

Voluntary Report – Voluntary - Public Distribution

Date: December 19, 2024

Report Number: TH2024-0076

Report Name: Regulation on Animals Developed Using Genome Editing Technology

Country: Thailand

Post: Bangkok

Report Category: Biotechnology and Other New Production Technologies, Biotechnology and Other New Production Technologies Addendum, Biotechnology - Plants and Animals, Cloning

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Report Highlights:

The report outlines the Department of Livestock Development's regulation on the criteria, methods, and conditions for certifying animals developed using genome editing technology. This regulation enables Thailand to access new animal breeds, enhancing the country's ability to improve livestock production and address challenges related to food security and sustainable agriculture. Following certification, the Department of Livestock Development would permit genome-edited animals to be imported into, bred within, and exported from Thailand.

General:

Following the publication of the Ministry of Agriculture and Cooperatives (MoAC) notification on the certification of Genome-Edited (GE) plants in the Royal gazette on July 16, 2024, which became effective 30 days after publication as detailed in the [GAIN Report on Thailand's Significant Move on Genome Editing Legislation](#), the Department of Livestock Development (DLD) has published its notification titled Criteria, Methods, and Conditions for Certification of Animals Developed Using Genome Editing Technology B.E. 2567(2024) on November 19, 2024, which will be effective 30 days after the published date.

The regulation outlines the requirements for certifying animals developed using genome editing technologies for agricultural purposes. The certification process applies to animals that have been genetically modified through techniques like site-directed nucleases (SDN) to produce desired traits without introducing foreign DNA from other species. The announcement specifies the qualifications for the animals, the formation of a certification committee, and the procedures for application submission, including required documentation and scientific evidence. It also includes provisions for monitoring, suspension, revocation, and cancellation of certificates, along with the appeal process. Applicants are responsible for covering associated costs, and the regulation aims to ensure safe and responsible use of genome-edited animals in agriculture.

-Unofficial Translation-

Notification of the Department of Livestock Development

Re: Criteria, Methods, and Conditions for Certification for Animals Developed Using Genome Editing Technology B.E. 2567 (2024)

Whereas the Ministry of Agriculture and Cooperatives has issued an announcement on the certification of living organisms developed from genome editing technology for agricultural use, B.E. 2567 (2024), it is appropriate to establish criteria, methods, and conditions for obtaining certification for animals developed from genome editing technology to proceed smoothly.

By virtue of the authority under Section 32, Paragraph 2 of the Administrative Organization Act B.E. 2534 (1991), as amended by the Administrative Organization Act (No. 5) B.E. 2545 (2002), in conjunction with Clause 4 (3) of the Ministry of Agriculture and Cooperatives Notification on the Certification of Organisms Developed from Genome Editing Technology for Agricultural Use, B.E. 2567 (2024), the Director-General of the Department of Livestock Development hereby issues the following announcement.:

Clause 1: This notification is called "Department of Livestock Development Announcement on Criteria, Methods, and Conditions for Certification of Animals Developed Using Genome Editing Technology for Agricultural Use, B.E. 2566 (2023)."

Clause 2: This announcement shall come into effect after thirty days from the date of its publication in the Government Gazette.

Clause 3: In this announcement:

"Animal" means animals as defined in Section 4 of the Animal Epidemic Act B.E. 2558 (2015).

"Genome Editing Technology (GE)" means techniques for specifically and precisely modifying and editing the genetic code of living organisms to obtain genes with desired characteristics, such as correcting defective genes that may cause serious hereditary diseases.

"Animals developed from genome editing technology" refers to animals that have been genetically improved, similar to mutation or hybridization, where the final product contains genetic material from donor organisms that can naturally interbreed with the living organism.

"Certificate" means a certificate for animals developed from genome editing technology.

"Committee" means the committee considering applications for certification of animals developed from genome editing technology.

"Officer" means officers of the Livestock Biotechnology and Biodiversity Research and Development Group, Bureau of Biotechnology in Livestock Production of the Department of Livestock Development.

"Director-General" means the Director-General of the Department of Livestock Development.

Clause 4: The Director-General of the Department of Livestock Development shall be in charge of this announcement, and the Bureau of Biotechnology in Livestock Production shall be responsible for implementing this announcement.

