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The "**Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering**",
reviewed and passed at the Conference of the Standing Committee of the Ministry of Agriculture
dated April 25, 1996. enters into effect on the date of its
issuance

Minister of Agriculture: Liu Jiang
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SAFETY ADMINISTRATION IMPLEMENTATION
REGULATION ON AGRICULTURAL BIOLOGICAL
GENETIC ENGINEERING

Chapter One: General Principles

1. This implementation regulation (hereinafter referred to as the "Implementation Regulation") is aimed at promoting research and development in the area of agricultural biological genetic engineering in China, strengthening safety administration, preventing possible hazards caused by genetic engineered organism and its product to human health, environment on which human beings rely for existence and agricultural ecological equilibrium in accordance with the Safety Administration Regulation on Genetic Engineering (hereinafter referred to as the "Regulation") published by the State Science and Technology Commission.

2. The genetic engineering items covered In the "Implementation' Regulation" include recombinant DNA technology by using the vector system, and introduction of recombinant DNA into organism by using physical, chemical and biological means.

3. The "Implementation Regulation" is applicable to agricultural organisms whose genome constitution has been changed by using genetic engineering technologies. The scope of agricultural organism includes plants and animals related to agricultural production, plant-related microorganisms, veterinary microorganisms, aquatic animals and plants. The following organisms are not included:

(I) Plants obtained by using the following methods:

(1) Plants obtained via spontaneous generation, and by using artificial selection and hybridization technologies;

(2) Plants obtained from mutagenesis via chemical or physical means; and

(3) Plants obtained by using organ culture, tissue culture and cell culture as well as protoplast fusion technology and chromosome ploidy manipulation.

(II) Animals obtained via spontaneous generation and by using artificial selection, artificial insemination (excluding recombinant DNA), superovulation, embryo chimera, embryo partition, nucleus transfer or ploidy manipulation technology.

(III) Genetically modified microorganisms obtained by using the following methods (excluding virus and subvirus) :

(1) Chemical and physical mutagenesis; and

(2) Transfer of non-recombinant DNA via transduction, transformation, conjugation processes.

4. The "Implementation Regulation" is applicable to all agricultural biological genetic engineering work underway in the territory of the People's Republic of China, including experimental research, pilot experiments, environmental release or industrial production of genetic engineered organisms.

When agricultural biological genetic engineered organism and its products imported from outside China are planned to be used in pilot experiment, environment release and industrial production in the territory of the People's Republic of China, the applicant must first hold the certificate of conducting similar work in the country of origin, and must submit application in accordance with the procedures stipulated in the "Implementation Regulation". Otherwise, no application will be accepted and processed.

5. The Ministry of Agriculture will establish a Safety Administration Office for Agricultural Biological Genetic Engineering to be in charge of the Implementation of the "Implementation Regulation". A Safety Committee. for Agricultural Biological Genetic Engineering will be set up to handle the safety evaluation of pilot experiments, environment release or industrial production of agricultural biological genetic engineered organism and its final products throughout the country.

The production and business administration of agricultural chemicals, veterinary drugs and other biologicals, as well as agriculture-related plant seeds and seedlings will be implemented in accordance with relevant regulations of the State.

Chapter Two: Safety Classes and Safety Evaluation

6. According to Potential risk levels, genetic engineering work is divided into four safety classes :

Safety class I: genetic engineering work of this class has no threat to human health and ecological environment.

Safety class II: genetic engineering work of this class has low-level risk to human health and ecological environment,

Safety class III: genetic engineering work of this class has intermediate-level risk to human health and ecological environment.

Safety class IV: genetic engineering work of this class has high-level risk to human health and ecological environment.

7. The following procedures should be followed in safety evaluation and safety class determination of genetic engineered organisms:

I. Safety class determination of recipient organism:

(I) Recipient organism which accords with one or more than one conditions listed below will be classified as Safety Class I:

1. Recipient organism which has never occurred unfavorable impact on human health and ecological environment;

2. Recipient organism which has little possibility of evolving into harmful organism;

3. Due to the short life cycle, the specifically investigated recipient organism which has extremely little possibility of survival in natural environment after the completion of the experiment.

(II) Recipient organisms of Safety Class II refer to those which produce low-level risk to human health and ecological environment, but their risk can be completely avoided by adopting safety control measures.

(III) Recipient organisms of Safety Class III refer to those which produce intermediate-level risk, to human health and ecological environment, but their risk can be fundamentally avoided by adopting safety control measures.

(IV) Recipient organisms of Safety Class IV refer to those which produce high-level risk to human health and ecological environment, and there is no appropriate safety measure to avoid the occurrence of such risk outside confined facilities. For example:

1. Harmful organism which may exchange their genetic material with other organisms with high frequency;

2. There is no effective technique to prevent the escape and spread of the harmful organism or its product;

3. There is no effective technique to guarantee that the harmful organism, after its escape, can be captured or eliminated before it produces unfavorable impact on human health and ecological environment.

II. Determination of the impact of genetic manipulation on safety class

The major basis for the evaluation of the impact of genetic manipulation on safety class: The direct and indirect impact of genetic engineered organism and its products on human health and ecological environment, as well as its impact produced via the occurrence of genetic information exchange with other organisms.

People involved in genetic engineering work must make precise evaluation on genetic manipulation, including gene transfer methods, characteristics of vectors, and the source, function, expression and stability of genes, etc.

The impact of genetic manipulation on the safety of recipient organism is divided into three types, i.e., improving the safety of recipient organism, having no impact on the safety of recipient organism, and reducing the safety of recipient organism.

Type I Genetic manipulations which improve the safety of recipient organism include:

Deleting certain (some) gene (s) or inhibiting the expression of these genes, such as pathogenic genes, fertility genes, adaptability genes, etc.

Type 2 Genetic manipulations which have no effect on the safety of recipient organisms

include:

1. Genetic manipulation in which the changes of the recipient organism's phenotype or genotype have no impact on human health and ecological environment, such as certain marker genes with no risks;

2. Genetic manipulation in which the changes of the genetic trait of the known or expectable recipient organism have no unfavorable effect on human health and ecological environment, such as the storage protein gene for improving nutrition values.

