

**Voluntary Report** – Voluntary - Public Distribution

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**Report Name:** MARA Issues First Ever Gene-Editing Guidelines

**Country:** China - People's Republic of

**Post:** Beijing

**Report Category:** Biotechnology - Plants and Animals, Planting Seeds, Policy and Program Announcements

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**Report Highlights:**

On January 24, 2022, the Ministry of Agriculture and Rural Affairs (MARA) issued Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial), which for the first time establish application procedures and requirements for gene-edited plants. The Guidelines, which cover gene-edited plants that do not introduce exogenous genes, were not notified to the WTO and MARA is not soliciting domestic comments. This report contains an unofficial translation of the Guidelines.

## **Summary:**

The *Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial)* establish application procedures and requirements for gene-edited plants that do not introduce exogenous genes. For gene-edited plants that introduce exogenous genes, application for safety evaluation must still be made in accordance with the [Guideline for Safety Evaluation of Genetically Modified Plants](#) (link in Chinese). The Guidelines define gene-edited plants for agricultural use as plants and their products obtained by targeted modification of specific genomic sites with genetic engineering technology, which are used for agricultural production or agricultural product processing.

Applications fall under four requirement categories based on the risk profile of the target trait: 1) target traits that do not increase risk of environmental and food safety; 2) target traits that may increase environmental safety risk; 3) target traits that may increase food safety risk; 4) target traits that may increase environmental and food safety risk. Within each requirement category separate requirements are provided for product applications for production (cultivation) and applications for import (as materials for processing).

The Guidelines do not indicate a process for determining how to classify gene-edited products within each risk category, nor do they provide specific types of data accepted. Industry sources have suggested the Guidelines appear to provide a more streamlined approval process than what currently exists for genetically engineered plants, especially for production applications. However, it remains unclear if the requirements for imported gene-edited plants for processing would benefit from a similar streamlining, including exemption from existing burdensome requirements for in-country field trials. (Note: foreign firms are prohibited from investing in China's crop biotech sector).

This report provides an unofficial translation of the text of the Guidelines. The Guidelines (in Chinese) can be found [here](#).

## **BEGIN TRANSLATION**

### **Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial)**

Gene-edited plants for agricultural use refer to plants and their products obtained by targeted modification of specific genomic sites with genetic engineering technology and used for agricultural production or agricultural product processing. For gene-edited plants that introduce exogenous genes, application for safety evaluation shall be made in accordance with the requirements of the *Guideline for Safety Evaluation of Genetically Modified Plants*. This Guideline is mainly aimed at gene-edited plants that do not introduce exogenous genes.

## **I. Application procedure**

For gene-edited plants without introducing exogenous genes, apply for safety evaluation according to the possible risks.

1. For gene-edited plants with target traits that increase neither environmental safety risk nor food safety risk, apply for the production application safety certificate after the intermediate test.
2. For gene-edited plants with target traits that may increase food safety risk, apply for the production application safety certificate with food safety data after the intermediate test.
3. For gene-edited plants with target traits that may increase environmental safety risk, the applicant shall carry out environmental release or pre-production testing to accumulate environmental safety data after the intermediate test. Afterwards apply for the production application safety certificate.
4. For gene-edited plants with target traits that may increase both environmental safety risk and food safety risk, the applicant shall carry out environmental release or pre-production testing to accumulate environmental safety data and food safety data after the intermediate test. Afterwards apply for the production application safety certificate.
5. Others
  - 1) Chinese-foreign contractual joint ventures, Chinese-foreign equity joint ventures, or wholly foreign-owned enterprises engaged in gene-edited plant research and testing within the territory of the People's Republic of China shall apply before the start of the experimental research. To apply for experimental research on gene-edited plants, an application form shall only contain target plants of the same species and the same target traits, and the experimental period is generally 1 to 2 years.
  - 2) For the first application for pre-production testing or safety certificate, the declared gene-edited plant samples, control samples and detection methods shall be provided.
  - 3) After receiving the application for safety certificate, the Ministry of Agriculture and Rural Affairs shall entrust technical testing institutions with testing conditions and capabilities to carry out testing.

## **II. General requirements**

### **1. Molecular characteristics**

#### **1) Target gene related data**

Describe the structure, function, metabolic (regulatory) pathway and safety of the target genes in detail.

Structure: complete DNA sequence and deduced amino acid sequence, position and copy number on chromosome, etc.

Function: biological function and character, e.g., drought resistance.

Metabolic (regulatory) pathway: where the products of target gene encoding are enzymes, provide information on its metabolic substrates, products and related metabolic pathways that may be affected; where the products of target gene encoding are regulatory factors, provide information such as regulatory networks and signal pathways that may be affected; where the products of target gene encoding are other types of proteins, indicate function and action mechanism.

