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Report Highlights:

On January 13, 2023, the Ministry of Agriculture and Rural Affairs (MARA) published a finalized updated "Guideline for Safety Assessment of Genetically Modified Plants." The finalized Guideline, which makes only minor changes to a previous draft version, will come into effect June 30, 2023. This report provides a translation of the final guideline, notes substantive changes with the current guideline in effect, and highlights changes made to the Guideline since the draft version was published in July 2022.

On January 13, 2023, MARA published a finalized revised Guideline for Safety Assessment of Genetically Modified (GM) Plants. The Guideline applies to bio-safety certificate application for both domestic production cultivation and importation of processing materials. The finalized Guideline makes only minor changes to the draft version, which was published for public comments in July 2022 (see GAIN Report CH2022-0084). The draft Guideline was not notified to the WTO.

Substantive changes compared with current Guideline in effect include:

1) The new Guideline changes the nature of biosafety assessments from being on a "crop variety and event" basis to solely on an "event" basis to be consistent with the Administrative Measures.
2) In addition to PCR and Southern blotting, sequence determination is added as a method to analyze integration of inserted sequence in plant genome.
3) Suitable Ecological Areas for Major Genetically Modified Crops are newly listed in the Guideline. It is required at least one production trial site should be set in each major ecological area for application of production safety certificate of an event.

This report provides an UNOFFICIAL translation of the Guideline. Changes between the draft version and the final version are highlighted in **RED** and deleted content is marked by strikethrough.

BEGIN TRANSLATION

Guideline for Safety Assessment of Genetically Modified Plants (Modified Version 2022)

The guideline is applicable for the genetically modified plants. According to the *Regulations on Safety of Agricultural Genetically Modified Organisms*, the definition of genetically modified plants is: the plants whose genomic structures have been modified by genetic engineering technologies for the use in agricultural production or agro-product processing, and its products.

I General Requirements

1 Molecular Characterization

Determine the integration and expression of the inserted sequence at gene level, transcriptional level and translational levels.

(1) Expression vector relevant information

i. Physical map of vector construction

Indicate in detail for the name, location and restriction enzyme digestion sites for all elements in the vector.

ii. Target gene

Describe in detail for the donor organisms, structure (including restriction enzyme sites in the gene), function and safety of the target gene

Donor organisms: e.g. Bt-cry1A gene was originated from *Bacillus thuringenisis* strain XX.

Structure: Complete DNA sequence and corresponding amino acid sequence

Function: Biological function and trait, like resistant to lepidopterous insects

Safety: Comprehensive assessment on the safety of target gene based on donor organism, history of safe use, gene structure, function and relevant safety test data, *etc*.

iii. Other major elements

Promoter: Origin of the donor organisms, size, DNA sequence (or literature), function, and history

of safe use.

Terminator: Origin of the donor organisms, size, DNA sequence (or literature), function, and history of safe use.

Marker gene: Origin of the donor organisms, size, DNA sequence (or literature), function, and history of safe use.

Reporter gene: Origin of the donor organisms, size, DNA sequence (or literature), function, and history of safe use.

Other sequences: Source (e.g., artificially synthesized or donor organism name), name, size, DNA sequence (or literature), function, and history of safe use.

(2) Integration of the inserted foreign sequence in plant genome

Using event specific PCR, Southern blotting, sequence determination etc., to analyze integration of inserted gene in plant genome, including copy number of target gene and marker gene, deletion of marker gene, reporter gene or other regulatory sequences, and integration sites, *etc*.

Event specific PCR detection of inserted sequence: sequence name, primer sequences, amplicon size, PCR condition, electrophoretic pattern of amplicon (including figure title, molecular weight marker, negative control, positive control, notes of electrophoresis lanes)

Southern blotting of inserted sequence: Digest total DNA of plant genome with more than two restriction enzymes, which can indicate the integration copy number and produce event specific molecular hybridization pattern. Provide at least such information as location of probe sequence, name of restriction enzyme, size of specific band, figure title, molecular weight marker, negative control, positive control, and notes of electrophoresis lanes.

Sequence determination: Use genome sequencing to obtain the event specific nucleic acid sequences that can verify the insertion site of foreign sequences, integration copy number. Provide the materials, methods, sequencing depth, data quality, sequence analysis methods, original data, analysis conclusions, etc. used for sequencing.

