

**NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH**  
**RE: SAFETY ASSESSMENT OF TECHNOLOGIES USED IN THE PRODUCTION OF PATHOGENS AND ANIMAL TOXINS, B.E. 2561 (2018)**

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Whereas it is expedient to determine the criteria, procedures, and conditions in relation to safety assessment of technologies used in the production of pathogens and animal toxins.

By the virtue of the provisions of Section 5 paragraph one and Section 6 (13) of the Pathogens and Animal Toxins Act, B.E. 2558 (2015), the Minister of Public Health with the advice of Pathogens and Animal Toxins Committee hereby issues the notification as follows:

Clause 1 This notification is called Notification of the Ministry of Public Health entitled "Safety Assessment of Technologies Used in the Production of Pathogens and Animal Toxins, B.E. 2561 (2018)".

Clause 2 This notification shall come into force as from the day following date of its publication in the Government Gazette.

Clause 3 Safety Assessment of Technologies Used in the Production of Pathogens and Animal Toxins refers to the assessments taking into account the results and impacts on the safety of individuals, the environment or the public arising from the use of such technologies.

Clause 4 The pathogens and animal toxins producer shall prepare a safety assessment report of the technologies used in the production of pathogens or animal toxins in the following cases:

(1) Produce pathogens.

(a) Group 1 Pathogens: Only for producing over 1,000 liters of liquid pathogens or over 200 kilograms of solid pathogens.

(b) Group 2 Pathogens: Only for producing over 10 liters of liquid pathogens or over 1 kilogram of solid pathogens.

(c) Group 3 Pathogens

(2) Produce animal toxins with a lethal dose (LD<sub>50</sub>) less than 100 ng/kg body weight.

(3) Implement technologies allowing the pathogen to alter their genes and resulting in the increased harm or virulence.

(4) Implement technologies allowing animal toxins to alter their properties and resulting in the increased harm.

Clause 5 The producer of pathogens or animal toxins under Clause 4 shall submit a report for the safety assessment of technologies used in the production of pathogens or animal toxins to the Department of Medical Sciences, Ministry of Public Health within thirty days from the commencement date of production of pathogens or animal toxins.

In the event that there is an incident demonstrating the insecurity of the technologies used for production process or in the case of technology changes, the producer of pathogens or animal toxins under paragraph one shall promptly submit the report to the Department of Medical Sciences, Ministry of Public Health.

The report under paragraph one and two shall contain details in the form attached to the notification.

The submission of reports under paragraph one and two may be delivered by post or electronic means.

(Unofficial Translation)

Clause 6 The Department of Medical Sciences, Ministry of Public Health shall consider the report under Clause 5 and notify the producer of pathogens or animal toxins of the consideration outcomes within forty-five days from the date of receiving the report.

The consideration process under paragraph one, the Department of Medical Sciences, Ministry of Public Health may propose the Pathogens and Animal Toxins Committee to appoint a subcommittee to consider and submit opinions on the assessment.

The consideration process under paragraph two, the Department of Medical Sciences, Ministry of Public Health shall notify the producer of pathogens or animal toxins of the consideration outcomes as soon as possible.

Clause 7 In the case that the consideration of Clause 6 found the implementing technologies may cause unsafe conditions or harm to persons, the environment or the public, the Director-General shall consider proceeding in accordance with Section 31.

Clause 8 The Department of Medical Sciences, Ministry of Public Health shall send a copy of the assessment result to the producer of pathogens or animal toxins.

Clause 9 The person receiving a certificate of notification or the licensee shall report the safety assessment report of the technologies used in the production of pathogens or animal toxins in the annual report.

Clause 10 The Director-General of Department of Medical Sciences shall act on behalf in accordance with this announcement.

Notified on the 30<sup>th</sup> day of March B.E. 2561 (2018)

Piyasakol Sakolsatayadorn  
The Minister of Public Health

**Report form for assessment of technologies used in the production of pathogens and animal toxins**

Producer (Organization name) .....

- Produce pathogens
- Producing Group 1 Pathogens over 1,000 liters
- Producing Group 1 Pathogens over 200 kilograms
- Producing Group 2 Pathogens over 10 liters
- Producing Group 2 Pathogens over 1 kilogram
- Producing Group 3 Pathogens
- Produce animal toxins with a lethal dose (LD<sub>50</sub>) less than 100 ng/kg body weight
- Implement technologies allowing the pathogens to alter their genes and resulting in the increased harm or virulence
- Implement technologies allowing animal toxins to alter their properties and resulting in the increased harm

Location of operation site .....

Characteristics of operation site .....

Pathogens/Animal toxins produced.....

Amount of production.....

Production necessity  
.....  
.....

Objective of production (notify product and by-product)  
.....  
.....

Processing period .....

Equipments  
.....  
.....

Technologies of production  
.....  
.....

Product and by-product that may cause harm to human and environment  
.....  
.....

Measures or procedures to eliminate or reduce harm and monitor measures  
.....  
.....

Reference (if any)  
.....  
.....

Reporter .....

Tel. ....

Date ..... / ..... / .....