"Medidas sobre la Administración de la Bioseguridad de OGMs Agrícolas"

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Measures for the Safety Evaluation Administration of Agricultural GMOs.

Chapter One: General

Article 1: These Measures are established in accordance with the Ag GMOs Safety Administration Regulations (Hereinafter referred to as "Regulations") in order to strengthen the safety evaluation administration of agricultural genetically modified organisms (hereafter referred to as Ag GMOs); safeguard the health of humans and the safety of animals, plants, and microorganisms; and protect the environment.

Article 2: In accordance with the Regulations, Ag GMO research, testing, production, processing, marketing and imports/exports are subject to the requirements of these Measures.

Article 3: These Measures apply to Ag GMOs specified in the Regulations; i.e. animals, plants, microorganisms and products with genetic structures that have been modified by genetic engineering technology for the use of agricultural production or processing. Ag GMOs include:

1. Genetically modified animals, plants (including planting seeds, breeding livestock, poultry and fish fry) and microorganisms.

2. Genetically modified animal products, plant products and microorganism products.

3. Products directly processed from genetically modified agricultural products.

4. Planting seeds, breeding livestock, poultry, fish fry, pesticides, veterinary medicines, fertilizer and additives with genetically modified animal, plant or microbe ingredients.

Article 4: Evaluations under these Measures are to detect the dangers or potential risks caused by Ag GMOs to humans, animals, plants and microorganisms and the environment. Three kinds of safety evaluations shall be conducted: for plants, animals, and microorganisms; on the basis of science, using case by case examinations; and under the administration of different safety classes and different stages.

Article 5: The Ag GMO Safety Committee of the State shall be established in accordance with Article 9 of the Regulations. The duty of the Ag GMO Safety Committee is to evaluate the safety of Ag GMOs. The Committee shall consist of experts in Ag GMO research, production, processing, inspection, quarantine, health and environmental protection. The committee members shall serve 3 year terms.

An Ag GMO Safety Administration Office in charge of the safety evaluation administration of Ag GMOs shall be established under the Ministry of Agriculture.

Article 6: Any work unit engaged in the research and testing of Ag GMOs shall establish an Ag GMO safety group. The legal representative of the unit shall be the group leader. The group shall be in charge of unit-wide Ag GMO safety administration and examination during the application for a safety evaluation.

Article 7: If needed, the Ministry of Agricultural may entrust the task of inspection to a technical inspection agency that has the appropriate conditions and ability to inspect Ag GMOs. Such an agency shall provide the basis for safety evaluation and administration.

Article 8: The Ag GMO Safety Certificate shall be obtained for GM planting seeds, breeding livestock, poultry, fish fry, pesticides, veterinary medicines, fertilizers and additives containing GM ingredients in accordance with the requirements of these Measures before examination, registration, evaluation and approval formalities are

initiated.

Chapter Two: Safety Classes and Safety Evaluation

Article 9: Ag GMO safety is subject to the Classification Evaluation and Administration System.

Ag GMOs are classified into the following 4 classes by the nature of their potential danger to humans, animals, plants, microorganisms and the environment.

Safety Class I: No danger for the time being;
Safety Class II: Low degree of danger;
Safety Class III: Medium degree of danger;
Safety Class IV: High degree of danger.

Article 10: The following steps shall determine the safety class of Ag GMOs:

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

Article 11: Determination of Receptor Organisms.

Receptor organisms are divided into 4 safety classes:

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

1. To date, no negative effect on human health and the 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 experiment.

(B) Receptor organisms shall be determined to be Safety Class II if the receptor organism might cause a low degree of danger to human health and the environment. However, such dangers can be prevented through safety control measures.

(C) Receptor organisms shall be determined to be Safety Class III if the receptor organism might cause a medium degree of danger to human health and the environment. In addition, such dangers can be prevented through safety control measures.

(D) Receptor organisms shall be determined to be Safety Class IV if the receptor organism might cause a high degree of danger to human health and the environment. In addition, such dangers cannot be effectively controlled except through storage or use in a sealed space. Receptor organisms of Safety Class IV include:

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

2. Hazardous organisms that, to date, have no effective technology for the prevention of the hazardous organisms and their derivatives from escaping or diffusing;

3. Hazardous organisms that, to date, once escaped, have no effective technology for the capture or elimination of the hazardous organisms before the hazard could have a negative influence on human health and the environment.

