

**PATHOGENS AND ANIMAL TOXINS ACT,
B.E. 2558 (2015)**

BHUMIBOL ADULYADEJ, REX.
Given on the 20th Day of August B.E. 2558;
Being the 70th 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 pathogens and animal toxins;
Be it, therefore, enacted by the King by and with the advice and consent of
the National Legislative Assembly, as follows:

Section 1. This Act is called the “Pathogens and Animal Toxins Act, B.E. 2558 (2015)”.

Section 2. This Act shall come into force after the expiration of one hundred and eighty days from the date of its publication in the Government Gazette.¹

Section 3. The following shall be repealed:

- (1) Pathogens and Animal Toxins Act, B.E. 2525 (1982);
- (2) Pathogens and Animal Toxins Act (No. 2), B.E. 2544 (2001).

Section 4. In this Act:

“pathogen” means:

- (1) microorganisms;

* Translated by Ms. Arriya Phasee under contract for the Office of the Council of State of Thailand's Law for ASEAN project. – Tentative Version – subject to final authorisation by the Office of the Council of State.

¹ Published in the Government Gazette, Vol. 132, Part 80a, Page 9, date 26th August B.E. 2558.

(2) biological substance;

(3) other germs as prescribed in the Notifications issued under section 6 (3).

In the case of (1), (2) and (3), they shall be capable of causing diseases in humans, livestock, beasts of burden or other animals prescribed in the Notifications issued under section 6 (3);

“animal toxin” means toxin from animals that causes a condition that prevents the body from working normally in humans, livestock, beasts of burden or other animals prescribed in the Notifications issued under section 6 (3);

“microorganisms” means bacteria, molds, viruses and parasites;

“biological substance” means:

(1) a culture or any part of it made or modified from animal toxins, microorganisms or other germs prescribed in the Notifications issued under section 6 (3);

(2) proteinaceous infectious particle (Prion);

“produce” means to cultivate, mix, prepare, transform, add volume, synthesise, repack or pack in mass;

“import” means to bring or order to bring into the Kingdom;

“export” means to take or send out of the Kingdom;

“sell” means to dispose of, distribute, dispense or exchange for trade purposes, and shall include having in possession for sale;

“transit” means to take or send through the Kingdom whether or not there is a transshipment or change of carriers in the Kingdom;

“possess” means to have in possession for the possessor himself or herself or for other persons;

“accompanying document” means paper or any other material which displays meanings or details of pathogens or animal toxins, inserted in or displayed on their container or package;

“label” means any picture, artificial mark or statement displayed on a container or package of pathogens or animal toxins for the purpose of identification or provision of relevant information;

“container” means any material which is used specifically to contain or wrap pathogens or animal toxins;

“finished product” means a physical item made from a production or transformation process, comprising of a pathogen or animal toxin as prescribed in the law on medical devices, the law on cosmetics, the law on drugs, the law on hazardous substances, the law on food and other related laws;

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“person receiving a certificate of notification” means a person who has received a certificate of notification under this Act and, in the case of a juristic person receiving a certificate of notification, shall also include representatives or persons authorised to act on behalf of such juristic person;

“licensee” means a person who has received a license under this Act and, in the case of a juristic person receiving a license, shall also include representatives or persons authorised to act on behalf of such juristic person;

“operator” means a person who controls the production, import, export, sale, transit or possession of pathogens or animal toxins and whose name appears on a certificate of notification or a license as the operator under this Act;

“operation personnel” means a person who operates the production, import, export, sale, transit or possession of pathogens or animal toxins and whose name appears on a certificate of notification or a license as the operation personnel under this Act;

“Director-General” means the Director-General of Department of Medical Sciences;

“Committee” means the Pathogens and Animal Toxins Committee;

“member” means a member of the Pathogens and Animal Toxins Committee;

“competent official” means a person appointed by the Minister to execute this Act;

“Minister” means the Minister having charge and control over the execution of this Act.

Section 5. The Minister of Public Health shall have charge and control over the execution of this Act and shall have the power to appoint or remove competent officials, issue Ministerial Regulations or Notifications and prescribe other acts for the execution of this Act, as well as to issue Ministerial Regulations prescribing fees not exceeding the rates provided in the Annex of this Act and reducing or exempting fees.

Such Ministerial Regulations and Notifications shall come into force upon their publication in the Government Gazette.

Section 6. For the purpose of safety protection and prevention of harm to the public, the Minister by and with the advice of the Committee shall have the power to prescribe in the Notifications the following:

- (1) the list of pathogens intended to be under the control under section 18;

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- (2) the list of animal toxins intended to be under the control under section 19;
- (3) other germs and other animals under section 4;
- (4) characteristics of the place of production or possession of pathogens and animal toxins, tools, equipment, accompanying documents, labels, containers or packages for each group of pathogens and animal toxins under section 18 and section 19, and quantities or amount of pathogens and animal toxins which can be possessed, as well as security systems and quality systems of production, import, export, sale, transit or possession of pathogens and animal toxins;
- (5) criteria, procedures and conditions for the production, import, export, sale, transit or possession of pathogens and animal toxins, which requires arrangement of an operator or operation personnel, as well as qualifications, number and duties of the operator and operation personnel;
- (6) criteria, procedures and conditions for import, export, sale, transit or possession of pathogens and animal toxins in the form of finished products;
- (7) criteria, procedures and conditions for medical diagnosis processes or post-mortem examination processes in relation to pathogens and animal toxins;
- (8) criteria, procedures and conditions in taking samples from drugs, food, health products or environment or conducting laboratory tests for the purpose of medical and public health in relation to pathogens and animal toxins;
- (9) criteria, procedures and conditions to be abided by agencies under section 28, and establishment of a biosafety control committee;
- (10) criteria, procedures and conditions in relation to studies and research for disease control, disease prevention and therapy;
- (11) criteria, procedures and conditions 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;
- (12) criteria, procedures and conditions in relation to the designation of areas prohibited or permitted for production, import, export, sale, transit or possession of pathogens and animal toxins, including pathogen and animal toxin checkpoints;
- (13) criteria, procedures and conditions in relation to safety assessment of technologies used in the production of pathogens and animal toxins;

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(14) criteria, procedures and conditions in relation to the termination of production, import, export, sale, transit and possession of pathogens and animal toxins;

(15) criteria, procedures and conditions in relation to transportation, destruction, handover and inactivation of pathogens and animal toxins;

(16) criteria, procedures and conditions in relation to the notification of an order of suspension and revocation of certificates of notification and licenses;

(17) criteria, procedures and conditions in relation to exercise of power, operations, performance of duties and qualifications of competent officials;

(18) 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.

