

Implementation Regulations on Safety Assessment of Agricultural Genetically Modified Organisms

(Adopted at the 5th Executive Meeting of the Ministry of Agriculture on July 11, 2001, promulgated by Decree No. 8 of the Ministry of Agriculture of the People's Republic of China on January 5, 2002)

Chapter 1 General Provisions

Article 1. These Implementation Regulations are formulated in accordance with the “Regulations on Safety of Agricultural Genetically Modified Organisms” (hereafter referred to as Regulations) for the purposes of strengthening the safety assessment administration of agricultural genetically modified organisms (hereafter referred to as agricultural GMOs), safeguarding human health and safety of animals, plants and microorganisms, and protecting the environment.

Article 2. The activities of research, testing, production, processing, marketing, import or export with respect to agricultural GMOs within the territories of the People’s Republic of China that are required to take safety evaluation by the Regulations must conform to these Implementation Regulations.

Article 3.. These Implementation Regulations shall apply to any agricultural GMO that is defined in the Regulations, i.e. animals, plants, microorganisms and their products that have been genetically modified by genetic engineering technologies for the use in agricultural production or processing. They mainly include:

- (1) Genetically modified animals, plants (including seeds, breeding livestock and poultry, and aquatic fry and seeds) and microorganisms;
- (2) Products of the genetically modified animals, plants and microorganisms;
- (3) Products directly processed from genetically modified agricultural products;
- (4) Seeds, breeding livestock and poultry, aquatic fry and seeds, pesticides, veterinary medicines and biologics, fertilizers, additives, and other products containing the genetically modified animals, plants, microorganisms, or their products.

Article 4.. These Implementation Regulations apply to the assessment of the danger or potential risk posed by the agricultural GMOs to human beings, animals, plants, microorganisms, and the environment. Safety assessment shall be divided into three categories: for plants, for animals and for microorganisms. The safety assessment shall be carried out on scientific and case-by-case bases, and by safety classes and work stages.

Article 5.. According to Article 9 of the Regulations, a national biosafety committee (NBC) shall be established and in charge of safety assessment of agricultural GMOs. The NBC shall be composed of experts who are engaged in biological research, production, processing, inspection and quarantine with respect to

agricultural GMOs, as well as experts in the fields of public health and environmental protection. The office term of the NBC shall be three years.

The Ministry of Agriculture shall set up an office for biosafety administration of agricultural GMOs (OBA), which will be in charge of the administration of the safety assessment of agricultural GMOs.

Article 6. Any organization engaged in research and testing of agricultural GMOs shall set up an institutional biosafety committee of agricultural GMOs (IBC), which shall be headed by the legal representative of the organization. The IBC shall be in charge of the supervision over the safety of agricultural GMOs and the examination of applications for safety assessment of agricultural GMOs in the organization.

Article 7.. The Ministry of Agriculture shall, based on the needs of the safety evaluation of agricultural GMOs, entrust the inspection of agricultural GMOs to technical inspection bodies with necessary facilities and capacity so as to provide data for safety assessment and management.

Article 8. The safety certificate of agricultural GMOs shall be obtained for genetically modified plant seeds, breeding livestock and poultry, and aquatic fry and seeds as required in these Implementation Regulations before the examination, registration, evaluation or approval is conducted in accordance with the provisions of relevant laws and administrative regulations.

This provision also applies to the seeds, breeding livestock and poultry, aquatic fry and seeds, pesticides, veterinary medicines and biologics, fertilizers, additives and others, which are either produced with agricultural GMOs or contain ingredients of agricultural GMOs.

Chapter 2. Safety Classes and Safety Assessment

Article 9. A class-based administration and evaluation system shall be instituted for the safety of agricultural GMOs.

Agricultural GMOs are classified into four classes according to the extent of their potential risks to human beings, animals, plants, microorganisms and the environment:

Safety class I: With no known risk.

Safety class II: With a low risk.

Safety class III: With a medium risk.

Safety class IV: With a high risk.

Article 10. Safety assessment and classification of agricultural GMOs shall take the following steps:

- (1) Determine the safety class of the recipient organism;
- (2) Determine the type of genetic manipulations that influence the safety class of recipient organisms;
- (3) Determine the safety class of the genetically modified organism(s);
- (4) Determine the type of production or processing activities that influence the safety class of genetically modified organism(s);
- (5) Determine the safety class of the genetically modified product(s).

Article 11. Determination of the safety class of the recipient organism

Recipient organisms are classified into four safety classes:

(1) Any recipient organism that meets one of the following conditions shall be determined as safety class I:

- a. Having never produced any negative effects on human health or the environment;
- b. With little possibility of evolving into a hazardous organism;
- c. Any short-life recipient organism used for special research use and with little possibility to survival in a natural environment after the completion of experiments.

(2) Any recipient organism, which may pose a low risk to human health or the environment but such risks can be entirely avoided through appropriate safety control measures, shall be determined as safety class II.

(3) Any recipient organism, which may pose a medium risk to human health or the environment but such risks can be basically avoided through safety control measures, shall be determined as safety class III.

(4) Any recipient organism, which may pose a high risk to human health or the environment and such risks cannot be avoided through any known safety control measure other than being kept in a containment facility, shall be determined as of safety class IV. This class includes:

- a. Any hazardous organism that is likely to have a high-frequency exchange of genetic materials with other organisms;
- b. Any hazardous organism that has no effective techniques so far for preventing itself or its product(s) from escape or spread;
- c. Any hazardous organism that has no effective technique so far for the capture or elimination before it causes negative effects on human health or the environment after its escape.

Article 12. Determination of the safety type of genetic manipulation

The influence of genetic manipulation on recipient may be divided into three types: increasing the safety, no influence on safety, and decreasing the safety.

Type 1: The genetic manipulation that increases safety of recipient organisms, such as removal of the known hazardous gene(s) or inhibition of the expression of such a gene or genes.

Type 2: The genetic manipulation that has no influence on the safety of recipient organisms

It includes:

a. Modification of the phenotype or genotype of recipient organisms without affecting human health and the environment.

b. Modification of the phenotype or genotype of recipient organisms without harmfully affecting human health and the environment.

Type 3: The genetic manipulation that decreases the safety of recipient organisms

It includes:

a. Modification of the phenotype or genotype of recipient organisms that may have harmful influence on human health or the environment.

b. Modification of the phenotype or genotype of recipient organisms with undetermined influence on human health or the environment.

Article 13. Determination of the safety class of agricultural genetically modified organisms

The safety class of genetically modified organisms shall be determined on the basis of the safety class of recipient organisms and the safety type and extent of genetic manipulation.

(1) Genetically modified organisms derived from safety class I recipient organisms

a. The safety class of the genetically modified organisms derived from recipient organisms of safety class I through Type 1 or Type 2 genetic manipulation shall still be determined as safety class I.

b. The safety class of the genetically modified organisms derived from recipient organisms of safety class I through Type 3 genetic manipulation shall be determined as

(a) Safety class I on condition that the safety decreases only a little and there is no need to take any safety control measures;

(b) Safety class II if the safety decreases to a certain extent but the potential risk can be completely avoided through safety control measures;

(c) Safety class III if the safety decreases to a great extent but the potential risk can be avoided through strict safety control measures;

(d) Safety class IV if the safety decreases to a great extent and the risk cannot be completely avoided even through safety control measures.

(2) Genetically modified organisms derived from class II recipient organisms

a. The safety class of the genetically modified organisms derived from recipient organisms of safety class II through Type 1 genetic manipulation shall be determined as

(a) Safety class I if the safety increases to such a great extent that they no longer adversely affect human health and the environment;

(b) Safety class II if the safety increases to a small extent that they may still pose a low risk to human health or the environment.

b. The safety class of the genetically modified organisms derived from recipient organisms of safety class II through Type 2 genetic manipulation shall still be determined as safety class II.

c. The safety class of the genetically modified organisms derived from recipient organisms of safety class II through Type 3 genetic manipulation shall be determined as safety class II, III or IV, depending on the extent to which safety is decreased. The criteria for safety classification are the same as that of recipient organisms.

(3) Genetically modified organisms derived from class III recipient organisms

a. The safety class of the genetically modified organisms derived from recipient organisms of safety class III through Type 1 genetic manipulation shall be determined as safety class I, II or III, depending on the extent to which safety is increased. The criteria for safety classification are the same as that of recipient organisms.

b. The safety class of the genetically modified organisms derived from recipient organisms of safety class III through Type 2 genetic manipulation shall be determined as safety class III.

c. The safety class of the genetically modified organisms derived from recipient organisms of safety class III through Type 3 genetic manipulation shall be determined as safety class III or IV, depending on the extent to which safety is decreased. The criteria for safety classification are the same as that of recipient organisms.

(4) Genetically modified organisms derived from class IV recipient organisms

a. The safety class of the genetically modified organisms derived from recipient organisms of safety class IV through Type I genetic manipulation shall be determined as safety class I, II, III or IV, depending on the extent to which safety is increased. The criteria for safety classification are the same as that of recipient organisms.

b. The safety class of the genetically modified organisms derived from recipient organisms of safety class IV through Type 2 or Type 3 genetic manipulation shall still

be determined as safety class IV.

Article 14. Determination of the safety class of genetically modified agricultural products

The safety class of the genetically modified agricultural products shall be determined on the basis of the safety class of the genetically modified organisms and the safety type and extent of the production or processing activities.

(1) The influence of production or processing activities on the safety class of genetically modified organisms may be divided into three types:

- Type 1: Increasing the safety;
- Type 2: No influence on safety;
- Type 3: Decreasing the safety.

(2) Genetically modified products derived from genetically modified organisms of safety class I

a. The safety class of the genetically modified products derived from genetically modified organisms of safety class I through Type 1 or 2 production or processing activities shall still be determined as safety class I.

b. The safety class of the genetically modified products derived from genetically modified organisms of safety class I through Type 3 production or processing activities may be determined as safety class I, II, III or IV, depending on the extent to which safety is decreased. The criteria for safety classification are the same as that of recipient organisms.

(3) Genetically modified products derived from genetically modified organisms of safety class II

a. The safety class of the genetically modified products derived from genetically modified organisms of safety class II through Type 1 production or processing activities shall be determined as

(a) Safety class I if the safety increases to such a great extent that they no longer adversely affect human health and the environment;

(b) Safety class II if the safety increases to a certain extent but they may still pose a low risk to human health or the environment.

b. The safety class of the genetically modified products derived from genetically modified organisms of safety class II through Type 2 production or processing activities shall still be determined as safety class II.

c. The safety class of the genetically modified products derived from genetically modified organisms of safety class II through Type 3 production or processing activities shall be determined as safety class II, III or IV, depending on the extent to which safety is decreased. The criteria for safety classification are the same as that of

recipient organisms.

(4) Genetically modified products derived from genetically modified organisms of safety class III

a. The safety class of the genetically modified products derived from genetically modified organisms of safety class III through Type 1 production or processing activities may be determined as safety class I, II or III, depending on the extent to which safety is increased. The criteria for safety classification are the same as that of recipient organisms.

b. The safety class of the genetically modified products derived from genetically modified organisms of safety class III through Type 2 production or processing activities shall still be determined as safety class III.

c. The safety class of the genetically modified products derived from genetically modified organisms of safety class III through Type 3 production or processing activities may be determined as safety class III or IV, depending on the extent to which safety is decreased. The criteria for safety classification are the same as that of recipient organisms.

(5) Genetically modified products derived from genetically modified organisms of safety class IV

a. The safety class of the genetically modified products derived from genetically modified organisms of safety class IV through Type 1 production or processing activities may be determined as safety class I, II, III or IV, depending on the extent to which safety is increased. The criteria for safety classification are the same as that of recipient organisms.

b. The safety class of the genetically modified products derived from genetically modified organisms of safety class IV through Type 2 or Type 3 production or processing activities shall still be determined as safety class IV.

Chapter 3. Application and Approval

Article 15. Any organization or person engaged in research of safety class III or IV agricultural GMOs, or in the testing, import, production or processing of safety class I, II, III or IV agricultural GMOs within the territories of the People's Republic of China shall, according to the category and safety class and in successive work stages of agricultural GMOs, submit reports or applications to the OBA for safety assessment review.

Article 16. The Ministry of Agriculture shall carry out safety review of agricultural GMOs twice a year. The deadline for accepting the first batch of

applications is March 31 and the deadline for accepting the second batch is September 30 each year. The Ministry of Agriculture shall respond whether the application is accepted or not within two months after receiving the application. A decision on the application will be made within three months after the application deadlines.

Article 17.. Any organization engaged in the testing or import of agricultural GMOs and any organization or person engaged in the production or processing of agricultural GMOs shall comply with the following procedures before submitting reports or applications to the OBA for safety assessment review:

(1) The applicant shall make a safety assessment of the relevant activities of agricultural GMOs and complete the application documents (see Appendix V).

(2) The applicant shall organize the IBC to make a technical examination of the application materials;

(3) The applicant shall obtain approval from the agricultural administrative department(s) of the people's government of the province, autonomous region or municipality directly under the Central Government where the testing will be conducted or the safety certificate will be used.

(4) The applicant shall provide relevant technical data and materials.

Article 18. Those who engaged in the laboratory research and/or testing of agricultural GMOs in the People's Republic of China shall meet the following conditions:

(1) Have a special agency within the territories of the People's Republic of China;

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

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

(4) Establish an IBC of agricultural GMOs.

Article 19. Organizations that report the laboratory research and/or restricted field-testing and apply for enlarged field-testing, productive testing, or a safety certificate shall follow the relevant reporting or application procedures, requirements, safety assessment standards and technical forms formulated by the Ministry of Agriculture on genetically modified plants, animals, and microorganisms for safety assessment at each stage of agricultural GMO activities (see Appendices I, II, III, IV and V).

