

OFFICIAL EMBLEM
MINISTERIAL REGULATION
NOTIFICATION AND ISSUANCE OF THE CERTIFICATE OF NOTIFICATION FOR PRODUCTION, IMPORT,
EXPORT, SALE, TRANSIT OR POSSESSION OF GROUP 2 PATHOGENS OR GROUP 1 ANIMAL TOXINS
B.E. 2563 (2020)

By virtue of the provisions pursuant to Section 5 paragraph one, Section 21 paragraph three, 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,

“Certificate of Notification” means the certificate of notification for production, import, export, sale, transit or possession of Group 2 pathogens or Group 1 animal toxins.

Clause 2 The submission of an application, the issuance of a receipt of notification, and the issuance of a certificate of notification 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 notification, a certificate of notification, 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 CERTIFICATE OF NOTIFICATION

Clause 4 Any person who intends to produce, import, export, sell, transit, or possess Group 2 Pathogens, or Group 1 Animal Toxins, shall submit an application for a certificate of notification to the Director-General, together with the information, documents or evidence as follows.

- (1) Identification Card No. in case where the natural person applies for a certificate of notification;
- (2) Juristic Person Name and Registration No. in case where the Juristic person applies for a certificate of notification;
- (3) Certificate of residence in the case where the person applying for a certificate of notification, 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 certificate of notification is not an authorized signatory person on behalf of a juristic person;
- (5) Documents or evidence showing the appearance 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);

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

Clause 5 The person applying a certificate of notification for production 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 items.

(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 certificate of notification 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 a certificate of notification for import, export, sale, or possession 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 certificate of notification 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 production of pathogens or animal toxins.

Clause 7 The person applying for a certificate of notification for transit of pathogens or animal toxins pursuant to Clause 4 shall submit the documents stating the details of vehicle used in transportation and 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 certificate of notification, the Director-General shall verify the application for a certificate of notification, 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 certificate of notification and a receipt of notification pursuant to Section 21 paragraph two shall be issued to the person applying for a certificate of notification to be used as temporary evidence in production, import, export, sale, transit, or possession of Group 2 Pathogens or Group 1 Animal Toxins during the time of which the Director-General has not yet issued a certificate of notification. If they are improper or incomplete, the said fault shall be recorded and informed to the person applying for a certificate of notification to amend the

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application for a certificate of notification 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 certificate of notification is not submitted by electronic means, the Director-General and the person applying a certificate of notification shall sign in the said record.

In the case where the person applying for a certificate of notification neither amends the application for a certificate of notification 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 certificate of notification 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 certificate of notification as well as information, documents, and evidence are proper and complete, the Director-General shall complete considering the application for a certificate of notification within ninety days. If the person applying for a certificate of notification has qualifications and non-prohibited characteristics pursuant to Section 23, the Director-General can order to issue a certificate of notification.

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

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

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

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

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

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

CHAPTER II

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

Clause 12 In the case where the person receiving a certificate of notification wishes to amend a particular in the certificate of notification, he/she shall submit the application for amendment or change of a particular in the certificate of notification to the Director-General, together with the information, documents, or evidence relating to the particular in the certificate of notification 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 Certificate of Notification.

The provisions in Clause 8 and Clause 10 shall be applied in considering the application for amendment or change of particulars in a certificate of notification *mutatis mutandis*.

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 informed 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 2 PATHOGENS OR GROUP 1 ANIMAL TOXINS HAVE A HIGHER LEVEL OF SEVERITY THAN THE LEVEL SPECIFIED IN A CERTIFICATE OF NOTIFICATION

Clause 13 In carrying out the production, import, export, sale, transit or possession of Group 2 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 certificate of notification, the person receiving a certificate of notification shall comply as follows.

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

(2) Inform 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 inform the intention whether he/she wishes not to continue to carry out the higher level. If he/she wishes not to continue to carry out the higher level, the person receiving a certificate of notification shall destroy or hand over the said pathogens or animal toxins pursuant to Section 35, and inform the operating result to the Director-General within three days.