CHAPTER I PATHOGENS AND ANIMAL TOXINS COMMITTEE

Section 7. There shall be a committee called the “Pathogens and Animal Toxins Committee”, consisting of:

- (1) the Permanent Secretary of Ministry of Public Health as Chairperson;
- (2) fourteen ex officio members, namely the Director-General of Department of Land Transport, the Director-General of Department of Foreign Trade, the Director-General of Department of Disease Control, the Director-General of Department of Fisheries, the Director-General of Department of Livestock Development, the Director-General of Customs Department, the Director-General of Department of Treaties and Legal Affairs, the Director-General of Department of International Organisations, the Secretary-General of National Research Council of Thailand, the Secretary-General of Office of Natural Resources and Environmental Policy and Planning, a representative of the Ministry of Defence, a representative of the Ministry of Science and Technology, a representative of the Office of the Council of State and a representative of the Office of the National Security Council;
- (3) five qualified members appointed by the Minister from professionals having the knowledge and experience in pathogens or animal toxins, by and with the advice of the Medical Council of Thailand, the Veterinary Council of Thailand, the Medical Technology Council, the Pharmacy Council of Thailand and the Council of Science and Technology Professionals, one from each council;

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(4) seven qualified members appointed by the Minister from persons having the knowledge, expertise, past performance records and experience in the fields of animal toxins, bacteria, molds, infectious diseases, viruses, parasites and biotechnology, one from each field.

The Director-General shall be a member and secretary, and the Director-General shall appoint two government officials of the Department of Medical Sciences who are responsible for the work related to pathogens or animal toxins as assistant secretaries.

The appointment of qualified members shall be in accordance with the criteria, procedures and conditions prescribed in the Notifications by the Minister.

Section 8. A qualified member shall not possess the following prohibited characteristics:

- (1) being bankrupt or having been bankrupt due to dishonesty;
- (2) being incompetent or quasi-incompetent;
- (3) having been subject to an imprisonment penalty by a final judgment to imprisonment, except for an offence committed through negligence or a petty offence;
- (4) having been expelled, dismissed or discharged from an official service, a State agency or a private agency on the grounds of dishonest performance of duties or gross misconduct or deemed as having committed dishonest acts and malfeasance in official service;
- (5) being a person whose certificate of notification or license under this Act is being suspended;
- (6) being a person whose certificate of notification or license under this Act has been revoked during a period of three years prior to the date of appointment;
- (7) being a person whose license to conduct his or her profession is being suspended or has been revoked.

Section 9. A qualified member shall hold office for a term of three years from the date of appointment. A qualified member who vacates office may be reappointed, but may not hold office for more than two consecutive terms.

In the case where a qualified member vacates office upon the expiration of the term, but a new qualified member has not yet been appointed, such qualified member shall continue to perform his or her duties until a new qualified member has been appointed.

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In the case where a qualified member vacates office prior to the expiration of the term and a new qualified member has not yet been appointed to replace the vacated position, the remaining members shall be able to continue performing their duties.

When a qualified member vacates his or her office prior to the expiration of the term, the Minister shall appoint a replacement qualified member, unless the remaining term of the qualified member who vacates the office is less than one hundred and eighty days, in which case, the appointment of a replacement qualified member may be omitted.

The qualified member who has been appointed to fill a vacancy shall be in office for the remaining term of office of the qualified member whom he or she replaces.

Section 10. In addition to vacating office on the expiration of term, a qualified member vacates office upon:

- (1) death;
- (2) resignation;
- (3) being dismissed by the Committee's resolution with the vote of not less than two-thirds of the total number of the members on the grounds of negligence in the performance of duty or disgraceful behavior;
- (4) being disqualified pursuant to section 7 (3) or (4) or possessing any prohibited characteristics under section 8.

Section 11. At a meeting of the Committee, the presence of not less than one-half of all members is required to constitute a quorum.

At a meeting of the Committee, if the Chairperson is not present at the meeting or is unable to perform the duties, the meeting shall elect one member to preside over the meeting.

A decision of the meeting shall be made by a majority of votes. In casting a vote, each member shall have one vote. In the case of an equality of votes, the presiding member shall have an additional vote as the casting vote.

Section 12. The Committee shall have the power and duties as follows:

- (1) to provide recommendation or opinions to the Minister on the establishment of policy and measures on the safety protection and prevention of harm from pathogens and animal toxins under this Act to the public;
- (2) to provide recommendation to the Minister on the issuance of Notifications for the execution of this Act;

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(3) to determine the settlement criteria under section 80;

(4) to perform any other acts as stipulated in the laws to be the power and duties of the Committee, or as assigned by the Council of Ministers or the Minister.

Section 13. The Committee may appoint a sub-committee to consider any matter or carry out any act as assigned by the Committee.

The Committee may stipulate a quorum, meeting procedures and work procedures of the sub-committee as appropriate.

Section 14. In the execution of duties under this Act, the Committee shall have the power to issue a written summons requiring any person to come to give statements or furnish explanations, documents, information, evidence or any related objects in support of consideration.