Article 20. The laboratory research on agricultural GMOs of safety class I or II shall be subject to the approval of the IBC of agricultural GMOs. The laboratory research

on agricultural GMOs of safety class III or IV shall be reported to the OBA before commencement of the research.

When reporting to the OBA, the organization engaged in the research shall provide the following materials:

- (1) A written report on the laboratory research (see Appendix V);
- (2) The safety class of agricultural GMOs and justification for the class determination;
- (3) Appropriate safety facilities and safety management measures.

Article 21 When agricultural GMOs (safety class I, II, III, and IV) are intended for a restricted field-testing after the laboratory research, the organization engaged in the testing shall report to the OBA.

When reporting to the OBA, the organization engaged in the testing shall provide the following materials:

- (1) A written report on the restricted field-testing (see Appendix V);
- (2) A summary report on the laboratory research;
- (3) The safety class of agricultural GMOs and justification for the class determination;
- (4) Appropriate safety facilities and safety control and precautionary measures of the laboratory.

Article 22 When agricultural GMOs (safety class I, II, III, and IV) are intended for an enlarged field-testing after the restricted field-testing or for a productive testing after the enlarged field-testing, the organization engaged in the testing shall apply to the OBA. Only after passing the safety assessment of the NBC and obtaining the approval of the Ministry of Agriculture, can the relevant testing of agricultural GMOs be conducted as required in the approval document.

When submitting an application mentioned in the preceding paragraph, the organization engaged in the testing shall provide the following materials:

- (1) An application for safety assessment (see Appendix V);
- (2) The safety class of agricultural GMOs and justification for the class determination;
- (3) Inspection report(s) from technical inspection body entrusted by the MOA;
- (4) Relevant safety research contents and safety management measures;
- (5) Summary report(s) on the tests in the preceding testing stage(s).

Article 23 When an agricultural GMO is intended to apply for a safety certificate after finishing productive testing, the organization engaged in the testing shall apply

to the OBA. Only after passing the safety assessment of the NBC and obtaining the approval of the Ministry of Agriculture, can the safety certificate of agricultural GMOs be issued.

When submitting an application mentioned in the preceding paragraph, the organization engaged in the testing shall provide the following materials:

- (1) An application for safety assessment (see Appendix V);
- (2) The safety class of agricultural GMOs and justification for the class determination;
- (3) Inspection report(s) from technical inspection body entrusted by the MOA;
- (4) Summary report(s) on the tests in the stages of restricted field-testing, enlarged field-testing, and productive testing.
- (5) Other relevant materials.

Article 24 A safety certificate of agricultural GMOs shall clearly indicate the name (serial number), scale, scope, time limit of agricultural GMOs, as well as persons responsible and safety control measures.

Any organization or person engaged in the production or processing and any organization engaged in import of agricultural GMOs shall perform their activities as required in the safety certificate and perform the relevant obligations as stipulated in the safety certificate.

Article 25 When introducing agricultural GMOs from outside the People's Republic of China or exporting agricultural GMOs to the People's Republic of China, the introducing entity or exporter shall provide relevant safety assessment materials in accordance with "Implementation Regulations on Safety of Import of Agricultural Genetically Modified Organisms".

Article 26 When submitting an application for safety assessment of agricultural GMOs, the applicant shall pay review/examination fees and necessary inspection fees in accordance with the relevant regulations of the Ministry of Finance and the State Development Planning Commission.

Article 27 Staff members of the organization responsible for accepting and approving applications for safety assessment of the agricultural GMOs and experts participating in the review/examination of the applications shall keep technical and business secrets for applicants. If the safety assessment bears on the interest of any of the above-mentioned persons or his/her close relatives, the person shall withdraw from the safety assessment.

Chapter 4 Technical Inspection Administration

Article 28 Based on the needs of the safety assessment and administration of agricultural GMOs, the Ministry of Agriculture may entrust the inspection to technical inspection bodies with adequate inspection facilities and capacity.

Article 29 A technical inspection body shall meet the following basic qualifications:

- (1) It shall be fair and authoritative, and establish relatively independent section(s) with full-time staffs;
- (2) It shall have equipment and inspection means suitable for the inspection task and in compliance with the national (or industrial) standards;
- (3) It shall be strict in observing the technical norms for inspection and the inspection data issued shall be exact and authentic;
- (4) It shall have appropriate safety control measures.

Article 30 Duties and responsibilities of the technical inspection bodies:

- (1) Provide technical services for the safety assessment and administration of agricultural GMOs;
- (2) Undertake the task of qualitative and quantitative inspection, identification, and reexamination of agricultural GMOs entrusted by the Ministry of Agriculture or by applicants;
- (3) Issue inspection reports and make scientific judgements;
- (4) Study inspection techniques and methods, and undertake or participate in formulating or revising the safety assessment standards and technical rules;
- (5) Destroy, after inspection, all inspected samples safely without any preservation;
- (6) Keep technical and business secrets for consignors and applicants.

Chapter 5 Supervision and Monitoring

Article 31 The Ministry of Agriculture is responsible for the supervision and administration of the safety of agricultural GMOs, the guidance of the work of safety control and monitoring of the agricultural GMOs in different ecological regions, and the establishment of a nationwide system of supervision, administration, and monitoring for the safety of agricultural GMOs.

Article 32 The agricultural administrative departments of the local governments

above the county level is, in accordance with the Articles 39 and 40 of the Regulations, responsible for the supervision and administration of the safety of agricultural GMOs in their respective administrative areas.

Article 33 Organizations and persons shall, in accordance with the stipulations of Article 41 of the Regulations, cooperate with the agricultural administrative departments during the supervision and inspection process.

Article 34 Organizations engaged in the testing and/or production of the agricultural GMOs shall, during the working process and after the work is finished, regularly submit testing summary report, production plan, and progress report to the Ministry of Agriculture and the local agricultural administrative department at the provincial level where the testing of agricultural GMOs is conducted and/or the production or application of agricultural GMOs is made. Annual production plans for the production and application of agricultural GMOs shall be submitted before March 31. An annual progress report shall be submitted before December 31. An annual testing summary report shall be submitted before December 31 on restricted field-testing, enlarged field-testing, or productive testing.

Article 35 Organizations engaged in the testing and/or production of agricultural GMOs shall, in accordance with the requirements of these Implementation Regulations, determine safety control measures and accident-preventing emergency measures, and keep a record of safety supervision in anticipation of examination.

The safety control measures include physical control, chemical control, biological control, environmental control, and scale control (see Appendix IV)..

Article 36 In order to avoid diffusion and environmental pollution, effective and reliable measures shall be taken to destroy and inactivate agricultural GMOs of safety class II, III or IV before waste disposal and/or emission. Once agricultural GMOs are found to have spread, remained, or caused harm, shall effective measures be taken immediately to control and eliminate the agricultural GMOs and the situation be reported to the local agricultural administrative departments.

Article 37 During the process of storage, movement, transportation, destruction or inactivation of agricultural GMOs, proper safety management measures shall be taken, specific equipments or spaces shall be available, and personnel for safety management and record-keeping shall be specified.

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

Chapter 6 Penalty Provisions

Article 39. Those who, in violation of the stipulations of these Implementation Regulations, conduct a laboratory research of agricultural GMOs of safety class III or IV, or a restricted field-testing of agricultural GMOs without first making a report to the Ministry of Agriculture, shall be penalized in accordance with Article 43 of the Regulations.

Article 40. Those who, in violation of these Implementation Regulations, conduct an enlarged field-testing or a productive testing without approval, or with approval but fail to take safety management measures as required, or conduct tests beyond the authorized scope or time period, shall be penalized in accordance with Article 44 of the Regulations.

Article 41. Those who, in violation of these Implementation Regulations, put agricultural GMOs into production or application after the completion of productive testing without obtaining the safety certificate of agricultural GMOs, shall be penalized in accordance with Article 45 of the Regulations.

Article 42. Those who forge, falsify, transfer, buy or sell safety certificates of agricultural GMOs, examination and approval documents or other related approval documents shall be penalized in accordance with Article 53 of the Regulations.

Article 43. Those who, in violation of these Implementation Regulations, issue approval documents, safety certificates and other related approval documents, or fail to perform the duty of supervision and administration after issuing the aforesaid certificates and/or documents shall be penalized in accordance with Article 55 of the Regulations.

Chapter 7 Supplementary Provisions

Article 44. For the purposes of these Implementation Regulations, terms and

definitions are as follows:

- (1) 'Gene' means a functional and structural unit of genetic materials that control the traits of an organism, mainly referring to a DNA fragment with genetic information.
- (2) 'Genetic engineering technologies' includes recombinant DNA technology with a vector system, and technologies that introducing a recombinant DNA molecule into an organism by physical, chemical, or biological methods.
- (3) 'Genome' means sum of chromosomal and extrachromosomal genetic materials of a specific organism.
- (4) 'DNA', abbreviation for deoxyribonucleic acid, means the molecule of genetic material that encodes genetic information of living organism.
- (5) 'agricultural genetically modified organism (GMO)' means an animal (with the exception of human beings), plant, microorganism and the product derived therefrom whose genetic structure has been modified by genetic engineering technologies for the use in agricultural production or processing.
- (6) 'target gene' means any gene that has been used in purposes for the modification of genetic structures of recipient cells and the expression of its genetic effects
- (7) 'recipient organism' means any organism into which a recombinant DNA molecule is introduced.
- (8) 'seeds' means planting or reproductive materials of agricultural crops and trees, including seeds, fruitage as well as roots, stems, seedlings, sprouts, leaves, etc.
- (9) 'laboratory research' means any work of genetic manipulation or GMO research in a laboratory and contained system.
- (10) 'restricted field-testing' means any small-scale test of GMOs in a contained system or under confined conditions.
- (11) 'enlarged field testing' means any moderate-scale test in natural conditions with appropriate safety control measures.
- (12) 'productive testing' means any large-scale test prior to commercial production and use of GMOs.
- (13) 'contained system' means a closed or semi-closed system in which physical barriers are employed, either alone or together with chemical and/or biological barriers.
- (14) 'physical control measures' means physical means employed to restrict the survival and spread of genetically modified organism and its products outside the experimental areas, e. g. the installation of fences to prevent the escape of genetically modified organisms from the experimental areas or being carried away by human beings or animals to areas outside the experimental areas.
- (15) 'chemical control measures' means chemical means employed to restrict the

survival, spread or residual of genetically modified organism and its products, e. g., the disinfection of biological materials, tools and facilities.

- (16) 'biological control measures' means biological means employed to restrict the survival, spread or residual of genetically modified organism and products derived therefrom, and to restrict the transfer of hereditary materials from genetically modified organisms to other organisms, e. g. setting up effectively isolated areas as well as monitoring areas, clearing away species near the experimental areas which might hybridize with the genetically modified organisms, preventing the flowering of the genetically modified organisms, or removing reproductive organs, or flowering periods of genetically modified organisms not meeting each other etc. with the objective of preventing the transfer of the target genes of the genetically modified organisms to relevant organisms.
- (17) 'environmental control measure' means methods which make use of environmental conditions to restrict the survival, reproduction, spread or residual of genetically modified organisms and products derived therefrom, e. g. controlling temperature, moisture, photo-period, etc.
- (18) 'scale control measure' means methods which reduce the number of genetically modified organisms and products derived therefrom or reduce the area of experimental areas at the best way, with the objective of reducing the possibilities of a rapid and broad spread of the genetically modified organisms and products derived therefrom. And a fairly thorough elimination of the genetically modified organisms and products derived therefrom can be conducted when unexpected outcomes do take place.

Article 45. The Ministry of Agriculture is responsible for the explanation of these Implementation Regulations.

Article 46. These Implementation Regulations shall enter into force from March 20, 2002. "Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering " issued in Order No. 7 of the Ministry of Agriculture dated on July 10, 1996 shall be repealed at the same time.

Appendix I

Safety Assessment of Genetically Modified Plants

I. Safety Assessment of GM Plants

1. Safety assessment of recipient plant

1.1. General information of recipient plant:

- 1.1.1. Latin name, common name and other names;
- 1.1.2. Classification information;
- 1.1.3. Name of recipient plant variety (or line);
- 1.1.4. Wild species or cultivated species;
- 1.1.5. Place of origin and time of introduction;
- 1.1.6. Usage;
- 1.1.7. Information of application in China;
- 1.1.8. Any proved negative influence on human health or the environment;
- 1.1.9. Possibility of recipient plant evolving into hazardous plant (e.g. weeds) based on historical record;
- 1.1.10. Any record of long history of safe use;

1.2. Biological characteristics of recipient plant:

- 1.2.1. Annual or perennial;
- 1.2.2. Toxicity to human or other organisms; if toxic, specify the location and property of the toxicity;
- 1.2.3. Allergenicity; if allergen, specify its location and property;
- 1.2.4. Sexual or asexual reproduction, if sexual, self-pollination or outcross, insect-pollination or wind-pollination;
- 1.2.5. Rate of outcross with the same species or hybridization with closely related species under natural conditions;
- 1.2.6. Fertility (fertile or sterile; if sterile, specify sterile type);
- 1.2.7. Life cycle;
- 1.2.8. The ability of survival or reproduction under natural condition, including winterization, summering and stress-tolerance;

1.3. Environment of recipient plant:

- 1.3.1. Geographic distribution and natural habitat in China;
- 1.3.2. Ecological conditions required for growth and development, including possible influence of the changes in natural and cultivation conditions on its geographical distribution range;
- 1.3.3. Whether or not a component in ecological environment;
- 1.3.4. Ecological relationship(s) with other plants in the ecological system,

including any influence of changes in the ecological environment on the above relationship(s) and whether the changes may produce or increase negative influence on human health and the environment;

1.3.5. Ecological relationship(s) with other organisms (animals and microorganisms) in the ecosystem, including any influence on the above relationship(s) by change of the ecological environment and subsequent negative influence or enhancing the negative influence on human health and the environment;

1.3.6. The extent of influence on and potential risk to the environment;

1.3.7. If any uncommon plant species in China is involved in the application, please provide information about the natural habitat, related natural predator(s), parasite(s), competitor(s), or symbiont(s);

1.4. Genetic variation of recipient plant:

1.4.1. Genetic stability;

1.4.2. Any record of negative influence on human health or the environment caused by genetic variation;

1.4.3. Possibility of exchange of genetic materials with other plant species or genus under natural condition;

1.4.4. Possibility of exchange of genetic materials with other organisms (e.g., micro-organisms) under natural condition;

1.5. Methods of monitoring and possibility of controlling recipient plant.

1.6. Other information on recipient plant.

1.7. Determine the safety class of recipient plant based on above evaluation and in light of the standard in Article 11 of these Implementation Regulations.

