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Report Highlights:

The Ministry of Agriculture and Rural Affairs (MARA) released MARA Decree [2022] No. 2, announcing the revised Administrative Measures for the Safety Assessment of Agricultural GMOs. The finalized Measures, which were previously notified to the WTO under (SPS N CHN 1241), came into force on January 21, 2022. The Measures change the nature of biosafety assessments from being on a "crop variety and event" basis to solely on an "event" basis. The change facilitates variety registration of genetically engineered (GE) crop varieties for domestic cultivation and provides for the biosafety assessment of GE crops containing "stacked" traits. This report provides an unofficial translation of MARA Decree [2022] No. 2.

Background:
On November 12, 2021, MARA solicited domestic comments for the draft revised Administrative Measures for the Safety Assessment of Agricultural GMOs (see GAIN report CH2021-0139) and on December 3, 2021, notified the same draft to the WTO SPS Committee (see GAIN report CH2021-0165). Decree [2022] No. 2 is the final version of these previously notified measures.

This report provides an unofficial translation of the text of the Measures and Annex 1.

In comparison to the previously notified Measures, changes to MARA Decree [2022] No.2 include:

1. Change the authority's name from Ministry of Agriculture to the Ministry of Agriculture and Rural Affairs (MARA);
2. Revised text in Article 4.2 of Chapter III of the Annex 1 from "An application shall contain only one species or genre event. Its name shall be consistent with the name and the number in the early experimental stage." to "An application shall contain only one species or genre event. Its name shall be corresponding to the name and the number in the early experimental stage."

Note: Decree [2022] No. 2 also includes revisions of three additional regulations: 1) Administrative Measures for Major Crops Variety Registration; 2) Administrative Measures for Crop Seed Production and Operation License; and 3) Regulations on Nomenclature of New Varieties of Agricultural Plants. FAS China will publish separate GAIN reports on these regulations.

BEGIN TRANSLATION

Administrative Measures for the Safety Assessment of Agricultural GMOs

Chapter I General Provisions

Article 1 These Measures are established in accordance with the Administrative Rules for Safety of Agriculture GMOs (hereinafter referred to as "the Rules") in order to strengthen the safety assessment of agricultural genetically modified organisms (hereafter referred to as agriculture GMOs), safeguard human health and safety of animals/plants/microorganisms, and protect the ecological environment.

Article 2 Activities on agriculture GMO research, trials, production, processing, operation and imports/exports within China, which are required by the Rules to conduct safety assessment, should follow these Measures.

Article 3 These Measures apply to agriculture GMOs specified in the Rules, i.e., plants and animals, microorganisms and their products whose genomic structures have been modified by genetic engineering technologies for the use in agricultural production or processing, which mainly include:

(1) Genetically modified animals and plants (including plant seeds, breeding livestock and poultry, aquatic fingerings) and microorganisms;

(2) Products of genetically modified animals, plants and microorganisms;

(3) Products directly processed from genetically modified agricultural products;

(4) Seeds, breeding livestock and poultry, aquatic fingerings, pesticides, veterinary drugs, fertilizers, additives and other products containing genetically modified animals, plants and microorganisms, or containing ingredients of such products.

Article 4 These Measures assess the dangers or potential risks caused by agriculture GMOs to human, animals/plants, microorganisms and the ecological environment. The safety assessment is administered in three categories (plants, animals, and microorganisms) based on science, following the case-by-case principle; the assessments are carried out pursuant to risk grades and are divided into different stages.

Article 5 Pursuant to Article 9 of the Rules, China establishes the National Agriculture Biosafety Committee (NBC), which is responsible for safety assessment of agriculture GMOs. The NBC is composed of experts in agriculture GMO research, production, processing, inspection, quarantine, health and environmental protection; tenure of each Committee is five years.

The Ministry of Agriculture sets up an Agriculture GMO Safety Administration Office, which oversees safety assessment of agriculture GMOs.

Article 6 The entities engaging in research and trials of agriculture GMOs take the primary accountability in agriculture GMO safety; they are required to establish the agriculture GMO Safety Task Forces led by the legal representatives of the entities; the Task Force is responsible for safety management and review of safety assessment applications.

Any entity engaging in the research and trials of agriculture GMOs should establish the standard operation procedure for agriculture GMOs trials and reinforce the traceability of trials of agriculture GMOs.

Article 7 Pursuant to agriculture GMO safety assessment need, the Ministry of Agricultural will entrust testing institutes with proper testing conditions and capacities to test agriculture GMOs; the testing results will be reference for safety assessment and administration.

Article 8 The GM planting seeds/breeding livestock/ poultry/ fish fingerings, and planting seeds/breeding livestock/poultry/ aquatic fingerings /pesticides/veterinary drugs/fertilizer/ additives that are produced from agriculture GMOs or containing ag GMO substances should obtain the Agriculture GMO Safety Certificate pursuant to these Measures before getting review/registration or evaluation/approval according to relevant laws and administrative rules.

Chapter Two: Safety Grades and Safety Assessment

Article 9 China adopts the graded safety assessment on agriculture GMOs.

Agriculture GMOs are classified into the following four grades by the nature of their potential danger to human, animals, plants, microorganisms and the ecological environment:

Safety Grade I: No danger for the time being yet;

Safety Grade II: Low level danger;

Safety Grade III: Medium level danger; Safety

Grade IV: High level danger.

