

(Unofficial Translation)

NOTIFICATION OF MINISTRY OF PUBLIC HEALTH
RE: STUDIES AND RESEARCH FOR DISEASE CONTROL, DISEASE PREVENTION AND THERAPY
B.E.2561 (2018)

Whereas it is expedient to define the criteria, procedures, and conditions relating to studies and research for disease control, disease prevention and therapy in relation to pathogens and animal toxins;

By virtue of section 5 paragraph one and section 6 (10) 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 Studies and Research for Disease Control, Disease Prevention and Therapy B.E.2561 (2018)”.

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:

“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
STUDIES AND RESEARCH ON GROUP 1 PATHOGENS

Clause 4 A person who conducts studies and research on Group 1 Pathogens shall operate as follows:

(1) to conduct in the place where its characteristics are in accordance with the Notifications issued under section 6 (4) of Pathogens and Animal Toxins Act B.E.2558 (2015);

(2) to comply with the criteria, procedures, and conditions issued under section 6 (11) of Pathogens and Animal Toxins Act B.E.2558 (2015) in the case of emergency or necessity for public interests or for protection and prevention of harm arising from pathogens and animal toxins or for national security, and restrictions or permissions of the production, import, export, sale, transit or possession of pathogens and animal toxins in such emergency or necessity;

(3) to comply with the criteria, procedures, and conditions issued under section 6 (13) of Pathogens and Animal Toxins Act B.E.2558 (2015) in relation to safety assessment of technologies used in the production of pathogens and animal toxins.

CHAPTER II
STUDIES AND RESEARCH ON GROUP 2 PATHOGENS OR GROUP 1 ANIMAL TOXINS

Clause 5 A person who conducts studies and research on Group 2 Pathogens or Group 1 Animal Toxins shall operate as follows:

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(1) to conduct in the place where its characteristics are in accordance with the Notifications issued under section 6 (4) of Pathogens and Animal Toxins Act B.E.2558 (2015);

(2) to arrange an operator and operation personnel in the Notifications issued under section 6 (5) of Pathogens and Animal Toxins Act B.E.2558 (2015);

(3) to comply with the criteria, procedures, and conditions issued under section 6 (11) of Pathogens and Animal Toxins Act B.E.2558 (2015) in the case of emergency or necessity for public interests or for protection and prevention of harm arising from pathogens and animal toxins or for national security, and restrictions or permissions of the production, import, export, sale, transit or possession of pathogens and animal toxins in such emergency or necessity;

(4) to comply with the criteria, procedures, and conditions issued under section 6 (13) of Pathogens and Animal Toxins Act B.E.2558 (2015) in relation to safety assessment of technologies used in the production of pathogens and animal toxins;

(5) to comply with the criteria, procedures, and conditions issued under section 6 (18) of Pathogens and Animal Toxins Act B.E.2558 (2015) in relation to the preparation and submission of annual reports with respect to production, import, export, sale, transit or possession of pathogens and animal toxins.

CHAPTER III

STUDIES AND RESEARCH ON GROUP 3 PATHOGENS OR GROUP 2 ANIMAL TOXINS

Clause 6 A person who conducts studies and research on Group 3 Pathogens or Group 2 Animal Toxins shall operate as follows:

(1) to conduct in the place where its characteristics are in accordance with the Notifications issued under section 6 (4) of Pathogens and Animal Toxins Act B.E.2558 (2015);

(2) to arrange an operator and operation personnel in the Notifications issued under section 6 (5) of Pathogens and Animal Toxins Act B.E.2558 (2015);

(3) to comply with the criteria, procedures, and conditions issued under section 6 (11) of Pathogens and Animal Toxins Act B.E.2558 (2015) in the case of emergency or necessity for public interests or for protection and prevention of harm arising from pathogens and animal toxins or for national security, and restrictions or permissions of the production, import, export, sale, transit or possession of pathogens and animal toxins in such emergency or necessity;

(4) to comply with the criteria, procedures, and conditions issued under section 6 (13) of Pathogens and Animal Toxins Act B.E.2558 (2015) in relation to safety assessment of technologies used in the production of pathogens and animal toxins;

(5) to comply with the criteria, procedures, and conditions issued under section 6 (18) of Pathogens and Animal Toxins Act B.E.2558 (2015) in relation to the preparation and submission of annual reports with respect to production, import, export, sale, transit or possession of pathogens and animal toxins.

CHAPTER IV
STUDIES AND RESEARCH ON GROUP 4 PATHOGENS OR GROUP 3 ANIMAL TOXINS

Clause 7 A person who conducts studies and research on Group 4 Pathogens or Group 3 Animal Toxins for the specific purpose of disease control, disease prevention and therapy shall operate as follows:

(1) a person who intends to conduct studies and research on Group 4 Pathogens or Group 3 Animal Toxins shall submit an application for a license to conduct studies and research to the Director-General in accordance with the form prescribed by the Director-General and published in the Government Gazette along with attaching details of project, purpose of studies and research, a place, tools and equipment, details about an operator and operation personnel, the number or quantity of pathogens or animal toxins, experimental methods, and details about safety assessment of technologies used in the studies and research;

(2) upon receipt of an application under (1) the Director-General shall submit it to the Pathogens and Animal Toxins Committee for advice and the Director-General shall complete the consideration of the application within one hundred and eighty days from the date of submission.

In respect of such advice the Pathogens and Animal Toxins Committee may appoint a sub-committee to give their consent under paragraph one.

In the case where the Director-General orders not to issue a license for conducting studies and research, the applicant shall have the right to file an appeal against the order to the Minister within thirty days from the date of receipt of the notification of an order of non-issuance of a license to perform studies and research, and the Minister's decision shall be final.

Notified on the 24th day of January B.E.2561 (2018)

Piyasakol Sakolsatayadorn

Minister of Public Health