Full DNA sequence of inserted sequence: full DNA sequence of which actually inserted into the genome of recipient plant, and flanking sequences for both sides of the insertion site (above 300 bp). Provide the primer names, sequences, and amplicon size for the event specific PCR validation.

(3) Expression of the inserted sequence

i. Expression at transcriptional level (RNA)

Using RT-PCR or Northern blotting *etc.*, to analyze expression of the major inserted sequences (such as target gene and marker gene, *etc.*) at transcriptional level, including the expressed major tissues and organs (like root, stem, leaf, fruit and seed, *etc.*).

RT-PCR detection: primer sequence, length of amplified product, RT-PCR condition, electrophoretic pattern of amplified product (including figure title, molecular weight marker, negative control, positive control, notes of electrophoresis lanes).

Northern blotting: Location of probe sequences, size of specific bands, Northern blotting condition, hybridization pattern (including figure title, molecular weight marker, negative control, positive control, notes of electrophoresis lanes).

ii. Expression at translational level (protein)

Using ELISA or Western blotting *etc.*, to analyze protein expression of major inserted sequences (such as target gene and marker gene, *etc.*) at transcriptional level, including expressed major tissues and organs (like root, stem, leaf and seed, *etc.*).

ELISA detection: Describe quantitative detection method in detail, including related antibody, negative control, positive control, results of optical density determination, and standard curve, *etc*.

Western blotting: name of related antibody, size of specific band, Western blotting condition,

hybridization pattern (including figure title, molecular weight marker, negative control, positive control, notes of electrophoresis lanes, loading amount of sample and positive control).

2 Genetic Stabilities

(1) Integration stability of target gene

Using Southern blotting, sequence determination or event specific PCR, to determine the integration of target gene into transformants, and to identify copy number of target gene in transformants and segregation in offspring, which should provide no less than three generations data.

(2) Expression stability of target gene

Using Northern blotting, RT-PCR, Western blotting, and ELISA *etc.*, to indicate expression stability of target gene at transcriptional (RNA) and (or) translational (protein) levels in different generations of transformants (including expression information in different developmental stages and different organs), which should provide no less than three generations data.

(3) Phenotypic stability of target trait

Investigate phenotypic of target trait in different generations with proper methods. Provide no less than three generations data.

3 Environmental Safety

(1) Ability of survival and competition

Provide data and conclusion for the GM plants such as seed amount, seeds weight, vigor, seed dormancy, survival capability of over winter and over summer season, disease and insect resistance, growth vigor, growth period, shattering and volunteers *etc.* by comparing with receptor plant or parent line.

If receptor plant was perennial (e.g., forage, lawns for seed production) asexual propagation or target trait makes survival competitiveness increase (such as drought tolerance and salt tolerance, *etc.*), pertinent supplemental information should be provided according to case-by-case principle.

(2) Environmental effects of gene flow

i. Relevant information of receptor species

If wild relatives exist, provide information of their geographical distribution range, occurrence frequency, biological characteristics (growing stages, growth habit, days to flowering, reproduction character, dispersing pathway of seeds and vegetative propagation organs), and the genetic relationship with wild relatives (genome type, natural cross-pollination with cultivars, fertility of F1 hybrid, and survival and fruiting ability of its offspring).

If a plant type which can cross with the same species exists, provide information of the distribution and harm for the plant type of the same species.

ii. Risk of foreign gene flow

If wild relatives exist or a plant type in the same species which can intercross with each other exists, and no relevant information and data are available, design the trial to evaluate risk of foreign gene flow and the possible ecological consequence, such as the test of gene flow frequency, expression of foreign gene in wild relatives, whether or not target gene has changed ecological adaptability of wild relatives. If relevant information and data are available, provide test results such as pollen particle size and pollen germination rate of GM plants and receptor plants, and evaluate the risk of foreign gene flow and its possible consequences based on the test results and existing data.

(3) Efficacy assessment

Provide efficiency assessment report of GM plants. If GM plants show pest resistance, resistance efficacy data on target organism need to be provided. If GM plants show herbicides tolerance, tolerance efficacy data on target herbicide need to be provided.

Resistance efficacy means the results of resistance substance generated by the pest resistant GM plants, to target organisms, which is generally evaluated through the difference between GM plants and receptor plants in number changes of target organism, hazard degree, plant growth and yield, *etc*. For disease/insect resistant GM plants, provide bioassay report of GM plant on target organisms, and data and conclusion of seasonal occurrence damage and population dynamics of target organisms in GM plants and receptor plants.