Article 10 Safety assessment and safety grading of agriculture GMOs are carried out in the following steps:

1. Determine the safety grade of the receptor organism;
2. Determine the type of genetic operations that affect the safety grade of receptor organisms;
3. Determine the safety grade of GMOs;
4. Determine the influence of production and processing on GMO safety;
5. Determine the safety grade of the GM products.

Article 11 Determination of the receptor organisms.

Receptor organisms are divided into 4 safety grades:

(A) Receptor organisms that meet one of the following conditions should be determined to be Safety Grade I:

1. To date, no negative effect on human health or the ecological environment has occurred;
2. The possibility that the GM organism will evolve into a hazardous organism is low;
3. The receptor organism is for special research use and has a short life. It is unlikely for the receptor organism to survive in a natural environment after the trials.

(B) The receptor organisms should be determined to be of Safety Grade II if they might cause a low degree of danger to human health and the ecological environment. However, such dangers can be prevented through safety control measures.

(C) The receptor organisms should be determined to be of Safety Grade III if they might cause medium degree of danger to human health and the ecological environment. In addition, such dangers can be prevented through safety control measures.

(D) The receptor organisms should be determined to be of Safety Grade IV if they might cause a high degree of danger to human health and the ecological environment. In addition, such dangers cannot be effectively controlled except through storage or use in a confined facility. Receptor organisms of Safety Grade IV include:

1. Hazardous organisms that is likely to have frequent exchange of genetic material with other organisms;

2. Hazardous organisms that, to date, lack effective technologies to prevent it or its derivatives from escaping or diffusing;

3. Hazardous organisms that, to date, lack effective technologies to capture or eliminate it before it causes negative impact on human health and the ecological environment.

Article 12 Determination of the way in which genetic operations affect the safety grade of receptor organisms

Genetic operations' impact on the receptor organisms' safety grade are in three types, i.e. they improve the receptor organisms' safety; they have no effect on the receptor organisms' safety; they reduce the receptor organisms' safety.

Type 1: Genetic operations that improve safety of the receptor organisms

Include: genetic operations that removes the gene/some genes known to be dangerous or depress the gene/some genes that present dangerous gene expression.

Type 2: Genetic operations that do not affect safety of the receptor organisms Includes:

1. Genetic operations that change the receptor organisms' phenotype or genotype, which cause no impact to human health and the ecological environment;

2. Genetic operations that change the receptor organisms' phenotype or genotype, which cause no negative impact to human health and the ecological environment.

Type 3: Genetic operations that reduce safety of the receptor organisms Includes:

1. Genetic operations that change the receptor organisms' phenotype or genotype, which may cause negative impact to human health and the ecological environment;

2. Genetic operations that change the receptor organisms' phenotype or genotype, but not sure what impact the operations may have to human health and the ecological environment.

Article 13 Determine the safety grade of agriculture GMOs

The safety grade of agriculture GMOs should be determined by the safety grade of the receptor organisms, as well as the type and degree of the genetic operations' impact on the receptor organisms' safety grade.

(A) GMOs whose receptor organism is classified as in Safety Grade I

1. The GMO, whose receptor organisms is in the Safety Grade I, obtained through Type 1 or Type 2 genetic operations should be in the Safety Grade I.

2. The GMOs, whose receptor organisms is in the Safety Grade I, obtained through Type 3 genetic operations; if the safety decline is slight and it is not necessary to take any safety control measures, then the GMOs' safety grade is still I. If there is a modest decline in safety and the potential danger can be avoided completely through proper safety control measures, then the GMOs' safety grade is II. If there is a serious decline in safety, but the potential danger can be avoided through strict safety

control measures, then the GMOs' safety grade is III. If there is serious decline in safety, and the potential danger cannot be avoided through safety control measures, then the GMOs' safety grade is IV.

(B) GMOs whose receptor organism is classified as in Safety Grade II

1. The GMOs, whose receptor organisms is in the Safety Grade II, obtained through Type 1 genetic operations; if the safety improves and no longer causes negative impact to human health and the ecological environment, then the GMOs' safety grade is I. If the safety improves, but still has low-level risks to human health and the ecological environment, then the safety grade is still II.

2. The GMOs, whose receptor organisms is in the Safety Grade II, obtained through Type 2 genetic operations, and its safety grade is still II.

3. The GMOs, whose receptor organisms is in the Safety Grade II, obtained through Type 3 genetic operations; based on the degree of safety decline, the GMOs' safety grade can be II, III, or IV, the standard for classification is the same as that of the receptor organisms.

(C) GMOs whose receptor organism is classified as in Safety Grade III

1. The GMOs, whose receptor organisms is in the Safety Grade III, obtained through Type 1 genetic operations; based on the degree of safety improvement, the GMOs' safety grade can be I, II or III, the standard for classification is the same as that of the receptor organisms.

2. The GMOs, whose receptor organisms is in the Safety Grade III, obtained through Type 2 genetic operation, and its safety grade is still II.

3. The GMOs, whose receptor organisms is in the Safety Grade III, obtained through Type 3 genetic operations; based on the degree of safety decline, the GMOs' safety grade can be III or IV, the standard for classification is the same as that of the receptor organisms.

(D) GMOs whose receptor organism is classified as in Safety Grade IV.