2. Safety assessment of genetic manipulation

2.1. Description of introduced or modified traits in GM plant.

2.2. Information about actual inserted or deleted sequence(s):

2.2.1. Size and structure of the inserted sequence and method for characterizing its traits;

2.2.2. Size and function of deleted region;

2.2.3. Nucleotide and deduced amino acid sequence of target gene;

2.2.4. Position of and detecting method for the inserted sequence in plant cell (whether integrated into chromosome, chloroplast, mitochondria, or in non-integrated form);

2.2.5. Copy number of the inserted sequence;

2.3. Physical map of target gene and vector, the name, source, structure, character and safety of vector, including pathogenicity or any possibility of evolving

pathogenicity.

2.4. Information about inserted fragment in vector:

- 2.4.1. Size and function of promoter and terminator, the name of its donor organism;
- 2.4.2. Size and function of marker and report genes, the name of its donor organism;
- 2.4.3. The name and source of other expression regulatory sequences (e.g., artificially synthesized or name of donor organism);

2.5. Method of gene transformation

2.6. Information about expression of inserted sequence

- 2.6.1. Organ or tissue where the inserted sequence expressed, e.g., root, stem, leaf, flower, fruit, seed, etc.
- 2.6.2. Expression quantity of inserted sequence and its analytic method
- 2.6.3. Stability of expression of inserted sequence

2.7. Determine the safety class of genetic manipulation based on above evaluation and in light of the standard of Article 12 of these Implementation Regulations.

3. Safety assessment of GM plant

3.1. Genetic stability of GM plant.

3.2. The difference in environmental safety between GM plant and its recipient or parental plant:

- 3.2.1. Mode and rate of reproduction;
- 3.2.2. Mode and ability of dispersal;
- 3.2.3. Time of dormancy;
- 3.2.4. Adaptation;
- 3.2.5. Ability of survival and competition;
- 3.2.6. Possibility of transferring genetic materials from GM plant to other plants, animals or micro-organisms;
- 3.2.7. Possibility of becoming weeds;
- 3.2.8. Influence on target and non-target organisms by insect-resistant GM plant, including influence on beneficial and harmful organisms in the environment;
- 3.2.9. Other beneficial or harmful influence on the environment;

3.3. The difference of influence on human health between GM plant and recipient or parental plant:

- 3.3.1. Toxicity;
- 3.3.2. Allergenicity;

- 3.3.3. Anti-nutrition elements;
 - 3.3.4. Nutritional compositions;
 - 3.3.5. Antibiotics resistance;
 - 3.3.6. Other influence on human health and food safety;
 - 3.4. Determine the safety class of GM plant based on above evaluation and in light of the Article 13 in this Implementation Regulations.
4. Safety assessment of the products derived from GM plant
 - 4.1. Influence of producing and processing activities on the safety of GM plant.
 - 4.2. Stability of products of GM plant.
 - 4.3. The difference in environment safety between products made from GM plant and GM plant.
 - 4.4. The difference of influence on human health between products made from GM plant and GM plant.
 - 4.5. Determine the safety class of products derived from GM plant in light of Article 14 of these Implementation Regulations.

II. Experimental plan for GM plants

1. Test Site
 - 1.1. Provide geographic, meteorological information of the test site(s); general description of the environment at the site; specify the actual position of the site.
 - 1.2. Natural ecosystem or agricultural ecosystem surrounding the site; if it is a natural ecosystem, specify the distance between the site and agricultural region; if agriculture ecosystem, specify the names of common diseases and pest of this crop, and information about the severity and prevalence.
 - 1.3. List the names of related cultivated and wild species around the site; the name of common weeds and information about their harmfulness.
 - 1.4. List main animal species around the site, whether they are rare, endangered, or protected species.
 - 1.5. Any beneficial or non-beneficial factors for the survival, reproduction, dispersal, and spread of GM plant in the environment, especially the possibility of other organisms obtaining target gene from GM plant.
2. Test design
 - 2.1. The period of field test (initial and end dates).
 - 2.2. Test size (not include the area of isolation materials).
 - 2.3. Information about plantation of GM plant:
 - 2.3.1. Name of cultivar, strain, or serial number of GM plant;
 - 2.3.2. Specify the planting area of every cultivar, strain, or materials in each site;

- 2.3.3. The number of GM plant;
- 2.3.4. How to pack and transport GM plant to the test site;
- 2.3.5. Mechanically planting or manually planting;
- 2.4. Information about planned utilization of chemical pesticide during the growth season of GM plant.
- 2.5. Information about harvesting GM plant and its products:
 - 2.5.1. Does GM plant bear fruit;
 - 2.5.2. Mechanically or manually harvesting, how to prevent leaking of GM plant materials;
 - 2.5.3. How to store GM plant and its products after harvesting.
- 3. Safety control measures
 - 3.1. Measures for isolation:
 - 3.1.1. Isolation distance;
 - 3.1.2. Plant species used for isolation and how to arrange them;
 - 3.1.3. Measures to prevent pollen spreading outside the test site;
 - 3.1.4. Other measures for isolation;
 - 3.2. Measures for preventing spread of GM plant and transgene.
 - 3.3. Emergent measures for treating accident during field test.
 - 3.4. How to treat the remaining materials that can not be harvested.
 - 3.5. Monitoring the test site after harvesting:
 - 3.5.1. Person in charge of monitoring test site and correspondence information;
 - 3.5.2. Any border marker at the test site;
 - 3.5.3. Measures and time for monitoring after test.

III. Application requirements for safety assessment of GM plants at each stage

- 1. Reporting requirements for restricted field testing
 - 1.1. The title of the project: including 1) the name of target gene(s); 2) the name of recipient plant; 3) the location (province); 4) the stage of testing. For example, “The restricted field testing of insect-resistant Bt cotton in Hebei and Beijing”.
 - 1.2. Numbers of GM lines in one application: not exceeding 20 lines.
 - 1.3. Experiment location and size: Limited to 2 provinces and 3 locations per province, the total acreage is not more than 4 mu (0.27 ha). The location description should be in detail (including province, county/city, town and village).
 - 1.4. Experiment duration: 1~2 years (It could be prolonged for perennials).
 - 1.5. Following data should be included in the application:
 - 1.5.1 The nucleotide sequence and the deduced amino acid sequence of target gene(s);
 - 1.5.2 Restriction map of the vector and the target gene;
 - 1.5.3 Data of target gene’s integration into plant genome and its expression

(such as PCR assay, Southern blotting/hybridization, Northern blotting analysis);

1.5.4 Testing methods of new trait(s) and products of introduced gene(s);

1.5.5 Topographic and isolation maps of test site;

1.5.6 Experiment design (including the main indexes and analytic methods in the safety assessment, such as the genetic stability, agronomic characters, adaptability to the environment, survival competitive ability of GM plants and the expression level of target gene(s) in various organs of the plant and so on).

2. Application requirements for enlarged field testing

2.1 The title of the project: including 1) the name of foreign gene(s); 2) the name of recipient plant; 3) the location (province); 4) the stage of testing, for example “ The enlarged field testing of Bt cotton NY12 and NM36 in Hebei and Beijing ”.

2.2 Numbers of GM lines in one application: not exceeding 5 lines.

2.3 Experiment location and size: Limited to 2 provinces and 7 locations per province, the total acreage is not more than 2 ha. The location should be in detail (including the names of province, county/city, town and village).

2.4 Experiment duration: 1~2 year (It could be prolonged for perennials).

2.5 Following data should be included in the application:

2.5.1 The nucleotide sequence and the deduced amino acid sequence of target gene;

2.5.2 Restriction map of the vector and the target gene;

2.5.3 Data of target gene integration into plant genome and its expression (such as PCR assay, Southern blotting/hybridization, Northern blotting analysis, Western blotting and the analysis on the expression of target gene);

2.5.4 Testing methods of new characters and its products of foreign gene;

2.5.5 Report of research and restricted field testing;

2.5.6 Topographic map of experiment location(s);

2.5.7 Experiment design (including the main indexes and analytic methods in the safety assessment, such as the genetic stability, agronomic characters, environmental adaptability, survival competitive ability of GM plants and the expression level of target gene(s) in various organs of the plant, the possibility of outcross with relevant species and the drift of target gene, the influence on non-target organisms and so on).

3. Application requirements for productive testing

- 3.1 The title of the project: including 1) the name of foreign gene(s); 2) the name of recipient plant; 3) the location (province); 4) the stage of experiment, for example “The productive testing of Bt cotton NY12 in Hebei and Beijing”.
- 3.2 Number of GM lines in one application: 1 line for one application, the line should have passed previous test.
- 3.3 Experiment location and size: Limited to 2 provinces and 5 locations per province, the total acreage is more than 2 ha. The location should be in detail (including the names of province, county/city, town and village).
- 3.4 Experiment duration: 1~2 year (It could be prolonged for perennials).
- 3.5 Following data should be included in the application:
 - 3.5.1 The nucleotide sequence and the deduced amino acid sequence of target gene;
 - 3.5.2 Restriction map of the vector carrying target gene;
 - 3.5.3 Data of target gene integration into plant genome and its expression (such as PCR assay, Southern blotting/hybridization, Northern blotting analysis);
 - 3.5.4 Testing methods of new characters and its products of foreign gene;
 - 3.5.5 The copy of approval document of enlarged field testing;
 - 3.5.6 Reports of restricted field testing and enlarged field testing, summary report of safety evaluation;
 - 3.5.7 Topographic map of experiment location;
 - 3.5.8 Experiment design (including the main indexes and analytic methods in the safety assessment, such as the genetic stability, agronomic characters, adaptability to the environment, survival competitive ability of GM plants, the influence of GM plant on non-target organisms, food safety including the composition of nutrients, anti-nutrients, and the content of toxic compounds and allergen, the safety of marker gene, necessary data of acute or sub-acute animal test and so on);
 - 3.5.9 For GM plants obtained by hybridization of GM plant with non-GM plant or other GM plant, the applicant should report the name of GM line and the selection procedure as well as data certifying the transgene origin.

4 Application requirements for the safety certificate

- 4.1 The title of the project: including 1) the name of foreign gene(s); 2) the name of recipient plant; 3) the location (province), for example “The safety certificate on the application of Bt cotton NY12 in Shandong”.

- 4.2 Numbers of GM lines (or variety) in one application: 1 line, its name should be consistent with that in previous stage.
- 4.3 The safety certificate should be applied for one line or cultivar of a GM plant in one provincial administrative region where the productive test has been done.
- 4.4 The safety certificate is usually for no more than 5 years.
- 4.5 Following data should be included in the application:
- 4.5.1 The nucleotide and the deduced amino acid sequence of target gene.
 - 4.5.2 Restriction maps of the vector and target gene;
 - 4.5.3 Data of target gene integration into plant genome and its expression (such as PCR assay, Southern blotting/hybridization, Northern and Western blotting analysis, analysis on the expression of target gene);
 - 4.5.4 Testing methods of new characters and its products of target gene;
 - 4.5.5 Photocopies of approval documents for each testing stage;
 - 4.5.6 Summary report on testing results of each stage and safety evaluation;
 - 4.5.7 Comprehensive report on the safety assessment of the GM plant on the environment.
 - 4.5.8 Comprehensive report of food safety, including 1) report of animal toxicity; 2) report of allergy; 3) comparison report of nutrients and anti-nutrients comparisons between GM and non-GM plants;
 - 4.5.9 The application status of related GM plant in China and abroad;
 - 4.5.10 Field supervision plan, including supervising methods, control strategy on the resistance of target insect(s), research plan on long term environmental effects, etc;
 - 4.5.11 Other related documents.
- 4.6 The safety certificate can only be applied after productive test.
- 4.7 Only after the safety certificate is granted can the GM plants be used as germplasm resources. The safety evaluation of GM selective lines derived from GM plant could be from productive test.

Appendix II

Safety Assessment of Genetically Modified Animal

I Safety Assessment of GM animal

1 Safety assessment of the recipient animal

1.1 General information of the recipient animal:

- 1.1.1 Scientific name, common name and other name(s);
- 1.1.2 Position in taxonomy;
- 1.1.3 Species of the recipient animal for test;
- 1.1.4 The recipient animal is a wild type species or a domestic species;
- 1.1.5 Place of the origin and date of introduction;
- 1.1.6 Usage;
- 1.1.7 Application status in China;
- 1.1.8 Did it cause unfavorable impact on human health and the environment?
- 1.1.9 Historically, probabilities of the recipient animal evolving to harmful animal;
- 1.1.10 Does it have a record of long-term safe application?

1.2 Biological characteristics of the recipient animal.

- 1.2.1 Biological characteristics in various stages of development and the cycle of life;
- 1.2.2 Its edibility;
- 1.2.3 Reproductive mode of recipient animal and its reproductive capability;
- 1.2.4 Migration modes and capability;
- 1.2.5 The population establishment capability of recipient animals, including the impact of competitive and aggressive behavior of recipient animals on their population establishment capability, the impact of population size on its reproductive and migrating capability;
- 1.2.6 Its attacking ability and toxicity to human and other animals;
- 1.2.7 Possibilities of influence on ecological environment.