Section 15. The Department of Medical Sciences, Ministry of Public Health shall be in charge of general affairs of the Committee and the sub-committee, and shall have the power and duties as follows:

(1) to conduct or provide support for the conduct of study, analysis and research on pathogens and animal toxins;

(2) to monitor and evaluate the implementation of the policy and measures on the safety protection and prevention of harm from pathogens and animal toxins to the public;

(3) to be the central information base of pathogens and animal toxins;

(4) to coordinate and cooperate with the relevant State agencies, educational institutes, international organisations or private organisations in the operations related to pathogens and animal toxins;

(5) to perform any other acts as assigned by the Minister, the Committee or the sub-committee, or as stipulated in the laws to be the power and duties of the Department of Medical Sciences, Ministry of Public Health.

CHAPTER II

PATHOGENS AND ANIMAL TOXINS CONTROL

Section 16. No person may use pathogens or animal toxins for the following purposes:

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(1) to carry out any act which causes danger to other persons or other persons' health;

(2) to carry out any act which causes damage to the environment.

Section 17. No person may conceal, cover up or destroy pathogens or animal toxins to obstruct a competent official's performance of duties in relation to disaster prevention and mitigation or provision of emergency medical service under the relevant laws.

Section 18. For the purpose of pathogens control, the Minister by and with the advice of the Committee shall have the power to prescribe in the Notification the list of pathogens, classified into 4 groups as follows, taking into account prevention methods, treatment methods, dispersal and quantities or amount of pathogens, in consistence with the degree of risk of causing diseases or hazards which may occur in humans, the community, livestock, beasts of burden or other animals prescribed in the Notifications issued under section 6 (3):

(1) Group 1 Pathogens, which include the pathogens that pose a low risk or low hazard;

(2) Group 2 Pathogens, which include the pathogens that pose a moderate risk or moderate hazard;

(3) Group 3 Pathogens, which include the pathogens that pose a high risk or high hazard;

(4) Group 4 Pathogens, which include the pathogens that pose a very high risk or very high hazard.

Section 19. For the purpose of animal toxins control, the Minister by and with the advice of the Committee shall have the power to prescribe in the Notification the list of animal toxins, classified into 3 groups as follows, taking into account treatment methods and quantities or amount of animal toxins, in consistence with the degree of risk of causing a condition that prevents the body from working normally or causing hazards which may occur in humans, livestock, beasts of burden or other animals prescribed in the Notifications issued under section 6 (3):

(1) Group 1 Animal Toxins, which include the animal toxins that cause a condition that prevents the body from working normally, but not at a serious level and effective treatment is available;

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(2) Group 2 Animal Toxins, which include the animal toxins that cause a condition that prevents the body from working normally at a serious level and effective treatment is available;

(3) Group 3 Animal Toxins, which include the animal toxins that cause a condition that prevents the body from working normally at a serious level and effective treatment is not available.

CHAPTER III
PRODUCTION, IMPORT, EXPORT, SALE, TRANSIT OR POSSESSION
OF PATHOGENS AND ANIMAL TOXINS

Section 20. A person who produces, imports, exports, sells, transits or possesses Group 1 Pathogens under section 18 (1) shall comply with the Notifications issued under section 6 (4), (10), (11), (12), (13), (14) and (15).

Section 21. Any person who intends to produce, import, export, sell, transit or possess Group 2 Pathogens under section 18 (2) or Group 1 Animal Toxins under section 19 (1) shall notify the Director-General in writing in order to obtain a certificate of notification.

Upon receipt of the notification under paragraph one, the Director-General shall issue a receipt of notification for temporary use as evidence in the production, import, export, sale, transit or possession of pathogens or animal toxins under paragraph one during the period when the Director-General has not issued a certificate of notification.

The notification, the issuance of a receipt of notification, the issuance of a certificate of notification, the term of a certificate of notification, the renewal of a certificate of notification and the issuance of a replacement certificate of notification under paragraph one or paragraph two shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

A person who produces, imports, exports, sells, transits or possesses pathogens or animal toxins under paragraph one shall also comply with the Notifications issued under section 6 (4), (5), (10), (11), (12), (13), (14), (15) and (18).

A receipt of notification under paragraph two shall be effective until the Director-General has issued a certificate of notification or an order of non-issuance of a certificate of notification.

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Section 22. Any person who intends to produce, import, export, sell, transit or possess Group 3 Pathogens under section 18 (3) or Group 2 Animal Toxins under section 19 (2) shall file an application for a license with the Director-General, and such person may produce, import, export, sell, transit or possess such pathogens or animal toxins when the Director-General has already issued the license.

The application for a license, the permission, the term of a license, the renewal of a license and the issuance of a replacement license under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

A person who produces, imports, exports, sells, transits or possesses pathogens or animal toxins under paragraph one shall also comply with the Notifications issued under section 6 (4), (5), (10), (11), (12), (13), (14), (15) and (18).

Section 23. The Director-General will issue a certificate of notification under section 21 or a license under section 22 if it appears that the applicant for a certificate of notification or a license has qualifications and possesses no prohibited characteristics as follows:

(a) Qualifications

(1) being an owner of an entity which intends to apply for a certificate of notification or a license;

(2) being not less than twenty years of age;

(3) having domicile in Thailand;

(4) having the place of production or possession of pathogens or animal toxins, tools, equipment, containers or packages, and quantities or amount of pathogens or animal toxins, as well as security systems and quality systems of production, import, export, sale, transit or possession of pathogens or animal toxins according to the Notifications issued under section 6 (4);

(5) having an operator and operation personnel in accordance with the Notifications issued under section 6 (5);

(b) Prohibited characteristics

(1) being bankrupt or having been bankrupt due to dishonesty;

(2) being incompetent or quasi-incompetent;

(3) having been subject to an imprisonment penalty by a final judgment to imprisonment, except for an offence committed through negligence or a petty offence or

where the applicant had completed serving the sentence for at least five years prior to the date of application for a certificate of notification or a license;

(4) being a person whose certificate of notification or license under this Act is being suspended;

(5) being a person whose certificate of notification or license under this Act has been revoked during a period of two years prior to the date of application for a certificate of notification or a license;

(6) using a commercial name which is duplicate or similar to the commercial names of the persons receiving a certificate of notification or the licensees whose certificates of notification or licenses are being suspended or have been revoked for a period of less than two years.