Type 3 Genetic manipulations which reduce the safety of recipient organisms include:

1. Genetic manipulations which cause the occurrence of known or expectable genetic changes of recipient organisms and produce additional unfavorable impact on human health and ecological environment. Such as gene introduction which can produce harmful toxins;

2. Genetic manipulations which affect gene expression, have inadequate knowledge of its outcomes, and have uncertainty of whether or not the risk of the final genetic engineered organism is greater than that of the recipient organism.

III. Determination of the safety class of genetic engineered organisms

The safety class of genetic engineered organisms is determined on the basis of the safety class of the recipient organism as well as the impact type and impact level of the genetic manipulation on the recipient organisms.

I.(I) Genetic engineered organism from recipient organism of safety Class I

II. The genetic engineered organism obtained from recipient organism of Safety Class I via Type I or Type 2 genetic manipulations still belongs to Safety Class I.

III. The genetic engineered organism obtained from recipient organism of Safety Class I via Type 3 genetic manipulation still belongs to Safety Class I only if the safety reduction is very small and there is no need to adopt any safety control measures. If the safety has certain degree of reduction but its potential risk can be avoided through appropriate safety control measures, the safety class should be determined as Safety Class II. If the safety has been seriously reduced but its potential risk can be avoided through strict safety control measures, the safety class should be determined as Safety Class III. If the safety has been seriously reduced and its potential risk can not be completely avoided through safety control measures, the safety class should be determined as Safety Class IV.

(II) Genetic engineered organism from recipient organism of Safety Class II

1. The genetic engineered organism obtained from recipient organism of Safety Class II via Type 1 genetic manipulations belongs to Safety Class I, if the safety has increased to the extent that it no longer has any unfavorable impact on human health and ecological environment. If the safety level has been increased but it still has low-level risk on human health and ecological environment, the genetic engineered organism obtained from recipient organism of Safety Class II via Type 1 genetic manipulation belongs to Safety Class II.

2. The genetic engineered organism obtained from recipient organism of Safety Class II via Type 2 genetic manipulations belongs to Safety Class II.

3. The genetic engineered organism obtained from recipient organism of Safety Class II via Type 3 genetic manipulations belongs to Safety Classes II, III or IV on the basis of the extent of safety decrease, with the same classification standard as that of the recipient organisms.

(III) Genetic engineered organism from recipient organism of Safety Class III

1. The genetic engineered organism obtained from recipient organism of Safety Class III via Type 1 genetic manipulations belongs to Safety Classes I, II and

III on the basis of the extent of safety increase, with the same classification standard as that of the recipient organisms.

2. The genetic engineered organism obtained from recipient organism of Safety Class III via Type 2 genetic manipulations belongs to Safety Class III

3. The genetic engineered organism obtained from recipient organism of Safety Class III via Type 3 genetic manipulations belongs to Safety Classes III or IV on the basis of the extent of safety decrease, with the same classification standard as that of the recipient organisms.

(IV) Genetic engineered organism from recipient organism of Safety Class IV

1. The genetic engineered organism obtained from recipient organism of Safety Class IV via Type I genetic manipulations belongs to Safety Classes I, II, III or IV on the basis of the extent of safety increase, with the same classification standard as that of the recipient organisms.

2. The genetic engineered organism obtained from recipient organism of Safety Class IV via Types 2 or 3 genetic manipulations belongs to Safety Class IV.

Please refer to Appendixes I, II, III, IV and V for more information on the safety evaluation of the genetic engineered organisms, including plants, animals, plant-related microorganisms, veterinary microorganisms and aquatic animals and plants, and their products.

8. Before conducting relevant experimental researches, pilot experiment environment release and industrial production, institutions carrying out genetic engineering work should determine the safety class and work out corresponding safety control measures on the basis of the safety evaluation of the genetic engineered organism and its products.

Chapter Three: Application and Approval

9. Institutions carrying out genetic engineering work should submit applications to relevant administrative departments at different levels according to the safety class of the genetic engineering work before being approved to kick off.

10. Institutions carrying out Safety Class I and Safety Class II genetic engineering experimental research should get approval from the heads of their institution's administration. The work of Safety Class III should be examined by the chief administrators of the institutions and then be submitted to relevant departments under the State Council for approval. The work of Safety Class IV should be examined by the Ministry of Agriculture and then be submitted to the National Genetic Engineering Safety Committee for approval.

11. Genetic engineering pilot experiments of Safety Class I should get approval from the chief administrators at the institutional level and be submitted to the Ministry of Agriculture for record. The work of Safety Classes II and III should be approved by the Ministry of Agriculture and be submitted to the National Genetic Engineering Safety Committee for record. The work of Safety Class IV should be examined by the Ministry of Agriculture and be submitted to the National Genetic Engineering Safety Committee for approval.

12. Genetic engineering industrial production, environment release of genetic engineered organisms, if in Safety Class I to III scope, should be approved by the Ministry of Agriculture. The work in Safety

Class IV should be examined by the Ministry of Agriculture and be submitted to the National Genetic Engineering Safety Committee for approval.

13. Institutions carrying out genetic engineering work should have their legal representatives to be in charge of the setting up of a genetic engineering safety administration group, and organize the examination of the application materials submitted by the institutions themselves and give safety instruction on relevant work.

14. Twenty copies of application forms along with relevant technical documents should be submitted to the relevant administrative departments. The Ministry of Agriculture accepts application approval twice a year, the receptive deadlines for application are March 31 and September 30 every year. Application materials which fail to meet the requirements (for example, incomplete documents) will be disqualified for approval.

15. Institutions carrying out genetic engineering work should go through the following application procedures:

1. The chief of the planned genetic engineering project (applicant) should evaluate the safety of the project and fill in the application (refer to Appendix VII for the format).

2. The Genetic Engineering Safety Administration Group of the institution should conduct technical evaluation on the submitted technical documents of the application.