1.3 The status of pathogens of recipient animal and their potential influence.

- 1.3.1 Dose the recipient animal has certain defined susceptible contagious pathogen?
- 1.3.2 In natural environment, the pathogens of the recipient animal and their distribution, the negative impact of the occurrence and spread of these pathogens on economic performances of the recipient animal, as well as on

human health and the environment;

1.3.3 Other influences of recipient animal's pathogens on environment.

1.4 The ecological environment of the recipient animal.

1.4.1 Geographic distribution in China and natural environment. Will this natural distribution changes with the changes of conditions?

1.4.2 The ecological environment for its growth and development;

1.4.3 Is the recipient animal a component in the ecological environment? The influence of the recipient animal on grassland and water resources;

1.4.4 Dose the recipient animal has ecological specificity, e.g. the adaptability to environment etc;

1.4.5 Habit of the recipient animal. Can it survive by itself, or is it symbiotic?

1.4.6 Survival ability, mechanisms and conditions for the recipient animals in environment. The influence of natural enemies, forages or other biological elements on its survival and the influence of climate, soil, water source and other non-biological factors on its survival;

1.4.7 The ecological relationship between the recipient animal and other animals in ecosystem. Dose the change of the ecological environment affect the relationship? Will it cause or increase unfavorable influence on human health and ecological environment?

1.4.8 The ecological relationship between recipient animals and other organisms (plants and microorganisms). Dose the change of the ecological environment affect the relationship? Will it cause or increase unfavorable influence on human health and ecological environment?

1.4.9 Impact of the recipient animal on ecological environment and its potential risk level;

1.4.10 The data of the natural environment of the recipient animal and its enemies, parasites, competitor and symbiotic should be described in detail when domestic non-traditional animal species were involved;

1.5 Genetic variations of the recipient animal.

1.5.1 Genetic stability of the recipient animal. Can it integrate with exogenous DNA? Dose it have exchange factors? Is there any interaction between active virus materials and its normal chromosomes? Can abnormal genotype and phenotype induced by gene mutation be observed?

1.5.2 Is there any data indicating unfavorable impact of genetic variation on

human health and ecological environment?

1.5.3 Possibilities of exchanging genetic material with other species under natural conditions;

1.5.4 Possibilities of exchanging genetic material with microorganisms (especially pathogens) under natural conditions.

1.6 Monitoring methods and possibilities of monitoring and control of the recipient animal.

1.7 Other data of the recipient animal.

1.8 Based on the above-mentioned evaluations, determine the safety class of the recipient animal in the light of related standards stipulated in Article 11 of these Implementation Regulations.

2 Safety assessment of genetic manipulation

2.1 Description of phenotype and characteristics introduced and modified in GM animal

2.2 Data of Inserted or deleted sequence as follows:

2.2.1 Size and structure of inserted sequence. Analysis methods for determining its characteristics.

2.2.2 Size and function of deleted region.

2.2.3 The nucleotide sequence of the target gene and its deduced amino acid sequence.

2.2.4 Localization of inserted sequence in animal cells (Does it integrate into chromosome, cytochondriome? Or does it exist in the form of non-integration?) and determination methods.

2.2.5 Number of copies of inserted sequence.

2.3 Map of construction for the target gene and vector, the designation and source of vector. Does the vector have pathogenicity or whether it may evolve into being pathogenic? If it is viral vector, indicate its role and whether it can replicate in the recipient animal.

2.4 Data of all fragments in the inserted region of the vector

2.4.1 Size and function of the promotor and terminator and the designation of its donor organism.

2.4.2 Size and function of the marker gene and reportor gene and the designation of its donor organism.

- 2.4.3 The designation and source of other regulating sequence for expression (e.g. artificial synthesis or donor organism).
 - 2.5 GM method.
 - 2.6 Data of expression for the inserted sequence.
 - 2.6.1 Data of expression for the inserted sequence and analysis methods, such as figure of Southern blot and PCR-Southern analysis etc.
 - 2.6.2 Organs, tissues and amounts of expression of the inserted sequence.
 - 2.7 Based on the above-mentioned evaluation, determine the safety class of the genetic manipulation in light of standards stipulated in Article 12 of this Implementation Regulation.
 3. Safety assessment of GM animal
 - 3.1 Have the following characteristics of the GM animal been changed in comparison with the recipient animal?
 - 3.1.1 Survival capability in nature.
 - 3.1.2 Economical performances.
 - 3.1.3 Reproductive, genetic and other biological characteristics.
 - 3.2 Genetic stability of the inserted sequence.
 - 3.3 Gene expression product, concentration of the product and its distribution in the edible tissues.
 - 3.4 Capability of transferring genetic materials to other organisms and the possible outcomes.
 - 3.5 Data of toxic or harmful effect produced by genetic manipulation to human health and environment.
 - 3.6 Does the GM animal have unpredictable damage on human health or ecological environment?
 - 3.7 Techniques of detection and identification for GM character of GM animal.
 - 3.8 Based on the above-mentioned evaluation and relevant regulation on food health, determine the safety class of the GM animal in light of related standards stipulated in Article 13 of this Implementation Regulation.
 4. Safety assessment of product(s) from GM animal
 - 4.1. Stability of the product from the GM animal.
 - 4.2. Influence of productive and processing activities on safety of GM animal.

- 4.3. Difference between GM animal and its product in environmental safety.
- 4.4. Difference between GM animal and its product in influence on human health.
- 4.5. Determining the safety class of the product of GM animal in light of related standards stipulated in Article 14 this Implementation Regulation.

II. Experiment plan of the GM animal

1. Test site
 - 1.1 Test site and its surroundings as well as the meteorological data.
 - 1.2 The ecological type of the test site.
 - 1.3 Animal category surrounding the test site.
 - 1.4 Favorable and unfavorable factors of the ecological environment of the experimental site for the survival, propagation, spread and transmission of the GM animal, especially the possibility of acquiring target gene from the GM animal by other organisms in the environment.
2. Experiment design.
 - 2.1 Starting date and terminating date of the experiment.
 - 2.2 Designations of breed or variety (code) of the GM animals.
 - 2.3 Scale of all breed or variety (code) of GM animals in each experimental site.
 - 2.4 Production, packaging, preservation and transportation methods of GM animal and its products.
 - 2.5 Dosage and disposal method of remainder of GM animal and its products.
 - 2.6 Breeding, slaughter, processing and methods of storage and transportation of GM animals.
3. Control measures for safety.
 - 3.1 Ways of isolation and the map of the experimental design.
 - 3.2 Methods of disposing of remainders of slaughtered and processed GM animals.
 - 3.3 Measures of preventing spread of GM animals.
 - 3.4 Emergency measures in case of the occurrence of unexpected accidents during the implementation process of the experiments.
 - 3.5 Supervisors and their corresponding address during the experiments.

3.6 Monitoring measures and duration after the experiment completion.

III Data requirements for application of GM animal in each stage.

1 Documents required for restricted field testing.

1.1 Project title: Four parts should be included: A) the designation of target gene, the designation of GM animal, the designation of province (city or region) where the experiment is to be performed and the designation of experimental stage. For example, the restricted field testing of growth-promoting GH gene –transferring carp in Hunan and Shanghai.

1.2 Number of GM animal in test: The lines of GM animal (material) are not more than 5 in an application, and these lines should be acquired from the same recipient animal and the same target gene by means of the same genetic manipulation. Moreover, each line should have definite designation or code.

1.3 Experiment site and scale: Not more than 2 provinces, and not more than 3 sites in each province. Total scale (maximum): 10-20 heads for big animal (horse, cattle), 20-40 for middle or small animal (swine, sheep), 100-200 for poultry (chicken, duck etc.), 2000-5000 for fish, etc. The province (city or autonomous region), county and village for the experiment should be specified definitely.

1.4 Experiment duration: generally, 1-2 years (if the interval between generations is over several years, it should be decided according to concrete conditions).

1.5 The following related data should be provided:

1.5.1 The nucleotide sequence of the target gene and its deduced amino acid sequence.

1.5.2 The map of the construction for the target gene and the vector.

1.5.3 The molecular detection or identification (PCR, Southern hybridization or Northern analysis) of the expression of target gene integrated into animal.

1.5.4 Techniques for detection and identification of GM character and its products.

1.5.5 Location maps of experimental sites and breeding isolation area.

1.5.6 Experimental design (including main indexes and research methods of safety assessment, e.g. expression stability of target characters, economic performance, survival ability, adaptability of GM animals

and expression and efficacy of exogenous functional genes in the tissues and organs of the animals.

2. Documents required for application of enlarged field testing.
 - 2.1 Project title: Four parts should be included, the designation of target gene, designation of GM animal, designation of the experimental province (city or district) and designation of experimental stages. For example, The enlarged field testing of growth-promoting GH gene –transferring carp A12 and T19 in Hunan.
 - 2.1 Number of GM animals in experiment There are not more than 3 lines of GM animals in an application, and these lines should be acquired from the same species of the recipient animal, the same target gene, and the same gene manipulation, and each line should has designation or code in accordance with that in the restricted field testing.
 - 2.2 Experiment site and scale: not more than 2 provinces and not more than 3 sites in each province. Total scale (maximum) is 150 for big animals (horse and cattle), 500 for middle and small animals (pig, sheep etc.) ,3000 for poultry (chicken ,duck etc.) or 10000-50000 for fishes etc. The province (city and autonomic region), county and village for the experiment should be pointed definitely.
 - 2.3 Experiment duration: generally, 1-2 years (if the interval between generations is over several years, it should be decided according to concrete conditions).
 - 2.4 The related data should be provided for application of enlarged field testing:
 - 2.4.1 The nucleotide sequence of the target gene and its deduced amino acid sequence.
 - 2.4.2 The construction map of the target gene and vector.
 - 2.4.3 The molecular detection and identification results (PCR, Southern-blot or Northern-blot, expression results of target protein) of the target gene integrated and expressed in the animals.
 - 2.4.4 Techniques for detection and identification of the GM characters and its products.
 - 2.4.5 The summary report of the restricted field-testing results and the experiment of safety assessment.
 - 2.4.6 The location map of test site and isolation.
 - 2.5.7 Experiment design (including main indexes and research methods of safety

assessment, e.g. stability, economic performances, survival rivalry, adaptability of GM animals, expression, stability and efficacy of exogenous functional genes in the tissues and organs of the animals, detection of gene drifting and the influence on non-target animals).

3 Documents required for application of productive testing.

3.1 Project title: Four parts should be included: A) the designation of the target gene, B) designation of GM animals, C) designation of GM animal, D) designation of the experimental province (city or district) and designation of experimental stages. For example, the productive testing of promoting growth GH gene-transferring carp A112 in Hunan.

3.2 Number of GM animals in the experiment: There is only one line or variety of GM animals in an application, and the line should have definite designation in accordance with that in the previous testing stage.

3.3 Experiment site and scale: The experiment should be carried out in the province (city or autonomous region) authorized with the enlarged field testing, not more than 2 provinces and not more than 2 sites in each province. Total scale (maximum) is 1000 for big animals (horse and cattle), 10000 for middle and small animals (pig, sheep etc.), 20000 for poultry (chicken, duck etc.) or 100 thousand – 300 thousand for fish etc. The province (city and autonomic region), county and village for the experiment should be specified definitely.

3.4 Experiment duration Generally 1-2 years for an application of productive testing (The interval between generations is longer, it should be decided according to concrete conditions).

3.5 The related appendix data should be provided for application of productive testing as follows:

3.5.1 The nucleotide sequence of the target gene and its deduced amino acid sequence.

3.5.2 The construction map of target gene and vector.

3.5.3 The molecular detection and identification results (PCR, Southern-blot or Northern-blot, expression results of target protein) of the target gene integrated and expressed in the animals.

3.5.4 Techniques for detection and identification of the GM characters and its products.

- 3.5.5 The photocopy of approval for the stage of enlarged field testing.
- 3.5.6 The summary report of the restricted field testing results and the experiment of safety assessment.
- 3.5.7 The location map of the experiment site.
- 3.5.8 Experiment design (including main index and research methods of safety assessment, e.g. stability, economic performance, survival capability, adaptability of GM animals, expression, stability and efficacy of exogenous functional gene in the tissues and organs of the animals, detection of gene drifting, the influence on non-target animals, food safety, e.g. the analysis of nutrient components, anti-nutrition factor, data about toxicity, allergeny, acute or sub-acute animal experiment).
- 3.5.9 For animals derived from hybridization of conventional animal with GM animal as parent, the parental names and related data about selecting process, as well as experimental data for verifying their gene resources should be provided.

4 Documents required for application of safety certificate.

- 4.1 Project title: It should include the designation of the target gene, designation of GM animals, designation of the applied province (city or autonomous region). For example, Safety certificate of growth-promoting GH gene-transferring carp A112 in Hunan.
- 4.2 An application should contain only 1 species of GM animal, and the species should have definite name in accordance with that in the previous experimental stages.
- 4.3 A safety certificate of one species of GM animals should be applied in the administrative region of the province where productive test has been authorized.
- 4.4 The validity of the safety certificate is no more than 5 years generally.
- 4.5 The related appendix and data should be provided for application of safety certificate as follows:
 - 4.5.1 The nucleotide sequence of the target gene and its deduced amino acid sequence.
 - 4.5.2 The construction map of the target gene and vector.