(4) Effect of pest resistant GM plant on non-target organism

Based on the GM plants, specificity and mode of action of the protein expressed by the foreign gene, selectively provide assessment report of the potential influence on related non-target herbivore organism, beneficial organism (such as natural enemies insects, resource insects and pollination insects *etc*.) and protective species, *etc*.

For proteins with sufficient test data, if the protein expressed by the foreign gene is equivalent to the protein, the effect on related non-target organisms can be assessed based on the existing data.

(5) Effect on community structure of ecosystem and status evolution of pest

Based on the GM plants, specificity and mode of action of the protein expressed by the foreign gene, selectively provide effects of GM plant on the structure and biodiversity of related animal community, plant community and microorganism community, and risk assessment report of status evolution of pest in the GM plant ecosystem including disease and insect pests.

(6) Resistance risk of target organism

Resistance of target organism defines that sensitive target individual is eliminated through selection and contest, and resistant one survives, reproduces and gradually develops into high resistant population, due to feeding on GM plants for many generations. For disease and insect pest resistant GM plants, provide the information of their mode of action mechanism and characteristics to target organism, sensitivity base data of target organisms before the GM plant commercialized, evidence and conclusion of the risk assessment of resistance, and, resistance monitoring strategies and management measures to be taken.

4 Food Safety

Evaluate relative safety of GM plants and non-GM plants based on the case-by-case principle.

Selection of conventional counterpart: For GM plants of vegetative propagation, use non-GM parent plants as control; For GM plants of sexual reproduction, use non-transgenic plants whose genetic background are comparable with GM plant as control. Control should be comparable with GM plants in planting environment (time and location).

(1) Toxicology assessment of newly expressed substance

i. Information of newly expressed protein

Provide information of molecular and biochemical characterization about newly expressed protein (including expressed proteins of target gene and marker gene), including molecular weight, amino acid sequence, posttranslational modification and function description *etc*. If expressed product is enzyme, provide enzyme activity and its influence factors (e.g., pH, temperature, and ion intensity), substrate specificity, and reaction product *etc.*

Provide amino acid homology information between newly expressed protein and known toxin and anti-nutrients (e.g., protein inhibitor and plant lectin, *etc.*).

Provide data of the expression levels of newly expressed protein in edible or feeding parts of plants.

Provide heat stability data, and data of protein digestion stability in simulated gastric fluid *in vitro*, if necessary, provide effects of processing activities (~~heat~~ temperature and processing way) on newly expressed protein.

If expressed protein *in vitro* is used as test material for safety assessment, provide equivalence analysis between newly expressed protein in plants and that *in vitro* (such as molecular weight, protein sequencing analysis, immunogenicity and protein activity, *etc.*).

ii. Toxicology test of newly expressed protein

If newly expressed proteins have no history of safe use, and safety information is inadequate, must provide acute oral toxicity information. For information of 28-day feeding study, it depends on expression level of the newly expressed protein in plant, and intake level of human being. Conduct immunotoxity detection if necessary. Reasons need to be interpreting if relevant toxicology experiment data has not been provided.

For proteins with sufficient toxicology experiment data, if the protein expressed by the foreign gene is equivalent to the protein, relevant data can be provided.

iii. Assessment of newly expressed non-protein substance

If the newly expressed substance is non-protein, such as fat, carbohydrate, nucleic acid, vitamin and other components *etc.*, toxicity assessment may include toxin metabolism dynamics, genetic toxicity, sub-chronic toxicity, chronic toxicity/carcinogen, and reproductive and developmental toxicity *etc*. The toxicology experiments that will be conducted are based on case-by-case principle. For non-protein substances for which sufficient experiment data is available, relevant data can be provided.

iv. Estimate of intake

Provide expression of foreign gene in edible parts of plants. Estimate the maximum intake by human being, which includes the total intake level of the same type of GM plants and intake frequency according to the food consumption of typical human being. When estimating the intake amount, take into account the effects of processing activities on content of GM expressed substance, and provide determination method of protein expression.

(2) Allergenicity assessment

Conduct allergenicity assessment of the protein if foreign gene produces a new protein or creates new protein by changing metabolism pathway.

Provide the information of whether gene donor contains allergen, whether inserted gene encodes allergen.

Provide homology analysis of amino acid sequences between newly expressed protein and known allergen.

