

Pathogen and Animal Toxin Act, B.E. 2525 (1982)

As amended by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001)

Translation

BHUMIBOL ADULYADEJ, REX.

Given on the 7th Day of August B.E. 2525,

Being the 37th Year of the Present Reign

His Majesty King Bhumibol Adulyadej is graciously pleased to proclaim that;
Whereas it is expedient to revise the law on harmful pathogen and animal toxin control;
Be it, therefore, enacted by the King, by and with the advice and consent of the National Assembly, as follows:

Section 1

This Act is called the "Pathogen and Animal Toxin Act, B.E. 2525 (1982)".

Section 2

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

Section 3

The Harmful Pathogen and Animal Toxin Control Act, B.E. 2475 (1932) shall be repealed.

All laws, rules and other regulations in so far as they have been provided in this Act, or are contrary to or inconsistent with the provisions of this Act, shall be replaced by this Act.

Section 4

In this Act,

"Pathogen" means:

- (1) micro-organisms;
- (2) other germs as prescribed by the Ministerial Regulation;
- (3) product from (1) or (2);

which are capable of causing disease in human being, livestock, beast of burden or other animals as prescribed by the Ministerial Regulation.

"Animal toxin" means poisonous substance produced by animal which is capable of causing diseases in human being, livestock, beast of burden or other animals as prescribed by the Ministerial Regulation, e.g. snake venom, insect toxin and puffer fish toxin;

"Produce"⁽²⁾ means an incubation, mix, process, transform, or separate or joint containing;

"Dispose" mean sale, dispensation, distribution, exchange, give, loss, damage, discard or destruction;

"Import" means taking or ordering into the Kingdom;

"Export" means taking or sending out of the Kingdom;

"Transit" means taking or conveying through the Kingdom by transferring or changing of carriers;

"Competent official" means a person appointed by the Minister for the execution of this Act

"Director-General" means the Director-General of the Department of Medical Sciences.

"Minister" means the Minister having charge and control of the execution of this Act.

Section 5

No person shall produce, possess, dispose, import, export or transit of pathogen or animal toxin without license granted by the Director-General.

The application for, and the issuance of, license shall be in accordance with the rules, procedure and conditions as prescribed by the Ministerial Regulation.

Section 5/1⁽³⁾

The provisions of Section 5 shall not apply to a Ministry, Sub-Ministry, Department, local administration, scientific educational institute or infirmary which is State agency, the Government Pharmaceutical Organization and the Thai Red Cross Society; particularly to the works concerning the control, prevention or treatment of disease, and study or research.

The exempt agency under paragraph one shall act in compliance with the rules, procedure and conditions as prescribed by the Ministerial Regulation.

Section 6

The Director-General may grant the license to produce, possess, dispose, import, export or transit of pathogen or animal toxin if the applicant:

- (1) being of not less than twenty years of age;
- (2) having residence in Thailand;
- (3) not being a person of unsound mind, an incompetent or quasi-incompetent person;
- (4) not having been sentenced that he or she had committed an offence which dishonest intention is an element thereof or an offence under the law on harmful pathogen and animal toxin control or under this Act, and such offence carries a penalty of imprisonment;
- (5) having place of production, possession, disposal or storage, and equipment for production, disposal, storage, control or maintenance of quality of pathogen or animal toxin, of the characteristic and quantity as prescribed by the Ministerial Regulation.

In the case where the applicant is a juristic person, its representative shall have the qualifications under (1) and (2) and shall not being under the prohibitions under (3) or (4).

Section 7

The licenses related to pathogen and animal toxin are, *viz.*

- (1) license to produce pathogen and animal toxin;
- (2) license to possess pathogen and animal toxin;
- (3) license to dispose of pathogen and animal toxin;
- (4) license to import pathogen and animal toxin;
- (5) license to export pathogen and animal toxin;
- (6) license to transit pathogen and animal toxin.

The licensee of the license under (1), (4), (5) or (6) is deemed to be the licensee of the licenses under (2) and (3) for the pathogen or animal toxin produced, imported, exported or transited by such licensee, as the case may be.

The licensee of the license under (3) is deemed to be the licensee of the licenses under (2).

Section 8⁽⁴⁾

The license under Section 5 shall be valid until the 31st Day of December of the year of its issuance. If the licensee desires to renew the license, the licensee shall submit an application for renewal of such license prior to its expiration date. Upon such submission,

the licensee may continue his or her business until refusal order to such application is given by the Director-General.

The application for, and the granting of, renewal of license shall be in accordance with the rules, procedure and conditions as prescribed by the Ministerial Regulation.

Section 9

In the case where the Director-General refuses to grant or renew the license, the applicant for the license or for the renewal of license is entitled to appeal in writing to the Minister within thirty days as from the date of receiving of such refusal order.