3. Application should be submitted along with related technical documents.

16. Application should include the following major technical documents:

1. Application form;

2. The biological characteristics of the recipient, gene, vector and genetic engineered organism, as well as the basis for the determination of the safety class;

3. The impact of the genetic engineered organism and product on human health;

4. The favorable and unfavorable factors of the ecological environment of the release site on the survival, propagation, spread and transmission of the genetic engineered organism, especially the possibility of acquiring target gene from the genetic engineered organism by other organisms in the environment.

5. The monitoring method of the genetic engineered organism; and

6. The proposed safety control measures and emergency measures to prevent the happening of accidents.

17. Application of the industrial production and large-scale application of genetic engineered products should be submitted along with technical documents of pilot experiment and environment release of the genetic engineered organism, and should accord with the stipulations of relevant regulations and laws.

18. All experimental researches, pilot experiments, environment releases or industrial production of agricultural biological genetic engineered organisms meeting the following requirements should be given approval and certificates issued at the same time:

- 1.No doubt has been found on the safety evaluation of the project applied;

- 2.No threat to public health and ecological environment has been found if the genetic engineering project applied has adopted safety control measures which are up to modern scientific and technological standards, according to the requirement of its safety class.

- 3.The project chief and staff members are qualified for conducting genetic engineering work and have acquired necessary professional knowledge and safety operation knowledge. They have no hesitation in carrying out the obligations specified in the "Implementation Regulation".

- 4.The project accords with relevant state regulations and laws.

19. Institutions which accept the application of agricultural biological genetic engineering work should sign and issue approval or disapproval documents to applicants within 3 months starting from the deadline of each acceptance.

20. The staffs in the approval office and specialists who are involved in the approval process are responsible for keeping the technical secrets for applicants. Avoidance should be exercised for applications of personal involvement.

Chapter Four: Safety Control Measures

21. Institutions carrying out genetic engineering work should formulate safety control measures and emergency measures to prevent the occurrence of accidents in accordance with the safety class of the genetic engineering experimental research, pilot experiment, environment release and industrial production of the genetic engineered organism as well as the ecological environment of the release site.

22. Safety control measures include physical control, chemical control, biological control, environment control, scale control , etc.

23. Experimental research, pilot experiment, environment release and industrial production of genetic engineered organism of Safety Classes I, II, III and IV should adopt corresponding safety control measures. Please refer to Appendix VI for the details of the safety control measures and emergency measures.

24. Institutions carrying out genetic engineering work should work out relevant safety measures to handle waste materials according to the safety class. The remaining genetic engineered organisms of Safety Classes II, III and IV should be killed before discharge to prevent spread and environment pollution.

25. In the case of pilot experiment of the genetic engineered organisms of Safety Classes II, III and IV, monitoring should be conducted to the experimental area and its surrounding environment according to the approved monitoring duration after the completion of the pilot experiment. In the case of finding the spread and residue of any genetic engineered organism, effective measures must be taken to eliminate it.

26. Genetic engineered organisms should be stored in specific containers. The storage site should have its physical control fit in with their safety class.

The storage of genetic engineered organisms should be supervised by a specific person.

Institutions carrying out genetic engineering work should compile a list of storage catalogues for inspection.

27. Transporting or transferring genetic engineered organisms should guarantee that specific containers used fit the safety class of the organisms. It should also be guaranteed that transportation or transfer strictly abide by relevant state laws and regulations on transporting or mailing of biological materials.

28. Institutions or individuals carrying out genetic engineering work should write down a detailed safety control record and keep the record for a period of no less than 10 years for inspection.

29. During the implementation period of proved pilot experiment and environment release of genetic engineered organisms of Safety Classes III and IV, safety inspection must be conducted by the project institutions themselves and the results of such inspection should be submitted to the relevant approval departments for inspection.

30. Institutions if causing harm to human health or causing environment pollution due to carrying out genetic engineering work must take immediate measures to prevent the harm of the pollution from spreading and report to relevant administrative departments.

Chapter Five: Legal Responsibilities

31. In any of the following cases, relevant administrative departments will issue warnings, stop operation according to actual conditions of violation.

1. The genetic engineering project begins operation without approval;
2. Equipment, apparatus, laboratories which do not fit in with regulations have been used;
3. The safety control measures adopted fall to meet the requirements stipulated in the approval documents;
4. Violation of safety operation regulations of genetic engineering work; and
5. Violation of other rules under the Regulation and this "Implementation Regulation".

32. The responsible unit of those violating the Regulation and the "Implementation Regulation", and causing one of the following results must immediately stop the violation and take measures to handle the pollution and compensate for losses. In case a crime is caused, those who are directly responsible for will take criminal responsibilities according to laws:

1. Causing serious environment pollution;
2. Causing damage or harm to public health;
3. Causing severe damage to ecological resources and ecological balance; and
4. Causing great economic losses.

33. The approval office staff who has direct responsibility for neglecting duties, receiving bribes or practicing irregularities will be punished with administrative disciplinary measures by the higher authorities.

Chapter Six: Supplementary Provisions

34. The meaning of the special terms in this "Implementation Regulation":

1. DNA, short for deoxyribonucleic acid, is the genetic material for genetic information of living things.

2. Gene, is a functional and structural unit of genetic information which controls characteristic of living things. It is the DNA fragment with genetic information.

3. Target gene is the gene for the modification of genetic constitution of recipient cells, and for the expression of genetic information of recipient cells.

4. Vectors are the DNA molecules capable of transferring heterologous DNA into recipient cells and capable of self-replication.

5. Recipient organisms are those organisms into which recombinant DNA molecules will be introduced.

6. Genome refers to the sum total of the chromosomes and all extrachromosomal genetic materials of a specific organism.

7. Recombinant DNA technology refers to the technology which artificially modifies the genetic constitution of the organisms with vector systems. i. e., the technology of recombining heterologous DNA and vector DNA with enzymes in vitro and introducing the recombinant DNA molecules into recipient cells with the objective to multiply heterologous DNA and realize its functional expression.

