(Unofficial Translation)

OFFICIAL EMBLEM

MINISTERIAL REGULATION

APPLICATION FOR A LICENSE AND PERMISSION OF PRODUCTION, IMPORT, EXPORT, SALE, TRANSIT OR POSSESSION OF GROUP 3 PATHOGENS OR GROUP 2 ANIMAL TOXINS

B.E. 2563 (2020)

By virtue of the provisions pursuant to Section 5 paragraph one, Section 22 paragraph two, Section 26 paragraph two, Section 30 paragraph three, and Section 33 paragraph three of the Pathogens and Animal Toxins Act B.E. 2558 (2015), the Minister of Public Health has issued the following Ministerial Regulation.

Clause 1 In this Ministerial Regulation,

"License" means the production, import, export, sale, transit or possession licenses of Group 3 Pathogens or Group 2 Animal Toxins.

Clause 2 The submission of an application and permission hereunder shall be mainly carried out by electronic means. While the electronic means has not yet been usable for carrying out the foregoing, the application shall be submitted by means of the registered mail or the application shall be submitted at the Department of Medical Sciences, Ministry of Public Health, or other place as specified and promulgated by the Director-General in the Government Gazette.

Clause 3 A receipt of license, a license, a notice in case where pathogens or animal toxins have a higher level of severity, a notice of termination of operation, and an application hereunder shall be in the form specified and promulgated by the Director-General in the Government Gazette.

CHAPTER I
APPLICATION FOR A LICENSE

Clause 4 Any person who intends to produce, import, export, sell, transit, or possess Group 3 Pathogens, or Group 2 Animal Toxins, shall submit an application for a license to the Director-General, together with the information, documents or evidence as follows.

(1) Identification Card No. in the case where the natural person applies for a license;

(2) Juristic Person Name and Registration No. in case where the juristic person applies for a license;

(3) Certificate of residence in case where the person applying for a license, or a representative(s) of juristic person, or a person(s) authorized to act on behalf of the juristic person has non-Thai nationality;

(4) Power of Attorney in case where the person applying for a license is not an authorized signatory person on behalf of a juristic person;

(5) Documents or evidence showing the characteristics of the place of production, or possession of pathogens or animal toxins in accordance with the Notifications issued pursuant to Section 6 (4);

(6) Documents or evidence showing the qualifications of the operator and the operation personnel in accordance with the Notifications issued pursuant to Section 6 (5);

(7) Consent on the Director-General's access to information pursuant to (1) and (2) for verification benefit.

Clause 5 The person applying for a production license of pathogens or animal toxins pursuant to Clause 4 shall submit the additional documents or evidence as follows.

(1) Map showing the location of the place of production of pathogens or animal toxins, and structures in the nearby areas;

(2) Proper layout plan of the structures inside the area of the place of production of pathogens or animal toxins pursuant to scale showing the following particulars.

(a) Partition of room, space, or area used in production and used in storage of pathogens or animal toxins derived from production;

(b) Storage location of pathogens or animal toxins derived from production;

(c) Pipe or drain, system, and wastewater or drain water disposal process;

In the case where the person applying for a license pursuant to paragraph one is not the owner of the place of production of pathogens or animal toxins, he/she shall also attach a letter of consent of the owner of the place of production of pathogens or animal toxins.

Clause 6 The person applying for the import, export, sale, or possession licenses of pathogens or animal toxins pursuant to Clause 4 shall submit the following additional documents or evidence.

(1) Map showing the location of the place of possession of pathogens or animal toxins, and structures in the nearby areas;

(2) Proper layout plan of the structures inside the area of the place of possession of pathogens or animal toxins pursuant to scale showing the following items.

(a) Partition of room, space, or area used in storage of pathogens or animal toxins;

(b) Storage location of pathogens or animal toxins;

(3) Details of the carrier in case of transportation of pathogens or animal toxins

In the case where the person applying for a license pursuant to paragraph one is not the owner of the place of possession of pathogens or animal toxins, he/she shall also attach a letter of consent of the owner of the place of possession of pathogens or animal toxins.

Clause 7 The person applying for a transit license of pathogens or animal toxins pursuant to Clause 4 shall submit the documents stating the details of vehicles used in transportation and also the routes used in transportation.

In the case of stop, he/she shall also submit the document stating the details of stop location.