1. The GMOs, whose receptor organisms is in the Safety Grade IV, obtained through Type 1 genetic operations; based on the degree of safety improvement, the GMOs' safety grade can be I, II, III or IV, the standard for classification is the same as that of the receptor organisms.

2. The GMOs, whose receptor organisms is in the Safety Grade IV, obtained through Type 2 or 3 genetic operations, and its safety grade is still IV.

Article 14 Determine the safety grade of agriculture GMO products

The safety grade of agriculture GMO products should be determined in accordance with the safety grade of agriculture GMOs, as well as the type and degree of impact of production and processing activities on the agriculture GMOs' safety grade.

(A) The impact of production and processing activities on agriculture GMO products' safety grade can be categorized into three types:

Type 1: improves the safety of GMOs;

Type 2: no impact on the safety of GMOs;

Type 3: reduces the safety of GMOs.

(B) GM products made from GMOs of the Safety Grade I

1. The GMO products, obtained through Type 1 or 2 production/processing activities of GMOs of the safety grade I, is in the safety grade I.

2. The GMO products, obtained through Type 3 production/processing activities of GMOs of the safety grade I, based on the level of safety decline, can be classified into safety grade I, II, III, or IV; the standard for classification is the same as that of the receptor organisms.

(C) GM products made from GMOs of the Safety Grade II

1. The GMO products, obtained through Type 1 production/processing activities of GMOs of the safety grade II, if the safety improves to no longer causing negative impact to human health and the ecological environment, then its safety grade is ; if the safety improves, but the product still imposes low-level danger to human health or ecological environment, then the product's safety grade is still II.

2. The GMO products, obtained through Type 2 production/processing activities of GMOs of the safety grade II, the product's safety grade is still II.

3. The GMO products, obtained through Type 3 production/processing activities of GMOs of the safety grade II, based on the level of safety decline, can be classified into safety grade II, III, or IV; the standard for classification is the same as that of the receptor organisms.

(D) GM products made from GMOs of the Safety Grade III

1. The GMO products, obtained through Type 1 production/processing activities of GMOs of the safety grade III, based on the degree of safety improvement, the GMO products' safety grade can be I, II or III, the standard for classification is the same as that of the receptor organisms.

2. The GMO products, obtained through Type 2 production/processing activities of GMOs of the safety grade III, the GMO products' safety grade is still III.

3. The GMO products, obtained through Type 3 production/processing activities of GMOs of the safety grade III, based on the degree of safety decline, the GMO products' safety grade can be III or IV, the standard for classification is the same as that of the receptor organisms.

(E) GM products made from GMOs of the Safety Grade IV

1. The GMO products, obtained through Type 1 production/processing activities of GMOs of the safety grade IV, based on the degree of safety improvement, the GMO products' safety grade can be I, II, III or IV, the standard for classification is the same as that of the receptor organisms.

2. The GMO products, obtained through Type 2 or Type 3 production/processing activities of GMOs of the safety grade IV, the GMO products' safety grade is still IV.

Chapter Three Application and Approval

Article 15 Any work unit or individual conducting research of agriculture GMOs of the Safety Grade III and IV, or conducting trials and importing of agriculture GMOs of any safety grade should, based on the category and the safety grade of the agriculture GMOs, file reports or applications to the Agriculture GMO Safety Administration Office for each stage of the activities.

Article 16 MARA, pursuant to relevant laws and regulations, accepts applications for safety assessment of agriculture GMOs. The applications that are accepted by MARA will be transmitted to the NBC for safety assessment. NBC conducts at least two bio-safety assessments each year. Receiving the biosafety assessment results (by the NBC), MARA will give feedback (to the applicant) pursuant to the Administrative License Law and the Administrative Rules for Safety of Agriculture GMOs.

Article 17 The entities engage in trials and import of agriculture GMOs and entities/individuals engage in the production and processing of agriculture GMOs should complete the following procedures before submitting applications to the Agriculture GMO Safety Administration Office for safety assessment:

1. The applicant has conducted safety assessment of the agriculture GMOs, and has filed the report/application;
2. The applicant has organized the bio-safety task force in the entity to conduct technical review of the application materials;
3. The applicant provides relevant technical materials.

Article 18 The entities engage in research and trials of agriculture GMOs in China should meet the following conditions:

1. Have a specialized technical institution in China;
2. Encourage entities engaged in agricultural GMO experiments to establish or share specialized experiment bases;
3. Have full-time technical staff conducting research and trials of agriculture GMOs;
4. Have equipment and facilities suitable for testing and research;
5. Has established the "agricultural GMOs safety management group".

Article 19 An entity reports to MARA about its research and intermediary trial, or applies to MARA for environmental release/productive trial/bio-safety certificate, to file the report or the application to MARA, should follow the relevant report format, application requirements, standards for safety assessments and technical procedures by MARA (please refer to Annex I, II, III and IV).

Article 20 An entity engages in experiments and research on agriculture GMOs of the Safety Grade I and II should get approval by the "agricultural GMOs safety management group" of the entity; an entity engage in experiments and research on agriculture GMOs of the Safety Grade III and IV should report the Agriculture GMO Safety Administration Office before starting the research.

When reporting to the Agriculture GMO Safety Administration Office, the researcher should provide the following materials:

1. Report on trials research;

2. The safety grade of the agriculture GMOs and the basis for determining the grade;
3. Relevant laboratory safety facilities and measures for safety administration and protection.