- 4.5.3 The molecular detection and identification results (PCR test, Southern-blot or Northern-blot, expression results of target protein) of the target gene integrated and expressed in the animals
- 4.5.4 Techniques for detection and identification of GM trait and its products.
- 4.5.5 The photocopies of approval for each experimental stage.
- 4.5.6 The summary reports on results of all stages and safety assessment experiment.
- 4.5.7 The report of comprehensive evaluation for genetic stability, economic performances, competitiveness, adaptability of the GM animals.
- 4.5.8 Data of expression of exogenous gene in all tissues and organs of GM animals.
- 4.5.9 Comprehensive evaluation report on the environmental influence of GM animals.
- 4.5.10 Report of detection for safety of food: A) Report of animal toxicological experiment, B) Report of evaluation on food allergen, C) Analysis report of nutritional components and anti-nutrition factor in comparison with non-GM animals.
- 4.5.11 General description of the productive application of such GM animals in China and abroad.
- 4.5.12 Proposal for monitoring and control of possible survival area of such GM animals, including techniques for monitoring and control measure for resistance treatment and research method for long-term environmental impact.
- 4.5.13 Other relevant documents.
- 4.6 The productive testing of GM animals must be authorized by the Ministry of Agriculture, and the safety certificate can only be applied after the testing.
- 4.7 GM animals can only be utilized as breeding resource after the acquisition of the safety certificate. Animals contain GM components, which come from the hybridization of conventional breed with GM animals should apply for safety assessment from productive testing stage.

Appendix III

Safety Assessment of Genetically Modified Microorganisms

On the basis of requirement of safety assessment, genetically modified microorganisms are divided into GM microorganisms for plant use, GM microorganisms for animal use and other GM microorganisms.

Part I. Safety assessment of GM microorganisms for plant use

1. Safety assessment of recipient microorganism
 - 1.1 background data of recipient microorganism
 - 1.1.1 scientific name, popular name and other names
 - 1.1.2 taxonomic position
 - 1.1.3 name of strain of the recipient microorganism used in test
 - 1.1.4 Is it a wild-type or cultural strain
 - 1.1.5 place of origin and date of introduction
 - 1.1.6 usage
 - 1.1.7 application in China
 - 1.1.8 proved negative influence on human health or the environment, if any;
 - 1.1.9 possibility of the recipient microorganism evolving into harmful organisms based on historical record
 - 1.1.10 Does it have a long-term safety application record?
 - 1.2 Biological characteristics of recipient microorganism
 - 1.2.1 the period of fertility and the time of generation
 - 1.2.2 mode and capability of propagation
 - 1.2.3 nutrient requirement suitable for growth
 - 1.2.4 Host plant range
 - 1.2.5 Capability, mode and influencing factors of its colonization, survival, spread and transmission in the environment.
 - 1.2.6 Pathogenicity to humans and animals, does it produce toxic materials?
 - 1.2.7 Pathogenicity to plants
 - 1.2.8 Other important biological characteristics
 - 1.3 Ecological environment of recipient microorganism
 - 1.3.1 Geographic distribution and natural environment in China, will the natural distribution change along with the change of certain conditions?

- 1.3.2 The ecological environment conditions required for its growth and development, including temperature, humidity, acidity, alkalinity, illumination, air, etc.
 - 1.3.4 Is it a component of the environment? Its impact on the environment, such as soil of farmland, vegetation, dry land, grassland and water areas.
 - 1.3.4 Does it have ecological specificity, e.g., the adaptability to environment, etc.
 - 1.3.5 The ecological relations with other microorganism in the ecological system, including impact on the relations caused by change of ecological environment, does it produce or increase unfavorable impact on human health and ecological environment.
 - 1.3.6 The ecological relations with other organisms (animals and plants) in the ecological system, including impact on the relations caused by change of the environment, does it produce or increase unfavorable impact on human health and ecological environment.
 - 1.3.7 The impact on ecological environment and its potential risk level
 - 1.3.8 When involving plant species which are not usually planted in China, describe in detail its natural environment, and data on its natural enemy, parasitic organism, competitive organism and symbiotic organism.
- 1.4 The genetic variations of recipient microorganism
 - 1.4.1 The genetic stability of recipient microorganism
 - 1.4.2 Plasmid status, plasmid stability and its potential risk level
 - 1.4.3 Transposon or transposable elements status and its potential risk level
 - 1.4.4 Is there any data indicating that the occurrence of genetic variation has produced unfavorable impact on human health and the environment.
 - 1.4.5 Possibilities of exchanging genetic material with other microorganisms (especially to pathogens) under natural conditions
 - 1.4.6 Possibilities of exchanging genetic material with plants under natural conditions
 - 1.4.7 Possibilities of exchanging genetic material with animals under natural conditions
- 1.5 Monitoring methods and possibility of monitoring
 - 1.6 Other data on recipient microorganism
 - 1.7 Determine the safety class of the recipient microorganism in accordance with the related standards stipulated in article 11 of these Implementation Regulations

2. The safety assessment of genetic manipulation
 - 2.1 Descriptions of introduced or modified genotypes or of characteristics of GM microorganism for animal use.
 - 2.2 data on insertion sequence or excision sequences
 - 2.2.1 The size and structure of insertion sequence, analytic methods for identifying its characteristics
 - 2.2.2 The size and function of excision region
 - 2.2.3 The nucleotide sequence of the target gene and its deduced amino acid sequence.
 - 2.2.4 Number of copies of insertion sequences
 - 2.3 Name and source of vector, characteristics and safety of vector, is there any possibility of its transferring into other microorganisms which does not contain these genes in natural environment; restriction map of the vector
 - 2.4 data on insertion region in the vector
 - 2.4.1 the size and function of promotor and terminator, name of its donor organism.
 - 2.4.2 The size and function of marker gene or reporter gene, name of its host organism
 - 2.4.3 The name and source of other expression or regulation sequences (e.g. artificial synthesis or name of donor organism)
 - 2.5 genetically modifying methods
 - 2.6 Survival prospects and expression stability of target gene
 - 2.7 Methods for detecting and identifying target gene
 - 2.8 Molecular structure, replicative characteristics and safety of recombinant DNA
 - 2.9 Determine the safety class of the genetic manipulation in accordance with the related standards stipulated in article 12 of these Implementation Regulations

3. Safety assessment of genetically modified microorganisms for plant use
 - 3.1 In comparison with recipient microorganism, have the following characteristics of the GM microorganism changed:
 - 3.1.1 colonization capability
 - 3.1.2 survival capability
 - 3.1.3 spread and transmission capability
 - 3.1.4 Toxicity and pathogenicity
 - 3.1.5 capability of genetic variation

- 3.1.6 possibilities of monitoring
 - 3.1.7 Ecological relations with plants
 - 3.1.8 Ecological relations with other microorganism
 - 3.1.9 Ecological relations with other organism (animal or human), possibility of human contact and its risk level, measure to eliminate unfavorable impact.
 - 3.1.10 Other important biological characteristics
 - 3.2 Species of applied plant and usage. In comparison with bio-pesticide or bio-fertilizer, its behavioral characteristics and relative safety
 - 3.3 Application range, probably survival area in environment and potential impact after wide-spread application
 - 3.4 The favorable or unfavorable impact on target organism
 - 3.5 The favorable or unfavorable impact on non-target organism
 - 3.6 Methods to monitor and identify GM trait of GM microorganism
 - 3.7 Determine the safety class of GM microorganism by referencing related standards stipulated in article 13 of these Implementation Regulations.
- 4. Safety assessment of products of GM microorganisms for plant use
 - 4.1 Stability of products of GM microorganism
 - 4.2 Effect of activities of production and processing on the safety of GM microorganism
 - 4.3 Difference of impact on environmental safety between GM microorganism and its product
 - 4.4 difference of impact on human health between GM microorganism and its product
 - 4.5 Determine the safety class of products of GM microorganism by referencing related standards stipulated in article 14 of these Implementation Regulations

II. Experimental plan of GM microorganisms for plant use

1. Test site

1.1 Meteorological or topographic data of test site, descriptions in general of environment of test site, and indication of the location of the test plot.

1.2 Ecological type of the surroundings in the test site

1.3 Animal and plant species in the experiment areas

1.4 Favorable and unfavorable factors of the ecological environment of the experiment site for survival, propagation, spread and transmission of the plant-related genetically modified microorganism, especially the possibility of acquiring the target gene from the plant-related genetically modified microorganism by other organism in the environment.

2. Design of field testing
 - 2.1 Starting and ending date of the field experiment
 - 2.2 Name and number of test strains
 - 2.3 Location and area of experiment
 - 2.4 Production, packaging, preservation and transportation methods
 - 2.5 Dosage and usage, the disposal methods for the remaining part
 - 2.6 Planting methods, field management practices of test plants.
3. Safety control measures
 - 3.1 Safety isolation measures in experiment site
 - 3.1.1 Isolation methods and isolation distance
 - 3.1.2 Measures to prevent the spread of the GM microorganism
 - 3.1.3 Emergency measures in case of the occurrence of unexpected accidents during the course of the testing
 - 3.1.4 Responsible person for monitoring during the course of the experiment and its contact address
 - 3.2 During the test and after the test, sampling and harvesting methods, the disposal methods for the residues and remaining part.
 - 3.3 Monitoring measures after the completion of the experiment:
 - 3.3.1 Safety monitoring plan in test site and the surroundings after the test is completed.
 - 3.3.2 Monitoring duration after the test is completed.
 - 3.3.3 Person responsible for monitoring and its contact address

III. Data requirement of application for different stages of safety assessment of GM microorganisms for plant use

1. Requirement of application for restricted field-testing
 - 1.1 Title of project: should include four parts, namely, name of target gene, name of GM microorganism, provinces (cities, autonomous regions) where the experiment will be conducted, testing stage, for example, restricted field-testing of CryIAc gene-transferring *Bacillus thuringiensis* NY23 in Guangdong.
 - 1.2 Number of strains of genetically modified microorganisms used in experiment: no more than twenty strains for one application. These strains shall be constructed using the same recipient (no more than five recipients), the same target and the same genetic manipulation, and shall have definitive name for each GM strain.
 - 1.3 Experiment sites and scale: no more than two provinces, no more than 3 sites for each provinces, no more than 4 mu (about 0.27 hectares) of total

experimental area for each application. The provinces (municipalities or autonomous regions), counties (towns), villages in which experimental sites located should be clearly confirmed.

1.4 Experiment duration: One or two years generally

1.5 When submitting the restricted field testing application, in general, following materials shall be provided:

1.5.1 The nucleotide sequence of the target gene and its deduced amino acid sequence.

1.5.2 Map of target gene and vector, and strategy of construction of genetically modified microorganism

1.5.3 Experimental reports on toxicology of recipient and genetically modified microorganism and other relevant references

1.5.4 The map of location and isolation

1.5.5 Experiment design on the basis of requirement of safety assessment

2. Requirement of application for enlarged field testing

2.1 Title of project: should include four parts, namely, name of target gene, name of GM microorganism, provinces (cities, autonomous regions) where the experiment will be conducted, testing stage, for example, enlarged field-testing of CryIAc gene-transferring *Bacillus thuringiensis* NY23 in Guangdong.

2.2 Number of strains of GM microorganisms used in experiment: no more than twenty strains for one application. These strains were constructed using the same recipient (no more than five recipients), the same target gene and the same genetic manipulation. Definitive names of strains are required and matching the names used at restricted field-testing stage.

2.3 Experiment sites and scale: no more than two provinces, no more than 5 sites for each provinces, no more than 40 mu(about 2.7 hectares) of total experimental area for each application. The provinces(municipalities or autonomous regions), counties (towns), villages in which experimental sites located should be clearly confirmed.

2.4 Experiment duration: one or two years generally for an application.

2.5 When submitting the enlarged field-testing application, in general, following materials shall be provided:

2.5.1 The nucleotide sequence of the target gene and its deduced amino acid sequence.

2.5.2 Map of target gene and vector, and strategy of construction of genetically modified microorganism

2.5.3 Experimental reports on toxicology of recipient and GM microorganism and other relevant references

- 2.5.4 Data required for monitoring
 - 2.5.5 The map of location
 - 2.5.6 Summary reports on safety assessment of restricted field-testing stage.
 - 2.5.7 Experiment design on the basis of requirement of safety assessment
3. Requirement of application for productive testing
- 3.1 Title of proposed project: should include four parts, namely, name of target gene, name of GM microorganism, provinces (cities, autonomous regions) where the experiment will be conducted, testing stage, for example, productive testing on CryIAc gene-transferring *Bacillus thuringiensis* NY23 in Guangdong.
 - 3.2 Number of strains of GM microorganisms for experiment: Only one strain of GM microorganism for one application, definitive names of strains are required and matching the names used at proceeding testing stages.
 - 3.3 Experiment sites and scale: Should be conducted in provinces (municipality, autonomous regions) which are approved for environmental release, no more than two provinces, no more than 3 sites for each provinces, more than 300 mu (20 hectares) of total experimental area for each application. The province(municipality, autonomous region), county, town, village in which experimental sites located should be clearly confirmed.
 - 3.4 Experiment duration: One or two years generally for an application.
 - 3.5 When submitting the productive testing application, in general, following attachments should be provided:
 - 3.5.1 The nucleotide sequence of the target and its deduced amino acid sequence.
 - 3.5.2 Map of target gene and vector, and strategy of construction of genetically modified microorganism
 - 3.5.3 Experimental reports on toxicology of recipient and genetically modified microorganism by detection authority and other reference
 - 3.5.4 Copy of approval for enlarged field testing stage.
 - 3.5.5 Data required for monitoring
 - 3.5.6 Summary reports on safety assessment of stages of restricted field testing and enlarged field testing.
 - 3.5.7 Location map of experimental and productive sites of genetically modified microorganism
 - 3.5.8 Experimental design on the basis of safety assessment.
4. Requirement of application for Safety certificate
- 4.1 Title of project: should include name of target gene, name of genetically modified microorganism, provinces (cities, autonomous regions) where safety

certificate will be applied, for example, safety certificate for CryIAc gene-transferring *Bacillus thuringiensis* NY23 in Guangdong.