A person applying for a certificate of notification, a person applying for a license, an operator and operation personnel may be the same person.

In the case where a juristic person applies for a certificate of notification or a license, a representative(s) or a person(s) authorised to act on behalf of such juristic person shall have the qualifications under paragraph one (a) (2) and (3) and possess no prohibited characteristics under paragraph one (b) (1), (2), (3), (4) and (5).

Section 24. A certificate of notification under section 21 and a license under section 22 shall be classified as follows:

- (1) production of pathogens and animal toxins;
- (2) import of pathogens and animal toxins;
- (3) export of pathogens and animal toxins;
- (4) sale of pathogens and animal toxins;
- (5) transit of pathogens and animal toxins;
- (6) possession of pathogens and animal toxins.

A person receiving a certificate of notification or a licensee under (1), (2), (3), (4) or (5) shall be deemed to be a person receiving a certificate of notification or a licensee under (6) as well.

Section 25. Subject to the provisions of section 21 and section 22, a person receiving a certificate of notification or a licensee shall have the following duties:

(1) to present the certificate of notification or the license at the open and noticeable place at the premises specified in the certificate of notification or the license;

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(2) to arrange to have a pathogen or animal toxin account and an account related to production, import, export, sale, transit or possession of pathogens or animal toxins according to the list of pathogens under section 18 or the list of animal toxins under section 19;

(3) to arrange to have a document stating details of safety assessment of technologies used in the production of pathogens or animal toxins and arrange the same to be kept for at least five years for inspection by competent officials.

Section 26. If any information relating to particulars in a certificate of notification or a license has changed or a person receiving a certificate of notification or a licensee wishes to amend a particular in the certificate of notification or the license, an application shall be submitted to the Director-General, except for a temporary relocation or change of the place of import, the place of export, the place of sale or the place of possession due to a necessary and urgent cause which renders the submission of an application impracticable, in which case, the relocation or change of such places may be made on a temporary basis and the Director-General shall be notified immediately.

The application for, and the permission of amendment of particulars and the notification of temporary relocation or change of places under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

Section 27. The provisions of section 21 and section 22 shall not apply to the following cases:

(1) import, export, sale, transit or possession of pathogens or animal toxins in the form of finished products;

(2) medical diagnosis processes or post-mortem examination processes, including collection of samples to be used in such processes;

(3) taking samples from drugs, food, health products or environment, or laboratory testing for medical and public health purposes.

The implementation under paragraph one (1), (2) and (3) shall be in accordance with the Notifications issued under section 6 (6), (7) and (8).

Section 28. An agency conducting studies and research for the purpose of disease control, disease prevention and therapy, which intends to produce or possess pathogens or animal toxins shall arrange to have an operator and operation personnel for

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such agency in accordance with the Notifications issued under section 6 (5) and shall arrange to have a biosafety control committee in accordance with the Notifications issued under section 6 (9) as well as complying with the Notifications issued under section 6 (10).

An agency under paragraph one includes:

- (1) Ministries, *Ta-buang*s, Departments, educational institutes or infirmaries of the State, public organisations or other State agencies;
- (2) the Government Pharmaceutical Organisation;
- (3) the Thai Red Cross Society.

After the requirements under paragraph one have been complied with, such agency shall be deemed to have become a person receiving a certificate of notification under section 21 or a licensee under section 22 until the Director-General notifies an order of non-issuance of a certificate of notification or a license, as the case may be.

Section 29. No person may produce, import, export, sell, transit or possess Group 4 Pathogens under section 18 (4) or Group 3 Animal Toxins under section 19 (3), except for the purpose of studies and research for disease control, disease prevention and therapy in accordance with the Notifications issued under section 6 (10).

Section 30. In carrying out the production, import, export, sale, transit or possession of pathogens or animal toxins under section 20, section 21 and section 22, if it appears that the pathogens or animal toxins have a higher level of severity than the level requiring compliance under section 20 or the level specified in a certificate of notification or a license, the person who is required to comply with section 20, the person receiving a certificate of notification or the licensee shall notify the Director-General at prompt.

After the notification has been made under paragraph one, such person shall be deemed to have become a person receiving a certificate of notification under section 21 or a licensee under section 22 until the Director-General issues an order of non-issuance of a certificate of notification or a license, and during such period the criteria, procedures and conditions under section 21, section 22 or section 29, as the case may be, shall be complied with, and if such person wishes to continue to carry out the higher level, such person shall request for a certificate of notification or a license or shall comply with section 29, but if such person wishes not to continue to carry out the higher level, the provision of section 35 shall apply, *mutatis mutandis* and such person shall notify the result of the operation to the Director-General at prompt.

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The notification under paragraph one and paragraph two shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

CHAPTER IV

IMPLEMENTATIONS IN UNSAFE AND DANGER SITUATIONS, EMERGENCY OR NECESSITY

Section 31. In the case of unsafe situations for, and danger to persons, the environment or the public due to the processes or steps in relation to the production, import, export, sale, transit or possession of pathogens or animal toxins, the person receiving a certificate of notification or the licensee shall immediately notify the Director-General of the cause of such circumstances, the level of severity and the quantities or amount of the pathogens or animal toxins.

Upon receipt of the notification under paragraph one, the Director-General shall perform any one of the following actions:

(1) to issue a written order instructing the person receiving a certificate of notification or the licensee to cease the production, import, export, sale or transit of pathogens or animal toxins on a temporary basis within a period of time prescribed by the Director-General;

(2) to issue a written order instructing the person receiving a certificate of notification or the licensee to hand over or destroy the pathogens or animal toxins within a period of time prescribed by the Director-General;

(3) to order to perform any other actions to ensure safety and prevention of harm to persons, the environment or the public.

In the case where expenses occur from performing the actions under paragraph two (1), (2) or (3), the person receiving a certificate of notification or the licensee shall be responsible for such expenses.