8. Genetic engineered organisms refer to organisms coming from the genetic manipulation, including genetic engineered animals, plants, microorganisms, etc.

9. Genetic engineering products are products of the genetic engineered organisms, its components or products coming from the expression of target gene in genetic engineered organisms.

10. Genetic engineering work refers to genetic engineering experimental research, pilot experiment, environment release of genetic engineered organisms or genetic engineering industrial production.

11. Genetic engineering experimental research refers to laboratory-scale research work on genetic manipulation conducted within a control system.

12. Genetic engineering pilot experiment refers to experiment or pilot production in a control system aimed at verification and supplement of relevant data, determination and perfection of technical rules (product specifications and operation processing rules), to test the key technology for large scale production, before the application of genetic engineering experimental research results into industrial production (falling into production pattern and appraisal).

13. Environment release of genetic engineered organisms refer to research, production and application of genetic engineered organisms in an open system, including releasing genetic engineered organisms into natural ecological environments, such as cropland, grazing land, forests, mineral deposits and water areas, etc.

14. Genetic engineering industrial production refers to commercial production of drugs, agricultural chemicals, veterinary chemicals, feed, fertilizers, food, additives, raw materials of the chemical industry in the control system by using genetic engineered organisms. It also includes the technological processes of utilizing genetic engineering in metallurgy, oil exploration and waste treatment.

15. Control system refers to the confinement or semi-confinement operation system established through physical and biological controls. Any operation, system not fitting in with the above-mentioned control conditions is called an open system.

16. Physical control measures refer to physical means adopted to restrict the survival and spread of genetic engineered organism and its products outside the experimental areas, e.g., the installation of fences to prevent the escape of genetic engineered organisms from the experimental areas or being carried away by human beings or animals to areas outside the experimental areas.

17. Chemical control measures refer to chemical means adopted to restrict the survival, spread or residual of genetic engineered organism and its products outside the experimental areas, e. g., the disinfection of biological materials, tools and facilities.

18. Biological control measures refer to biological means adopted to restrict the survival, spread and residual of genetic engineered organism and its products outside the experimental area, and to restrict the transfer of genetic materials from the genetic engineered organism to other organisms, e. g., setting up effective isolated areas as well as monitoring areas, clearing away species near the experimental areas which might hybridize with the genetic engineered organisms, preventing the flowering of the genetic engineered organisms, or removing reproductive organs, etc. with the objective of preventing the transfer of the target genes of the genetic engineered organisms to relevant organisms.

19. Environment control measures refer to methods which make use of environment conditions to restrict the reproduction of genetic engineered organisms and their products outside the experimental areas, e. g. , controlling temperature, moisture, photo-period, etc.

20. Scale control measures refer to methods which reduce the number of genetic engineered organisms and their products 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 genetic engineered organisms and their products. And a fairly thorough elimination of the genetic engineered organisms and their products can be conducted when unexpected outcomes do take place.

35. The Ministry of Agriculture is responsible for the interpretation of the "Implementation Regulation".

36. The "Implementation Regulation" enters into effect on the date of its issuance.

Appendix I

Safety Assessment of Plant Genetic Engineered Organism and Its Products

1 Safety Assessment of Recipient Plant

1.1 Historical background of the recipient plant.

1.1.1 The recipient plant is a wild species or a cultivar (indicate the scientific name and its uses).

1.1.2 Place of origin and date of introduction of the recipient plant

1.1.3 Historically, the possibility of the recipient plant evolving into harmful plant (e.g., weed, etc.).

1.2 Biological characteristics of the recipient plant

1.2.1 The recipient plant an annual or a perennial.

1.2.2 Is the recipient plant toxic to human beings and other organisms? If it is toxic, indicate the location of the toxin in the recipient plant and the nature of the toxicity.

1.2.3 Reproductive modes of recipient plant, sexual or asexual. If in the case of sexual reproductive modes, is it self pollination or allogamy or normal allogamy? Then is it insect pollination or wind pollination?

1.2.4 The cross-fertilization rate of the recipient plant with plants of the same species and close species in nature.

1.2.5 The recipient plant is fertile or sterile, and the level of fertility. If it is sterile, what type of sterility does the recipient plant belongs to.

1.2.6 The survival and reproductive competitive capability of the recipient plant in nature, such as the winter hardiness, summer hardiness, stress tolerance , etc.

1.3 The geographical distribution of the recipient plant in China, the ecological environment conditions required for its growth and development, as well as its ecological relation with relevant species.

1.4 On the basis of the above-mentioned evaluations, determine the safety class of the recipient plant by referencing related standards stipulated in Item I of Article 7 of this "Implementation Regulation".

2 Safety Assessment of Genetic Manipulation

2.1 What donor organism does the target gene come from? What method is used to acquire the gene? (e.g., artificial synthesis, PCR [polymerase chain reaction] amplification or molecular cloning) Is it a structural gene or regulator gene?

2.2 The uses of the target gene and the function of its gene product.

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

2.4 The map of the constructs (the target gene and the vector), the name and source of the vector. Is the vector pathogenic or whether it can evolve to be pathogenic?

2.5 What type of promoter and terminator is used? And their sources.

2.6 The name of the marker gene and reporter gene as well as their sources.

2.7 Transformation method.

2.8 What selection system is used to screen the genetic engineered organism? The technical data on the integration of target gene onto the plant genome should be provided.

2.9 On the basis of the above-mentioned evaluation , determine the safety class of the genetic manipulation by referencing related standards stipulated in Item II of Article 7 of this "Implementation Regulation".

3 Safety Assessment of Genetic Engineered Organism and Its Product

3.1 Is the expression of the target gene developmental specific or tissue specific?

3.2 Is the modified genetic characters stable?

3.3 In comparison with recipient plant, have the following characteristics of the genetic engineered organism and its product been changed?

A.Adaptability

B.Pathogenicity

C.Toxicity

D.Fertility

E.Dormancy duration

F.Competitive capability

G.Possibility of transforming to weeds, etc.