- 4.2 With the completion of the productive testing, safety certificate can be applied for the genetically modified microorganism. One safety certificate can be applied for only one genetically modified microorganism in only one province where have approved for productive testing.
- 4.3 Duration of safety certificate application one time is generally no more than five years.
- 4.4 When submitting the safety certificate application, in general, following attachments should be provided:
 - 4.4.1 The nucleotide sequence of the target and its deduced amino acid sequence.
 - 4.4.2 Map of target gene and vector, and strategy of construction of genetically modified microorganism
 - 4.4.3 Copy of approval for stages of enlarged field-testing and productive testing.
 - 4.4.4 Summary reports on safety assessment for stages of restricted field-testing, enlarged field-testing and productive testing.
 - 4.4.5 The comprehensive report on safety assessment of impact of genetically modified microorganism on human health and the environment.
 - 4.4.6 Production and application status of the GM microorganism in or outside China.
 - 4.4.7 Methods to monitor and identify the GM microorganism
 - 4.4.8 Methods to monitor the long-term impact of the GM microorganism on environment
 - 4.4.9 Other relevant data.

Part II . Safety Assessment of Genetically Modified Microorganisms for animal uses

- I. Safety Assessment of GM Microorganisms for animal uses
 1. Safety Assessment of Recipient Microorganism.
 - 1.1 Background of the recipient microorganism.
 - 1.1.1 Scientific designation , popular designation and other designation.
 - 1.1.2 Position in Taxonomy.
 - 1.1.3 The designation of recipient microorganism strain used in test.
 - 1.1.4 Is it a natural wild type strain or artificially cultivated strain
 - 1.1.5 Place of origin and date of introduction.
 - 1.1.6 Usage
 - 1.1.7 Application status in China.
 - 1.1.8 Did it cause unfavorable impact on human health and ecological

environment?

- 1.1.9 Historically, probabilities of the recipient microorganism evolving to harmful organism.
- 1.1.10 Does it have a record of safety of long-term application.
- 1.2 Biological characteristics of the recipient microorganism.
 - 1.2.1 Multiplication period and the time of generation.
 - 1.2.2 Replication mode and capability.
 - 1.2.3 Nutrient requirements optimal for growth.
 - 1.2.4 Animal species suitable for application.
 - 1.2.5 Mode, capability and influencing factors of its colonization, survival and spread and dissemination in environment.
 - 1.2.6 Pathogenicity to animals. Could it produce toxic substances?
 - 1.2.7 Its potential risk in human health and plants.
 - 1.2.8 Other important biological characteristics.
- 1.3 The ecological environment suitable for the recipient microorganism.
 - 1.3.1 Geographic distribution and natural survival environment. Will its natural environment be changed in the case of certain conditions change?
 - 1.3.2 The ecological environment condition for growth and development, including temperature, humidity, acidity, alkalinity, illumination and air etc.
 - 1.3.3 Does it has ecological specificity? Its adaptability in environment.
 - 1.3.4 The ecological relationship of the recipient microorganism with other microorganism in ecosystem. Can it be infected by pathogens (such as virus) of human and animals? Does the ecological environment change influence on the relationship between the recipient microorganism and other microorganisms, cause or increase unfavorable impact on animal health, human health and ecological environment?
 - 1.3.5 The impact on ecological environment and its potential risk level.
 - 1.3.6 The natural survival environment and other relevant information of the animal should be described in detail if animals which is not conventional species in China are involved.
- 1.4 Genetic variation of the recipient microorganism.
 - 1.4.1 Genetic stability.
 - 1.4.2 Plasmid status, stability and its potential risk level.
 - 1.4.3 Transposon and transposable elements status and its potential risk level.
 - 1.4.4 Possibilities of genetic variation occurrence and unfavorable impact on animal and human health or ecological environment.
 - 1.4.5 Possibilities of genomic exchange between the recipient microorganism and other microorganism (especially pathogens) under natural conditions.

- 1.5 Monitoring assay and possibilities of monitoring and control for the recipient microorganism.
 - 1.6 Other information of the recipient microorganism.
 - 1.7 Determine the safety class of the recipient microorganism by referencing related standards stipulated in Article 11 of the “Regulations on the Safety Administration”.
2. Safety Assessment of Genetic Manipulation.
 - 2.1 Descriptions of phenotype and characteristics introduced or modified of genetically modified microorganism for animal use.
 - 2.2 Data of inserted and deleted gene sequence.
 - 2.2.1 Size and structure of inserted gene and analytic method for determining its characteristics.
 - 2.2.2 Size and function of deleted gene region.
 - 2.2.3 The Nucleotide sequence and deduced amino acid sequence of the target gene.
 - 2.2.4 Number of copy of inserted gene sequence.
 - 2.3 Map of construction for the target gene with vector. Designation and source of vector. Characteristics and safety of vector. Can it be transferred into microorganisms which do not contain such genes in nature.
 - 2.4 Data of each fragment of region inserted in vector.
 - 2.4.1 Size and function of promotor and terminator and designation of its donor organism.
 - 2.4.2 Size and function of marker gene and reportor gene and designation of its donor organism.
 - 2.4.3 Designation and source of other expressing and regulating gene sequence (artificial synthesis or designation of donor organism).
 - 2.5 Methods for genetic manipulation.
 - 2.6 Stability of the target gene expression.
 - 2.7 Techniques for detecting and identifying the target gene.
 - 2.8 Molecular structure, replicative characteristics and safety of the recombinant DNA.
 - 2.9 Determine the safety class of genetic manipulation by referencing related standards stipulated in Article 12 of the Implementation Regulations
 3. Safety assessment of GM microorganisms for animal use
 - 3.1 Biological characteristics of genetically modified microorganism for animal. Objectives of its application. Its survival capability in nature. Capability of

- transferring genetic materials to other organisms and its possible outcomes.
Monitoring assay and possibility of monitoring and control.
- 3.2 Mechanism of genetically modified microorganism for animal and its safety to animals.
 - 3.2.1 Survival fate in the target animals and non-target animals in vivo.
 - 3.2.2 Impact of high-dosage inoculation on target animals and possible non-target animals.
 - 3.2.3 Its Relative safety in comparison with traditional products.
 - 3.2.4 Host range and the drifting level of vectors.
 - 3.2.5 Its Shedding and spread capability when immunized animals contact with target animals and non-target animals.
 - 3.2.6 Virulence reversion capability of the genetically modified microorganism during the reverse passages.
 - 3.2.7 Safety to pregnant animals.
 - 3.2.8 Safety to progeny of immunized animals.
 - 3.3 Safety of the genetically modified microorganism for animals and human.
 - 3.3.1 Potential risk level of human exposure, the potential direct impacts, short-term and long-term impacts, the approach for clearing unfavorable impacts.
 - 3.3.2 Potential risk level after extensive application.
 - 3.4 Safety to the ecological environment.
 - 3.4.1 Release scope, potential scope and influencing potential factors of the environment.
 - 3.4.2 Physical and chemical factors influencing the survival, multiplication and transmission of the genetically modified microorganism.
 - 3.4.3 Possibilities of infecting target animals and potential risks.
 - 3.4.4 Does the stability, rivalry, viability, variability and pathogenicity of the genetically modified microorganism vary from the surrounding?
 - 3.5 Assay for monitoring and identification of the genetically modified microorganism for animals.
 - 3.6 Determine the safety class of the GM microorganism for animal use by referencing related standards stipulated in Article 13 of the Implementation Regulations.
4. Safety Assessment of products from the GM microorganism for animal use.
 - 4.1 Stability of products derived from the GM microorganism.
 - 4.2 Influence of production or processing activities on safety of the GM microorganism.

- 4.3 Differences of the GM microorganism and its products in environmental safety.
- 4.4 Differences of the GM microorganism and its product in influence on human health.
- 4.5 Determine the safety class of the products from the GM microorganism for animal use by referencing related standards stipulated in Article 14 of the Implementation Regulations.

II Experiment plan of GM microorganisms for animal use

1. Experiment Site

- 1.1 The meteorological data of experiment site, general description of geographic environment of its surrounding, indication of location map of experiment site.
- 1.2 The ecological type of the surrounding in the experiment site.
- 1.3 Animal species in the surrounding of the experimental site.
- 1.4 Favorable and unfavorable factors of the ecological environment of the experimental site for the survival, propagation, spread and transmission of the genetically modified microorganism, especially the possibilities of acquiring the target gene from the genetically modified microorganism for animal by other organisms in the environment.

2. Experiment Program

- 2.1 Starting date and terminating date of the experiment.
- 2.2 Designation or code of the genetically modified microorganism for animal.
- 2.3 Scale of animals for the genetically modified microorganism in each experimental site.
- 2.4 Size of the experiment area.
- 2.5 Application of the genetically modified microorganism for animal.
- 2.6 Production, packaging and transportation approaches of the genetically modified microorganism for animal.
- 2.7 Dosage and disposal method of the genetically modified microorganism for animal, and the disposal method for the remainder.

3. Safety Control Measures

- 3.1 Safe isolation of experimental animals
 - 3.1.1 Ways and distance of isolation.
 - 3.1.2 The measures for preventing the spread of the genetically modified microorganism for animal.
 - 3.1.3 Safety control measures for whole process of feeding.
 - 3.1.4 Emergency measures in case of the occurrence of unexpected accidents during the implementation process of the experiments.
- 3.2 Methods adopted in the feeding and disposal way of experimental animals after

the experiment completion.

3.3 Monitoring measures for the experiment area after the experiment completion.

3.4 Monitoring duration after the experiment completion.

3.5 The monitoring supervisor and corresponding address.

III Requirements for application of the genetically modified microorganism for animal in each stage

1. Documents required for restricted field testing

1.1 Project title: Four parts should be included: A) the designation of the target gene, B) the designation of genetically modified microorganism and its products, C) the designation of experiment province (city and autonomous region), D) the designation of experiment stage. For example, the restricted field testing of the recombinant pox virus genetic engineering vaccine expressing Newcastle Disease Virus F gene in Jiangsu.

1.2 Number of the experimental genetically modified microorganism for animal: One document does not have more than 20 strains. These strains should be the same recipient microorganism (not more than 5 recipient strains), the same target gene, product acquired from the same genetic manipulation, and each genetically modified strain should have the definite designation or code.

1.3 Experiment site and scale: Not more than 3 provinces (cities, regions), not more than 2 areas in each province. The scale of experimental animal (maximum): 20 for big animals (horse, cattle), 40 for middle and small animals (pig, sheep etc.), 200 for poultry (chicken, duck etc.), 2000 for fishes. The province (city and autonomic region), county and village for the experiment should be pointed definitely.

1.4 Experiment period: In general 1 to 2 years.

1.5 The related appendix data should be provided in the restricted field testing as follows:

1.5.1 The Nucleotide sequence of the target gene and deduced amino acid sequence.

1.5.2 The map for construction of the target gene and vector.

1.5.3 The location map of the experiment site and experiment isolation.

1.5.4 Experiment design (including the main index, research methods etc for safety assessment, e.g. stability, rivalry and adaptability of genetically modified microorganism, the expression and kinetics of exogenous gene in the target animals etc).

2. Documents required for application of enlarged field-testing.

- 2.1 Project title: Four parts should be included: A) the designation of target gene, B) the designation of genetically modified microorganism and its products for animals, C) designation of the experimental province (city or autonomous region) and D) designation of experimental stages. For example, the enlarged field-testing of the recombinant poultry poxvirus vaccine NF16 and YF9 expressing NDV F gene in Jiangsu.
- 2.2 Number of the experimental genetically modified microorganisms: There are not more than 5 strains of microorganism in an application, and these strains should be acquired from the same recipient microorganism, the same target gene, the same gene manipulation, and each strain should have definite designation or code in accordance with that in the restricted field-testing.
- 2.3 Experiment site and scale: not more than 3 provinces and not more than 3 sites in each province. General scale (maximum) is 100 for big animals (horse and cattle), 500 for middle and small animals (pig, sheep etc.), 5000 for poultry (chicken, duck etc.) or 10000 for fishes. The province (city and autonomic region), county (town) and village for the experiment should be pointed definitely.
- 2.4 Experimental duration: In general, 1 to 2 years for an application.
- 2.5 The related appendix and data should be provided for the application of enlarged field-testing as follows:
- 2.5.1 The nucleotide sequence of the target gene and its deduced amino acid sequence.
 - 2.5.2 The construction map of target gene and vector.
 - 2.5.3 A summary report of safety assessment for the restricted field-testing should be provided.
 - 2.5.4 The report of toxicological test (e.g. acute, subacute and chronic test, mutagenicity and distortion test etc.)
 - 2.5.5 The location map of experiment site and experiment isolation.
 - 2.5.6 Experiment design (including the main index and research methods for safety assessment, e.g. stability, rivalry, adaptability of GM microorganism, expression and kinetics of exogenous gene in the target animals.
3. Documents required for application of productive testing
- 3.1. Project title: Four parts should be included: A) the designation of the target gene, designation of genetically modified microorganism, province (city or autonomous region) and testing stage. For example, the productive testing of the recombinant chicken poxvirus vaccine NF16 expressing NDV F gene in Jiangsu.

- 3.2. Number of the test GM microorganisms: only one GM microorganism in an application, and its designation should be in accordance with that in the previous testing stages.
 - 3.3. Experiment site and scale: The experiment should be conducted in the province (city or autonomous region) authorized with the enlarged field testing, not more than 2 provinces and not more than 3 sites in each province. General scale (maximum) is 1000 for big animals (horse and cattle), 10000 for middle and small animals (pig, sheep etc.), 20000 for poultry (chicken, duck etc.) or 100 thousand for fishes. The province (city and autonomic region), county (town) and village for the testing should be pointed definitely.
 - 3.4. Experimental duration: In general, 1 to 2 years for an application.
 - 3.5. The related appendix and data should be provided as follows:
 - 3.5.1. The nucleotide sequence of the target gene and its deduced amino acid sequence.
 - 3.5.2. The construction map of target gene and vector.
 - 3.5.3. The copy of approval in the stage of enlarged field testing.
 - 3.5.4. The summary report of safety assessment for the restricted field testing and enlarged field-testing.
 - 3.5.5. The report of food safety test (e.g. toxicological report of acute, subacute and chronic test, mutagenicity and distortion test).
 - 3.5.6. The report of the target gene or genetically modified microorganism for animals transferred into environment by monitoring.
 - 3.5.7. The location map of the test site.
 - 3.5.8. Experiment design (including main index and research methods for safety assessment, e.g. stability, rivalry and survival adaptability of GM microorganism, expression and kinetics of exogenous gene in the target animals).
4. Documents required for application of safety certificate
 - 4.1. Project title including the designation of the target gene, designation of GM microorganism, designation of the applied province (city or autonomous region). For example, Safety certificate of the recombinant chicken poxvirus vaccine NF16 expressing NDV F gene in Jiangsu.
 - 4.2. Only one GM microorganism for animal use can be applied in an application, and the designation should be in accordance with that in the previous testing I stages.
 - 4.3. A safety certificate of one genetically modified microorganism for animal use should be applied in the administrative region of the province which has been

authorized with productive testing.