Safety: comprehensively evaluate the impact of target gene modification on safety from the aspects of gene structure, function, metabolic (regulatory) pathway and relevant safety data.

## **2) Data related to gene editing methods**

### (1) Gene editing tool

Provide the name, type, and characteristics of the gene editing tool.

### (2) Physical map of vector construction

Indicate in detail the names, locations and enzyme digestion sites of all elements of the gene editing vector.

### (3) Elements of gene editing vector

Describe in detail the sources (such as synthetic or donor biological name), names, sizes, DNA (RNA) sequences, functions, safety application records, etc. of all elements of gene editing vector.

### (4) Gene editing method and process

Describe in detail the test design, operation process and screening process.

## **3) Target gene editing**

(1) Provide data on the changes of target genes or (and) target proteins caused by gene editing, including test methods, data quality, analysis methods, analysis conclusions, etc.

(2) Provide specificity detection data on gene-edited plants, including test methods, data quality, analysis methods, analysis conclusions, etc.

## **4) Vector sequence residue**

Analyze the residue of vector sequence (including skeleton sequence, main elements, etc.), including test methods, data quality, analysis methods, analysis conclusions, etc.

## **5) Off-target effects**

Analyze the off-target effects of gene editing, including test methods, data quality, analysis methods, analysis conclusions, etc.

## **2. Genetic stability**

### **1) Stability of target gene editing**

Detect the editing sites of target genes and the editing of target genes in different generations of plants, and provide test data on at least 3 generations.

### **2) Stability of target traits**

Investigate the performance of target traits in different generations of plants, and provide test data on at least 3 generations.

## **3. Environmental safety**

Where target traits do not increase environmental safety risk, provide the analysis data or information that target traits does not increase environmental safety risk. Where target traits may increase environmental safety risk, provide the environmental safety data with reference to the *Guideline for Safety Evaluation of Genetically Modified Plants*.

## **4. Food safety**

Where target traits do not increase food safety risk, provide the analysis data or data that target traits do not increase food safety risk. Where target traits may increase food safety risk, provide the food safety data with reference to the *Guideline for Safety Evaluation of Genetically Modified Plants*.

## **III. Stage requirements**

### **1. Gene-edited plants with target traits that increase neither environmental safety risk nor food safety risk**

#### **1) Apply for intermediate test**

(1) Provide relevant information on target genes and gene editing methods.

(2) Provide data on inbred or hybrid generation of each gene-edited material, and changes of target genes.

(3) Provide data on vector sequence PCR detection

(4) Provide bioinformatics analysis data on off-target effects.

#### **2) Apply for safety certificate**

It can be divided into two types: production application and imported as processing raw materials.

### **Type 1: production application**

- (1) Summarize data on experimental research and intermediate test stage, and provide a comprehensive safety evaluation report.
- (2) Provide data on molecular characteristics of gene-edited plants, including target gene editing, vector sequence residue and off-target effects.
- (3) Provide genetic stability data on gene-edited plants for at least 3 generations, including the stability of target gene editing and the performance of target traits.
- (4) Provide evaluation data on target traits and functional efficiency.
- (5) Provide specificity detection data on gene-edited plants.
- (6) Provide analysis data or materials that target traits increase neither environmental safety risk nor food safety risk.

### **Type 2: imported as processing raw materials**

- (1) Provide a comprehensive safety evaluation report.
- (2) Provide data on molecular characteristics of gene-edited plants, including target gene editing, vector sequence residue and off-target effects.
- (3) Provide specificity detection data on gene-edited plants.
- (4) Provide analysis data or materials that target traits increase neither environmental safety risk nor food safety risk.
- (5) Provide data on the exporting country or region that they have been proved by scientific experiments to be harmless to humans, animals, plants, microorganisms and the ecological environment.

## **2. Gene-edited plants with target traits that may increase food safety risk**

### **1) Apply for intermediate test**

- (1) Provide relevant information on target genes and gene editing methods.
- (2) Provide data on inbred or hybrid generation of each gene-edited material, and changes of target genes.
- (3) Provide data on vector sequence PCR detection.

(4) Provide bioinformatics analysis data on off-target effects.

## **2) Apply for safety certificate**

It can be divided into two types: production application and imported as processing raw materials.

### **Type 1: production application**

(1) Summarize data on experimental research and intermediate test stage and provide a comprehensive safety evaluation report.

(2) Provide data on molecular characteristics of gene-edited plants, including target gene editing, vector sequence residue and off-target effects.

(3) Provide genetic stability data on gene-edited plants for at least 3 generations, including the stability of target gene editing and the performance of target traits.

(4) Provide evaluation data on target traits and functional efficiency.

(5) Provide specificity detection data on gene-edited plants.

(6) Provide food safety evaluation data.