Provide heat stability data and data of protein digestion stability in simulated gastric fluid *in vitro*. For proteins with sufficient test data on the heat stability of newly expressed protein and protein digestion stability of simulated gastric fluid *in vitro*, if the protein expressed by the foreign gene is equivalent to the protein, relevant data and information can be provided.

If donor organism contains allergen, or newly expressed protein has sequence homology with known allergen, provide information of serological tests in which known allergen is used as antibody.

If receptor plant itself contains allergen, provide information of allergen components contents.

(3) Analysis of key composition

Provide basic information of test substance, including name, source, transformed gene and trait, planting time, location, special climate condition and storage condition. Test substance should be edible parts of raw agriculture commodity for GM plants, such as soybean, corn, cottonseed, and

rice seed *etc*. Samples at least 3 batched of different planting time planted in the same location or samples planted in 3 different locations should be provided.

Provide natural variance range and literature data of key composition counterpart control of the same species.

i. Nutrients: including protein, fat, carbohydrate, dietary fiber, mineral, and vitamins *etc*. If necessary, analysis information of amino acids in protein, and saturated fatty acid, monounsaturated fatty acid, polyunsaturated fatty acids in fat need to be provided. Chose the mineral and vitamins, which are of significant nutritional importance for plants or have more attribution to nutrition intake for human being, to conduct the mineral and vitamin determination.
ii. Natural toxin and harmful substance. For naturally occurred harmful substance which may have possible influence on health, different toxins such as gossypol in cottonseed, and glucosinolate and erucic acid in rapeseed should be analyzed according to different plant species.
iii. Anti-nutrient. The substance which affects the absorption and use of nutrients, and inhibits digestion enzyme, such as soybean trypsin inhibitor, soybean agglutinin, soybean oligosaccharide, phytic acid in corn, and tannin in rapeseed.
iv. Other components. Like water, ash and other inherent components in plant
v. Unexpected components. Possible new components due to transformation of foreign gene.

(4) Whole food safety assessment

90-day rat feeding study data should be provided. If necessary, provide rat chronic toxicity data, reproductive toxicity data and other feeding study data of other animals.

(5) Nutriology assessment

If any changes occur in nutrition and physiological function *etc.* of GM plant, nutriology assessment information should be provided.

i. Intake and utilization data of key nutrients in animals
ii. Intake level of nutrients for human being, and the assessment data of maximum possible intake effect on human dietary mode.

(6) Effects of production and processing on safety

Compared to non-GM counterpart, provide data for whether processing and storage may change the product properties of GM plant, including the effects of processing on degradation, elimination and denaturalization *etc.* of the transferred DNA and protein, such as the effects of oil extraction and refinement, microorganism fermentation, processing and storage of GM plant product on content of expressed protein in plants.

(7) Other safety assessment based on a case-by-case principle

For GM plants which key composition have significant changes, provide assessment data of effects of the changes on food safety and nutrition.

II Requirement on Different Stages

Application for safety evaluation of genetically modified plants should be finished according to the requirements set in *Measures on the Safety Evaluation Administration of Agricultural GMOs, and the following requirements of safety evaluation on different stages.* The following requirements are fundamental when applying a certain stage.

According to the demand of the safety evaluation and the particularity of the GM plants, increasing or decreasing of the testing items conducted by the technical testing institution is based on the case-by-case principle. For testing indicators that have no ~~technical~~ agricultural GM

technology testing institutions to carry out testing, MARA shall designate relevant agencies to conduct testing.

1 Application for Experimental Research

1) Foreign genes: including interest gene, marker gene, reporter gene, promoter, terminator and other regulating sequences. The name of foreign genes should be formally designated according to the international guidelines or the GenBank access number. Gene sequences should be provided for the foreign gene whose name has not formally designated.
2) Transgenic traits: including 10 types i.e., yield improvement traits, quality improvement traits, physiological improvement traits, improvement of heterosis, stress resistance, disease resistance, insect resistance, herbicide tolerance, bioreactor and others.
   Yield improvement traits: improvement in plant height, plant shape, grain number, grain size, and boll number so on.
   in Quality improvement traits: improvement in starch composition, protein composition, content of microelement, glucosinolate content, erucic acid content, content of saturated fatty acids, fiber quality, oil content etc.
   in Physiological improvement traits: improvement in growth stage, photosynthesis efficiency, nutrient utilization, seed vigor during conservation, and root vigor so on.
   Heterosis improvement: male sterility, fertility restoration, and improvement in fertility restoration.
   Stress resistance: improvement in drought resistance, flood resistance, cold resistance, and salt resistance so on.
3) Amount of transgenic materials for experimental use: only recipient organisms of the same species and with the same transgenic traits should be included in one application.
4) Experimental duration: normally 1–2 years.

