

NOTIFICATION OF MINISTRY OF PUBLIC HEALTH
RE: THE PREPARATION AND SUBMISSION OF ANNUAL REPORTS WITH RESPECT TO PRODUCTION,
IMPORT, EXPORT, SALE, TRANSIT OR POSSESSION OF PATHOGENS AND ANIMAL TOXINS
B.E.2561 (2018)

Whereas it is expedient to define the criteria, procedures, and conditions 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;

By virtue of section 5 paragraph one and section 6 (18) 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: the Preparation and Submission of Annual Reports with Respect to Production, Import, Export, Sale, Transit or Possession of Pathogens and Animal Toxins 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 A person receiving a certificate of notification, a licensee and an agency conducting studies and research under section 28 shall prepare annual reports with respect to production, import, export, sale, transit or possession of pathogens and animal toxins, which is the operational information during January to December delivered to the Department of Medical Sciences within March the following year, and shall keep the copy of such reports as evidence.

Clause 4 The annual reports shall have the details as follows:

- (1) Name of a person receiving a certificate of notification or a licensee’s name or name of an agency conducting studies and research under section 28;
- (2) Number of certificate of notification or a license number;
- (3) Number and name list of operators and operation personnel including number and name list of persons obtaining consent to gain access and to operate in the production, import, export, sale, transit or possession of pathogens or animal toxins;
- (4) Location of operational place as notified or requested for permission;
- (5) Information on operations in relation to pathogens and animal toxins.

Clause 5 The annual reports shall have a minimum of information accordance with the form annexed to the Notification.

Clause 6 In the case of production, import or possession of pathogens or animal toxins; the annual report shall have the operational information as follows:

- (1) Origin identification of pathogens or animal toxins being produced, imported or possessed;
- (2) Purpose of production, import or possession of pathogens or animal toxins;
- (3) Name list and amount of pathogens or animal toxins in each month when production, import or possession occurs; the scientific name of pathogens or animal toxins shall be identified in English.
- (4) In the case where destruction or other causes reduce an amount of pathogens or animal toxins; the causes, amount or procedures of destruction or reduction shall be identified and the remaining amount in each month shall be identified.

(Unofficial Translation)

In the case of handover of pathogens or animal toxins, identification of name, location, number of certificate of notification or a license number of the source of receipt, amount and date of receipt of such pathogens or animal toxins shall be provided.

Clause 7 In the case of sale, export or transit of pathogens or animal toxins, the annual report shall have the operational information as follows:

- (1) Origin identification of pathogens or animal toxins being sold, exported or transited;
- (2) Purpose of sale, export or transit of pathogens or animal toxins;
- (3) Name list and amount of pathogens or animal toxins in each month when sale, export or transit occurs; the scientific name of pathogens or animal toxins shall be identified in English;
- (4) Name list and location of a person receiving pathogens or animal toxins from a seller, exporter or transiter, an amount received and date of receipt of such pathogens or animal toxins;
- (5) In the case where destruction or other causes reduce an amount of pathogens or animal toxins; the causes, amount or procedures of destruction or reduction shall be identified and the remaining amount in each month shall be identified.

In the case of handover of pathogens or animal toxins, identification of name, location, number of certificate of notification or a license number of the source of receipt, amount and date of receipt of such pathogens or animal toxins shall be provided.

Clause 8 In the case where a person receiving a certificate of notification, a licensee or an agency conducting studies and research under section 28 notifies termination, non-renewal, unapproved renewal, revocation of certificate of notification or a license, or expiry of a certificate of notification or a license owing to decease of a person receiving a certification or a licensee, or other causes leading to inability to perform duties, or loss of the status of a juristic person; such persons shall prepare the annual reports under Clause 4, Clause 5, Clause 6 and Clause 7, as the case may be as from the date of submission of annual report the year before to the date of notification of termination, non-renewal, unapproved renewal, revocation of certificate of notification or a license, or expiry of a certificate of notification or a license owing to decease of a person receiving a certification or a licensee, inability to perform duties or loss of the status of a juristic person.

The reports under paragraph one shall be submitted to the Department of Medical Sciences within thirty days as from the date of notification of termination, non-renewal, unapproved renewal, revocation of certificate of notification or a license, or expiry of a certificate of notification or a license owing to decease of a person receiving a certification or a licensee, inability to perform duties or loss of the status of a juristic person.

Clause 9 Submission of annual reports in accordance with this Notification; a person receiving a certificate of notification, a licensee or an agency conducting studies and research under section 28 shall deliver reports via registered mail or shall assign other persons to deliver reports, and via electronic means.

Clause 10 In the case where there are reasonable grounds or the submitted annual reports are of inaccuracy, or incomplete particulars; the Director-General may order a person receiving a certificate of notification, a licensee or an agency conducting studies and research under section 28 to amend the reports to reach accuracy or completeness within the period of time prescribed.

In the case where no action to amend annual reports for accuracy and completeness is taken within the period of time prescribed under paragraph one, it shall be deemed to have submitted no annual reports.

This translation is provided by Department of Medical Sciences as the competent authority for information purposes only. Whilst Department of Medical Sciences has made efforts to ensure the accuracy and correctness of the translation, the original Thai text as formally adopted and published shall in all events remain the sole authoritative text having the force of law.

(Unofficial Translation)

Clause 11 The Department of Medical Sciences shall report the results of annual operations to inform the Pathogens and Animal Toxins Committee.

Clause 12 The Director-General of Department of Medical Sciences shall have charge and control over the execution of this Notification.

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

Piyasakol Sakolsattayaton

Minister of Public Health

FORM OF ANNUAL REPORT
IN ACCORDANCE WITH THE PATHOGENS AND ANIMAL TOXINS ACT B.E.2558 (2015)

Annual report of year B.E.:

Name of a person receiving a certificate of notification/ a licensee/ an agency conducting studies and research under section 28:

Certificate of notification number:

License number:

Location of operational premises as notified or requested for permission:

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The number of operators is, namely:

(1)

(2)

(3)

(4)

(5)

The number of operation personnel is, namely:

(1)

(2)

(3)

(4)

(5)

The number of persons obtaining consent to gain access and to operate in relation to pathogens or animal toxins is, namely:

(1)

(2)

(3)

(4)

(5)

The information on operations in relation to pathogens or animal toxins is as follows (information in accordance with Clause 6 or Clause 7):

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