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Report Name: MARA Updates Rules for Review of Gene-Edited Plants for Agricultural Use

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Report Highlights:

On April 28, 2023, the Ministry of Agriculture and Rural Affairs (MARA) issued Rules for Review of Gene-Edited Plants for Agricultural Use (Trial), which clarifies the classification criteria and requirements for evaluating gene-edited plants. The rules provide operational guidance in the areas of molecular function, environmental safety, and food safety, including acceptable data. This report contains an unofficial translation of the rules and a table comparing the new document with the previously issued Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial).

Summary:

The *Rules for Review of Gene-Edited Plants for Agricultural Use (Trial)* (hereafter “Review Rules”) clarify MARA’s classification criteria and data requirements for evaluating gene-edited plants. The Review Rules expand upon MARA’s *Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial)* (see [GAIN Report CH2022-0015](#) for more information), which for the first time established application procedures and requirements for gene-edited plants. The guidelines classified gene-edited plants into four categories based on the risk profile of the target trait but did not indicate a process for determining how to classify gene-edited products within each risk category or provide specific types of acceptable data.

The Review Rules expand upon the processes established under the guidelines by providing additional information in three areas: molecular characteristics, environmental safety, and food safety.

- *Molecular characteristics*: the Review Rules indicate the types of data and sequencing that should be provided related to target gene editing, vector sequence residues, and off-target effects.
- *Environmental safety*: the Review Rules indicate what information should be provided for gene-edited plants that may directly change the relationship between species, such as resistance to diseases and insects, and herbicide tolerance.
- *Food safety*: the Review Rules indicate what information should be provided for gene-edited plants that may change key components, such as quality improvement, high yield, etc.

The Review Rules also state that the above-mentioned molecular characteristics, environmental safety and food safety evaluations can all be carried out in the intermediate test stage. If data from the test stage show that the target trait does not increase the environmental safety risk, the safety certificate can be applied directly after passing the evaluation. If the data obtained in the intermediate test stage indicate that the target trait may increase environmental safety risks, environmental release or production tests need to be carried out, and safety certificates can only be applied after passing the safety evaluation. The Review Rules also state that environmental release or production tests should be carried out in the main suitable ecological zone of the test plants and that applications for a safety certificate for production at least one test site should be set up in each major suitable ecological zone.

This report provides an unofficial translation of the text of the Review Rules (Appendix 1) and comparison table (Table 1). The Review Rules (in Chinese) can be found [here](#).

Table 1. Comparison of the Content of the Guidelines and Review Rules

Area	Topic	Guidelines	Review Rules
Molecular Characteristics	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.	Provide data such as PCR amplification sequencing or whole-genome sequencing covering the edited site. For those who use whole-genome sequencing, coverage analysis data at the edited site should also be provided.
	Vector sequence residues	Analyze the residue of vector sequence (including skeleton sequence, main elements, etc.), including test methods, data quality, analysis methods, analysis conclusions, etc.	Provide data such as whole genome sequencing and its coverage analysis on the event vector.
	Off-target effects	Analyze the off-target effects of gene editing, including test methods, data quality, analysis methods, analysis conclusions, etc.	Provide data such as PCR amplification sequencing or whole-genome sequencing of expected off-target sites. Bioinformatics and other methods should be used to analyze expected off-target sites. For those using whole-genome sequencing, coverage analysis data at expected off-target sites should also be provided.
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	Different information is required based on whether the gene-edited plant may directly change the relationship between species. If yes, need to provide (1) target traits and evaluation of functional efficiency; (2) survival competitiveness; (3) impacts on the ecosystem community structure and evolution of pest

	<p>the <i>Guideline for Safety Evaluation of Genetically Modified Plants</i>.</p>	<p>status; (4) Gene-edited plants resistant to diseases and insects should also provide indoor bioassays for non-target organisms that may be affected; (5) Herbicide-tolerant gene-edited plants should also provide tolerance to at least 3 other commonly used (non-target) herbicides.</p> <p>If no, the last three items are not required.</p>
<p>Food Safety</p>	<p>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 <i>Guideline for Safety Evaluation of Genetically Modified Plants</i>.</p>	<p>Different information is required based on whether the gene-edited plant may change key components.</p> <p>If yes, need to provide (1) Analysis of key components; (2) Assessment of the impact of the maximum possible intake level on the dietary pattern of the population; (3) If gene editing leads to a significant increase in the expression of a certain protein or the generation of a new protein, a corresponding safety evaluation should also be performed on the protein; (4) If the above data indicate that the target trait may increase food safety risks, a 90-day feeding test on rats should also be provided.</p> <p>If no, the second is not required.</p>

Source: FAS China analysis.