3.4 On the basis of the above-mentioned evaluations, determine the safety class of the genetic engineered organism and its product by referencing related standards stipulated in Item III of Article 7 of this "Implementation Regulation".

4 Release Site

4.1 Please provide the topographic and meteorological data of the release site, describe, in general, the environment of the release site, and indicate the location of the experimental plot.

4.2 The surroundings of the experimental plot belongs to natural ecological type or agricultural ecological type. In the case of natural ecological type, please state the distance from the region of the agricultural ecological type.

4.3 List the names of related cultivars and wild species in the surroundings of the experimental plot.

4.4 Favorable and unfavorable factors of the ecological environment of the release site for the survival, propagation, spread and transmission of the genetic engineered organism, especially the possibility of acquiring target gene from the genetic engineered organism by other organisms in the environment.

5 Experiment Program

5.1 Starting date and terminating date of the field experiment.

- 5.2 Area of the experimental plot (excluding the area occupied by isolation materials).
- 5.3 Isolation measures.
 - 5.3.1 Isolation distance.
 - 5.3.2 Types of isolation plants and the composition modes.
 - 5.3.3 Methods adopted to prevent the spread of pollen outside the experimental plot.
- 5.4 Plantation of genetic engineered organism
 - 5.4.1 Dosage of genetic engineered organism
 - 5.4.2 Methods for packaging the genetic engineered organism and method for transporting the genetic engineered organism to the experimental plot.
 - 5.4.3 Mechanical method or artificial method has been used for the plantation of the genetic engineered organism.
 - 5.4.4 Measures to prevent the spread of the genetic engineered organisms.
- 5.5 Time category and dosage, of using agricultural chemicals.
- 5.6 Harvest of genetic engineered organism and its products.
 - 5.6.1 Does the genetic engineered organism set seeds?
 - 5.6.2 Mechanic harvesting or artificial harvesting? How to avoid losses?
 - 5.6.3 What method has been used to treat the residual part after harvest?
 - 5.6.4 What method has been, used to Preserve the genetic engineered organism and its products after harvest?
- 5.7 Post-harvest monitoring of the experimental plot.
 - 5.7.1 Responsible person for the monitoring of the experimental plot.
 - 5.7.2 Is there any border marker remained on the experimental plot?
 - 5.7.3 Monitoring measures and Monitoring duration after the completion of the experiment.
- 5.8 Emergency measures in case of unexpected accidents during the experiment process.

Appendix II

Safety Assessment of Animal Genetic Engineered Organism and Its Products

1 Safety Assessment of Recipient Animal

1.1 The environment the recipient animal and its progeny can access under unrestricted conditions, and the characteristics of such environment and the characteristics of the adjacent areas.

1.2 The attributes of the recipient animal.

1.2.1 Survival mechanisms and conditions of recipient animals under environment, the impact of natural enemies, forages or other biological elements on its survival and the impact of climate, soil, water source and other non-biological factors on its survival.

1.2.2 The reproductive and migration modes of recipient animals. The impact of population size on its reproductive and migrating capabilities.

1.2.3 The population establishment capability of recipient animals. Under experimental environment, the impact of competitive and aggressive behavior of recipient animals on their population establishment capability.

1.3 The status of recipient animals' disease or pathogenic factors and their potential impacts.

1.3.1 The impact of recipient animal's disease on the contacting environment. Does the recipient animal have certain specifically susceptible contagious diseases?

1.3.2 Under natural environment, due to the impact of pathogenic factors, the occurrence and spread of diseases in the recipient animals have significantly reduced their economic performances and have produced unfavorable impact on human health and ecological environment.

1.3.3 Is the characteristic of the unfavorable impact of recipient animals on other animals and human health influenced by ecological environment? If the recipient animals and their related animals live in a narrow ecological environment, can it reduce the unfavorable impact?

1.3.4 Do the recipient animals have the possibility of genetic material exchange with the pathogenic organisms?

1.4 Impact of recipient animals on ecological environment.

1.4.1 Is the recipient animal a composition part of the ecological environment? The impact of the recipient animal on grassland, water resources and other animals.

1.4.2 Does the recipient animal have ecological specificity, e.g., the adaptability to environment, etc.

1.4.3 Geographic distribution range and regional width of the recipient animal. Will the natural distribution change along with the change of certain conditions?

1.4.4 Habit of the recipient animal. Can it survive by itself, or Is it symbiotic? On the basis of these habits, is it possible to monitor and control the orientation of animals? Once escaped from the confined research system, will it cause unfavorable impact on human health and ecological environment?

1.5 Possibilities of producing variations by the recipient animal under natural or artificial conditions.

1.5.1 The genetic stability of the recipient animal. Does 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 Possibilities of exchanging genetic material with other organisms under natural conditions.

1.5.3 On the basis of the above-mentioned evaluation, determine the safety class of the recipient animal by referencing related standards stipulated in Item I of Article 7 of this "Implementation Regulation".

2 Safety Assessment of Genetic Manipulation

2.1 Source, structure, function and uses of the target gene.

2.2 Name, source, characteristics and safety of the vector. In the case of a virus vector, state its functions. Can it be replicated in the recipient animal?

2.3 Molecular structure, construct method and safety of the Recombinant DNA.

2.4 Transgenic method.

2.5 The product of target gene, and its expressive tissue specificity.

2.6 On the basis of the above-mentioned evaluation, determine the safety class of the genetic manipulation by referencing related standards stipulated in Item II of Article 7 of this "Implementation Regulation".

3 Safety Assessment of Animal Genetic Engineered Organism and Its Product

3.1 Gene expression product, concentration of the product and its distribution in the edible tissues.

3.2 On the basis of the above-mentioned evaluation and relevant regulations on food health, determine the safety class of the animal genetic engineered organism and its product by referencing related standards stipulated in Item III of Article 7 of this "Implementation Regulation".