2 Application of Pilot Test

1) Relevant information such as the structure of expression vector and of the foreign inserted sequence should be provided.

2) Information of generation No. of self-crossing or hybrid of each event, and corresponding PCR detection method of interest gene and marker gene, or event specific PCR detection method, should be provided.

3) Information of safety assessment of recipient plant and gene donor organism according to Guideline for Food Safety Assessment on Transgenic Plant and Product (NY/T1101-2006).

4) Information of molecular and biochemical characteristics of newly expressed protein, and information of homology search of the amino acid sequence of newly expressed protein with known toxins, anti-nutrients and allergens.

5) Information on mode of action of expressed protein in pest resistance plants and commercialized transgenic plants resistant to pests on target pests, and information on risk assessment of cross-resistance should be provided.

3 Application of Environmental Release

1) Related information of application of intermediate experiment and summarized report of intermediate experiment results should be provided.

2) Explain in detail the specific test materials used in the pilot test, including the cultivation process, material quantity and agronomic traits.

3) Provide information on the integration of the foreign inserted sequence of the into the plant genome, and indicate the name and generation number of the tested material. For example, the Southern blotting pattern and the number of inserted copies of the target gene and marker gene integrated into the plant genome, or the sequence determination results that can identify the insertion site and copy number of the target gene and marker gene in the plant genome, or the event specific PCR detection figures, etc.

4) Information of expression of interest gene at transcriptional or translational level should be provided.

5) Information of genetic stability of event, including stability of integration and expression and phenotype of interest gene and marker gene, should be provided.

6) For pest resistance transgenic plants, detection method of interest protein, expression amount of interest protein in various organs at different development stages, and efficiency of field resistance to target organisms should be provided.

7) Information of content of expressed protein (including expressed protein of interest gene and marker gene) in edible and feeding part of plants should be provided.

8) Information of cross-resistance of target pests to new pest resistance plants and commercialized pest resistance plants should be provided.

9) Provide information of indoors bioassay of possible non-target organisms that may be affected. For insect-resistant GM plants indoor bioassay data for at least 1 non-target herbivorous organism and at least 2 beneficial organisms should be provided. For disease-resistant GM plants, indoor bioassay data for at least 3 non-target pathogenic microorganisms should be provided.

10) Information of assessment of interest trait and functional efficiency, e.g. for pest resistance plants, types of target organisms should be defined, and indoors and field bioassay report should be provided. Herbicide-tolerant plants should provide data from the target herbicide tolerance test for at least 3 concentration gradients (1, 2, and 4 times the recommended dose).

11) For herbicide-tolerant GM plants, provide experimental data on tolerance to at least 3 other commonly used (non-target) herbicides (mainly including herbicides routinely used by receptor plants and herbicides sensitive to GM plants).

4 Application of Production Trial

There are two types of trial, one is event productive trial, and the other is production trial of the stacked event combination derived from at least two events that have obtained bio-safety certificates.

a. Application of Event Production Trial

（1） The trial should be conducted in the main suitable ecological zones of the test plants (see attached table).

（2） Provide the sample of the applied event, its control sample and detection method. The requirement on the sample: Seeds (with purity more than 99%); the requirement on the detection method: provide the information of inserted sequence and event specific nucleic acid testing method.

（3） Related information of application of environmental release, and summarizing report of environmental release results should be provided.

（4） Explain in detail the specific test materials used in the environmental release test, including the cultivation process, material quantity and agronomic properties.

（5） Provide information on the integration of foreign insert sequence of the event into the plant genome, and indicate the name and generation number of the tested material, including the Southern blotting figures and insertion copy number of foreign fragments (such as event backbone, target gene and marker gene, etc.) integrated into the plant genome, or sequence determination results that can identify the insertion site and copy number of foreign fragments in the plant genome ; and the event specific PCR detection figures.

（6） Information of expression of interest gene and marker gene at translational level, or interest gene (gene interfered by RNAi) at transcriptional or translational level.

（7） Provide the genetic stability data of the event for at least two generations, including stability of gene integration and expression, and stability of performance and trait should be provided.

Provide the genetic stability data of the transformant for at least 2 generations.