The decision of the Minister shall be final.

In the case where the Director-General refuses to renew the license, the Minister shall have the power to permit such applicant to continue his or her business during the period before giving decision.

Section 10

In the case where the license is lost, destroyed or materially damaged, the licensee shall notify the Director-General and submit an application for the substitution of license within fifteen days as from the date such loss, destruction or damage is known to him or her.

The application for, and the issuance of, the substitution of license shall be in accordance with the rules, procedure and conditions as prescribed by the Ministerial Regulation.

Section 11⁽⁵⁾

For the performance of duties, the competent official shall have the powers as follows:

- (1) to enter into the place of production, possession, disposal or storage of pathogen or animal toxin between sunrise and sunset or during working hours of such place for the purpose of inspection or control for the compliance with this Act;
- (2) to take an appropriate amount of specimen of pathogen or animal toxin for examination or analysis;
- (3) to summon relevant document or evidence from the licensee or other relevant persons;
- (4) to seize or attach the pathogen or animal toxin, equipment and instrument involving in the commission of an offence as well as container or parcel and relevant document for the benefit of legal proceedings if it appears a reasonable ground to suspect that there is an offence under this Act;
- (5) to summon any person to give statement or to submit an account, document or other evidences if there is a reasonable ground to believe that such statement, account, document or evidences are beneficial to the proving of an offence under this Act.

In the performance of duties of the competent official under paragraph one, the licensee or relevant person shall render appropriate facilities thereto.

Section 11/1⁽⁶⁾

As regard to all things seized or attached under Section 11 (4), in the case where their owner is not found or where the public prosecutor has the conclusive order to cease the legal proceedings or where the Court has no confiscation order thereto and the owner or possessor thereof fails to request for recovery or for revoking the attachment within ninety days as from the date of seizure or attachment or the date the conclusive order to cease the legal proceedings is known to him or her or the date of delivering of the final judgment of the Court, as the case may be, such things shall devolve on the Ministry of Public Health.

Section 11/2⁽⁷⁾

If any thing seized or attached under Section 11 (4) is perishable or its maintenance cost may exceed its value, the Director-General may order to destroy such thing or taking appropriate method thereto.

In the case where the thing seized or attached under paragraph one may be disposed, the competent official shall sell such thing by auction or sell it to the government agency. The net proceeds, after deducting the maintenance cost, disposition cost and all relevant charges, shall be seized in lieu of such thing.

Section 11/3⁽⁸⁾

If the keeping of thing seized or attached under Section 11 (4) may be harmful to public, the Director-General may order to destroy such thing or taking appropriate method thereto.

Section 11/4⁽⁹⁾

In the case where there is the ground to destroy or to take appropriate method to the thing seized or attached under Section 11/2 or Section 11/3, as the case may be, if there is an expense incurred therefrom, the owner of such thing shall be responsible to pay or compensate such expense to the Ministry of Public Health.

Section 12

In the performance of duties under this Act, the competent official shall represent his or her identification card to all relevant persons.

The identification card of the competent official shall be in the form as prescribed by the Ministerial Regulation.

Section 12/1⁽¹⁰⁾

In the performance of duties under this Act, the competent official shall be the competent official under the Penal Code.

Section 13

No licensee shall:

- (1) produce, possess, dispose, import, export or transit of pathogen or animal toxin other than those as specified in the license;
- (2) produce, possess, dispose, import, export or transit of pathogen or animal toxin at any place other than the place as specified in the license, except in case of direct disposal to another licensee.

Section 14

The licensee shall:

- (1) prepare monthly report stating the quantities of pathogen or animal toxin under his or her production, possession, disposal, importation, exportation or transit in accordance with the rules, procedure and conditions as prescribed by the Ministerial Regulation;
- (2) provide label specifying the common and scientific name of pathogen or animal toxin in English, net contents, manufacturing date, month and year, and place of production on the parcel or package thereof, and shall at least specify the common and scientific name of pathogen or animal toxin in English on the container thereof;
- (3) provide controlling measure for the production, possession, disposal, importation, exportation, transit or transportation of pathogen or animal toxin with a view to prevent them from spreading in accordance with the rules, procedure and conditions as prescribed by the Ministerial Regulation;
- (4) perform other acts as prescribed by the Ministerial Regulation.

Section 15

If it appears that any licensee violates this Act or the Ministerial Regulation issued under this Act, the competent official shall give written warning to such licensee. Such warning is not an excuse for the committed offence.

If the licensee fails to comply therewith, the Director-General shall have the power to suspend or revoke the license. In case of suspension of license, the suspension period shall not exceed one hundred and twenty days each time. In this regard, the licensee whom his or her license is suspended or revoked is entitled to appeal against the order in writing to the Minister within thirty days as from the date of receiving of such order.