Article 21 When the experimental research on Agriculture GMOs (Safety Grade I, II, III, and IV) concludes and moves to intermediary trial, the researcher should report to the Agriculture GMO Safety Administration Office.

When reporting to the Agriculture GMO Safety Administration Office, the entity conducting the trials should provide the following materials:

1. Report of the intermediary trial;
2. Summary report of the experimental research;
3. The safety grade of the agriculture GMOs and the basis for determining the grade;
4. Relevant content of safety research, and measures for safety management and safety control.

Article 22 After intermediary trial, if the research entity intends to proceed to environmental release after the intermediary trial, or proceed to productive trial after environmental release, it should file the application to the Agriculture GMO Safety Administration Office. Only after the application passes the safety assessment by the NBC and approved by the MARA could the research entity start the relevant trials following requirements in the permission document.

When submitting such an application, the research entity should provide the following materials as required by the applicable safety assessment guidance:

1. Application for safety assessment;
2. The safety grade of the agriculture GMOs and the basis for determining the grade;
3. Test reports issued by testing institutes with proper testing conditions and capacity;
4. Relevant content of safety research, and measures for safety management and safety control;
5. Summary report of the previous stage of trials.

To apply for productive trials, the research entity should submit samples of the agriculture GMOs, the controlled samples and testing methods as required.

Article 23 Within the valid time of the agriculture GMO safety approval document, the research entity, in case it needs to change the location of the trial, should file a report to the Agriculture GMO Safety Administration Office.

Article 24 The entity intends to apply for the bio-safety certificate after finishing the trials should file the application to the Agriculture GMO Safety Administration Office.

When filing the application, the applicant should provide the following materials as required by the applicable safety assessment guidance:

1. Application for safety assessment;
2. The safety grade of the agriculture GMOs and the basis for determining the grade;
3. Summary reports of the intermediary trial, the environmental release and the productive trial;
4. The samples of the agriculture GMOs, controlled samples, testing materials and testing methods required (by the safety assessment guidance), with the exception of the materials that have already been submitted as required by Article 22 of the Measures;
5. Other relevant materials.

Receiving the application, MARA will organize the NBC to conduct safety assessment, and entrust testing institutes with proper testing conditions and capacity to conduct tests; the agriculture GMOs passing the safety assessment and getting approval by the MARA will be issued the bio-safety certificates.

Article 25 The bio-safety certificate for agriculture GMOs should list the name (number), scale, scope, time limit of the agriculture GMOs, and the responsible individuals, and safety control measures, etc.

The entities or individuals engage in the production and processing of agriculture GMOs, and entities engage in import of agriculture GMOs should operate pursuant to the bio-safety certificate's requirements, and perform the obligations specified in the bio-safety certificate.

Article 26 When introducing agriculture GMOs from outside China or exporting agriculture GMOs to China, the introducing entity or exporter should provide relevant safety assessment documents as required in the Administrative Measures on Safety of Agriculture GMO Imports, and submit samples, controlled samples and testing methods along with the application for bio-safety certificate.

Article 27 Staff members involved in safety assessment application and reviews and experts participating in the reviews should keep the applicant's technologies and business proprietary confidential; the person should recuse him/herself if the application bears any interest to himself/herself or his/her close relative.

Chapter Four Administration of Technical Testing

Article 28 MARA, pursuant to the need of the safety assessment and its administrative work, entrusts testing institutes with proper testing conditions and capacity to conduct testing.

Article 29 A technical testing institute should have the following basic conditions:

1. Fair and authoritative, with relatively independent organization and specialized staff;
2. With equipment and inspection means that are suitable for the testing tasks and comply with national standard (or industry standard);
3. Strictly follow the technical standards for testing; the testing data generated are accurate and reliable;
4. The institute has appropriate safety control measures.

Article 30 Responsibilities and tasks of the testing institutes:

1. Provide technical services for the safety administration and safety assessment of agriculture GMOs;
2. Undertake the qualitative and quantitative inspections, appraisal, and re-examination tasks assigned by the Ministry of Agriculture or entrusted by the applicants;
3. Issue testing reports and make scientific judgements;
4. Research of (new) inspection technologies and methods, undertake or participate in the development/revision of assessment standards/regulations/rules;
5. Properly destroy all samples used in the tests; no sample should be kept after the tests;
6. Keep the applicant's technologies and business proprietary confidential.

Chapter Five Oversight, Safety Monitoring and Control

Article 31 MARA oversees agriculture GMO safety; it guides the monitoring and surveillance of agriculture GMO safety in different ecological regions and establishes the nation-wide agriculture GMO safety monitoring and surveillance system.

Article 32 Pursuant to provisions of the Article 39 and 40 of the Rules, the agriculture authorities of the county and above level municipal governments are responsible for oversight of agriculture GMO safety in their respective administrative regions.

Article 33 Relevant entities and individuals, pursuant to provisions in Article 41 of the Rules, should cooperate with the agriculture authorities' supervision and inspections.

Article 34 Entities engaging in trials and production of agriculture GMOs should accept MARA's supervision and inspection; they are required to report to the agriculture authorities in the county/provincial municipal governments about the previous year's trials and production to the agriculture authorities in the provincial and county-level municipal government before March 31 each year.

Article 35 The entities engage in the trials and production of agriculture GMOs should, in accordance with the provisions of these Measures, determine safety control and accident prevention measures; they are required to keep records of safety supervision measures for verification (by the authorities).