Clause 14 After being informed 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 certificate of notification can apply for a license pursuant to Section 22 or comply with Section 29 as the case may be, and the person receiving a certificate of

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notification wishes to continue to carry out a higher level of severity, the Director-General shall inform the person receiving a certificate of notification to apply for a license pursuant to Section 22 or comply with Section 29 within the period specified by the Director-General.

In the case where the person receiving a certificate of notification neither applies for a license pursuant to Section 22 nor complies with Section 29 within the period pursuant to paragraph one, it shall be deemed that the person receiving a certificate of notification wishes not to continue to carry out in a higher level, and the person receiving a certificate of notification shall destroy or hand over the said pathogens or animal toxins pursuant to Section 35, and inform the operating result to the Director-General within three days.

In the case where the Director-General deems to be unable to issue a license pursuant to Section 22 to the person receiving a certificate of notification, deems that the person receiving a certificate of notification fails to comply with Section 29, the Director-General shall give a notice to the person receiving a certificate of notification to destroy or hand over the said pathogens or animal toxins pursuant to Section 35, and inform the operating result to the Director-General within three days.

CHAPTER IV RENEWAL OF THE CERTIFICATE OF NOTIFICATION AND ISSUANCE OF THE REPLACEMENT CERTIFICATE OF NOTIFICATION

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

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

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

Clause 16 In the case where a certificate of notification is lost, destroyed, or damaged in materiality, the person receiving a certificate of notification shall submit the application for the replacement certificate of notification 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 certificate of notification;
- (2) A certificate of notification or certificate of notification no. in case where a certificate of notification is lost or damaged in materiality;
- (3) Other information, documents, or evidence as specified in the Application Form for the Replacement Certificate of Notification

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

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

CHAPTER V

NOTIFICATION OF TERMINATION OF PRODUCTION, IMPORT, EXPORT, SALE, TRANSIT, OR POSSESSION OF GROUP 2 PATHOGENS OR GROUP 1 ANIMAL TOXINS

Clause 17 The person receiving a certificate of notification who intends to terminate the production, import, export, sale, transit or possession of Group 2 Pathogens or Group 1 Animal Toxins, shall give a written notice to the Director-General in advance prior to the date of intended termination of the said operation, and shall be deemed that the certificate of notification 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 certificate of notification pursuant to paragraph one, the person receiving a certificate of notification 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 certificate of notification remains unexpired.

In the case where the person receiving a certificate of notification has informed the termination of operation relating to pathogens and animal toxins pursuant to paragraph one, the person receiving a certificate of notification shall destroy or hand over the remaining pathogens or animal toxins pursuant to Section 35, and quickly inform the said operating result to the Director-General, and return the certificate of notification to the Director-General to be further affixed with the cancellation seal of the said certificate of notification.

Given on the 29th day of July B.E. 2563 (2020)

Anutin Charnvirakul
Minister of Public Health

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Remark :- The reason to promulgate this Ministerial Regulation is the legislation of Section 21 paragraph three, Section 26 paragraph two, and Section 33 paragraph two of the Pathogens and Animal Toxins Act B.E. 2558 (2015) legislate 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, the issuance of a replacement certificate of notification, the application for amendment of particulars, the permission of amendment of particulars, the notification of relocation or change of places in a certificate of notification, and the notification of termination of production, import, export, sale, transit, or possession of Group 2 Pathogens or Group 1 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 certificate of notification shall quickly inform 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 certificate of notification in accordance with the rules, procedures, and conditions prescribed in the Ministerial Regulation. Therefore, the issuance of this Ministerial Regulation is required.

This translation is provided by Department of Medical Sciences as the competent authority for information purposes only. Whilst Department of Medical Sciences has made efforts to ensure the accuracy and correctness of the translation, the original Thai text as formally adopted and published shall in all events remain the sole authoritative text having the force of law.