Article 12: Determination of the way in which genetic operations affect the safety class of receptor organisms.

Genetic operations affect the safety class of receptor organisms in 3 ways; i.e. They improve safety; They have no effect on safety; They reduce safety.

Type 1: Genetic operations that improve the safety of receptor organisms. This includes operations aiming to eliminate or inhabit some gene(s) known to be dangerous.

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

This includes:

1. Apparent or genetic type transformations of the receptor organisms that cause no effect on human health and the environment;

2. Apparent or genetic transformations of the receptor organisms that cause no negative effect on human health and the environment;

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

This includes:

1. Apparent or genetic transformations of the receptor organisms that might have a negative effect on human health and the environment;

2. Apparent or genetic transformations of the receptor organisms when there is no certainty regarding negative effects on human health and the environment; Article 13: Determination of Ag GMO Safety Class.

The Safety Class of Ag GMOs shall be determined in accordance with the safety class of receptor organisms and by the type and degree of influence that genetic operations have on the safety class of receptor organisms.

(A) GMOs made from receptor organisms of Safety Class I.

1. The GMOs made from receptor organisms of Safety Class I through Type 1 or Type 2 genetic operations shall be categorized as Safety Class I.

2. The GMOs made from receptor organisms of Safety Class I through Type 3 genetic operation shall:

(a) fall under Safety Class I if the safety decline is slight and it is not necessary to take safety control measures;

(b) fall under Safety Class II if there is a modest decline in safety and the potential danger can be prevented completely through normal safety control measures;

(c) fall under Safety Class III if there is a serious decline in safety and the potential danger can be prevented through strict safety control measures;

(d) fall under Safety Class IV if there is so serious a decline in safety that the potential danger cannot be prevented through safety control measures.

(B) GMOs made from receptor organisms of Safety Class II.

1. GMOs made from receptor organisms of Safety Class II through Type 1 genetic operations shall:

(a) fall under Safety Class I if safety is improved enough to no longer have a negative effect on human health and the environment;

(b) fall under Safety Class II if the safety is improved, but still presents a low degree of danger to human health and the environment.

2. GMOs made from receptor organisms of Safety Class II through Type 2 genetic operations shall fall under

Safety Class II.

3. GMOs made from receptor organisms of Safety Class III through Type 3 genetic operations shall fall under Safety Class II, III, or IV depending on the degree to which safety is reduced. The standard for classification is the same as that of receptor organisms.

(C) GMOs made from receptor organisms of Safety Class III.

1. GMOs made from receptor organisms of Safety Class III through Type 1 genetic operations can fall under Safety Class I, II, or III, depending on the degree to which that safety is improved. The standard for classification is the same as that of receptor organisms.

2. GMOs made from receptor organisms of Safety Class III through Type 2 genetic operations fall under Safety Class III.

3. GMOs made from receptor organisms of Safety Class III through Type 3 genetic operations can fall under Safety Class III or IV, depending on the degree to which the safety is reduced. The standard for classification is the same as that of receptor organisms.

(D) GMOs made from receptor organisms of Safety Class IV.

1. GMOs made from receptor organisms of Safety Class IV through Type 1 genetic operations can fall under Safety Class I, II, III or IV, depending on the degree to which the safety is improved. The standard for classification is the same as that of receptor organisms.

2. GMOs made from receptor organisms of Safety Class IV through Type 2 or Type 3 genetic operations still fall under Safety Class IV.

Article 14: Determination of the Safety Class of Ag GM products

The safety class of Ag GM products shall be determined in accordance with the safety class of Ag GMOs and by the type and degree of influence that production and processing have on the safety class.

(A) The influence of production and processing of Ag GM products on the safety class of GMOs can be divided into 3 types:

Type 1: Those that improve the safety of GMOs

Type 2: Those that have no effect on the safety of GMOs

Type 3: Those that reduce the safety of GMOs

(B) GM products made from GMOs of Safety Class I.