Safety control measures include physical control, chemical control, biological control, environmental control, and scale control (see Annex IV).

Article 36 Before disposing or discharging the agriculture GMOs of the safety grade II/III/IV, effective measures should be taken to destroy or inactivate the organisms to avoid its spreading and pollution to the environment. Discovering spreading, residue or causing damage, (the entity) must take effective measures immediately to control and eliminate (spreading, residue or the damage), and report the situation to the local agriculture authority.

Article 37 Proper safety management and preventive measures should be taken in the process of storing, moving, transporting and destroying/inactivating the agriculture GMOs; such actions should be taken using specific equipment or locations, and designate specific persons for management and record keeping.

Article 38 If Agriculture GMOs are found to be dangerous to humans, animals, plants or the ecological environment, MARA has the authority stop production, processing, operation and import of the agriculture GMOs, withdraw the bio-safety certificate, and instruct the consigner to destroy the dangerous agriculture GMOs.

Chapter Six Punitive Measures

Article 39 MARA will, in accordance with Article 43 of the Rules, penalize the entities that violate these Rules by conducting trials and research of agriculture GMOs of the safety grades III and IV or conducting the intermediary trial of agriculture GMOs without reporting to the MARA.

Article 40 MARA will, in accordance with Article 44 of the Rules, panelize the entities that violate these Rules by conducting the environmental release/productive trials without permission, or with the permissions but fail to conduct the trails following the required safety control measures, or conducting the trails exceeding the permitted scope/time.

Article 41 MARA will, in accordance with Article 45 of the Rules, panelize the entities that have completed the productive trials but violate these Rules by putting the agriculture GMOs into production and use without obtaining the bio-safety certificate for agriculture GMOs,

Article 42 MARA will, in accordance with Article 53 of these Measures, penalize (the entity/individual) who counterfeit, fake, transfer or buy/sell the bio-safety certificate of agriculture GMOs, the approval document and other permission documents should be penalized in accordance with Article 53 of the Rules.

Article 43 Those who issue the agriculture GMO safety approval document, the bio-safety certificate, and other permission documents that are not in accordance with the requirements of these Measures or fail to perform the supervisory duty after issuing the safety certificate of Agriculture GMOs or approval documents, should be penalized in accordance with Article 55 of the Rules.

Chapter Seven: Supplementary Articles.

Article 44 Terms and definitions are as follows:

1. Gene: structural unit that controls the function of biological genetic substances, mainly referring to a DNA segment with genetic information.
2. Genetic engineering technologies: technologies that input reconstructed DNA molecules by using DNA reconstruction technology or by physical, chemical, or biological methods.
3. Genetic group: sum of chromosomes and non-chromosome genetic substances of a given organism.
4. DNA: abbreviation for deoxyribonucleic acid. It is the genetic substance storing biological genetic information.
5. Agriculture GMOs: animals, plants, microorganisms and their products whose genetic structures have been modified by genetic engineering technology for the use of agricultural production or processing.
6. Purpose genes: genes that modify the genetic composition of receptor cells and deliver their genetic effect.
7. Receptor organisms: organisms into which reconstructed DNA molecules are input.
8. Seeds: materials used to plant or reproduce agricultural crops and trees, including seeds, fruits, roots, seedlings, sprouts, leaves, etc.
9. Experimental research: genetic operation and GMO research conducted in a controlled system or under controlled conditions.
10. intermediary trial: small-scale trials conducted in a controlled system or under controlled conditions.
11. Environmental release: medium-scale trials conducted under natural conditions with proper safety protection.
12. Production testing: large-scale trials conducted before production and application.

13. Control system: closed or semi-closed operational system established by physical control, chemical control, or biological control.

14. Physical control: preventing GMOs and their derivatives from diffusing out of an experimental area by physical means, such as setting up a fence to prevent GMOs and their derivatives from escaping the experimental area or being taken by people or animals out of an experiment area.

15. Chemical control: preventing the survival, diffusion, or continuation of GMOs by chemical means, such as sterilizing biological materials, tools, and facilities.

16. Biological control: preventing the survival, diffusion or continuation of GMOs and their derivatives and preventing the transmission of genetic substance from GMOs to other organisms using biological methods, such as by setting up effective segregation areas and supervision areas, eliminating nearby organisms that might crossbreed with GMOs, preventing GMOs from blooming, or removing their propagating organs, so as to prevent purpose genes from transmitting to other relevant organisms.

17. Environmental control: using environmental conditions to limit the survival, propagation, diffusion or continuation of GMOs and their derivatives, such as controlling humidity, moisture, and light exposure periods.

18. Scale control: reducing to the greatest extent the quantity of experimental GMOs and their derivatives or the experimental zone area, so as to reduce the possibility that GMOs and their derivatives will diffuse. If unexpected consequences occur, the GMOs and their derivatives can be eliminated.

Article 45 The Ministry of Agriculture is responsible for interpreting these Measures.

Article 46 These Measures came into effect from March 20, 2002. The Agricultural Biological Engineering Safety Administration Measures promulgated on July 10, 1997 by the Ministry of Agriculture (MOA Decree [1996] No. 7) is nullified when these Measures comes into force.