Clause 8 Upon receipt of the application for a license, the Director-General shall verify the application for a license, and information, documents, and evidence whether they contain the proper and complete statements. If they are proper and complete, a receipt of application for a license shall be issued to the person applying for a license. If they are improper or incomplete, the said fault shall be recorded and notified to the person applying for a license to amend the application for a license or to deliver the information, documents or evidence properly and completely within the period specified by the Director-General. In the case where the application for a license is not submitted by electronic means, the Director-General and the person applying a license shall sign in the said record.

In the case where the person applying for a license neither amends the application for a license nor delivers the information, documents, or evidence properly and completely within the specified period pursuant

to paragraph one, it shall be deemed that the person applying for a license wishes not to continue to carry out, and the Director-General shall dispose of the issue from the directory.

Clause 9 In the case where the application for a license as well as information, documents, and evidence are proper and complete, the Director-General shall complete considering the application for a license and inspect the place of production or possession, tools, equipment, containers or packages, and security system, and quality system of production, import, export, sale, transit, or possession of pathogens or animal toxins within ninety days. If the person applying for a license has qualifications and non-prohibited characteristics pursuant to Section 23, the Director-General can order to issue a license.

In the case where the Director-General orders not to permit, a notice shall be given to the person applying for a license together with reason and right of appeal within seven days from the ordered date of not permission.

To facilitate the person applying for a license, the Director-General can also notify the person applying for a license by electronic means, together with a notice pursuant to paragraph two.

Clause 10 In the case where the Director-General issues the order of permission, a notice shall be given to the person applying for a license within seven days from the issued date of such order, and the person applying for a license shall pay the license's fee within thirty days from the received date of such notice. Upon payment of the license's fee by the person applying for a license, the Director-General shall issue the license to the person applying for a license in the form specified and promulgated by the Director-General and deliver the license to the person applying for a license by electronic means or by registered mail, unless the person applying for a license expresses his/her intention to receive the license by himself/herself.

In the case where the person applying for a license defaults to pay fee within the period pursuant to paragraph one, it shall be deemed that the person applying for a license wishes not to receive the license and the Director-General shall dispose the issue from the directory.

To facilitate the person applying for a license, the Director-General can notify and issue a receipt of notification for fee payment to the person applying for a license by electronic means, together with a notice pursuant to paragraph one.

Clause 11 The term of a license shall be one year from the issued date of the license.

CHAPTER II
APPLICATION FOR AMENDMENT OF PARTICULARS, PERMISSION OF AMENDMENT OF PARTICULARS, AND NOTIFICATION OF RELOCATION OR CHANGE OF PLACES

Clause 12 In the case where the person receiving a license wishes to amend a particular in the license, he/she shall submit the application for amendment or change of a particular in the license to the Director-General, together with the information, documents, or evidence relating to the particular in the license that he/she wishes to amend, and other information, documents or evidence specified in the Application Form for Amendment or Change of Particulars in a License.

The provisions in Clause 8 and Clause 10 shall be applied in considering the application for amendment or change of particulars in license mutatis mutandis. However, in case where the Director-General orders to

permit the relocation or change of the place of production, the place of import, the place of export, the place of sale, or the place of possession, such places shall be inspected.

In the case where 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 event which causes failure to submit the application pursuant to paragraph one, the relocation or change of such places may be made on a temporary basis, and the Director-General shall be notified about the place of storage, details of pathogens or animal toxins, and storage period either by any means within three days from the relocation or change date of such places.

CHAPTER III
NOTIFICATION IN CASE WHERE GROUP 3 PATHOGENS OR GROUP 2 ANIMAL TOXINS HAVE A HIGHER LEVEL OF SEVERITY THAN THE LEVEL SPECIFIED IN A LICENSE

Clause 13 During production, import, export, sale, transit or possession of Group 3 Pathogens or Group 2 Animal Toxins, if it appears that the pathogens or animal toxins have a higher level of severity than the level specified in a license, the person receiving a license shall comply as follows.

(1) Immediately discontinue the production, import, export, sale, or transit of pathogens or animal toxins.

(2) Notify the Director-General within three days, together with other information, documents, or evidence stating a level of severity of pathogens or animal toxins, and procedures for safety and prevention of hazard to the person, environment, or public, and notify the intention whether he/she will study and conduct a research pursuant to Section 29. If he/she wishes not study and conduct a research, the person receiving a license shall destroy or hand over the said pathogens or animal toxins pursuant to Section 35, and notify the operating result to the Director-General within three days.