1. GM products made from GMOs of Safety Class I through Type 1 or Type 2 production and processing fall under Safety Class I.

2. GM products made from GMOs of Safety Class I through Type 3 production and processing can fall under Safety Class I, II, III, or IV, depending on the degree to which safety is improved. The standard for classification is the same as that of receptor organisms.

(C) GM products made from GMOs of Safety Class II.

1. GM products made from GMOs of Safety Class II through Type 1 production and processing:

(a) fall under Safety Class I if safety is improved enough so as to no longer have a negative effect on human health and the environment;

(b) fall under Safety Class II if safety is improved so as to cause a low degree of danger to human health and the environment.

2. GM products made from GMOs of Safety Class II through Type 2 production and processing still fall under Safety Class II.

3. GM products made from GMOs of Safety Class II through Type 3 production and processing can fall under Safety Class II, III, or IV, depending on the degree to which safety is reduced. The standard for classification is the same as that for receptor organisms.

(D) GM products made from GMOs of Safety Class III.

1. GM products made from GMOs of Safety Class III through Type 1 production and processing can fall under Safety Class I, II, or III, depending on the degree to which safety is improved. The standard for classification is the same as that for receptor organisms.

2. GM products made from GMOs of Safety Class III through Type 2 production and processing fall under Safety Class III.

3. GM products made from GMOs of Safety Class III through Type 3 production and processing can fall under Safety Class III or IV, depending on the degree to which safety is reduced. The standard for classification is the same as that for receptor organisms.

(E) GM products made from GMOs of Safety Class IV.

1. GM products made from GMOs of Safety Class IV through Type 1 production and processing can fall under Safety Class I, II, III, or IV, depending on the degree to which safety is improved. The standard for classification is the same as that for receptor organisms.

2. GM products made from GMOs of Safety Class IV through Type 2 or Type 3 production and processing fall under Safety Class IV.

Chapter Three: Application, Examination, and Approval

Article 15: Any work unit or individual engaged in research of Safety Class II and IV Ag GMOs or in the testing and import of any Safety Class Ag GMOs shall, according to the different Ag GMOs and their safety class, report and apply to the Ag GMO Safety Administration Office for each stage of testing.

Article 16: The Ministry of Agricultural shall carry out safety evaluations of Ag GMOs twice a year. The deadline for an application lasts until March 31 and September 30 respectively. The Ministry of Agricultural shall respond whether the application is accepted or not accepted within 2 months after receiving the application. A decision on the application will be made within 3 months after the application deadline.

Article 17: Any work unit engaged in the testing and import of Ag GMOs and any work unit or individual engaged in the production and processing of Ag GMOs shall comply with the following procedures before applying to the Ag GMO Safety Administration Office for safety evaluation:

(1) The applicant shall complete an evaluation regarding the safety of the relevant Ag GMOs and complete the application document (see appendix V);

(2) The applicant shall organize its own Ag GMO safety group to examine the materials for application;

(3) The applicant shall obtain approval for conducting experiments and for using the safety certificate from the appropriate provincial agricultural administrative department;

(4) The applicant shall provide relevant technical materials.

Article 18: Those who engage in testing and research of Ag GMOs in the People's Republic of China shall meet the following conditions:

(1) Have a specialized technical institution in the People's Republic of China;

(2) Have full-time technical staff engaged in testing and research of Ag GMOs;

(3) Have equipment and facilities suitable for testing and research;

(4) Establish an Ag GMO Safety Administration Group.

Article 19: Work units that report the initial testing, research, and medium testing and that apply for environmental release, production testing, and a safety certificate shall follow the relevant reporting or application procedures in accordance with the Ministry of Agriculture requirements on GM plants, animals, and microorganisms safety evaluation at each stage of testing (see Appendix I, II, III, IV, and V)

Article 20: The testing and research on Ag GMOs of Safety Class I and II shall be subject to the approval of the work unit Ag GMO safety group. The testing and research on Ag GMOs of Safety Class III and IV shall be reported to the Ag GMO Safety Administration Office before implementation.