Annex 1

Safety Evaluation of GM Plants

I. Safety Evaluation of GM Plants

1. Safety Evaluation of recipient plants

1.1 Background information of recipient plants

1.1.1 Latin / Scientific name, popular/ common name and other names

1.1.2 Taxonomic status

1.1.3 Variety (or line) name of receptor

1.1.4 Wild or cultivated species

1.1.5 Original place and time of introduction

1.1.6 Usage

1.1.7 Domestic application status

1.1.8 Have they ever caused any negative effect on human health and ecological environment?

1.1.9 Possibility to become harmful plants judging from historical point of view

1.1.10 Is there record of long-term safe use

1.2 Biological features of receptor

1.2.1 Annual or perennial plants

1.2.2 Are they toxic to humans and other organisms? If so, indicate the position and features of the toxin

1.2.3 Do they contain allergen? If so, indicate the position and features of the allergen

1.2.4 Sexual multiplication or asexual multiplication? If sexual multiplication, is self-pollination or cross pollination? Is pollinated by insects or wind?

1.2.5 Ratio of outcrossing with the members of same or similar species under natural condition

1.2.6 Fertility (fertile or infertile; strong or weak in the ability. If infertile, indicate what kind of sterility)

1.2.7 Full producing period

1.2.8 Ability of surviving and reproducing in natural environment, including the ability of survival from winter, summer and stress.

1.3 Ecological environment of recipient plants

1.3.1Their geographical distribution and natural growing environment in China

1.3.2Ecological environment needed for their growth, including the possibility that the change of natural and cultivating conditions may affect their geographical distribution and scope

1.3.3Are they part of the ecological environment?

1.3.4Ecological relation with other plants in the ecological system. And will the change of ecological environment affect the relation(s)? And will the consequence bring or increase any negative effect on human health and ecological environment?

1.3.5Ecological relation with other organisms (animals and microorganisms) in the ecological system. And will the change of ecological environment affect the relation(s)? And will the consequence bring or increase negative effect on human health and ecological environment?

1.3.6Their influence on ecological environment and potential dangers

1.3.7If the application contains any plant not usually planted in China, the applicant shall describe the natural environment where the plant grows and provide materials about its natural eaters, parasites, competitors and growth sharers

1.4 Genetic variation of receptor plants

1.4.1Genetic stability

1.4.2Is there any record that genetic variation has ever caused negative effects to human health and ecological environment

1.4.3Possibility to exchange genetic substances with other plants under natural condition

1. 4.4Possibility to exchange genetic substances with other organisms (animals and microorganisms) under natural condition

1.5 Methods and possibility of supervising receptor plants

1.6 Other information about receptor plants

1.7 Safety classes of receptor plants are determined on the basis the above mentioned evaluations and by reference to the stipulation in Article 11 of the Measures.

2. Safety evaluation of genetic operation (manipulation)

2.1 Description about the trait of GM plants

2.2 Provide the following information for the insertion and deletion:

2.2.1 Size and structure of the inserted DNA sequence and the analyzing method

2.2.2 Size and function of the deleted sequence

2.2.3 DNA sequence of target gene; amino acid sequence encoded by target gene

2.2.4 Localization of inserted DNA in plant cell (is it inserted into chromosome, chloroplast and mitochondria or exists in non-integrated form) and the determining method

2.2.5 Insert/copy number of T-DNA

2.3 Target gene and vector map, the name, source, structure, feature and safety of vector, including whether the vector tends to cause disease or possibly transform to be disease source

2.4 Information of DNA element of T-DNA:

2.4.1 The size, function and donor organism of promoter and terminator;

2.4.2 The size, function and donor organism of mark gene and report gene;

2.4.3 Names sources for other regulating elements (like artificial synthesis or name of donor organism)

2.5 Method of genetic modification (gene transformation)

2.6 Information on expression of target gene

2.6.1 Organs or tissues which the interested protein will be expressed in, e.g. root, stem, leaf, flower, fruit, seed, etc.

2.6.2 Expression level and the analysis method

2.6.3 expression stability of target gene

2.7 Safety classes of genetic operation are determined on the basis of the above mentioned evaluation and by reference to the relevant standards in Article 12 of the Measures

3. GM plants safety evaluation

3.1 Genetic stability of GM plants

3.2 Difference in environmental safety between GM plants and non-GM counterpart

3.2.1 Reproduction method and reproduction rate

3.2.2 Propagation method and propagation ability

3.2.3Dormancy

3.2.4 Adaptability / Fitness

3.2.5 Ability of survival and competition

3.2.6 Possibility that the genetic material of GM plants transfer to other plants, animals and microorganisms 3.2.7

Possibility to become weeds

3.2.8 Impact of GM plants resistant to diseases and pests on target organisms and non-target organisms, including the influence / Impact on beneficial and pests / harmful organisms in the environment

3.2.9 Impact on other beneficial or pests within the eco-environment

3.3 Difference in influence on human health between GM plants and non-GM counterpart

3. 3.1Toxicity

3.3.2 Allergenicity

3.3.3 Anti-nutrients

3.3.4 Composition and nutrient

3.3.5 Resistance to Antibiotic

3.3.6 Other impact on human being and food safety

3.4 Safety classes of GM plants are determined on the basis the above mentioned evaluations and by reference to the stipulation in Article 13 of the Measure