Clause 14 After being notified pursuant to Clause 13, the Director-General shall consider other information, documents or evidence pursuant to Clause 13 (2). If it appears that the pathogens or animal toxins have a higher level of severity, and the person receiving a license can comply with Section 29, and the person receiving a license wishes to continue to carry out a higher level of severity, the Director-General shall notify the person receiving a license to comply with Section 29 within the period specified by the Director-General.

In the case where the person receiving a license breaches Section 29 within the period pursuant to paragraph one, it shall be deemed that the person receiving a license wishes not to continue to carry out in a higher level, and the person receiving a license shall destroy or hand over the said pathogens or animal toxins pursuant to Section 35 and notify the operating result to the Director-General within three days.

In the case where the Director-General deems that the person receiving for a license fails to comply with Section 29, the Director-General shall give a notice to the person receiving a license to destroy or hand over the said pathogens or animal toxins pursuant to Section 35 and notify the operating result to the Director-General within three days.

CHAPTER IV
RENEWAL OF THE LICENSE AND ISSUANCE OF THE REPLACEMENT LICENSE

Clause 15 The person receiving a license who wishes to renew a license shall submit an application to the Director-General within ninety days prior to expiration of a license, together with the license, other information, documents or evidence as specified in the Application Form for Renewal of the License.

Upon submission of the application for renewal of the license, the person receiving a license shall continue to carry out until the Director-General shall order not to permit the renewal of such license.

The provisions in Clause 8, Clause 9, and Clause 10 shall be applied in considering renewal of the license mutatis mutandis.

Clause 16 In the case where a license is lost, destroyed, or damaged in materiality, the person receiving a license shall submit the application for the replacement license to the Director-General within fifteen days from the acknowledged date of which the loss, demolition or damage in the materiality, together with the following information, documents, or evidence.

(1) A case report in case of loss of a license;

(2) A license or license no. in case where a license is lost or damaged in materiality;

(3) Other information, documents, or evidence as specified in the Application Form for the Replacement License

The provisions in Clause 8 and Clause 10 shall be applied in considering an application for a replacement license, and the issuance of a replacement license mutatis mutandis.

In the case where the application for the replacement license together with the information, documents, and evidence pursuant to paragraph one are proper and complete, the Director-General shall completely issue the replacement license within seven days.

CHAPTER V
NOTIFICATION OF TERMINATION OF PRODUCTION, IMPORT, EXPORT, SALE, TRANSIT, OR POSSESSION OF GROUP 3 PATHOGENS OR GROUP 2 ANIMAL TOXINS

Clause 17 The person receiving a license who intends to terminate the production, import, export, sale, transit or possession of Group 3 Pathogens or Group 2 Animal Toxins, shall give a notice to the Director-General in advance prior to the date of intended termination of the said operation, and shall be deemed that the said license is expired from the date of intended termination of the said operation.

Upon notification of termination of operation pursuant to paragraph one, during non-expiration of the license pursuant to paragraph one, the person receiving a license must comply with the Notifications pursuant to Section 6 (4), (5), (10), (11), (12), (13), (14), (15), and (18) throughout the period of which the license remains unexpired.

In the case where the person receiving a license has notified the termination of operation relating to pathogens and animal toxins pursuant to paragraph one, the person receiving a license shall destroy or hand over the remaining pathogens or animal toxins pursuant to Section 35, and quickly notify the said operating

result to the Director-General, and return the license to the Director-General to be further affixed with the cancellation seal of the said license.

Given on the 29th day of July B.E. 2563 (2020)
Anutin Charnvirakul
Minister of Public Health

(Unofficial Translation)

Remark :- The reason to promulgate this Ministerial Regulation is the legislation of Section 22 paragraph two, Section 26 paragraph two, and Section 33 paragraph two of the Pathogens and Animal Toxins Act B.E. 2558 (2015) on the application for a license, the permission, the term of a license, the renewal of a license, the issuance of a replacement license, the application for amendment of particulars, the permission of amendment of particulars, the notification of relocation or change of places in a license, and the notification of termination of production, import, export, sale, transit, or possession of Group 3 Pathogens or Group 2 Animal Toxins, in accordance with the rules, procedures, and conditions prescribed in the Ministerial Regulation in accompany with Section 30 of the said Act legislating that the person receiving a license shall quickly notify the Director-General of Department of Medical Sciences in case where the production, import, export, sale, transit or possession of pathogens or animal toxins have a higher level of severity than the level specified in the license in accordance with the rules, procedures, and conditions prescribed in the Ministerial Regulation. Therefore, the issuance of this Ministerial Regulation is required.