When reporting to the Ag GMO Safety Administration Office, the researcher shall provide the following materials:

(1) Report on experimental research (see Appendix V);

(2) The safety class of Ag GMOs and the basis for the class determination;

(3) Relevant laboratory safety facilities and measures for safety administration and protection.

Article 21: When the experimental research on Ag GMOs (Safety Class I, II, III, and IV) concludes and moves to medium testing, the researcher shall report to the Ag GMO Safety Administration Office.

When reporting to the Ag GMO Safety Administration Office, the researcher shall provide the following materials:

(1) Report on medium testing (see Appendix V);

(2) Summary report on experimental research;

(3) The safety class of Ag GMOs and the basis for the class determination;

(4) Relevant laboratory safety facilities and measures for safety administration and protection.

Article 22: When, after medium testing, Ag GMOs are intended for environmental release or for production testing after environmental release, the applicant shall apply to the Ag GMO Safety Administration Office. Only after passing the safety evaluation of the Ag GMO Safety Administration Office and obtaining the approval of the Ministry of Agricultural, can the researcher start the relevant tests as required in the approval document.

When submitting an application, the applicant shall provide the following materials:

(1) Application for safety evaluation (see Appendix V);

(2) The safety class of Ag GMOs and the basis for the class determination;

(3) Inspection report from the technical inspection agency specified by the Ministry of Agriculture;

(4) Relevant safety research contents and measures on safety administration and protection;

(5) Summary report of previous experiments.

Article 23: Testers that intend to apply for the safety certificate after finishing production testing shall apply to the Ag GMO Safety Administration Office. Only after passing the safety evaluation of the Ag GMO Safety Committee, and obtaining the approval of the Ministry of Agriculture, can the Ag GMO safety certificate be issued.

When making application, the applicant shall provide the following materials:

(1) Application for safety evaluation (see Appendix V);

(2) The safety class of Ag GMOs and the basis for class determination;

(3) Inspection report from the technical inspection agency specified by the Ministry of Agricultural;

(4) Summary report on the stages of medium testing, environmental release and production testing;

(5) Other relevant materials.

Article 24: The Ag GMO safety certificate shall indicate the name (number), scale, scope, time limit of Ag GMOs, individuals responsible for safety control measures, etc.

Work units or individuals engaged in the production, processing, and import of Ag GMOs shall perform activities in accordance with the Ag GMOs safety certificate requirements and perform the relevant obligations as specified in the certificate.

Article 25: When introducing Ag GMOs from outside China or exporting Ag GMOs to China, the introducing entity or exporter shall provide relevant safety evaluation documents as required in the Safety Administration Measures for Ag GMO Imports.

Article 26: Necessary examination fees and inspection fees shall be paid in accordance with the relevant regulations from the Ministry of Finance and the State Planning Commission at the time of application for Ag GMOs safety evaluation.

Article 27: Staff members responsible for evaluation and experts participating in the evaluation shall keep technical and commercial secrets for applicants. If the evaluation bears personally on any staff member or expert or their relatives, the person shall not take part in the evaluation.

Chapter Four: Technical Inspection Administration

Article 28: If needed for the purpose of Ag GMO safety evaluation and administration, the Ministry of Agricultural may entrust the task of inspection to a technical inspection agency that has adequate inspection conditions and capacity.

Article 29: A technical inspection agency shall meet the following basic conditions:

(1) It shall be fair and the final authority: a relatively independent agency with a full time staff;

(2) It shall have equipment and inspection means suitable for the function, and in compliance with, the national or industry standard;

(3) It shall be strict in carrying out technical inspections and inspection data shall be exact and authentic;

(4) It shall have relevant safety control measures in place.

Article 30: Duties and tasks of the inspection agency:

(1) Provide technical services for the safety administration and evaluation of Ag GMOs;

(2) Undertake the task of qualitative and quantitative inspection, appraisal, and examination of Ag GMOs entrusted by the Ministry of Agriculture or by applicants;

(3) Issue an inspection report and make scientific judgements;

(4) Research inspection technology and methods, undertake or participate in the making and modification of

evaluation standards and technical rules;

(5) Destroy all inspected samples safely after inspection;

(6) Keep technical and commercial secrets for consignors and applicants.