4. GM products safety evaluation

4.1 Impact of production and processing on safety of GM plants

4.2 Stability of GM products

4.3 Difference in environmental safety between GM products and GM plants

4.4 Difference in influence on human health between GM products and GM plants

4.5 Safety classes of GM plant products are determined on the basis the above mentioned evaluations and by reference to the stipulation in Article 14 of the Measure

II. Protocol for GM Plants testing

1. Testing site

1.1 Provide materials on the topography and meteorology of testing site; give a general description of testing site; indicate the detailed address where test is done

1.2 Do the Areas around the testing site belong to natural ecological type or agricultural ecological type. In the case of natural ecological type, indicate the distance from the area of agricultural ecological type; in the case of agricultural ecological type, indicate names of the typical diseases and pests that haunt the crops and the incidence of epidemic diseases

1.3 List the names of cultivated and wild plants and the typical weeds around the testing site; indicate the harms they do

1.4 List the species of main animals around the testing site. Are there rare, endangered or protected animals?

1.5 Whether the ecological environment of the testing site will affect the survival, production, extension and diffusion of the GM plants; especially, is it possible that other organisms in the environment acquire purpose genes from the GM plants?

2. Testing design

2.1 Beginning and ending time of field test

2.2 Area of the testing site (not including the area of isolation materials)

2.3 Materials on the planting of the GM plants

2.3.1 Event and material name (code) of the GM plants

2.3.2 Planting area of the GM plants of different events and materials in different testing sites

2.3.3 Quantity of the GM plants to be used

2.3.4 How to pack the GM plants and transport them to the testing site

2.3.5 Are the GM plants planted by machine or by people?

2.4 Plans on the use of pesticides during the full production period of GM plants

2.5 Materials on the GM plants and their products

2.5.1 Do the GM plants bear fruits?

2.5.2 Are they harvested by machine or by people? How to avoid loss?

2.5.3 How to store the harvested GM plants and their products?

3. Safety supervision measures

3.1 Separating measures

3.1.1 Isolation distance

3.1.2 Species of the separated plants and their distribution

3.1.3 How to prevent pollen from going out of the testing site

3.1.4 Other proposed isolation measures

3.2 Measures prevent the GM plants and their genes from diffusing

3.3 Emergency measures in case of unexpected accidents in the process of testing

3.4 How to handle the residuals left after harvest

3.5 Supervision of the testing site after harvest

3.5.1 The person in charge of the supervision and his or her phone number

3.5.2 Are boundary marks set in the testing site?

3.5.3 Supervision measures and supervision period after the test is finished

III. Requirement of the application for GM Plant Safety Evaluation in Different Stages

1. Requirement of application for Pilot test

1.1 Name of project: include the name of purpose gene, name of GM plant, name of the province (municipality or autonomous region) where test is done and name of testing stage, for example: the medium test of Bt antipest GM cotton in Hebei and Beijing

1.2 Quantity of GM plant materials for test: an application shall not contain more than 20 events. These events shall be acquired out of same receptor plants (not more than 5 species or genres), same purpose gene and same genetic operation, and each event shall have a definite name or code.

1.3 Testing site and scope: Tests shall be conducted in work unit's test sites. Area for each test shall not exceed 4 mu (except for perennial plants, which depend on concrete condition). The province (city or autonomous region), county (city), township, village and position coordinates of the test shall be given.

1.4 Testing period: usually one or two years for one application (for perennial plants, the period depends on concrete condition).

1.5 When medium test is reported, usually the following materials shall be submitted:

1.5.1 Ribonucleic sequence of purpose gene; deduced sequence of amino acid

1.5.2 Chart of purpose gene and carrier structure

1.5.3 Inspection or appraisal result of molecules whose purpose genes and plant gene group are integrated and expressed (results of PCR inspection and southern hybrid analysis or northern analysis)

1.5.4 Inspection and appraisal technology of transgenetic characteristics and the derivatives

1.5.5 Topographical chart and planting isolation chart of testing site

1.5.6 The operating procedures of medium tests (including storage, transportation, destroy, harvest, postharvest monitoring, measures for accidently release of GM plants and management of test sites);

1.5.7 Testing design (including the main index and research methods of safety evaluation, such as genetic stability, agronomic features, environmental adaptability and ability of survival and competition of GM plants, expression of outside genes in each organs of plant and the validity of their functional feature)

2. Requirement of the application for Environmental release

2.1 Name of project: include the name of purpose gene, name of GM plant, name of the province (municipality or autonomous region) where test is done and name of testing stage, for example: the environmental release of Bt anti-pest GM cotton NY12 and NM36 in Hebei and Beijing

2.2 Quantity of GM plant materials for test: event in an application shall be acquired out of the receptor plants of same species or genres, same purpose gene and same genetic operation, and each event shall have a definite name or code which corresponds to the stage of medium test.

2.3 Testing site and scope: Area for test shall be no more than 30 mu (normally larger than 4 mu, for perennial plants, the period depends on concrete condition). The province (city or autonomous region), county (city), township, village and position coordinates of the test shall be given.

2.4 Testing period: usually one or two years for one application (for perennial plants, the period depends on concrete condition).