（8） Information of surviving and competitive ability of the transgenic event should be provided.

（9） Information of gene flow of transgenic plant should be provided.

（10） Information of interest trait and functional efficacy should be provided. For example, for pest resistance transgenic plants, information of seasonal infection of target organisms on transgenic plants and recipient plant (non-transgenic) and population dynamics should be

provided.

（11）Information of risk assessment of target organisms on disease and pests resistant plants should be provided.

（12）Information of risk assessment of gene transformation on non-target organism, the structure of Ecosystem community and status evolution of pest should be provided.

（13）Information of protein *in vitro* digestion stability in simulated gastric fluid and heat stability of newly expressed protein should be provided.

（14）If necessary, toxicity assessment of the whole food should be provided.

（15）Provide the testing reports issued by the testing center a technical testing institution with testing conditions and capabilities, including: ① nucleic acid testing for event identification; ② the effects on the NTOs for the disease/insect resistant plant, and the survival and competitiveness ability for the GM drought (stress) tolerant plant.; ③ the expression level of the newly expressed protein in the edible and feeding parts, and the in vitro digestion stability in simulated gastric fluid.

b. Application for production trial of stacked event combination derived from at least two events that have obtained bio-safety certificates.

（1） The test should be conducted in the main suitable ecological zone of the test plants (see attached table).

（2） Provide the sample of the applied GM plant event combination, its control sample and detection method. The requirement on the sample: Seeds (homogenous, with purity more than 99%); the requirement on the detection method: provide the information of inserted sequence and event specific nucleic acid testing method.

（3） Comprehensive evaluation report on event which has got bio-safety certificate and the related annex.

（4） Provide the information on parent name and the breeding pedigree.

（5） Southern blotting figures and inserted copies of foreign sequence (such as backbone, interest gene and marker gene etc) into plant genome for each transgenic event, or event based PCR detection figures, and generation No. and name of testing material should be provided. Provide information on the integration of foreign inserted sequences of the event into the plant genome, and indicate the name and generation number of the tested material. For example, the Southern blotting figures and the number of inserted copies of foreign fragments (such as event backbone, target genes and marker genes) integrated into the plant genome, or sequence determination results that can identify the insertion site and copy number of foreign fragments in the plant genome, or the event specific PCR detection figures.

（6） Provide information on the expression of the target gene at the transcriptional or translational level.

（7） Provide the analysis data of the target traits of the event combination, including the interaction between the target traits.

5 Application of safety certificate

The safety certificate includes two types, one is bio-safety certificate for production use, the other is bio-safety certificate for importation as processing materials. The bio-safety certificate for production use includes that for event production and the bio-safety certificate (production application) includes the application for a safety certificate for event production and application for stacked event combination derived from at least two events that have obtained bio-safety certificates.

Type 1: Application for Bio- Safety Certificate (Production Application)

a. Application of production safety certificate for event

（1） Information of all experiment stages in the past should be summarized, and assessment report of environmental safety and food safety should be submitted.
At least one production trial site shall be set in each main suitable ecological zone, the cumulative number of trial sites for environmental release and production trial shall be no less than 6, and the distance between trial sites shall be no less than 300 kilometers.

（2） Provide the information on event's foreign inserted sequence integrated into plant genome, including the event specific molecular hybridization map used to verify the integration copies of foreign fragment (such as vector backbone, interest gene and marker gene), or the sequence determination results that can identify the insertion site and copy number of foreign fragments in the plant genome, the full-length DNA sequences of foreign fragment that were integrated into plant genome, the flanking sequence, and the event specific PCR detection map.

（3） Information of genetic stability of the transgenic event (at least 3 generations), which include genetic stability of integration of interest gene, stability of expression of interest gene, and stability of performance and trait, should be provided.

（4） Information of surviving and competitive ability of the transgenic event, natural sustaining ability and ability of establishing population should be provided.

（5） Information of gene flow of the transgenic event should be provided.

（6） Information of field assessment on interest trait and functional efficacy (at least 2 generations) should be provided.

（7） Provide the evaluation information of effects on NTOs, 6 species at least.

（8） Information of assessment of effects on biodiversity (at least 2 generations), and information of effects on the structure of Ecosystem community and status evolution of pest should be provided.

（9） To provide the baseline susceptibility data of the target organisms to the substances expressed in plants for resistance to diseases or insect pests; the methods and conclusions for resistance risk assessment of the target organisms. To provide IPM strategies on the target organisms, the resistance monitoring plan and resistance management (IRM) measures, etc.