4.4. The application duration of safety certificate is not more than 5 years.

4.5. The related appendix and data should be provided as follows:

- 4.5.1. The nucleotide sequence of the target gene and its deduced amino acid sequence.
- 4.5.2. The construction map of the target gene and vector.
- 4.5.3. The molecular detection and identification proposal of the target gene.
- 4.5.4. Structure of the recombinant DNA and its construction method.
- 4.5.5. The copy of approvals for all the experimental stage.
- 4.5.6. The summary report of safety assessment for all the experimental stage.
- 4.5.7. The report of the target gene and genetically modified microorganism for animals transferred into environment
- 4.5.8. The comprehensive evaluation report of its stability, survival rivalry and adaptability.
- 4.5.9. The report of the influence on non-target organisms.
- 4.5.10. The report of food safety test (e.g. toxicological report of acute, subacute and chronic test, mutagenicity and distortion test)
- 4.5.11. The outlined status about the production and application of the genetically modified microorganisms for animals in China and abroad.
- 4.5.12. Other relevant data required in the application.

4.6 A safety certificate of GM microorganisms for animal use shall be authorized by the Ministry of Agriculture to carry out productive testing, and the application shall not be performed prior to completion of the testing.

Part III. Safety assessment of other genetically modified microorganisms

1. Safety assessment of recipient microorganism

1.1 background data of recipient microorganism

1.1.1 scientific name, common name and other name

1.1.2 taxonomic position

1.1.3 name of strain of recipient microorganism used in test

1.1.4 Is it the wild-type strain or cultural strain

1.1.5 place of origin and date of introduction

1.1.6 usage

1.1.7 application status in China

1.1.8 have produced unfavorable impact on human health and ecological

environment

- 1.1.9 Historically, the possibility of the recipient microorganism evolving into harmful organism
- 1.1.10 Does it have a long-term safety application record
- 1.2 Biological characteristics of recipient microorganism
 - 1.2.1 the period of fertility and the time of generation
 - 1.2.2 Mode and capability of propagation
 - 1.2.3 nutrient requirement suitable for growth
 - 1.2.4 Host plant range
 - 1.2.5 Capability, mode and influencing factors of its colonization, survival, spread and transmission in environment.
 - 1.2.6 Pathogenicity to human and animal, does it produce toxic materials?
 - 1.2.7 Pathogenicity to plant
 - 1.2.8 Other important biological characteristics
- 1.3 Ecological environment of recipient microorganism
 - 1.3.1 Geographic distribution and natural environment in China, will the natural distribution change along with the change of certain conditions?
 - 1.3.2 The ecological environment conditions required its growth and development, included in temperature, humidity, acidity, alkalinity, illumination, air, etc.
 - 1.3.3 Is a component of the ecological environment? The impact on soil of farmland, vegetation, dry land, water area environment.
 - 1.3.4 Does it have ecological specificity, e.g., the adaptability to environment, etc.
 - 1.3.5 The ecological relations with other microorganism in ecological system, included in impact on the relations caused by change of the environment, does it produce or increase unfavorable impact on human health and the environment.
 - 1.3.6 The ecological relations with other microorganism in ecological system, included in impact on the relations caused by change of the environment, does it produce or increase unfavorable impact on human health and the environment.
 - 1.3.7 The impact on the environment and its potential risk level
 - 1.3.8 When involving plant species which were not usually planted in China, should describe in detail its natural environment, and data on its natural enemy, parasitic organism, competitive organism and symbiotic organism.
- 1.4 The genetic variations of recipient microorganism
 - 1.4.1 The genetic stability of recipient microorganism
 - 1.4.2 Plasmid status, plasmid stability and its potential risk level

- 1.4.3 Transposon or transposable elements status and its potential risk level
 - 1.4.4 Does it have data which the occurrence of genetic variations produce unfavorable impact on human health and ecological environment.
 - 1.4.5 Possibilities of exchanging genetic material with other microorganism (especial to pathogens) under natural conditions
 - 1.4.6 Possibilities of exchanging genetic material with plant under natural conditions
 - 1.4.7 Possibilities of exchanging genetic material with animal under natural conditions
 - 1.5 Monitoring methods and possibilities of monitoring
 - 1.6 other data on recipient microorganism
 - 1.7 Determine the safety class of the recipient microorganism by referencing related standards stipulated in article 11 of these Implementation Regulations
2. The safety assessment of genetic manipulation
- 2.1 Descriptions of introduced or modified genotypes or traits of GM microorganism.
 - 2.2 data on insertion sequence or excision sequences
 - 2.2.1 The size and structure of insertion sequence, analysis methods to identify its characteristics
 - 2.2.2 The size and function of excision region
 - 2.2.3 The nucleotide sequence of the target and its deduced amino acid sequence.
 - 2.2.4 Number of copy of insertion sequences
 - 2.3 Name and source of vector, characteristics and safety of vector, does it have possibilities to transfer into other microorganism in which does not contain these genes in natural environment; Map of constructs (vector)
 - 2.4 data on insertion region in vector:
 - 2.4.1 the size and function of promotor and terminator, name of its donor organism.
 - 2.4.2 The size and function of marker gene or reporter gene, name of its host organism
 - 2.4.3 The name and source of other expression or regulation sequences (e.g. artificial synthesis or name of host organism)
 - 2.5 genetically modified methods
 - 2.6 Survival prospects and expression stability of target gene
 - 2.7 Detecting and identifying methods of target gene
 - 2.8 Molecular structure, replicative characteristics and safety of recombinant DNA
 - 2.9 Determine the safety class of the genetic manipulation by referencing related

standards stipulated in article 12 of these Implementation Regulations

3. Safety assessment of other genetically modified microorganism
 - 3.1 In comparison with recipient microorganism, have the following characteristics of the other genetically modified microorganism changed:
 - 3.1.1 colonization capability
 - 3.1.2 survival capability
 - 3.1.3 spread and transmission capability
 - 3.1.4 Toxicity and pathogenicity
 - 3.1.5 capability of genetic variation
 - 3.1.6 possibilities of monitoring
 - 3.1.7 Ecological relations with plants
 - 3.1.8 Ecological relations with other microorganism
 - 3.1.9 Ecological relations with other organism (animal or human), possibility of human contact and its risk level, measure to eliminate unfavorable impact.
 - 3.1.10 Other important biological characteristics
 - 3.2 Species of applied plant and usage. In comparison with bio-pesticide or bio-fertilizer, its behavioral characteristics and relative safety
 - 3.3 Application range, probably survival area in environment and potential impact after wide- spread application
 - 3.4 The favorable or unfavorable impact on target organism
 - 3.5 The favorable or unfavorable impact on non-target organism
 - 3.6 Methods to monitor and identify genetically modified trait of GM microorganism
 - 3.7 Determine the safety class of GM microorganism by referencing related standards stipulated in article 13 of these Implementation Regulations
4. Safety assessment of products of other genetically modified microorganisms
 - 4.1 Stability of products of GM microorganism
 - 4.2 Effect of activities of production and processing on the safety of GM microorganism
 - 4.3 Difference of impact on environmental safety between GM microorganism and its product
 - 4.4 difference of impact on human health between GM microorganism and its product
 - 4.5 Determine the safety class of products of GM microorganism by referencing related standards stipulated in article 14 of these Implementation Regulations

II. Experiment plan

1. Test site

- 1.1 Meteorological or topographic data of test site, descriptions in general of environment of test site, and indication of the location of the test plot.
- 1.2 Ecological type of the surroundings in the test site
- 1.3 Animal and plant species in the test areas
- 1.4 Favorable and unfavorable factors of the ecological environment of the test site for survival, propagation, spread and transmission of the GM microorganism, especially the possibility of acquiring the target gene from the GM microorganism by other organism in the environment.

2. Design of field test

- 2.1 Starting and ending date of the field test
- 2.2 Name and number of test strains
- 2.3 Location and area of experiment
- 2.4 Production, packaging, preservation and transportation methods
- 2.5 Dosage and usage, the disposal methods for the remaining part
- 2.6 Planting methods, field management measures of test plants.

3. Safety control measures

- 3.1 Safety isolation measures in test site
 - 3.1.1 Isolation methods and isolation distance
 - 3.1.2 Measures to prevent the spread of the GM microorganism
 - 3.1.3 Emergency measures in case of the occurrence of unexpected accidents during the test
 - 3.1.4 Person responsible for monitoring during the test and its contact address
- 3.2 During and after the test, sampling and harvesting methods, the disposal methods for the residues and remaining part.
- 3.3 Monitoring measures after the test:
 - 3.3.1 Safety monitoring plan in experiment site and the surroundings after the experiment is completed.
 - 3.3.2 Monitoring duration after the experiment is completed.
 - 3.3.3 Responsible person for monitoring and its contact address

III. Requirement of application for different stages of safety assessment of other genetically modified microorganism

1. Requirement of application for restricted field-testing

- 1.1 Title of project: Should include four parts, namely, name of target gene, name of

genetically modified microorganism, provinces (cities, autonomous regions) where the experiment will be conducted, testing stage, for example, restricted field-testing on CryI gene-transferring *Bacillus subtilis* NS3 in Guangdong.

- 1.2 Number of strains of GM microorganisms used in experiment: no more than twenty strains for an application. These strains were constructed using the same recipient (no more than five recipients), the same target and the same genetic manipulation, and should have definitive name for each genetically modified strain.
 - 1.3 Experiment sites and scale: no more than two provinces, no more than 3 sites for each provinces, no more than 4 mu (about 0.27 hectares) of total experimental area for each application. The provinces (municipality, autonomous regions), counties (towns), villages in which experimental sites located should be clearly confirmed.
 - 1.4 Experiment duration: One or two years generally
 - 1.5 When submitting the restricted field-testing application, in general, following materials shall be provided:
 - 1.5.1 The nucleotide sequence of the target gene and its deduced amino acid sequence.
 - 1.5.2 Map of target gene and vector, and strategy of construction of genetically modified microorganism
 - 1.5.3 Experimental reports on toxicology of recipient and genetically modified microorganism and other relevant references
 - 1.5.4 The map of location and isolation
 - 1.5.5 Experiment design on the basis of requirement of safety assessment
2. Requirement of application for enlarged field-testing
- 2.1 Title of project: Should include four parts, namely, name of target gene, name of genetically modified microorganism and their code, name of provinces (cities, autonomous regions) where the experiment will be conducted, experiment stage, for example, enlarged field-testing of CryI gene-transferring *Bacillus subtilis* NS3 in Guangdong.
 - 2.2 Number of strains of genetically modified microorganisms used in experiment: no more than 5 strains for an application. These strains were constructed using the same recipient (no more than five recipients), the same target and the same genetic manipulation. Definitive names of strains are required and matching the names used at restricted field-testing stage.
 - 2.3 Experiment sites and scale: no more than two provinces, no more than 5 sites for each provinces, no more than 40 mu (about 2.7 hectares) of total

experimental area for each application. The provinces(municipality, autonomous regions), counties (towns), villages in which experimental sites located should be clearly confirmed.

2.4 Experiment duration: One or two years generally for an application.

2.5 When submitting the enlarged field-testing application, in general, following materials shall be provided:

2.5.1 The nucleotide sequence of the target gene and its deduced amino acid sequence.

2.5.2 Map of target gene and vector, and strategy of construction of genetically modified microorganism

2.5.3 Experimental reports on toxicology of recipient and genetically modified microorganism and other relevant references

2.5.4 Data required for monitoring

2.5.5 The map of location

2.5.6 Summary reports on safety assessment of restricted field-testing stage.

2.5.7 Experiment design on the basis of requirement of safety assessment

3. Requirement of application for productive testing

3.1 Title of proposed project: Should include four parts, namely, name of target gene, name of genetically modified microorganism and their codes, name of provinces (cities, autonomous regions) where the experiment will be conducted, experimental stage, for example, productive testing on CryI gene-transferring *Bacillus subtilis* NS3 in Guangdong.

3.2 Number of strains of genetically modified microorganisms for experiment: Only one strain of genetically modified microorganism for one application, definitive names of strains are required and matching the names used at previous experiment stages.

3.3 Experiment sites and scale: Should be conducted in provinces (municipality, autonomous regions) which are approved for environmental release, no more than two provinces, no more than 3 sites for each provinces, more than 300 mu (20 hectares) of total experimental area for each application. The province(municipality, autonomous region), counties (towns), villages in which experimental sites located should be clearly confirmed.

3.4 Experiment duration: One or two years generally for one application.

3.5 When submitting the application, in general, following materials shall be provided:

3.5.1 The nucleotide sequence of the target and its deduced amino acid sequence.

3.5.2 Map of target gene and vector, and strategy of construction of genetically

modified microorganism

3.5.3 Experimental reports on toxicology of recipient and genetically modified microorganism by detection authority and other reference

3.5.4 Copy of approval for enlarged field-testing stage.

3.5.5 Data required for monitoring

3.5.6 Summary reports on safety assessment of stages of restricted field testing and enlarged field testing.

3.5.7 Location map of test sites of genetically modified microorganism

3.5.8 Experimental design on the basis of safety assessment.

4. Requirement of application for Safety certificate

4.1 Title of project: Should include name of target gene, name of genetically modified microorganism, provinces(cities, autonomous region) where safety certificate will be applied, for example, safety certificate for CryI gene-transferring *Bacillus subtilis* NS3 in Guangdong.