Appendix 1

Begin Unofficial Translation

Rules for Review of Gene-Edited Plants for Agricultural Use (Trial)

I. Molecular characteristics

1. Target gene editing. Provide data such as PCR amplification sequencing or whole-genome sequencing covering the edited site. For those who use whole-genome sequencing, coverage analysis data at the edited site should also be provided. Relevant data should be able to illustrate the target gene editing in gene-edited plants.
2. Vector sequence residues. Provide data such as whole genome sequencing and its coverage analysis on the event vector. Relevant data should be able to illustrate the vector sequence residues in gene-edited plants.
3. Off-target situation. Provide data such as PCR amplification sequencing or whole-genome sequencing of expected off-target sites. Bioinformatics and other methods should be used to analyze expected off-target sites. For those using whole-genome sequencing, coverage analysis data at expected off-target sites should also be provided. Relevant data should be able to illustrate the off-target situation of gene-edited plants.

II. Environmental Safety

1. The following information should be provided for gene-edited plants that may directly change the relationship between species, such as resistance to diseases and insects, and herbicide tolerance:

- (1) Target traits and evaluation of functional efficiency.
- (2) Survival competitiveness, including plant height, coverage rate, reproduction coefficient, seed shattering, seed quantity, seed weight and germination rate, etc.
- (3) Impacts on the ecosystem community structure and evolution of pest status.
- (4) Gene-edited plants resistant to diseases and insects should also provide indoor bioassays for non-target organisms that may be affected.
- (5) Herbicide-tolerant gene-edited plants should also provide tolerance to at least 3 other commonly used (non-target) herbicides.

2. The following information should be provided for other gene-edited plants, such as stress resistance (drought resistance, salt and alkali resistance, frost resistance, high temperature resistance, etc.), quality improvement, and physiological trait improvement (efficient nutrient utilization, change in growth period, high yield, etc.):

- 1) Target traits and evaluation of functional efficiency.
- 2) Survival competitiveness, including plant height, coverage rate, reproduction coefficient, seed shattering, seed quantity, seed weight and germination rate, etc.

III. Food safety

1. The following information should be provided for gene-edited plants that may change key components, such as quality improvement, high yield, etc.:

- (1) Analysis of key components (including nutrients, functional components, anti-nutritional factors, endogenous toxins, endogenous allergens, etc.).
- (2) Assessment of the impact of the maximum possible intake level on the dietary pattern of the population.
- (3) If gene editing leads to a significant increase in the expression of a certain protein, the expression of the protein and its amino acid sequence similarity comparison with known toxic proteins, anti-nutritional factors, and allergens should also be provided.
- (4) If gene editing leads to the generation of new proteins, the following should also be provided: ①the expression level of the new protein; ②the comparison of the amino acid sequence similarity between the new protein and known toxic proteins, anti-nutritional factors and allergens; ③The digestion stability and thermal stability test of the new protein simulated gastric juice protein in vitro; ④Toxicology test of the new protein.
- (5) If the above data (items (1)-(4)) indicate that the target trait may increase food safety risks, a 90-day feeding test on rats should also be provided.

2. The following information should be provided for gene-edited plants that do not change key components, such as resistance to diseases and insects, tolerance to herbicides, stress resistance (drought resistance, salt tolerance, frost resistance, high temperature resistance, etc.), improvement of physiological traits (change in growth period, efficient use of nutrients, etc.):

- (1) Analysis of key components (including nutrients, functional components, anti-nutritional factors, endogenous toxins, endogenous allergens, etc.).
- (2) If gene editing leads to a significant increase in the expression of a certain protein, its amino acid sequence similarity comparison with known toxic proteins, anti-nutritional factors, and allergens should also be provided.
- (3) If gene editing leads to the generation of new proteins, the following should also be provided: ①the comparison of the amino acid sequence similarity between the new protein and known toxic proteins, anti-nutritional factors and allergens; ②The digestion stability and thermal stability test of the new protein simulated gastric juice protein in vitro; ③Toxicology test of the new protein.
- (4) If the above data (items (1)-(3)) indicate that the target trait may increase food safety risks, a 90-day feeding test on rats should also be provided.

IV. Evaluation Procedure

The above-mentioned molecular characteristics, environmental safety and food safety evaluations can all be carried out in the intermediate test stage. If the data obtained in the

intermediate test stage show that the target trait does not increase the environmental safety risk, the safety certificate can be applied directly after passing evaluation.

If the data obtained in the intermediate test stage indicate that the target trait may increase environmental safety risks, environmental release or production tests need to be carried out, and safety certificates can only be applied after passing the safety evaluation. Environmental release or production tests should be carried out in the main suitable ecological zone of the test plants.

To apply for a safety certificate for production application, at least one test site should be set up in each major suitable ecological zone.

End Unofficial Translation

Attachments:

No Attachments.