Chapter 1

Qualifications of Animals Developed from Genome Editing Technology

Clause 5: Animals developed from genome editing technology seeking certification must have the following qualifications:

(1) The animals must be developed using site-directed nuclease (SDN) technology or other technologies with equivalent or superior safety. For SDN1 (deletion) level operations, double-stranded DNA is cut at a specific location without inserting a DNA template. The cell then repairs the broken DNA without adding the missing part, resulting in a deletion mutation or random repair at that location, leading to gene knockout

(2) The newly developed animals must not contain any new DNA or novel genes from other species inserted into their chromosomes

Chapter 2

Committee for Considering Applications for Certification of Animals Developed from Genome Editing Technology

Clause 6: There shall be a committee for considering applications for certification of animals developed from genome editing technology, consisting of Director of the Bureau of Biotechnology in Livestock Production as the chairperson, Director of the Bureau of Animal Breeding Development, Director of the National Institute of Animal Health, Director of the Bureau of Animal Nutrition Development, experts in animal genetics and genetic diseases, Regional Livestock Officer in the area where certification is requested, Head of the Biodiversity Research and Development Group, Bureau of Animal Breeding Development, Head of the Feed Crop Research and Development Group, Bureau of Animal Nutrition Development as committee members, Head of the Livestock Biotechnology and Biodiversity Research and Development Group, Bureau of Biotechnology in Livestock Production as committee secretary, Veterinarian from the Livestock Biotechnology and Biodiversity Research and Development Group,

Bureau of Biotechnology in Livestock Production as assistant secretary. Experts with relevant knowledge may be invited to attend meetings on a case-by-case basis.

Clause 7: The committee shall have the following powers and duties:

- (1) Consider applications for certification under this announcement
- (2) Coordinate with external agencies in considering certification applications under this announcement
- (3) Issue letters requesting applicants to provide clarification or submit additional documentation
- (4) Conduct on-site inspections of operations seeking certification for animals developed from genome editing technology, as deemed appropriate for consideration
- (5) Provide recommendations to the Director-General regarding issuance, suspension, revocation, and cancellation of certificates, as appropriate
- (6) Appoint subcommittees or working groups as appropriate
- (7) Perform other duties as assigned by the Department of Livestock Development

Chapter 3

Application for Certification of Animals Developed from Genome Editing Technology

Clause 8: Any person wishing to obtain certification for animals developed from genome editing technology shall submit an application using Form Sor Por 1 attached to this announcement, along with the following documents or evidence, to the officers at the Bureau of Biotechnology in Livestock Production:

- (1) Objectives for developing genome-edited animals, such as for consumption, breeding, commercial use, etc.
- (2) Information on the species, breed, and origin of the animals, along with documentation showing the development process, pedigree, and details of the genome editing technology used, including characteristics related to changes in components resulting from genome editing technology
- (3) For animals, color photographs and image files showing the characteristic shape of the genome-edited animal breed, including front, side, and back views of both males and females, compared to the characteristic shape of non-genome-edited animals. If there are external phenotypic changes, clear comparative images should be provided
- (4) Research documents or credible scientific data demonstrating the key characteristics of the genome-edited animals seeking certification, including information on the use of such animals in other countries or results from government laboratory testing

Clause 9: Evidence of scientific procedures and supporting data for consideration must be provided, including:

- (1) Details of the animal breeding development process and procedures
- (2) Nucleotide sequences before and after genome editing at the cleaved site or surrounding areas
- (3) Amino acid sequences before and after genome editing (if applicable), or comparison with amino acid sequences produced by traditional methods in case of new amino acids
- (4) Sequence specificity (for CRISPR-Cas nuclease cases only)
- (5) Types of Cas proteins (variants of Cas proteins) (for CRISPR-Cas nuclease cases only)
- (6) Off-target analysis data (if available)
- (7) For techniques other than CRISPR-Cas nuclease, the committee will consider on a case-by-case basis
- (8) Officials may request additional documents to be used as supporting information for consideration.

Clause 10: Upon receiving the request along with the documents and evidence as per Clauses 8 and 9, the officials shall verify the accuracy and completeness of the request and the supporting documents, and shall proceed as follows:

(1) In the case where it is found that the request or the documents submitted by the applicant are incorrect or incomplete, the official shall notify the applicant to make corrections or submit the correct and complete documents within ten business days. If the applicant fails to make the corrections or submit the complete documents within the specified period, the application shall be considered canceled as of the day after the deadline has passed. The official shall notify the applicant in writing.

