



**Voluntary Report** – Voluntary - Public Distribution **Date:** August 26, 2024

**Report Number:** TH2024-0052

**Report Name:** Regulation on Plants Developed Using Genome Editing

Technology

Country: Thailand

Post: Bangkok

**Report Category:** Biotechnology and Other New Production Technologies

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### **Report Highlights:**

The report details the Department of Agriculture's regulation on the criteria, methods, and conditions for certifying genome-edited plants. This regulation enables Thailand to access new plant varieties, enhancing the country's ability to address food security and climate change challenges. Following certification, DOA would permit genome-edited plants to be imported to, cultivated within, and exported from Thailand.

#### General

Following the publication of the Ministry of Agriculture and Cooperatives (MoAC) notification on the certification of Genome-Edited (GEd) 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 Agriculture (DoA) published its notification titled 'Criteria, Methods, and Conditions for Certification of Plants Developed Using Genome Editing Technology' in the Royal Gazette on August 15, 2024. Certification of genome-edited plants would allow Thailand to import, cultivate and export these plants.

The notification outlines the key implementation measures as follows.

- Certification Requirements: The documentary evidence as prescribed in Clause 4 for certification must align with the data requirements outlined in the Technical Biosafety Committee's guideline (see attachment) issued in January 2024.
- Certification Timeline: DoA anticipates that the certification process will take approximately 2-3 months from the submission of the application<sup>1</sup> (Form Por Por 1), along with all other required documentary evidence. Upon completion of the process, the DoA will issue the Certificate of Plants Developed Using Genome Editing Technology (Form Por Por 2).
- Implementation Timeline: from August 16, 2024.

Unofficial Translation
Notification of Department of Agriculture
Re: Criteria, Methods, and Conditions for Certification of Plants Developed
Using Genome Editing Technology
B.E. 2567 (2024)

To promote plant variety improvement and development to address criticality in food security and climate change. By the virtue of Notification of Ministry of Agriculture and Cooperatives on Certification of Organism Developed through Genome editing Technology for Use in Agricultural Sector B.E. 2567. The Director General of DoA hereby issues a notification as follows

**Clause 1** This notification shall be called "Notification of DoA on Criteria, Methods, and Conditions for Certification of Plants Developed Using Genome Editing Technology B.E. 2567".

Clause 2 This notification shall enter into force on the day following the date of its publication in the Government Gazette henceforth.

Clause 3 In this notification:

<sup>1.50</sup> 

<sup>&</sup>lt;sup>1</sup> The application and supporting materials can be submitted in English, though a submission in Thai will likely shorten the review period.

"Plants" means plant of all types of plant species, including land plants, aquatic plants, and other types of plant and shall include mushrooms, predators, parasites, silkworms, algae, and agricultural microorganisms.

"Genome editing technology" means technique for genetic material alteration of organism with precision to achieve desirable characteristics, e.g., correcting defective genes that may cause severe hereditary disease.

"Plants developed using genome editing technology" means plants that undergone genetic improvement in the same manner as mutations or hybrids and the resulted final product contains genetic material from the donor organism that can naturally breed with the recipient organism.

"Official" means civil servants, government employees under the Biotechnology Research and Development Biotechnology Office of DoA or agencies assigned by the DoA

"Certificate" means certificate of plant developed using genome editing technology

"Committee" means Agricultural Biosafety Committee of DoA

"Subcommittee" means Agricultural Biosafety Evaluation Subcommittee of DoA

## Section 1 Application for certification of plants developed using genome editing technology

Clause 4 Anyone who wish to request the certification shall submit the application form (Por Por1), annexed to this notification, by electronic means of DoA or submit to official at Biotechnology Research and Development Biotechnology Office of DoA or agencies assigned by the DoA along with important documentary evidence regarding the development of plants using genome editing technology as follows.

- (1) Documents showing source of origin, breeding history, objectives, and detail on the development of variety using genome editing technology.
- (2) Methods used in editing genome, the edited gene and function.
- (3) Nucleotide sequence before and after genome editing at the cleaved site or at target edited site or surrounding of those areas.
- (4) Amino acid sequence before and after genome editing. In case of new amino acid, sequence of the new amino acids shall compare with amino acids derived from conventional breeding.
- (5) Evidence that the final product does not contain genetic material from donor organisms that do not naturally breed with the recipient.
- (6) Reference and report relevant with the development of genome edited plants that applied for certification (if any).

Clause 5 Applicant for certification must have the following qualifications.

- (1) A natural person
  - a. Be at least 20 years of age.

Be registered in civil registration of Department of Provincial Administration, Ministry of Interior.

- c. Volunteer to apply for certification and agree to abide by criteria, methods, and conditions of certification determined by DoA.
- d. Obtain license or other relevant legal documents
- e. Not being bankrupt, not an insane person or has mental infirmity

## (2) Legal entity

- a. Has status of legal entity according to law
- b. Has office located in Thailand
- c. Volunteer to apply for certification and agree to abide by criteria, methods, and conditions of certification determined by DoA.
- d. Obtain license or other relevant legal documents (if any)
- e. Managing director, executives, or partner is not bankrupt, not an insane person or has mental infirmity

Clause 6 Plant applied for certification must have qualification that was developed using genome editing technology and the final products contains genetic material from donor organism that can naturally breed with the recipient organism in a one of the following manners

- a. Editing genome at desired site without insertion of DNA template
- b. Editing genome at desired site with insertion of DNA template to alter or insert or delete nucleotides with specificity and precision to achieve desirable characteristics and the final products does not contain genetic material from donor that doesn't naturally breed with the recipient.

## **Section 2 Consideration of Application**

Clause 7 When the official received application form along with documentary evidence mentioned in Clause 4, the official shall verify the completeness of the required application form and required documentary evidence and, subsequently, proceed as follows.

- (1) In case of incomplete or inaccurate application submission, the official shall notify the applicant to complete or correct the application and required documentary evidence within seven (7) days after receiving notification from the official either by letter or electronic mail. If the applicant does not complete or correct within the specified period, it shall be considered that the application is canceled from the day after the specified period has elapsed but does not exclude the right to re-submit application.
- (2) In case of application and documents are considered complete, the official shall proceed the application along with documentary evidence to the Subcommittee who shall submit its opinion to the Committee with thirty (30) days to consider the application for certification.

Clause 8 When the Committee received opinion from the Subcommittee as mentioned in Clause 7 (2), the Committee shall consider certification of plant developed using genome editing technology within fifteen (15) days. In case of approval for certification, the Biotechnology Research and Development Office shall propose to Director General of DoA to issue certificate according to the form Por Por. 2 annexed to this notification. In case of disapproval for certification, the Biotechnology Research and Development Office shall notify the applicant within seven (7) days after the date of resolution of disapproval.

### **Section 3 Revocation of Certificate**

Clause 9 DoA may revoke certificate in the following cases.

- (1) The details of the submitted application and accompanying documentary evidence are inaccurate.
- (2) When the plant's characteristics do not conform to the certificate.

  In case of revocation, the person or entity must stop using or refencing the revoked certificate on the date of revocation.

# **Section 4 Expenses**

Clause 10 The applicant for certification is responsible for operational expenses as necessary and actually paid.

Notified on 9 August B.E. 2567 (2024) Rapibhat Chandarasrivongs Director General Department of Agriculture

#### **Attachments:**

TBC GEd Guideline ENG March 2024.pdf

Application Form (Por Por 1).pdf

Sample of Certificate of Plant Developed by GEd (Por Por 2).pdf