4 Release Site

4.1 Release site and its surroundings as well as the meteorological data.

4.2 Ecological type of the release site.

4.3 Animal species in the surroundings of the release site.

4.4 Favorable and unfavorable factors of the ecological environment of the release site for the survival, propagation spread and transmission of the genetic engineered organism, especially the possibility of acquiring the target gene from the genetic engineered organism by other organisms in the environment.

5 Experiment Program

5.1 Starting date and terminating date of the experiment.

5.2 Area occupied by the experiment.

5.3 Isolation and monitoring measures.

5.4 Methods adopted in the production, packaging, preservation and transportation of the genetic engineered organism and its product.

5.5 Dosage of the genetic engineered organism and its product as well as the disposal method for the residual part.

5.6 Methods adopted in the feeding, slaughtering, processing, preservation and transportation of the laboratory animals.

5.7 Disposal methods adopted for the residues and remaining part after the laboratory animals have been slaughtered and processed.

5.8 Emergency measures in case of unexpected accidents during the experiment process.

5.9 Monitoring measures and monitoring duration after the completion of the experiment.

Appendix III

Safety Assessment of Plant-Related Microorganism's Genetic Engineered Organism and Its Products

1 Safety Assessment of Recipient Microorganism

1.1 Environment to which the recipient microorganism can access.

1.2 Biological characteristics of the recipient microorganisms.

1.2.1 Scientific name and its taxonomic position.

1.2.2 Domestic distribution and application status.

1.2.3 Capability, mode and influencing factors of its colonization, survival, spread and expansion in environment.

1.3 the recipient microorganism on plants, animals and other microorganisms.

1.3.1 Impact of the recipient microorganism on plants and its potential risk level.

1.3.2 Impact of the recipient microorganism on animals and its potential risk level.

1.3.3 Impact of the recipient microorganism on other microorganisms and its potential risk level.

1.4 Impact of the recipient microorganism on human health and ecological environment and its potential risk level.

1.5 Plasmid status, the possibilities of the occurrence of genetic variations, and its potential risk level.

1.6 Monitoring method and possibilities of monitoring.

1.7 Other important biological characteristics.

1.8 On the basis of the above-mentioned evaluation, determine the safety class of the recipient microorganism by referencing related standards stipulated in Item I of Article 7 of this "Implementation Regulation".

2 Safety Assessment of Genetic Manipulation

2.1 Source, structure, function and uses of the target gene.

2.2 Name, source, characteristics and safety of the vector.

2.3 Molecular structure, construct method, replicative characteristics and safety of the Recombinant DNA.

2.4 Transgenic method.

2.5 Survival prospects and expression stability of the target gene.

2.6 On the basis of the above-mentioned evaluation, determine the safety class of the genetic manipulation by referencing related standards stipulated in Item II of Article 7 of this "Implementation Regulation".

3 Safety Assessment of Animal Genetic Engineered Organism

3.1 In comparison with recipient microorganism, have the following characteristics of the genetic engineered organism been changed?

A.Colonization capability;

B.Survival capability;

C.Spread and transmission capability;

D.Capability of genetic variation;

E.Ecological relations with plants, animals and other microorganisms;

F.Toxicity and Pathogenicity;

G.Monitoring capability;

H.Other relevant characteristics

3.2 On the basis of relevant regulations on biological agricultural chemicals, biological fertilizers, etc. evaluate the safety of the genetic engineered organism.

3.3 On the basis of the above-mentioned evaluation, determine the safety class of the plant-related microorganism's genetic engineered organism by referencing related standards stipulated in Item III of Article 7 of this "Implementation Regulation".

4 Safety Assessment of Genetic Engineered Product

4.1 In comparison with genetic engineered organism, have the safety of the genetic engineered products been changed?

4.2 On the basis of the above-mentioned evaluation, determine the safety class of the plant-related microorganism's genetic engineered organism by referencing related standards stipulated in Item III of Article 7 of this "Implementation Regulation".

5 Release Site

5.1 The location of the release site and its surroundings as well as the meteorological data.

5.2 The surroundings of the release site belongs to natural ecological type or agricultural ecological type.

5.3 Animal and plant species in the surroundings of the release site.

5.4 Favorable and unfavorable factors of the release site for the survival, propagation, spread and transmission of the genetic engineered organism, especially the possibility of acquiring target gene from the genetic engineered organism by other organisms in the environment.

6 Experiment Program

6.1 Starting date and terminating date of the experiment.

6.2 Experimental plants and the area of the experimental plot.

6.3 Isolation and monitoring measures.

6.4 Production, packaging, preservation and transportation methods of the genetic engineered organism and its products.

6.5 Dosage and usage of the genetic engineered organism and its products, and the disposal method for the remaining part.

6.6 Plantation, field management, harvest, processing preservation and transportation methods of the experimental plant.

6.7 Disposal method of the residues or remaining part after the harvest of the experimental plant.

6.8 Emergency measures in case of unexpected accidents during the implementation process of the experiment.

6.9 Monitoring measures and duration after the experiment is completed.

Appendix IV

Safety Assessment of Veterinary Microorganism's Genetic Engineered Organism and Its Products

1 Safety Assessment of Recipient Microorganism

1.1 Environment to which the recipient microorganism can access.

1.2 Biological characteristics of the recipient microorganisms.

1.2.1 Scientific name and its taxonomic position.

1.2.2 Domestic distribution and application status.

1.2.3 Capability, mode and influencing factors of its colonization, survival, spread and transmission in environment.

1.2.4 Does the recipient microorganism produce toxic materials?

1.3 Impact of the recipient microorganism on plants, animals and other microorganisms.

1.3.1 Impact of the recipient microorganism on human beings and its potential risk level.

1.3.2 Impact of the recipient microorganism on animals and its potential risk level.

1.3.3 Impact of the recipient microorganism on other microorganisms and its potential risk level. Does it suffer from the infection by human and animal pathogens (e. g. , virus) ?