(2) In the case where the request and documents submitted by the applicant are found to be correct and complete, the official shall forward the request and documents to the committee for consideration of the approval of animals developed from genome editing technology as per this notification.

(3) In the case where the committee approves the certification of animals developed from genome editing technology, the Department of Biotechnology for Livestock Production shall propose the Director-General for consideration and signing of the certificate of the breed of animals developed from genome editing technology according to the format of GPC-SV 2 at the end of this notification. The Department of Biotechnology for Livestock Production shall notify the applicant accordingly.

Chapter 4 Status Monitoring

Clause 11: Monitoring the status of animals developed from genome editing technology

(1) For animals developed from genome editing technology intended for breeding, commercial use, or consumption, detailed reports on their use at every stage must be provided. The committee may request additional information.

(2) In case new technologies are used, additional documents must be submitted to the committee within 60 days.

Chapter 5 Suspension, Revocation, and Cancellation of Certificates

Part 1

Suspension of certificates

Clause 12: When it appears that certified animals developed from genome editing technology are suspected of exhibiting characteristics inconsistent with the documents submitted to the Department of Livestock Development, the Director-General has the authority to suspend the certificate for up to 30 days at a time.

The committee shall consider and propose recommendations to the Director-General regarding certificate suspension. The suspension order must include reasons as specified in the administrative procedure law.

The suspended certificate holder must cease referencing the certificate during the suspension period until the Director-General revokes the suspension order or the suspension period expires.

Part 2

Revocation of certificates

Clause 13: The committee has the authority to review and submit recommendations to the Director-General for consideration of the revocation of the certificate in the following cases:

- (1) False information in the certificate application submitted to officials
- (2) Animals do not match the characteristics specified in the certificate
- (3) Complaints that the committee deems to have a serious impact on the certification
- (4) Has been ordered to suspend the certificate more than 2 times within a period of 2 years

Before revoking a certificate, the Director-General must inform the certificate holder of the facts leading to the revocation, providing sufficient opportunity to dispute and present evidence. The certificate holder must be notified in writing and respond to the Department of Livestock Development within the specified timeframe.

The revocation order must include reasons as specified in the administrative procedure law.

The holder of a revoked certificate must cease using or referencing the certificate from the date of revocation.

Part 3

Cancellation of certificates

Clause 14: The committee has the authority to review and submit recommendations to the Director-General for consideration of the revocation of the certificate in the following cases:

- (1) The certificate holder ceases the certified operation
- (2) The certificate holder becomes bankrupt or incapacitated
- (3) The certificate holder dies
- (4) The certificate holder transfers the business to another person
- (5) The certificate holder requests cancellation in writing

Before cancelling a certificate, the Director-General must inform the certificate holder or their heirs of the facts leading to the cancellation, providing sufficient opportunity to dispute and present evidence.

They must respond to the Department of Livestock Development within the specified timeframe.

The cancellation order must include reasons as specified in the administrative procedure law.

The holder of a cancelled certificate must cease using or referencing the certificate from the date of notification of the cancellation order.

Chapter 6

Appeals

Clause 15: An applicant whose certificate request has been denied, or a certificate holder whose certificate has been suspended or revoked, has the right to appeal within 30 days from the date of receiving the order notification. The appeal must be submitted in writing to the Director-General. The committee shall consider the appeal under this announcement within 30 days and submit their opinion to the Director-General.

The Director-General shall consider the appeal within 30 days from receiving the committee's opinion.

If the Director-General agrees with the appeal, whether in whole or in part, they shall proceed to modify the order according to their opinion within the specified timeframe. If the Director-General disagrees

with the appeal, whether in whole or in part, they shall report their opinion along with reasons to the higher authority responsible for considering appeals.

Chapter 7 Expenses

Clause 16: The applicant for the certificate shall be responsible for expenses incurred in carrying out the procedures under this announcement.

Announced on 29 October B.E. 2567 (2024)
Somchuan Ratanamungklanon
Director-General of the Department of Livestock Development

Attachments:

No Attachments.