（10） Completed information of food safety of toxicity, allergenicity, nutrients and anti-nutrients and the residual data of the target herbicide for the herbicide tolerant plants should be provided.

(11) If application needs to continue, data of commercialized plantation in last authorized period and

monitoring report of environmental influence should be provided. Herbicide-tolerant crops should provide target herbicide residue data. For those who apply for a safety certificate for the first time, a technical testing agency with testing conditions and capabilities will verify and test some important indicators.

b. Application of bio-safety certificate for stacked event combination derived from at least two events that have obtained bio-safety certificates.

(1) Provide the related information submitted when applying for production trial, and the summary report on production trial. At least one productive test site shall be set up in each main suitable ecological zone, and the distance between test sites shall be no less than 300 kilometers.

(2) Provide the information on parent name and the breeding pedigree.

(3)Provide the information on foreign inserted sequence integrated into plant genome, including the event specific molecular hybridization figures used to verify the integration copies of foreign sequence (such as vector backbone, target gene and marker gene), or the sequence determination results that can identify the insertion site and copy number of foreign fragments in the plant genome, the full-length DNA sequences of foreign fragment that were integrated into plant genome, the flanking sequence, or and the event specific PCR detection figures.

(4) Information of expression of interest gene and marker gene at translational level, or interest gene (gene interfered by RNAi) at transcriptional or translational level.

（5） Information of genetic stability, including stability of gene integration and expression, and stability of performance and trait should be provided.

（6） Information of interest trait and functional efficacy should be provided. For example, for pest resistance transgenic plants, information of seasonal infection of target organisms on transgenic plants and recipient plant (non-transgenic) and population dynamics should be provided.

（7） Provide baseline data on the susceptibility of target organisms to disease/insect resistant substances produced by GM plants, the basis and conclusion of resistance risk assessment; the proposed comprehensive management strategy, resistance monitoring plan and treatment measures of target organisms.

（8） Provide information on key component analysis.

（9） If application needs to continue, data of commercialized plantation in last authorized period and monitoring report of environmental influence should be provided. Herbicide-tolerant crops should provide target herbicide residue data.

For those who apply for a safety certificate for the first time, a technical testing agency with testing conditions and capabilities will verify and test some important indicators.

Type 2: Apply for Bio-safety certificate (import for processing materials)

(1) Provide the sample of the applied GM plant, its control sample and detection method. The requirement on the sample: Seeds (homogenous, with purity more than 99%); the requirement on the detection method: provide the information of inserted sequence and event specific nucleic acid

testing method.

(2) Provide the comprehensive report on environmental safety and food safety evaluation.

(3) Provide the information on foreign inserted sequence integrated into plant genome, including the event specific molecular hybridization pattern used to verify the integration copy number of foreign fragment (such as vector backbone, target gene and marker gene, etc.), or the sequence determination results that can identify the insertion site and copy number of foreign fragments in the plant genome, the full-length DNA sequence that was integrated into plant genome, the flanking sequence for both sides of the insertion sites, and the event specific PCR detection figure.

(4) Provide the information on food safety such as toxicity, allergenicity, nutrient and anti-nutrient and the residual data of the target herbicide for the herbicide tolerant plant, etc.

(5) Provide the information that proved harmless to human, animals and plants, microorganism and ecological environment with scientific experiments in export countries or regions.

For those who apply for a safety certificate for the first time, a technical testing agency with testing conditions and capabilities will verify and test some important indicators.

III. **Supplementary Provisions**

This Guideline will come into effect on June 30, 2023.

Annex: Types of suitable ecological zones for main GM crops (Reference)

Crops	Suitable Ecological Regions
Rice	South China Rice Region
	Central China Rice Region
	Southwest Plateau Rice Region
	North China Rice Region
	Northeast China Rice Region
	Northwest China Rice Region
Corn	Northern Spring Corn Region
	Huang-Huai-Hai Summer Corn Region
	Southwest Corn Region
	South China Corn Region
	Northwest Corn Region
Soybean	Northern Spring Soybean Region
	Huang-Huai-Hai Summer Soybean Region
	South China Soybean Region
Cotton	Yellow River Basin Cotton Region
	Yangtze River Basin Cotton Region
	Northwest Inland Cotton Region

END TRANSLATION

Attachments:

No Attachments.