

Pathogens and Animal Toxins Act
B.E. 2525 (C.E. 1982)

Promulgated by
His Majesty King Bhumibol Adulyadej
On 7th August, B.E. 2525 (C.E. 1982)
In the 37th year of his reign

His Majesty King Bhumibol Adulyadej, having deemed it appropriate to amend the law on the control of pathogens and animal toxins, and in consultation with and with the approval of the Parliament, decrees that the law shall be amended as follows:

Item 1. This statute is called "The Pathogens and Animal Toxins Act B.E. 2525."

Item 2. This statute shall enter into force as of the day following its publication in the Royal Gazette.

Item 3. "The Pathogens and Animal Toxins Control Act of B.E. 2475" is hereby invalidated.

All other rules and regulations which are identical to those contained in this statute or which are not in compliance with the provisions set down in this statute shall be disregarded and replaced by this statute.

Item 4. In this statute, "pathogens" means:

- (1) micro-organisms,
- (2) other pathogens specified by ministerial regulation,
- (3) products from (1) or (2),

capable of causing disease in humans, livestock, animal carriers, or other animals specified by ministerial regulation.

"Animal toxins" refers to animal-derived toxins which are capable of causing illness or disease in humans, livestock, animal carriers, or other animals specified by ministerial regulation. Examples include snake venom, insect toxins, and toxin from blowfish.

"To produce" means to grow, blend, cook, process, or package, but does not refer to pathogens cultivated in scientific research institutes or medical facilities for the purpose of post mortem examination, disease treatment or control, or for educational purposes.

"To distribute" means to sell, dispense, distribute, exchange, give, discard, damage or destroy.

"To import" means to bring into the Kingdom or take delivery from abroad.

"To export" means to take or ship out of the Kingdom.

"To transit" means to transport through the Kingdom, transferring or changing vessels.

"Officers" refers to persons appointed by the Minister to carry out the provisions of this statute.

"The Director General" refers to the Director General of the Medical Services Department.

"The Minister" refers to the Minister responsible for enforcement of this statute.

Item 5. No one may produce, possess, distribute, import, export, or transit pathogens or animal toxins without a permit from the Director General.

The procedures for requesting and issuing such permits shall be in compliance with the criteria and conditions specified by ministerial regulation.

Item 6. The Director General will issue a permit to produce, possess, distribute, import, export, or transit pathogens or animal toxins when he is satisfied that the applicant,

- (1) is 25 years of age or older;
- (2) is a resident of Thailand;
- (3) is not insane or mentally infirm;

(4) has not been convicted of an offence committed in bad faith, or been found in violation of any of the provisions of the Pathogens and Animal Toxins Control Act or this statute, which carry a penalty of imprisonment,
(5) has proper facilities for production, possession, distribution, or storage, and equipment used to produce, distribute, store, control or maintain the quality of pathogens or animal toxins of the type and quantity specified by ministerial regulation.

When the applicant is a juristic person, the person representing the juristic person must meet the criteria in (1) and (2) and must not be ineligible for the reasons specified in (3) or (4).

Item 7. The following types of permits are issued pertaining to pathogens and animal toxins: permits,

- (1) to produce pathogens and animal toxins;
- (2) to possess pathogens and animal toxins;
- (3) to distribute pathogens and animal toxins;
- (4) to import pathogens and animal toxins;
- (5) to export pathogens and animal toxins;
- (6) to transit pathogens and animal toxins.

Anyone holding permit type (1), (4), (5) or (6) shall also be deemed as holding permit types (2) and (3) for the pathogens or animal toxins he is authorized to produce, import, export, or transit, as the case may be.

Anyone holding permit type (3) shall also be deemed as holding permit type (2).

Item 8. Permits referred to in Item 5 are valid for a period of one year, starting from the day of issue. Permit holders wishing to renew their permit must submit a request prior to the expiry of their present permit. After submitting the renewal request, permit holders may continue in operation until such time as the Director General denies the renewal request.