The notification under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

Section 32. In the case of emergency or necessity for public interests or for protection and prevention of harm which may occur to humans, livestock, beasts of burden or other animals prescribed in the Notifications issued under Section 6 (3) or for national

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security, the Minister by and with the advice of the Committee shall have the power to prescribe in the Notifications any of the following:

- (1) restrictions or permissions of the production, import, export, sale, transit or possession of prescribed pathogens or animal toxins;
- (2) areas prohibited or permitted for production, import, export, sale, transit or possession of pathogens or animal toxins, including temporary suspension of such actions;
- (3) pathogen or animal toxin checkpoints;
- (4) designation of experts, State agencies or other agencies in the country and abroad for safety assessment of technologies used in the production of pathogens or animal toxins, and determination of the expenses for such assessment;
- (5) other related matters.

CHAPTER V

TERMINATION OF PRODUCTION, IMPORT, EXPORT, SALE, TRANSIT OR POSSESSION OF PATHOGENS AND ANIMAL TOXINS

Section 33. Any person receiving a certificate of notification or licensee who intends to terminate the production, import, export, sale, transit or possession of pathogens or animal toxins shall notify in writing to the Director-General prior to the date of intended termination, and the certificate of notification or the license shall be deemed to have expired from the date of intended termination.

The notification of termination under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

Section 34. If the Director-General issues an order of non-renewal of a certificate of notification under section 21 or a license under section 22, the person receiving a certificate of notification or the licensee shall terminate the production, import, export, sale or transit of pathogens or animal toxins from the date of receipt of such non-renewal order, and the certificate of notification or the license shall expire in accordance with the term specified in the certificate of notification or the license.

Section 35. In the case where a person receiving a certificate of notification or a licensee has notified the termination of production, import, export, sale, transit or possession of pathogens or animal toxins under section 33 or the Director-General has

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issued an order of non-renewal of the term of a certificate of notification or license under section 34, the person receiving a certificate of notification or the licensee shall destroy or hand over the remaining pathogens or animal toxins to other persons receiving a certificate of notification or licensees.

The destruction or handover of pathogens or animal toxins to other persons receiving a certificate of notification or licensees under paragraph one shall be completed within thirty days. If it is unable to be completed within such specified period of time, the Director-General may extend the period of time for not more than thirty days in accordance with the Notifications issued under section 6 (15).

The Notification under paragraph two may require the State agencies or private agencies having the experience and expertise in relation to pathogens or animal toxins to perform an action on behalf of the person receiving a certificate of notification or the licensee as necessary, including requiring the person receiving a certificate of notification or the licensee to be responsible for the expenses incurred from such action.

Section 36. In the case where a person receiving a certificate of notification or a licensee dies or loses the status of a juristic person, the heir, executor, liquidator, operator or operation personnel shall notify the Director-General within fifteen days from the date on which the person receiving a certificate of notification or the licensee dies or loses the status of a juristic person. Such notification shall be deemed as a notification of termination of the production, import, export, sale, transit or possession of pathogens or animal toxins under section 33, and the heir, executor or liquidator shall destroy or hand over the remaining pathogens or animal toxins in accordance with section 35.

In the case where the heir intends to continue to produce, import, export, sell, transit or possess the pathogens or animal toxins, he or she shall comply with section 21 or section 22, as the case may be.

The notification under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

CHAPTER VI

SUSPENSION AND REVOCATION OF CERTIFICATE OF NOTIFICATION AND LICENSE

Section 37. If any person receiving a certificate of notification or licensee fails to comply or incorrectly complies with this Act, Ministerial Regulations or Notifications

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issued under this Act or conditions specified in the certificate of notification or the license, the Director-General shall issue a written warning requiring compliance or rectification of such person's action within a specified period of time. If such person fails to comply with the warning, the Director-General shall order to suspend the certificate of notification or the license, but this may not eradicate offences already committed.

In the case where a case is brought before the court against a person receiving a certificate of notification or a licensee for an offence under this Act, the Director-General may suspend the certificate of notification or the license pending the final judgment of the court.

The person receiving a certificate of notification or the licensee whose certificate of notification or license has been suspended shall cease the production, import, export, sale or transit of pathogens or animal toxins under such certificate of notification or license on a temporary basis for a specified period of time and may not apply for any certificate of notification or license under this Act during the suspension period. The Director-General may prescribe conditions to be observed by the person whose certificate of notification or license has been suspended for safety protection and prevention of harm from pathogens or animal toxins.

Section 38. The Director-General shall have the power to cancel the order of suspension of a certificate of notification or a license before the expiration of the period when it appears that the person whose certificate of notification or license has been suspended has correctly complied with this Act, Ministerial Regulations or Notifications issued under this Act or conditions specified in the certificate of notification or the license.

Section 39. The Director-General shall have the power to order to revoke a certificate of notification or a license when it appears that:

- (1) a person receiving a certificate of notification or a licensee is disqualified or possesses any prohibited characteristics under section 23;
- (2) a person receiving a certificate of notification or a licensee violates the order of suspension of a certificate of notification or a license under section 37 or has had the certificate of notification or the license suspended twice or more on the same grounds;
- (3) a person receiving a certificate of notification or a licensee has been sentenced by a final judgement of offence under this Act;
- (4) a person receiving a certificate of notification or a licensee fails to comply or incorrectly complies with this Act, Ministerial Regulations or Notifications issued under this

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Act or conditions specified in the certificate of notification or the license which has caused or may cause serious damage or harm to the public.

The person receiving a certificate of notification or the licensee whose certificate of notification or license has been revoked shall cease the production, import, export, sale or transit of pathogens or animal toxins under such certificate of notification or license immediately upon receipt of the order of revocation of the certificate of notification or the license, and may not apply for any certificate of notification or license under this Act until the period of two years from the date of the revocation has elapsed.

The provision of section 35 shall apply, *mutatis mutandis* to the person receiving a certificate of notification or the licensee whose certificate of notification or license has been revoked.