(7) Provide analysis data or materials that target traits do not increase environmental safety risk.

### **Type 2: imported as processing raw materials**

(1) Provide a comprehensive safety evaluation report.

(2) Provide data on molecular characteristics of gene-edited plants, including target gene editing, vector sequence residue and off-target effects.

(3) Provide specificity detection data on gene-edited plants.

(4) Provide food safety evaluation data.

(5) Provide analysis data or materials that target traits do not increase environmental safety risk.

(6) Provide data on the exporting country or region that they have been proved by scientific experiments to be harmless to humans, animals and plants, microorganisms and the ecological environment.

## **3. Gene-edited plants with target traits that may increase environmental safety risk**

### **1) Apply for intermediate test**

- (1) Provide relevant information on target genes and gene editing methods.
- (2) Provide data on inbred or hybrid generation of each gene-edited material, and changes of target genes
- (3) Provide data on vector sequence PCR detection.
- (4) Provide bioinformatics analysis data on off-target effects.

## **2) Apply for environmental release or pre-production testing**

- (1) Provide relevant data provided for applying for intermediate test and summary report of intermediate test results.
- (2) Provide data on molecular characteristics of gene-edited plants, including target gene editing, vector sequence residue and off-target effects.
- (3) Provide genetic stability data on gene-edited plants for at least 2 generations, including the stability of target gene editing and the stability of target character expression.
- (4) Provide evaluation data on target traits and functional efficiency.
- (5) Provide specificity detection data on gene-edited plants.
- (6) Provide an environmental safety evaluation and food safety evaluation test scheme.

## **3) Apply for safety certificate**

It can be divided into two types: production application and imported as processing raw materials.

### **Type 1: production application**

- (1) Summarize data on previous test stages and provide a comprehensive safety evaluation report
- (2) Provide genetic stability data on gene-edited plants for at least 3 generations, including the stability of target gene editing and the performance of target traits.
- (3) Provide evaluation data on target traits and functional efficiency.
- (4) Provide specificity detection data on gene-edited plants.
- (5) Provide environmental safety evaluation and food safety evaluation data.
- (6) Provide analysis data or materials that target traits do not increase food safety risk.



## **Type 2: imported as processing raw materials**

- (1) Provide a comprehensive safety evaluation report.
- (2) Provide data on molecular characteristics of gene-edited plants, including target gene editing, vector sequence residue and off-target effects.
- (3) Provide specificity detection data on gene-edited plants.
- (4) Provide environmental safety evaluation data.
- (5) Provide analysis data or materials that target traits do not increase food safety risk.
- (6) Provide data on the exporting country or region that has been proved by scientific experiments to be harmless to humans, animals and plants, microorganisms and the ecological environment:

## **4. Gene-edited plants with target traits may increase both environmental safety risk and food safety risk**

### **1) Apply for intermediate test**

- (1) Provide relevant information on target genes and gene editing methods.
- (2) Provide data on each gene-edited material, inbred or hybrid generation, and changes of target genes.
- (3) Provide data on vector sequence PCR detection.
- (4) Provide bioinformatics analysis data on off-target effects.

### **2) Apply for environmental release or pre-production testing**

- (1) Relevant data provided by applying for intermediate test and summary report of intermediate test results.
- (2) Provide data on molecular characteristics of gene-edited plants, including target gene editing, vector sequence residue and off-target effects.
- (3) Provide genetic stability data on gene-edited plants for at least 2 generations, including the stability of target gene editing and the stability of target character expression.
- (4) Provide evaluation data on target traits and functional efficiency.
- (5) Provide specificity detection data on gene-edited plants.

(6) Provide an environmental safety evaluation and food safety evaluation test scheme.

### **3) Apply for safety certificate**

It can be divided into two types: production application and imported as processing raw materials.

#### **Type 1: production application**

- (1) Summarize data on previous test stages and provide a comprehensive safety evaluation report
- (2) Provide genetic stability data on gene-edited plants for at least 3 generations, including the stability of target gene editing and the performance of target traits.
- (3) Provide evaluation data on target traits and functional efficiency.
- (4) Provide specificity detection data on gene-edited plants.
- (5) Provide environmental safety evaluation and food safety evaluation data.

#### **Type 2: imported as processing raw materials**

- (1) Provide a comprehensive safety evaluation report.
- (2) Provide data on molecular characteristics of gene-edited plants, including target gene editing, vector sequence residue and off-target effects.
- (3) Provide specificity detection data on gene-edited plants.
- (4) Provide environmental safety evaluation and food safety evaluation data.
- (5) Provide data on the exporting country or region that they have been proved by scientific experiments to be harmless to humans, animals and plants, microorganisms and the ecological environment.

**END OF TRANSLATION**

#### **Attachments:**

No Attachments.