1.3.4 Does it have long-term safety application record.

1.4 Impact of the recipient microorganism on ecological environment and its potential risk level.

1.5 Plasmid status, possibilities of the occurrence of genetic variations and its potential risk level.

1.6 Monitoring method and possibilities of monitoring.

1.7 Other important biological characteristics.

1.8 On the basis of the above-mentioned evaluation, determine the safety class of the recipient microorganism by referencing related standards stipulated in Item I of Article 7 of this "Implementation Regulation".

2 Safety Assessment of Genetic Manipulation

2.1 Source, structure, function and usage of the target gene.

2.2 Name , source, characteristics and safety of the vector. Does it have resistant labeling gene? In the case of having resistant labeling gene, can it transfer to microorganisms which do not contain such genes in nature?

2.3 Molecular structure and construct method, replicative characteristics and safety of the Recombinant DNA.

2.4 Transgenic method.

2.5 Survival prospects and expression stability of the target gene.

2.6 On the basis of the above-mentioned evaluation, determine the safety class of the genetic manipulation by referencing related standards stipulated in Item II of Article 7 of this "Implementation Regulation".

3 Safety Assessment of Genetic Engineered Organism and Its Product

3.1 Biological characteristics of the genetic engineered organism. Objectives of the application. Survival capability in nature. Capability of transferring genetic materials to other organisms and its possible outcomes. Monitoring method and possibilities of monitoring and control.

3.2 Safety of the genetic engineered organism and its products to animals.

3.2.1 Survival prospect in the bodies of the target animals and non-target animals.

3.2.2 Impact of high-dosage inoculation on target animals and possible non-target animals.

3.2.3 Relative safety of the genetic engineered organism and its product in comparison with traditional products.

3.2.4 Host range and the drifting level of vectors.

3.2.5 Toxin excretion and spread capability of immunized animal when contacting target animals and non-target animals.

3.2.6 Toxicity recovery capability of the genetic engineered organism during reverse passages.

3.2.7 Safety to pregnant animals.

3.2.8 Safety to the progeny of the immunized animals.

3.3 Safety of the genetic engineered organism and its product to human beings.

3.3.1 Possibility of human contact and its risk level.

3.3.2 Potential risk level after broad application.

3.4 Safety of the genetic engineered organism and its product to ecological environment.

3.4.1 Release scope in environment.

3.4.2 Physical and chemical factors influencing the survival, multiplication and transmission of the genetic engineered organism.

3.4.3 Possibilities of infecting target animals or potential risks.

3.5 On the basis of the above-mentioned evaluation, determine the safety class of the veterinary microorganism's genetic engineered organism and its product by referencing related standards stipulated in Item III of Article 7 of this "Implementation Regulation".

4 Release Site

4.1 Location of the release site and its surroundings as well as the meteorological data.

4.2 The ecological type of the release site.

4.3 Animal and plant species in the surroundings of the release site.

4.4 Favorable and unfavorable factors of the release site for the survival, propagation, spread and transmission of the genetic engineered, especially the possibility of acquiring target gene from the genetic engineered organism by other organisms in the environment.

5 Experiment Program

5.1 Starting date and terminating date of the experiment.

5.2 Name and number of experimental animals, and the area of the experimental area.

5.3 Isolation and monitoring measures.

5.4 Production, packaging, preservation and transportation methods of the genetic engineered organism and its products.

5.5 Dosage and usage of the genetic engineered organism and its products, and the disposal method for the remaining part.

5.6 Feeding method of the experimental animals and disposal method after the experiment is completed.

5.7 Emergency measures in case of the occurrence of unexpected accidents during the implementation process of the experiment.

5.8 Monitoring measures and duration after the experiment is completed.

Appendix V

Safety Assessment of Genetic Engineered Organism and Its Products Acquired from Aquatic Animal and Plant

1 Safety Assessment of Recipient Aquatic Animal and Plant

1.1 Scientific name and taxonomic position.

1.2 Domestic distribution and application status.

1.3 Reproductive, genetic and other biological characteristics.

1.4 Is it toxic and pathogenic to human beings? Does it have attacking behavior against human beings?

1.5 Enrichment capability to toxic and hazardous materials.

1.6 Are there any eutrophication and swamping hazards on water areas environment?

1.7 Hazards on the diversity of aquatic organisms.

1.8 Other relevant physiological and behavioral characteristics. On the basis of the above-mentioned evaluation, determine the safety class of the recipient aquatic animal and plant by referencing related standards stipulated in Item I of Article 7 of this "Implementation Regulation-".

2 Safety Assessment of Genetic Manipulation

2.1 Source, structure, function and usage of the target gene.

2.2 Name, source, characteristics and safety of the vector.

2.3 Molecular. structure, construct method, replicative characteristics and safety of the Recombinant DNA.

2.4 Transgenic method.

2.5 Expression stability of the target gene.

2.6 On the basis of the above-mentioned evaluation, determine the safety class of the genetic manipulation by referencing related standards stipulated in Item II of Article 7 of this "Implementation Regulation".

3 Safety Assessment of Genetic Engineered Organism and Its Product

3.1 In comparison with the recipient aquatic animal and plant, have the following characteristics of the genetic engineered organism and its product changed?

A.Survival capability in nature;

B.Toxicity;

C.Pathogenicity;

D.Attacking behavior;

E.Enrichment capability on toxic and harmful materials;

F.Eutrophication and swamping on water areas environment;

G.Reproductive, genetic and other biological characteristics; and

H.Influence on the diversity of aquatic animal and plant.

3.2 Capability of transferring genetic materials to other organisms and the possible outcome.

3.3 Is there any unexpected hazard on human health and water area ecological environment?

3.4 On the basis of the above-mentioned evaluation, determine the safety class of the genetic engineered organism and its product acquired from aquatic animal and plant by referencing related standards stipulated in Item III of Article 7 of this "Implementation Regulation".

4 Release Site

4.1 Location of the release site and its surroundings as well as the hydrological data.

4.2 The ecological type of the release water areas.

4.3 Animal and plant species in the release water areas.

4.4 Favorable and unfavorable factors of the release site for the survival, propagation, spread and transmission of the genetic engineered organism, especially the possibility of acquiring target gene from the genetic engineered organism by other organisms in the environment.