Section 40. The Director-General shall notify in writing an order of suspension of a certificate of notification or a license under section 37 or an order of revocation of a certificate of notification or a license under section 39 to a person receiving a certificate of notification or a licensee for acknowledgment within five days from the date of such order.

The Director-General may deliver the notification under paragraph one via mail with return receipt requested, fax, electronic means or other means, taking into account urgent necessity and convenience as appropriate, in accordance with the Notifications issued under section 6 (16).

CHAPTER VII COMPETENT OFFICIALS

Section 41. In the execution of this Act, a competent official shall have the power as follows:

(1) to enter the place of production, import, export, sale, transit or possession of pathogens or animal toxins during the period from sunrise to sunset or during office hours of such place for the purpose of inspection or control to ensure compliance with this Act;

(2) to take the samples of pathogens or animal toxins at a reasonable amount for inspection or analysis;

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(3) to confiscate or seize pathogens or animal toxins and any tools, equipment or materials involved in an offence, as well as containers or packages and related documents for the benefit of the legal proceedings if there are reasonable grounds to suspect that there is commission of offence under this Act;

(4) to issue a letter of inquiry or a written summons to any person to come to give statements or furnish explanations, documents, information, evidence or any necessary objects for examination or in support of the competent official's consideration.

The positions or levels of a competent official who is to have the power as referred to in paragraph one, the extent of the power or the persons from which a competent official must seek approval before exercising his or her power, as well as the performance of duties and qualifications of competent officials at each position or level shall be in accordance with the Notifications issued under section 6 (17).

Section 42. A person receiving a certificate of notification, a licensee and the persons having a duty related to the production, import, export, sale, transit or possession of pathogens or animal toxins shall render appropriate facilities to a competent official who performs the duty under section 41.

Section 43. The confiscated or seized item under section 41 (3) shall be vested in the Ministry of Public Health if it appears that:

(1) the owner could not be identified or no one claimed ownership or possession of the item within ninety days from the date of confiscation or seizure;

(2) there is no legal proceeding and the owner or occupier did not make a request for the return of such item within ninety days from the date of receipt of an order of non-legal proceeding;

(3) there is a legal proceeding and a public prosecutor issues a final order of non-prosecution or the court orders not to forfeit such item and no one made a request for the return within ninety days from the date of the public prosecutor's issuance of the final order of non-prosecution or the date of the court's issuance of the final judgement, as the case may be.

Section 44. In the case where the confiscated or seized item under section 41 (3) is perishable or nearing the end of its stated useful life or will, if retained, be exposed to a risk of damage or harm to the public or incur maintenance expenses exceeding its value or be more burdensome to the official service than its usability for other purposes, the

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Director-General may order the item to be destroyed or take other appropriate measures in accordance with the methods prescribed by him or her.

If the confiscated or seized item under paragraph one may be sold by a public auction or by other means prescribed by the Director-General, a competent official shall proceed with the sale. The net amount gained, after deducting related expenses and charges, shall be seized in lieu of the item.

Section 45. In the case where the confiscated or seized item must be destroyed or dealt with appropriately under section 44, if expenses occur, the owner of such item shall be responsible to pay or compensate that amount to the Ministry of Public Health.

Section 46. In the execution of the duties under this Act, the competent official shall produce his or her identification card to the persons concerned.

The identification card of a competent official shall be in accordance with the form prescribed in the Ministerial Regulations.

Section 47. In the execution of the duties under this Act, the competent official shall be an officer under the Criminal Code.

CHAPTER VIII APPEALS

Section 48. In the case where the Director-General orders not to issue a certificate of notification or a license or orders not to renew the term of a certificate of notification or a license, the applicant for a certificate of notification or the applicant for a license or the person receiving a certificate of notification or the licensee shall have the right to file an appeal in writing with the Minister within thirty days from the date of receipt of the notification of an order of non-issuance of a certificate of notification or a license or an order of non-renewal of a certificate of notification or a license, as the case may be.

The Minister's decision shall be final.

Section 49. The person receiving a certificate of notification or the licensee whose certificate of notification or license has been suspended or revoked shall have the

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right to file an appeal in writing with the Minister within thirty days from the date of receipt of the notification of an order of suspension or revocation of a certificate of notification or a license, as the case may be.

The Minister's decision shall be final.

The appeal under paragraph one shall not be cause to suspend the enforcement of the order of suspension or revocation of a certificate of notification or a license.

Section 50. The Minister shall complete the consideration of the appeal under section 48 and section 49 within sixty days from the date of receipt of the appeal. If the consideration cannot be completed within such period of time due to a cause of necessity, a written notice shall be given to the appellant before the expiry of such period. In this regard, the period of time for the consideration of the appeal may be extended for not more than sixty days from the expiry date.

CHAPTER IX CIVIL LIABILITIES

Section 51. A person receiving a certificate of notification, a licensee, an owner or occupier of pathogens or animal toxins shall be responsible for the damage arising from the production, import, export, sale, transit, possession or dispersal of pathogens or animal toxins, except where such person can prove that the damage was caused by *force majeure*, war, terrorism or by the fault of the injured person.

In addition to the damage to be responsible for under paragraph one, a person receiving a certificate of notification, a licensee, an owner or occupier of pathogens or animal toxins shall be responsible for all expenses actually paid by the official service in order to deal with pathogens or animal toxins, assist, move, give treatment or alleviation or provide removal of damage and restore it to original or near original condition.

Section 52. Any person who uses or enables the use of pathogens or animal toxins on another person thereby causing death or injury to the body or health shall be responsible for such person's damage arising from the use of such pathogens or animal toxins unless it can be proven that precautions have been taken in conformity with

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technical standards, or that the damage was caused by *force majeure* or by the fault of the injured person.

Section 53. The right to claim for compensation for damage arising from pathogens or animal toxins or the use of pathogens or animal toxins under this chapter shall be barred by prescription after the lapse of three years from the date on which the injured person has knowledge of the damage and the person liable to pay compensation, but the prescription shall not exceed ten years from the date on which the damage occurs due to the pathogens or animal toxins or the use of the pathogens or animal toxins.

