A biosafety control committee established by an agency shall have no less than five members, consisting of qualified members who have the knowledge and expertise in studies and research on pathogens or animal toxins at a capability level of supervision of the use of pathogens or animal toxins in research, ensuring safety for researchers, people, and environment.

Clause 11 A biosafety control committee shall have the power and duties as follows:

(1) to supervise the safety of use of pathogens and animal toxins in studies and research of the agency;

(2) to consider and set guidelines on safety in the production and possession of pathogens and animal toxins used in studies and research in consistence with the degree of risk of causing diseases or hazards;

(3) to monitor, inspect and evaluate the safety of use of pathogens and animal toxins in research of the agency;

(4) to coordinate and cooperate with the Department of Medical Sciences in supervising the use of pathogens and animal toxins in studies and research of the agency to ensure safety and compliance with the law;

(5) to have other power and duties in relation to the studies and research assigned by the agency.

Notified on the 25th day of January B.E.2560 (2017)
Piyasakol Sakolsatayadorn
Minister of Public Health