The decision of the Minister shall be final.

An appeal against the order to the Minister shall not stay the execution of the suspension or revocation order.

Section 16

In the case where the licensee desires to cease business operation under the license, he or she shall notify the Director-General in writing within fifteen days prior to the date of the cessation of operation.

Section 17

In the case where the Minister affirms the decision of the Director-General in refusing the renewal of license under Section 9 or where the license is revoked under Section 15 or where the licensee ceases his or her business operation under Section 16, the licensee shall destroy the remaining pathogen or animal toxin under control of the competent official or dispose the remaining to another licensee or a person whom the Director-General deems appropriate. Such destruction or disposal shall be made within thirty days as from the date the affirmation decision of the Minister in refusing the renewal of the license under Section 9 is known to him or her or the date of acknowledgement of the revocation order under Section 15 or the date of ceasing of business operation under Section 16, as the case may be, provided that such period is extended by the Director-General.

If the licensee fails to conduct such destruction or disposal within the period under paragraph one, the competent official shall finish such act in place of the licensee. In this case, the licensee shall be responsible for all expenses incurred therefrom.

Section 18

Whoever violates Section 5 paragraph one shall be liable to imprisonment for a term of not exceeding ten years or to a fine of not exceeding one hundred thousand Baht, or to both.

Section 19

Any licensee who produces, possesses, disposes, imports, exports or transits of pathogen or animal toxin after the expiration of the license while failing to submit an application for the renewal of license under Section 8 paragraph one shall be liable to a daily fine of not exceeding five hundred Baht through the period such license is invalid.

Section 20

Any licensee who fails to comply with Section 10 paragraph one shall be liable to a fine of not exceeding one thousand Baht.

Section 21

Whoever fails to submit document or evidence under Section 11 (3), or fails to give statement or to submit an account, document or other evidence under Section 11 (5), or obstructs or fails to render facilities to the competent official during the performance of duties under Section 11 paragraph two, shall be liable to a fine of not exceeding five thousand Baht.

Section 22

Any licensee who violates Section 13 (1) shall be liable to imprisonment for a term of not exceeding five years or to a fine of not exceeding fifty thousand Baht, or to both.

Section 23

Any licensee who violates Section 13 (2) or fails to comply with Section 14 (1) or (4) or Section 16 shall be liable to a fine of not exceeding five thousand Baht.

Section 24

Any licensee who fails to comply with Section 14 (2) shall be liable to a fine of not exceeding ten thousand Baht.

Section 25

Any licensee who fails to comply with Section 14 (3) shall be liable to imprisonment for a term of not exceeding five years or to a fine of not exceeding fifty thousand Baht, or to both.

Section 25/1⁽¹¹⁾

With regard to the offences under this Act which are punishable with fine only, the Director-General or person entrusted by the Director-General shall have the power to settle them.

Section 26

The license granted under the provisions of the law on harmful pathogen and animal toxin control which is valid on or before the date this Act comes into force shall remain valid until its expiry date. If such licensee desires to continue his or her business operation thereafter, he or she shall submit the application for the license under this Act. In this case, the applicant shall be entitled to continue his or her business operation under the expired license until receiving of the new license or until the date the order refusing to grant the license is informed by the Director-General. In the case where the new license is granted, the licensee shall act in compliance with this Act within one hundred and eighty days as from the date of granting of license.

Section 27

The Minister of Public Health shall have charge and control of the execution of this Act and shall have the power to appoint the competent official, issue Ministerial Regulation prescribing fees not exceeding the rates hereto attached, granting exemption of fee and prescribing other acts for the execution of this Act.

Such Ministerial Regulation shall come into force upon its publication in the Government Gazette

Countersigned by

General P. Tinsulananda

Prime Minister

Fees Rates

- (1) An application form 10 Baht each
- (2) A license to produce pathogen and animal toxin 500 Baht each
- (3) A license to possess pathogen and animal toxin 500 Baht each
- (4) A license to dispose of pathogen and animal toxin 500 Baht each
- (5) A license to import pathogen and animal toxin 500 Baht each
- (6) A license to export pathogen and animal toxin 500 Baht each
- (7) A license to transit pathogen and animal toxin 500 Baht each
- (8) A substitution of license 100 Baht each
- (9) Fee for a renewal of each kind of license is equal to fee imposed to such license

Published in the Government Gazette, Vol. 99, Part 113, Special Issue,
Dated 16th August B.E. 2525 (1982).

Amendment

- (2) As amended by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).
- (3) As added by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).
- (4) As amended by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).
- (5) As amended by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).
- (6) As added by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).
- (7) As added by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).
- (8) As added by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).
- (9) As added by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).
- (10) As added by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).
- (11) As added by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).

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