If there is a negotiation in respect of the compensation between the person who is understood to be liable for the compensation and the person entitled thereto, the prescription shall be interrupted until it appears that such negotiation has failed.

Section 54. A liable person under section 51 or section 52 who has paid compensation to the injured person shall have the right of recourse against a person who has contributed to the cause of injury. The right of recourse shall be exercised within three years from the date of payment of compensation. The person exercising the right of recourse, however, shall have the right of recourse only for the part of the damage that is over and above such person's responsibility.

Section 55. The provisions of this chapter shall not prejudice or limit the duties and civil liabilities of a person provided under the provisions of other chapters or other laws.

CHAPTER X PENALTY PROVISIONS

Section 56. Any operator or operation personnel who violates or fails to comply with the duties prescribed in the Notifications issued under section 6 (5) shall be liable to a fine not exceeding fifty thousand baht.

Section 57. Any person who fails to come to give statements or fails to furnish explanations, documents, information, evidence or any objects in accordance with the Committee's order under section 14 or a competent official's written summons under

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section 41 (4), shall be liable to imprisonment for a term of not exceeding one month or to a fine not exceeding ten thousand baht or to both.

Section 58. Any person who commits an act under section 16 (1) shall be liable to imprisonment for a term of six months to ten years, and to a fine of fifty thousand baht to one million baht.

If the act under paragraph one causes death to another person, the person who commits such act shall be liable to life imprisonment or imprisonment for a term of five years to twenty years, and to a fine of five hundred thousand baht to two million baht.

If the act under paragraph one causes grievous bodily harm to another person, the person who commits such act shall be liable to imprisonment for a term of one year to ten years, and to a fine of one hundred thousand baht to one million baht.

Section 59. Any person who commits an act under section 16 (2) shall be liable to imprisonment for a term of not exceeding three years or to a fine not exceeding three hundred thousand baht or to both.

Section 60. If an offence under section 58, paragraph one or section 59 is committed through negligence, the offender shall be liable to imprisonment for a term of not exceeding one year or to a fine not exceeding one hundred thousand baht or to both.

If the offence under paragraph one causes death to another person, the offender shall be liable to imprisonment for a term of not exceeding ten years or to a fine not exceeding one million baht or to both.

If the offence under paragraph one causes grievous bodily harm to another person, the offender shall be liable to imprisonment for a term of not exceeding three years or to a fine not exceeding three hundred thousand baht or to both.

Section 61. If an offence under section 58, paragraph one or section 59 is committed with an intention to coerce or force the public, State agencies, Thai Government, foreign governments or international organisations to carry out or refrain from carrying out any act which will cause serious damage or create disorder by causing the public to be terrified, the offender shall be liable to the death penalty, life imprisonment or imprisonment for a term of four years to twenty years, and to a fine of four hundred thousand baht to two million baht.

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Section 62. Any person who violates section 17 shall be liable to imprisonment for a term of not exceeding two years or to a fine not exceeding two hundred thousand baht or to both.

Section 63. Any person who produces, imports, exports, sells, transits or possesses Group 1 Pathogens in violation of or non-compliance with section 20 shall be liable to a fine not exceeding fifty thousand baht.

Section 64. Any person who produces, imports, exports, sells, transits or possesses Group 2 Pathogens or Group 1 Animal Toxins without notifying the Director-General in order to obtain a certificate of notification under section 21, paragraph one, shall be liable to imprisonment for a term of not exceeding two years or to a fine not exceeding two hundred thousand baht or to both.

Any person under paragraph one who violates or fails to comply with section 21, paragraph four shall be liable to a fine not exceeding one hundred thousand baht.

Section 65. Any person who produces, imports, exports, sells, transits or possesses Group 3 Pathogens or Group 2 Animal Toxins without obtaining a license under section 22, paragraph one, shall be liable to imprisonment for a term of not exceeding three years or to a fine not exceeding three hundred thousand baht or to both.

Any person under paragraph one who violates or fails to comply with section 22, paragraph three shall be liable to a fine not exceeding two hundred thousand baht.

Section 66. Any person receiving a certificate of notification or licensee who fails to perform the duty under section 25 (1) shall be liable to a fine not exceeding ten thousand baht.

Any person under paragraph one who fails to perform the duty under section 25 (2) or (3) shall be liable to a fine not exceeding fifty thousand baht.

Section 67. Any person receiving a certificate of notification or licensee who violates or fails to comply with section 26 shall be liable to a fine not exceeding fifty thousand baht.

Section 68. Any person who violates or fails to comply with section 27, paragraph two shall be liable to a fine not exceeding fifty thousand baht.

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Section 69. Any person who produces, imports, exports, sells, transits or possesses Group 4 Pathogens or Group 3 Animal Toxins in violation of or non-compliance with section 29 shall be liable to imprisonment for a term of not exceeding ten years or to a fine not exceeding one million baht or to both.

Section 70. Any person required to comply with section 20, person receiving a certificate of notification or licensee who fails to make a notification to the Director-General under section 30, paragraph one shall be liable to imprisonment for a term of not exceeding two years or to a fine not exceeding two hundred thousand baht or to both.

Any person under paragraph one who violates or fails to comply with section 30, paragraph two shall be liable for the punishment prescribed in section 64, paragraph two, section 65, paragraph two, section 69 or section 74, as the case may be.

Section 71. Any person receiving a certificate of notification or licensee who fails to make a notification to the Director-General under section 31, paragraph one shall be liable to a fine not exceeding fifty thousand baht.

If any person receiving a certificate of notification or licensee fails to comply with section 31, paragraph two (1), (2) or (3), such person shall be liable to a fine not exceeding one hundred thousand baht.

Section 72. Any person who violates or fails to comply with section 32 (1) or (2) shall be liable to a fine not exceeding one hundred thousand baht.