5 Experiment Program

5.1 Starting date and terminating date of the experiment:

5.2 Area of the water areas of the experiment.

5.3 Isolation and monitoring measures.

5.4 Dosage and usage of the genetic engineered organism and its products , and the disposal method for the remaining part.

5.5 The capture, processing, preservation and transportation methods of the genetic engineered organism and its products.

5.6 Disposal method of the residues and remaining part of the genetic engineered organism and its product after capturing and processing.

5.7 Emergency measures in case of the occurrence of unexpected accidents during the implementation process of the experiment.

5.8 Monitoring measures and duration after the experiment is completed.

Appendix VI

Safety Control Measures of Agricultural Biological Genetic Engineered Organism and Its Products

In order to avoid potential unfavorable impact of agricultural organism's genetic engineering on human health and ecological environment, it is essential to formulate corresponding safety control measures for different classes of genetic engineering work.

1 Laboratory Safety Control Measures

1.1 Control measures for Safety Class I

Laboratory and its operation should accord with the requirements of common biological laboratory.

1.2 Control measures for Safety Class II

1.2.1 Laboratory requirements:

In addition to the same laboratory requirements of Safety Class I, it is required that the laboratory must be equipped with ultra-aseptic working table, disinfecting facilities and autoclave sterilizing equipment for waste disposal.

1.2.2 Operation requirements:

In addition to the same operational requirements of Safety Class I, it is essential to meet the following requirements:

1.2.2.1 Try all means to avoid the production of aerosol during the operation process.

1.2.2.2 Operate (handle) the experiments within the designated area of the laboratory.

1.2.2.3 Wastes should be kept in seepage-proof and non-fragile containers and conducted inactivation treatment.

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

1.2.2.5 It is essential to prevent all unrelated organisms, such as insects and rodents from entering the laboratory. In the case of an accident, in which harmful target gene, vector, genetic engineered organism do escape and spread, emergency measures must be taken immediately.

1.2.2.6 The safety control measures for veterinary microorganism's genetic engineered organism should also accord with the relevant regulations for veterinary biologicals.

1.3 Control measures for Safety Class III

1.3.1 Laboratory requirements:

In addition to the same laboratory requirements of Safety Class II, it is essential to meet the following requirements:

1.3.1.1 Laboratory should be located within the isolated area and have striking warning signs. Before entering the operation room, laboratory workers should pass through a special locker room (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 wall, floor and ceiling inside the laboratory should be smooth, water-proof, leak-proof and corrosion-protected.

1.3.1.3 Windows should be air-tight.

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 operation requirements of Safety Class II, it is essential to meet the following requirements:

1.3.2.1 The entry of a person into the laboratory must be approved by the project leader.

1.3.2.2 Everyone must change work clothes and wear gloves and other protection tools in the locker room before entering the laboratory and must take a shower before leaving the laboratory. It is forbidden to wear work clothes outside the laboratory and work clothes must be autoclave sterilized 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 I

Laboratory and its operation should accord with relevant requirements stipulated in the "Implementation Regulation".

2 Control Measures for Pilot Experiment and Environment Release of Genetic Engineered Organism

2.1 Control measures for Safety Class I

It is required to adopt common biological isolation methods to put experiment under necessary range of control.

2.2 Control measures for Safety Class II

2.2.1 It is essential to adopt appropriate isolation measures to control the entry and exit of both animals and people. 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 guarantee that the experimental organisms will never enter the natural water areas despite of disastrous climates within 10 years.

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

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

2.2.4 Adopt corresponding 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 the genetic engineered organism.

2.3 Control measures for Safety Class III

2.3.1 It is essential to adopt appropriate isolation measures, and prohibit the entry and exit of unauthorized personnel, animals, poultry and vehicles. It is also essential to equip the laboratory with solarium, artificially controlled industrialized husbandry facilities, containers for collecting and eliminating genetic engineered organism 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 the take-away of genetic engineered organism from 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 genetic engineered organism 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 genetic engineered organism and its product outside the experimental areas, or set up the experimental areas in desert, alpine frigid regions where the genetic engineered organism cannot survive and spread if it were to escape.

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

2.3.6 It is also essential to disinfect and treat fish ponds, livestock barns and soil after the completion of the experiment, with the objective of preventing the escape and survival of the genetic engineered organism.

2.4 Control measures for Safety Class IV

The control measures should be reported to the National Genetic Engineering Safety Committee and implementation should be conducted in accordance with relevant requirements.

2.5 The control measures of the pilot experiment and environment release of veterinary microorganism's genetic engineered organism and its product should also accord with relevant regulations of veterinary biologicals.

3 Emergency Measures

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

3.2 If genetic engineered organism has already been spread, it is essential to adopt effective measures immediately according to its safety class.

3.3 In the case of a spreading area of genetic engineered organism which has already produced unfavorable effect, it is imperative to isolate personnel within the area for the time being and put them under medical monitoring.

3.4 It is essential to undertake trailing monitoring over spreading areas until no more risk exists.

Note: This English version may not exactly be corresponding to the Chinese one because of translation. In case of any contradiction between two, the explanation should be according to the Chinese original.

Appendix VII
Application for
Safety Assessment of Agricultural Biological
Genetic Engineered Organism and Its Products

Name of the Project:

Applicant institution:

Administrative Department:

Applicant:

Address:

Postal Code:

Telephone No.

Fax. No.:

Reporting Date:

Printed by the Ministry of Agriculture, People's Republic of China in 1996.

Instruction for filling the application form:

1. Applicant should read carefully the "Safety Administration Regulation on Genetic Engineering", the "Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering", and related appendixes as well as relevant regulatory documents before filling this form.
2. The form must be completed item by time conscientiously, earnestly and realistically according to the required format. It is required to furnish corresponding floppy disks along with the form for the convenience of computer processing.
3. Type or print legibly with pen.

Form 1, Form 2, Form 3, Form 4, Form 5. (not available)