Applications for permit renewal and the issue of such shall be in compliance with criteria, procedures and conditions set down by ministerial regulation.

Item 9. In the event that the Director General denies a permit application or permit renewal request, the applicant has the right to appeal the decision in writing to the Minister within thirty days of receiving notification from the Director General that his permit application or permit renewal request has been denied.

The decision of the Minister is final.

In the event that the Director General has denied a permit renewal request, and the Minister has not yet ruled on the applicant's appeal, the Minister is authorized to allow the applicant to continue to operate should the applicant file a request to do so.

Item 10. In the event that a permit is lost, destroyed or mutilated, the permit holder shall inform the Director General and request a new copy within 15 days of becoming aware of the loss, destruction or mutilation of the original permit.

Requests for replacement permits and the issue of such shall be in compliance with criteria, procedures and conditions set by ministerial regulation.

Item 11. In performing their duties, the officers are granted the following powers:

- (1) to enter facilities where pathogens or animal toxins are produced, possessed, distributed or stored at any time between sunrise and sunset for the purpose of inspecting and ensuring compliance with the provisions contained in this statute;
- (2) to take samples of pathogens or animal toxins, as needed, for the purpose of inspection or analysis;
- (3) to demand relevant documents or other evidence from permit holders or other relevant parties;
- (4) to seize or confiscate pathogens or animal toxins as well as packaging or containers and all relevant documents with a bearing on legal proceedings arising from suspected violations of this statute;
- (5) to summon individuals for questioning or to order the handing over of records, documents or other evidence when there is sufficient reason to believe that such may aid in substantiating suspected violations of this statute.

Permit holders or other relevant parties shall facilitate and give reasonable assistance to officers in the performance of their duty.

Item 12. When performing their duties under the law, officers shall show proper identification to the party or parties concerned.

This identification shall conform to the specifications set by ministerial regulation.

Item 13. A permit holder may not,

- (1) produce, possess, distribute, import, export, or transit pathogens or animal toxins in any way other than that specified in the permit;
- (2) produce, possess, distribute, import, export or transit pathogens or animal toxins in any location other than that specified in the permit, except when distributing pathogens or animal toxin directly to another permit holder.

Item 14. Permit holders must comply with the following. They must:

- (1) keep monthly records of quantities of pathogens or animal toxins produced, possessed, distributed, imported, exported, or transited. These records must conform to the criteria, methods and conditions specified by ministerial regulation.
- (2) label outer packaging of the pathogens or animal toxins with its name and scientific name in English, the amount, and date and place of production. Labels on containers must indicate, as a minimum, the name and scientific name of the pathogen or animal toxin.
- (3) implement controls over production, possession, distribution, import, export, or transport of pathogens or animal toxins to prevent them from spreading. These controls shall conform to specifications set by ministerial regulation.
- (4) comply with all other requirements specified by ministerial regulation.

Item 15. When it appears that a permit holder has violated this law or the ministerial regulation issued pursuant to this law, officers shall issue a warning. This warning does not, however, excuse the permit holder from responsibility for violations already committed. If after receiving the warning, the permit holder fails to make the necessary amends, the Director General is authorized to suspend or revoke the permit. A suspension order may not exceed 120 days. Anyone whose permit has been suspended or revoked has the right to appeal in writing to the Minister within thirty days of receiving notification from the Director General.

The decision of the Minister is final.

The Director General's order to suspend or revoke a permit shall remain in force throughout the appeal process.

Item 16. In the event that a permit holder wishes to terminate the activity or activities authorized by the permit, the permit holder shall notify the Director General in writing of his intention to do so within 15 days of the intended date of termination.