4.2 With the completion of the productive testing, safety certificate can be applied for the genetically modified microorganism. One safety certificate can be applied for only one genetically modified microorganism in only one provinces where have approved for productive testing.

4.3 Duration of safety certificate application is generally no more than five years.

4.4 When submitting the safety certificate application, in general, following material should be provided:

4.4.1 The nucleotide sequence of the target and its deduced amino acid sequence.

4.4.2 Map of target gene and vector, and strategy of construction of genetically modified microorganism

4.4.3 Copy of approval for stages of enlarged field testing and productive testing.

4.4.4 Summary reports on safety assessment for stages of restricted field-testing, enlarged field- testing and productive testing.

4.4.5 The comprehensive report on safety assessment of impact of genetically modified microorganism on human health and the environment.

4.4.6 Production and application status of the genetically modified microorganism in or outside China.

4.4.7 Methods to monitor and identify the genetically modified microorganism

4.4.8 Methods to monitor the long-term impact of the genetically modified microorganism on environment

4.4.9 Other relevant data.

Appendix

Safety control measures for agricultural GMOs and their products

In order to prevent the potential risks of agricultural GMOs to human health and the environment, safety control measures are formulated for all classes of genetic engineering work.

1. Laboratory safety control

1.1 Control measures for Safety Class I

Laboratory and operation should meet the requirements of general biological laboratory.

1.2 Control measures for Safety Class II

1.2.1 Lab requirements: Apart from the requirements for Safety Class I, clean bench, sterilizing facilities and autoclave for waste disposal must be equipped.

1.2.1 Operation requirements:

Apart from the requirements for Safety Class I, it is essential to meet the following requirements:

1.2.2.1 To avoid the formation of aerosol during operation process.

1.2.2.2 Operate the experiments within the designated area of the lab.

1.2.2.3 Wastes must be given inactivation treatment and kept in waterproof and fragility resistant containers.

1.2.2.4 Researchers should wear work clothes during genetic manipulation, and leave them in the laboratory before leaving the laboratory.

1.2.2.5 Organisms that are not related to the research should be prevented from entering the lab, such as insects and rodent animals. In case of an accident, in which harmful target gene, vector, GMOs do escape and spread, emergency measures must be taken immediately.

1.2.2.6 Safety control measures for veterinary microorganism should also conform with the relevant regulations for veterinary biological products.

1.3 Control measures for Safety Class

1.3.1 Laboratory requirements: In addition to the requirements for Safety Class I, it is essential to meet the following requirements:

1.3.1.1 Laboratory should be located within an isolated area and have striking warning signs. Before entering the operation room, laboratory workers should pass through a special changing room, which is equipped with

shower facilities. In addition, automatic door and air shower should be equipped at the doorway of the operation room.

1.3.1.2 The walls, floor and ceiling inside the laboratory should be smooth, waterproof, leak-proof and anti-corrosive.

1.3.1.3 Windows should be airtight.

1.3.1.4 Laboratory should be equipped with autoclave sterilizing facilities.

1.3.1.5 Operation room should be equipped with negative-pressure circulatory purification facilities and waste water treatment equipment.

1.3.2 Operation requirements: In addition to the same requirements for Safety Class ,it is essential to meet the followings:

1.3.2.1 Any person who enter into the laboratory must be approved by the project leader.

1.3.2.2 Everyone must take work clothes, wear gloves and other protective tools in the locker room before entering the laboratory, and take shower before leaving the lab. It is forbidden to wear work clothes outside the laboratory. The work clothes must be autoclaved before washing.

1.3.2.3 Working table must be cleaned and disinfected immediately after use.

1.3.2.4 Laboratory containers used for transferring materials must be double-layered, non-fragile and air-tight.

1.3.2.5 Used containers and all laboratory utensils must be sterilized before leaving the laboratory.

1.3.2.6 All organisms and active materials used in genetic manipulation must be taken care of by special personnel, and stored in specific containers or facilities.

1.4 Control measures for Safety Class Laboratory and its operation should accord with relevant requirements stipulated in the “Implementation Regulation”.

2. Control measures for restricted field testing, enlarged field testing and productive test of GMOs

2.1 It is required to adopt common biological isolation methods and arrange experiment in a restricted area. The isolation distances of some crops are listed in table 1.

2.2 Control measures for Safety Class

2.2.1 It is essential to adopt appropriate isolation measures to control the entry and exit of both unrelated animals and persons. It is necessary to set up a solarium to prevent the entry of insects, set up dams and boards to prevent

the escape of aquatic organisms. Aquatic organisms should be controlled within a small-scale artificial water area so as to ensure that the experimental organisms will never enter natural water areas.

2.2.2 It is essential to conduct timely sterilization for tools and related facilities.

2.2.3 Effective biological isolation measures should be adopted, such as the selection of experimental plot within the geographical area where GMOs can not hybridize with related organisms.

2.2.4 Adopt corresponding physical, chemical, biological, environmental and scale control measures.

2.2.5 It is also essential to disinfect and treat fish ponds, livestock barn and soil after the completion of the experiment, so as to prevent the escape and survival of GMOs.

2.3 Control measures for Safety Class

2.3.1 It is essential to adopt appropriate isolation measures, and prohibit the entry of unauthorized personnel, animals, poultry and vehicles. It is also essential to equip the laboratory with solarium, artificially controlled industrialized husbandry facilities, specific containers for collecting and eliminating GMOs and related facilities in accordance with the objectives of the experiment.

2.3.2 It is essential to undertake timely disinfecting treatment of tools and related facilities, prevent GMOs being carried outside the experimental areas, eliminate plants, insects, microorganisms and rodents which are not related to the experiment by using herbicide, insecticide, fungicide and rodent poison bait.

2.3.3 It is essential to adopt the most effective biological isolation measures to prevent related organisms from hybridization, transduction, transformation, conjugation, parasitism and heteroecism with the GMOs within the experimental areas.

2.3.4 It is essential to adopt strict environmental control measures, such as the utilization of environment (humidity, moisture, temperature, etc.) to restrict the survival and propagation of the GMOs and its product outside the experimental areas, or set up the experimental areas in desert, alpine frigid regions where the GMOs can not survive even if it escaped or spread.

2.3.5 It is essential to strictly control the experiment scale. When necessary, GMOs can be eliminated at any time

2.3.6 After experiment, the residuals apart from the harvested shall be collected and destroyed; ponds, livestock barn and soil shall be thoroughly sterilized so as to prevent GMOs from surviving.

2.3.7 Safety control measures shall be reported to the national biosafety committee of agricultural GMOs and be performed according to the requirements after approval.

2.4 Control measures for Safety Class

Apart from the requirements for Safety Class III, the requirements for experimental conditions and facilities and the disposal of test materials should be more stringent. The safety control measures should be reported to the national biosafety committee of agricultural GMOs and be performed according to the requirements after approval.

2.5 The control measures of the restricted field-testing and enlarged field-testing for veterinary GMOs and their products should also accord with relevant regulations of veterinary biologics.

3 Emergency Measures

3.1 When accidental spread of GMOs occurred, it is imperative to close the accident site as soon as possible, make a thorough investigation into the cause immediately, adopt effective measures to prevent continuous spread of the GMOs, and submit report to the relevant administrative departments.

3.2 In case of dispersal of GMOs that has already produced unfavorable effect, it is imperative to isolate personnel within the area temporally and put them under medical care.

3.3 It is essential to undertake continuous monitor over spreading areas until no more risk exists.

Table 1. Isolation distance for some crops

Crop Species	Isolation Distance (m)	Note
<i>Zea mays L.</i>	300	or isolation of florescent stage for over 25 days
<i>Triticum aestivum</i>	100	or isolation of florescent stage for over 20 days
<i>Hordeum vulgare</i>	100	or isolation of florescent stage for over 20 days
<i>Brassica L.</i>	1000	-
<i>Gossypium L.</i>	150	or isolation of florescent stage for over 20 days
<i>Oryza sativa L.</i>	100	-
<i>Glycine max(L.)Merrill</i>	100	-
<i>Lycopersicum esculentum Mill</i>	100	-
<i>Nicotiana tabacum</i>	400	-
<i>Sorghum vulgare Pers.</i>	500	-
<i>Solanum tuberosum L.</i>	100	-
<i>Cucurbita pepo</i>	700	-
<i>Trifolium repens</i>	300	-
<i>Lolium perenne</i>	300	-
<i>Capsicum annum</i>	100	-

Appendix

Project No.:

Category:

**APPLICATION FORM FOR SAFETY ASSESSMENT
OF AGRICULTURAL GMO**

(project title)

(application institution)

(submission date)

Ministry of Agriculture, P.R.China

Application form for safety assessment of agricultural GMOs

Project Title:

Application Institution:

Applicant:

Address:

Post Code:

Telephone Number:

Fax:

E-mail:

Submission date:

INSTRUCTIONS

1. Applicants should carefully read the “Implementation Regulations on the Safety Assessment of Agricultural GMOs”, the “Implementation Regulations on the Safety of Import of Agricultural GMOs”, the “Implementation Regulations on the Labeling of Agricultural GMOs” and related appendixes as well as relevant regulatory documents before filling out this form.
2. This form can also be used for the reports of lab research and restricted field testing, but the names could be changed to “Report on Lab Research of Agricultural GMOs”, or “Report on Restricted Field Testing of Agricultural GMOs”. Some unnecessary details could be omitted, for instance, the experimental plan could be omitted in “Report on Lab Research of Agricultural GMOs”
3. Application documents should include: contents, application form, summary of project content, the aim and significance of the project, related background reference, safety evaluation documents, experimental plan, related appendixes, approval document by the biosafety committee at the institutional level, approval by the institution, approval from relevant agricultural administration office of the province (city or autonomous region).

Form 2 is applicable to the application of lab research, restricted field testing, enlarged field testing and productive testing. Form 3 should be filled out for the application for the safety certificate of agricultural GMOs.

The safety assessment, experimental plan in the application and related appendixes should be filled out according to appendix , and .

4. Application form should be filled out in Chinese, in 10 copies, in A4 paper, in Song font of No 4 minus with single line space and standard word space. A floppy disk or CD should also be enclosed. Application that fails to meet the requirements will not be accepted.
5. Applicant may mark the documents that are confidential and explain why.
6. For the same GMO, which has been approved for enlarged field testing or productive testing, the documents for the safety assessment can be omitted when this test need to be repeated in the same site.
7. Deadlines for application: The Ministry of Agriculture accepts application twice a year. The deadlines for application are March 31 and September 30.
8. Receptive department: Center of Science and Technology Development, The Ministry of Agriculture;
Address: Building 18, Maizidianjie, Chaoyang District, Beijing, China; Post Code: 100026;

Payment: Center of Science and Technology Development, The Ministry of Agriculture; Bank: Chaoyang Branch of Beijing Agricultural Bank; Account number: 873-9732

CONTENT

- 1. Application form**
- 2. Summary of project**
- 3. Objectives and significance**
- 4. Background references**
- 5. Safety assessment**
- 6. Experimental design**
- 7. Related documents**
- 8. Approvals by the biosafety committee of agricultural GMOs of the applicant's institution**
- 9. Approvals by the applicant's institution**
- 10. Approvals by the relevant safety administrative office of province (city or autonomous region).**

Table 2.

APPLICATION FORM FOR TESTING

Project name					
Project type	A. Laboratory Research B. Restricted field testing C. Enlarged field testing D. Productive testing				
Project source					
General information on the GMOs to be tested					
Category	A. Animal		B. Plant		C. Microorganism
Recipient Organism	Chinese Name		Latin name		
	Classification		Safety class		
Target gene	Name		Source		
	Biological Function				
Vector				Source	
Marker gene				Source	
Reporter gene				Source	
Method of transformation				Type of genetic manipulation	1 2 3 (select one)
Safety class of GMO				Safety class of GMO products	
Dates of initiation and completion of the test					
Experimental site					
Experimental size					
Applicant					
Name			Sex	Date of Birth	
Education			Professional title		
Institution and address					
When and where has the applicant undertaken what kinds of research activities					
Principal participants of the project					
Name	Age	Education	Title	Institution	Task in this project

Table 3.

Application form for the Safety certificate of agricultural GMO

Project title						
Project source						
General information on GMO	Category	A. Animal		B. Plant	C. Microorganism	
	Name of GMO					
	Recipient organism	Chinese name			Latin name	
		Classification			Safety class	
	Target gene	Name			Source	
		Biological function				
	Vector			Source		
	Marker gene			Source		
	Report gene			Source		
	Transformation method			Manipulation type	1 2 3 (select one)	
Safety class of GMO						
Safety class of GMO product						
General information of test	Restricted field testing	GMO name and No.				
		Time, site and scale of test				
	Enlarged field testing	GMO name and No.				
		No. of approval document				
	Productive testing	Approval time, site and scale				
		GMO name and No.				
No. of approval document						
	Approval time, site and scale					

Scope of application(province, city or autonomous region)								
Duration of application (years)								
Information of institution	Institution name				Legal representative			
	Address and correspondence information							
General information of the research institution	Institution name				Legal representative			
	Address and correspondence information							
	Principal participants of the project							
	Name			Sex			Birth date	
	Education				Professional title			
	When and where has the applicant undertaken genetic engineering work							
	Participants of the project							
	Name	Age	Education	Title	Institution	Task in this project		

(Note: The column of “General information of test” could be left unfilled in the case of direct application of the safety certificate for the import of GMOs)