Chapter Five: Superintendence and Safety Monitoring

Article 31: The Ministry of Agriculture shall supervise Ag GMO safety by guiding the work of monitoring for the safety of Ag GMOs in different types of areas and by establishing a nationwide Ag GMO safety monitoring system.

Article 32: Agricultural administrative departments of local governments above the county level shall, in accordance with Article 39 and 40 of the Regulations, be responsible for the supervision of local Ag GMO safety.

Article 33: Work units and individuals shall, in accordance with Article 41 of the Regulations, cooperate with the agricultural administrative department during the supervision process.

Article 34: Work units engaged in the experiment and production of Ag GMOs shall, during the working process or after the work is finished, regularly submit an experimental summary, production plan, and progress report to the Ministry of Agriculture and the local agricultural administrative department above the provincial level. Annual production plans for the production and application of Ag GMOs shall be submitted before March 31. An annual progress report shall be submitted before December 31. An annual experimental summary report on medium testing, environmental release, and production testing shall be submitted before December 31.

Article 35: Work units engaged in the experiment and production of Ag GMOs shall, in accordance with the requirements of these Measures, determine safety control and accident prevention measures, and keep a record of safety supervision in anticipation of examination.

Safety control measures include physical control, chemical control, biological control, environmental control, and scale control (see Appendix V).

Article 36: Before Safety Class II, III, and IV Ag GMOs are discarded or released, effective measures such as destruction and sterilization shall be taken to avoid diffusion and environmental pollution. Once Ag GMOs are found to be diffused, active, or to have done harm, effective measures must be taken immediately to control and eliminate the Ag GMOs and the situation shall be reported to the local administrative department.

Article 37: During the process of storage, transmission, transportation, destruction and sterilization of Ag GMOs, proper measures of safety administration and protection shall be taken. Special spaces for equipment shall be available and personnel for record keeping shall be specified.

Article 38: If Ag GMOs are found to be dangerous to humans, animals, plants or the environment, the Ministry of Agriculture has the right to prohibit production, processing, operation and import of the Ag GMOs, recall the safety certificate of Ag GMOs, and ask the owner to destroy the dangerous Ag GMOs.

Chapter Six: Enforcement

Article 39: Those who fail to abide by these Measures by conducting experiments and research in Ag GMOs of Safety Class III and IV, or conduct the medium testing of Ag GMOs without reporting to the Ministry of Agriculture, shall be penalized in accordance with Article 43 of the Regulations.

Article 40: Those who, unauthorized, conduct environmental release and production testing, or authorized, but do not take safety administration and protection measures as required, or conduct experiments beyond the authorized scope or time period, shall be penalized in accordance with Article 44 of the Regulations.

Article 41: Those who, without the Ag GMOs safety certificate, put Ag GMOs into production and use after production testing shall be penalized in accordance with Article 45 of the Regulations.

Article 42: Those who counterfeit, forge, transfer, buy, or sell the safety certificate of Ag GMOs and approval documents shall be penalized in accordance with Article 53 of the Regulations.

Article 43: Those who issue the safety certificate of Ag GMOs and approval 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 Ag GMOs or approval documents, shall be penalized in accordance with Article 55 of the Regulations.

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. Ag 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. Medium testing: small-scale experiments conducted in a controlled system or under controlled conditions.

11. Environmental release: medium-scale experiments conducted under natural conditions with proper safety protection.

12. Production testing: large-scale experiments 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 shall interpret these Measures.

Article 46: These Measures shall be effective from March 20, 2002. The Agricultural Biological Engineering Safety Administration Measures promulgated on July 10, 1996 by the Ministry of Agriculture under order number 7 shall be nullified.

Appendix I GM Plants Safety Evaluation (omitted).

Appendix II GM Animals Safety Evaluation (omitted).

Appendix III GM Microorganisms Safety Evaluation (omitted).

Appendix IV Safety Control Measures for Ag GMOs and Their Derivatives (omitted).

Appendix V Ag GMO Safety Evaluation Application Form Samples (omitted).