

**PATHOGEN AND ANIMAL TOXIN ACT,
B.E. 2525 (1982)**

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”.

Section 2. This Act shall come into force as from the day following the date of its publication in the Government Gazette.¹

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 The Harmful Pathogen and Animal Toxin Control Act, B.E. 2475 (1932) shall be repealed.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

¹Published in the Government Gazette, Vol. 99, Part 113, Special Issue, dated 16th August B.E. 2525 (1982).

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

“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 licence granted by the Director-General.

The application for, and the issuance of, licence 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 Organisation 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 licence 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 licences related to pathogen and animal toxin are, *viz.*

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

³As added by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).

(6) licence to transit pathogen and animal toxin.

The licensee of the licence under (1), (4), (5) or (6) is deemed to be the licensee of the licences 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 licence under (3) is deemed to be the licensee of the licences under (2).

Section 8.⁴ The licence 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 licence, the licensee shall submit an application for renewal of such licence 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 licence 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 licence, the applicant for the licence or for the renewal of licence 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 licence, 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 licence is lost, destroyed or materially damaged, the licensee shall notify the Director-General and submit an application for the substitution of licence 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 licence 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;

⁴As amended by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).

⁵As amended by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).

(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, posses, dispose, import, export or transit of pathogen or animal toxin other than those as specified in the licence;

⁶As added by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).

⁷As added by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).

⁸As added by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).

⁹As added by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).

¹⁰As added by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).

(2) produce, possess, dispose, import, export or transit of pathogen or animal toxin at any place other than the place as specified in the licence, 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 licence. In case of suspension of licence, the suspension period shall not exceed one hundred and twenty days each time. In this regard, the licensee whom his or her licence 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 licence, 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 licence under section 9 or where the licence 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 licence 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 licence while failing to submit an application for the renewal of licence under section 8 paragraph one shall be liable to a daily fine of not exceeding five hundred Baht through the period such licence 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 licence 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 licence under this Act. In this case, the applicant shall be entitled to continue his or her business operation under the expired licence until receiving of the new licence or until the date the order refusing to grant the licence is informed by

¹¹As added by the Pathogen and Animal Toxin Act (No. 2), B.E. 2544 (2001).

the Director-General. In the case where the new licence is granted, the licensee shall act in compliance with this Act within one hundred and eighty days as from the date of granting of licence.

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