Item 17. In the event that the Minister concurs with the Director General's decision not to renew a permit as in Item 9, or in the event that a permit has been revoked as in Item 15, or in the event that a permit holder wishes to terminate the activity or activities for which he has received authorization as in Item 16, the permit holder shall destroy all remaining stocks of pathogens or animal toxins under the supervision of the appointed officers, or he may transfer the remaining stocks to another authorized permit holder or to another party deemed suitable by the Director General within thirty days of notification of the Minister's decision not to renew the permit, as in Item 9, or notification of the decision to revoke the permit as in Item 15, or the day on which the permit holder ceases operation, as in Item 16, as the case may be, except in cases where the Director General grants an extension.

If the permit holder fails to comply with paragraph 1, the officers shall take all necessary steps to ensure compliance instead, and the permit holder shall bear responsibility for all related costs.

Item 18. Anyone who violates Item 5, paragraph 1, shall be subject to a prison sentence not to exceed 10 years or a fine not in excess of 100,000 baht, or both.

Item 19. Anyone with a permit to produce, possess, distribute, import, export, or transit pathogens or animal toxins who continues to produce, possess, distribute, import, export, or transit such materials after the expiry of his permit and who has not filed a request for a permit renewal as stipulated in Item 8, paragraph 1, shall be subject to a daily fine not in excess of 500 baht for the entire period during which the permit was expired.

Item 20. Any permit holder who fails to comply with Item 10, paragraph 1, shall be subject to a fine not in excess of 1,000 baht.

Item 21. Any person who fails to turn over documents or evidence as required in Item 10(3), or who fails to appear for questioning or to turn over records, documents or other evidence as required in Item 11(5), or who obstructs or refuses to facilitate the work of officers in the performance of their duties as stipulated in Item 11, paragraph 2, shall be subject to a fine not in excess of 5,000 baht.

Item 22. Any permit holder who violates Item 13(1) is subject to imprisonment for a period not to exceed 5 years, or to a fine not to exceed 10,000 baht, or both.

Item 23. Any permit holder who violates Item 13(2) or who fails to comply with Item 14(1) or (2) or Item 16 is subject to a fine not to exceed 5,000 baht.

Item 24. Any permit holder who violates Item 14(2) is subject to a fine not to exceed 10,000 baht, or both.

Item 25. Any permit holder who violates Item 14(3) is subject to imprisonment for a period not to exceed 5 years, or to a fine not to exceed 50,000 baht, or both.

Item 26. Permits issued under the previous Pathogens and Animal Toxins Control Act and which have not expired at the time the present statute enters into force shall remain valid until their date of expiry. Holders of such permits who wish to continue in operation and who have submitted a request for a permit renewal under the provisions of this statute shall be allowed to continue to operate under their current permit until a new permit has been issued or until such time as the Director General notifies holders of his decision not to grant the request for a permit renewal. Permit holders issued a new permit under the provisions of this statute shall be required to make all necessary changes to ensure full compliance with the current law within 180 days of the date of issue of the new permit.

Item 27. The Minister of Public Health shall be responsible for enforcement of this statute and is authorized to appoint officers, issue ministerial regulations, set a table of fees not to exceed those appended to this statute, to exempt payment of fees, and to carry out other activities as required for the enforcement of this statute.

The ministerial regulation shall enter into force upon its publication in the Royal Gazette.

By order of His Majesty the King and on his behalf,
General P. Tinasulanonda
Prime Minister

(99 Royal Gazette 5, Volume 113 (special edition), 16 August B.E. 2525 (1982))

FEES

(1) Application	10 baht
(2) Permit to produce pathogens/animal toxins	500 baht
(3) Permit to possess pathogens/animal toxins	500 baht
(4) Permit to distribute pathogens/animal toxins	500 baht
(5) Permit to import pathogens/animals toxins	500 baht
(6) Permit to export pathogens/animals toxins	500 baht
(7) Permit to transit pathogens/animal toxins	500 baht
(8) Replacement copy	100 baht
(9) Fees for permit renewals are equivalent to fees for initial permits as above.	

Remarks: The reason for enacting this statute is that the Pathogens and Animal Toxins Control Act of B.E. 2475 is insufficiently strict and does not reflect present realities. The enactment of this law is needed to protect public safety and health, and welfare.