2.5 When environmental release is applied for, usually the following materials shall be submitted:

2.5.1 Ribonucleic sequence of purpose gene; deduced sequence of amino acid

2.5.2 Chart of purpose gene and carrier structure

2.5.3 Inspection or appraisal result of molecules whose purpose genes and plant gene group are integrated and expressed (results of PCR inspection and southern hybrid analysis or northern analysis; results of purpose gene derivative expression)

2.5.4 Inspection and appraisal technology of transgenetic characteristics and the derivatives

2.5.5 Summary report on experimental research and medium test

2.5.6 Topographical chart of the testing site

2.5.7 The operating procedures of environmental release tests (including storage, transportation, destroy, harvest, post-harvest monitoring, measures for accidently release of GM plants and management of test sites); 2.5.8 Testing design (including the main

index and research methods of safety evaluation, such as genetic stability, agronomic features, environmental adaptability and ability of survival and competition of GM plants, expression of outside genes in each organs of plant, the stability of their functional features, ability to copulate with relevant species, genetic excursion and influence on non-target organisms)

3. Requirement of the application for pre-production test

3.1 Name of project: include the name of purpose gene, name of GM plant, name of the province (municipality or autonomous region) where test is done and name of testing stage, for example: the productive test of Bt anti-pest GM cotton NY12 in Hebei and Beijing

3.2 Quantity of GM plant materials for test: an application shall contain no more than 5 species, the species shall belong to the same event. Its name shall be same as that in early experimental stage.

3.3 Testing site and scope: the sites (for preproduction test) shall be conducted in the ecological area suitable for the tested plants; Area for test shall be more than 30 *mu* (except for perennial plants, which depend on concrete condition). The province (city or autonomous region), county (city), township, village and position coordinates of the test shall be given.

3.4 Testing period: usually one or two years for one application (for perennial plants, the period depends on concrete condition).

3.5 When productive test is applied for, usually the following materials shall be submitted:

3.5.1 DNA sequence of purpose gene; amino acid sequence encoded from inserted DNA

3.5.2 Structure of purpose gene and vector

3.5.3 Molecule detection of purpose genes, plant genome and detection on its derivative products (results of PCR detection and southern hybrid analysis or northern analysis; results of purpose gene derivative expression)

3.5.4 Detection and validated technology of transgenetic characteristics and the derivatives

3.5.5 Photocopies of approval documents for the stage of environmental release

3.5.6 Summary report on testing results of each stage and safety evaluation

3.5.7 Topographical chart of the testing site

3.5.8 The operating procedures of pre-production tests (including storage, transportation, destroy, harvest, postharvest monitoring, measures for accidently release of GM plants and management of test sites);

3.5.9 Testing design (including the main index and research methods of safety evaluation, such as genetic stability and ability of survival and competition of GM plants, genetic

excursion detection, influence on nontarget organisms, food safety, nutrient ingredient analysis, anti-nutrition gene, toxins and allergens are contained or not, safety of mark gene, necessary data of acute or sub-acute animal test)

3.5.10 If the plants are acquired through hybridization between the plants whose parents are genetically modified and regular species of plants (or other species of GM plants), materials on their parental plants and the breeding process as well as testing data showing the genetic source shall be provided.

4. Requirement of the application for safety certificate

4.1 Name of project: include the name of purpose gene and the name of the GM plant, etc. such as BioSafety Certificate of cry1Ac GM anti-pest cotton XY12.

4.2 An application shall contain only one event. Its name shall be corresponding to the name and the number in the early experimental stage.

4.3 The validity period of the first-time application for a biosafety certificate should not exceed five years; if it needs to be renewed, an application should be submitted to the MARA's GMO Safety Management Office within one year before the expiration of the validity period; After evaluation by the NBC, an opinion on whether to approve and extend the validity period is proposed for MARA to make the decision.

4.4 When safety certificate is applied for, usually the following materials shall be submitted:

4.4.1 DNA sequence of target gene; amino acid sequence encoded from inserted DNA

4.4.2 Structure of target gene and vector

4.4.3 Molecule detection or appraisal result of target genes, plant genome and its derivative products (results of PCR detection and southern hybrid analysis or northern analysis; results of purpose gene derivative expression)

4.4.4 Detection and validated technology of transgenetic characteristics and the derivatives

4.4.5 Photocopies of approval documents for each stage

4.4.6 Summary report on testing results of each stage and safety evaluation

4.4.7 Report of a comprehensive evaluation on GM plants safety in ecological environment

4.4.8 Comprehensive evaluation report on food safety, including 1) report on necessary animal toxicity testing; 2) testing report on food allergy evaluation; 3) analysis on the nutrient ingredients and anti-nutrition genes by comparing with non-GM plants

4.4.9 Application of the GM plants both at home and abroad

4.4.10 Field supervision plan, including supervising technology, resistance treatment measures, research plan on long-term environmental effect, etc.

4.4.11 Other relevant materials needed for examination

4.5 The GM plants as the object of application for safety certificate shall be put into productive test only after approval is obtained from MARA and the application for safety certificate shall be made only after the test is finished.

4.6 An events combination obtained by hybrid of two or more events that have biosafety certificates (respectively) shall apply for biosafety assessment from the pre-production tests.

Integration of events that have obtained biosafety certificates should file reports to the MARA GMO Safety Management; before commercialization, (the applicant) should also submit the testing reports for consistency of the target traits and the event characteristics, which is issued by a technical testing agency with the testing conditions and capabilities.

END OF TRANSLATION

Attachments:

20211112-GAIN report CH2021-0139-for Domestic Comments.pdf

20211214-China notified the revision of the GMO safety assessment measures to the WTO.pdf