Section 73. Any person receiving a certificate of notification or licensee who violates or fails to comply with section 33 or section 34 shall be liable to a fine not exceeding one hundred thousand baht.

Section 74. Any person receiving a certificate of notification or licensee who fails to comply with section 35, paragraph one shall be liable to a fine not exceeding one hundred thousand baht and to an additional fine at a daily rate of not exceeding five thousand baht until due compliance with legal requirements.

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Section 75. Any heir, executor, liquidator, operator or operation personnel who fails to comply with section 36, paragraph one shall be liable to a fine not exceeding ten thousand baht.

Any heir, executor or liquidator who violates or fails to comply with section 36, paragraph two shall be liable to a fine not exceeding one hundred thousand baht and to an additional fine at a daily rate of not exceeding two thousand baht until due compliance with legal requirements.

Section 76. Any person receiving a certificate of notification or licensee who violates or fails to comply with section 37, paragraph three shall be liable to imprisonment for a term of not exceeding two years or to a fine not exceeding two hundred thousand baht or to both.

Section 77. Any person receiving a certificate of notification or licensee who fails to comply with section 39, paragraph two shall be liable to imprisonment for a term of not exceeding three years or to a fine not exceeding three hundred thousand baht or to both.

Section 78. Any person receiving a certificate of notification, licensee or person having a duty related to the production, import, export, sale, transit or possession of pathogens or animal toxins who fails to provide convenience to a competent official under section 42 without valid reason or reasonable excuse, shall be liable to imprisonment for a term of not exceeding one month or to a fine not exceeding ten thousand baht or to both.

Section 79. In the case where the offender liable under this Act is a juristic person, if the commission of the offence of such juristic person is originated by an order or an act of any person, or by omission of an order or an act, which is the duty of the managing director, manager or any person who is responsible for the operation of such juristic person, such person shall also be liable for the punishment prescribed for such offence.

Section 80. All offences under this Act which are only punishable by a fine may be settled by the Director-General or a person appointed by the Director-General in accordance with the criteria prescribed by the Committee. Upon payment by the accused of

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the settled amount of the fine within thirty days from the date of settlement, the case shall be deemed settled under the provisions of the Criminal Procedure Code.

TRANSITORY PROVISIONS

Section 81. At the initial term, the Committee shall consist of the members under section 7 (1) and (2), and the Director-General shall be a member and secretary who shall provisionally perform the duties of the Committee under this Act until the qualified members under section 7 (3) and (4) have been appointed, which shall not be later than ninety days from the effective date of this Act. The Director-General shall appoint two government officials of the Department of Medical Sciences who are responsible for the work related to pathogens or animal toxins as assistant secretaries.

Section 82. A license which has been issued under the Pathogens and Animal Toxins Act, B.E. 2525 (1982) prior to the effective date of this Act shall continue to be valid until its expiration date.

Section 83. An agency exempted from obtaining a license, which has complied with section 5/1 of the Pathogens and Animal Toxins Act, B.E. 2525 (1982) as amended by the Pathogens and Animal Toxins Act (No. 2), B.E. 2544 (2001) prior to the effective date of this Act may continue to produce or possess pathogens or animal toxins, but must accomplish the requirements specified in section 28 within one hundred and eighty days from the effective date of this Act. After such requirements have been complied with, such agency shall be deemed to have become a person receiving a certificate of notification or a licensee under this Act until the Director-General notifies an order of non-issuance of a certificate of notification or a license, as the case may be.

Section 84. Any request for permission or application filed under the Pathogens and Animal Toxins Act, B.E. 2525 (1982) and pending consideration shall be deemed as a notification or application under this Act, *mutatis mutandis*. In the case where any part of such notification or application deviates from the criteria under this Act, the Director-General shall have the power to order a person who makes such notification or files such application to perform actions in order to be in conformity with this Act.

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Section 85. All Ministerial Regulations or Notifications issued under the Pathogens and Animal Toxins Act, B.E. 2525 (1982) applicable prior to the effective date of this Act shall continue in force insofar as they are not in conflict or inconsistent with this Act until the Ministerial Regulations or Notifications issued under this Act come into force.

The issuance of Ministerial Regulations or Notifications shall be completed within two years from the effective date of this Act. If the deadline cannot be met, the Minister shall report the reasons for such inability to the Council of Ministers.

Countersigned by:

General Prayut Chan-o-cha
Prime Minister

Office of the Council of State

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RATE OF FEES

(1) Certificate of notification for production of pathogens and animal toxins	per copy	10,000	baht
(2) Certificate of notification for import of pathogens and animal toxins	per copy	10,000	baht
(3) Certificate of notification for export of pathogens and animal toxins	per copy	10,000	baht
(4) Certificate of notification for sale of pathogens and animal toxins	per copy	10,000	baht
(5) Certificate of notification for transit of pathogens and animal toxins	per copy	10,000	baht
(6) Certificate of notification for possession of pathogens and animal toxins	per copy	10,000	baht
(7) License to produce pathogens and animal toxins	per copy	10,000	baht
(8) License to import pathogens and animal toxins	per copy	10,000	baht
(9) License to export pathogens and animal toxins	per copy	10,000	baht
(10) License to sell pathogens and animal toxins	per copy	10,000	baht
(11) License to transit pathogens and animal toxins	per copy	10,000	baht
(12) License to possess pathogens and animal toxins	per copy	10,000	baht
(13) Replacement certificate of notification	per copy	5,000	baht
(14) Replacement license	per copy	5,000	baht
(15) Application for a license under (7) to (12)	per copy	1,000	baht
(16) Application for a replacement certificate of notification or a replacement license under (13) and (14)	per copy	1,000	baht
(17) Application to amend a particular in a certificate of notification	per copy	1,000	baht
(18) Application to amend a particular in a license	per copy	1,000	baht
(19) Renewal of a certificate of notification or a license, to be charged for each renewal equal to the fee applicable to each issue of the pertinent type of a certificate of notification or a license			

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