

Regulations on Safety of Agricultural Genetically Modified Organisms

(Adopted at the 38th Meeting of the State Council on May 9,2001, promulgated by Decree No. 304 of the State Council of the People's Republic of China, and effective as of the date of promulgation)

Chapter I General Provisions

Article 1 These Regulations are formulated for the purposes of strengthening safety administration of agricultural genetically modified organisms (hereafter referred to as agricultural GMOs), safeguarding human health and safety of animals, plants and microorganisms, protecting the environment, and promoting research on agricultural GMOs.

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 must conform to these Regulations.

Article 3 'Agricultural GMOs' referred to in these Regulations means animals, plants, microorganisms and their products whose genomic structures have been modified by genetic engineering technologies for the use in agricultural production or processing, which mainly include:

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

'Safety of agricultural GMOs' referred to in these Regulations means the protection of human beings, animals, plants and microorganisms and the environment from the danger or risk posed by agricultural GMOs.

Article 4 The competent agricultural administrative department of the State Council is responsible for the nationwide supervision and administration of the safety of agricultural GMOs.

The competent agricultural administrative departments of the local people's governments at or above the county level are responsible for the supervision and administration of the safety of agricultural GMOs within their respective administrative areas.

The competent public health administrative departments of the local people's governments at or above the county level are, in accordance with the relevant provisions of the Food Hygiene Law of the People's Republic of China, responsible

for the supervision and administration of the hygiene and safety of genetically modified food within their respective administrative areas.

Article 5 The State Council establishes a system of joint ministry conference for the safety administration of agricultural GMOs.

The joint ministry conference for the safety administration of agricultural GMOs shall be composed of officials from relevant departments of agriculture, science and technology, environmental protection, public health, foreign trade and economic cooperation, inspection and quarantine, and be responsible for the decision-making and coordination of major issues with respect to the safety administration of agricultural GMOs.

Article 6 The State institutes a class-based administration and evaluation system for the safety of agricultural GMOs.

Agricultural GMOs are classified into classes I, II, III and IV according to the extent of their potential risks to human beings, animals, plants, microorganisms and the environment. The standards for the classification are to be formulated by the competent agricultural administrative department of the State Council.

Article 7 The State establishes a safety evaluation system for agricultural GMOs.

The standards and technical norms for the safety evaluation 10s are to be formulated by the agricultural administrative department of the State Council.

Article 8 The state institutes a labeling system for agricultural GMOs.

The catalogue of agricultural GMOs subject to the labeling administration is to be formulated, adjusted and issued by the agricultural administrative department of the State Council in consultation with relevant departments of the State Council.

Chapter II Research and Testing

Article 9 The agricultural administrative department of the State Council shall strengthen the safety evaluation administration of research and testing of agricultural GMOs, and set up a biosafety committee responsible for safety evaluation of agricultural GMOs.

The biosafety committee of agricultural GMOs shall be composed of experts who are engaged in biological research, production, processing, inspection and

quarantine with respect to agricultural GMOs, as well as those in the fields of public health and environmental protection.

Article 10 Based on the needs of the safety evaluation of agricultural GMOs, the agricultural administrative department of the State Council may entrust the inspection of agricultural GMOs to technical inspection bodies with necessary facilities and capacity.

Article 11 Any organization engaged in research and testing of agricultural GMOs shall have safety facilities and measures commensurate with the safety class so as to ensure the safety of research and testing of agricultural GMOs, and establish a biosafety group of agricultural GMOs responsible for the safety of their respective activities.

Article 12 Any organization that conducts research into agricultural GMOs determined as class III or class IV shall report to the agricultural administrative department of the State Council prior to the commencement of the research.

Article 13 The testing of agricultural GMOs shall generally go through three stages, i.e. restricted field-testing, enlarged field-testing and productive testing.

The 'restricted field-testing' means a small-scale test conducted within a contained system or under controlled conditions.

The 'enlarged field-testing' means a medium-scale test conducted in natural conditions with appropriate safety control measures.

The 'productive testing' means a large-scale test prior to commercial production and application.

Article 14 When an agricultural GMO needs to move on to the stage of restricted field-testing after the completion of research in laboratory, the organization conducting the test shall report to the competent agricultural administrative department of the State Council.

Article 15 When a testing of agricultural GMOs needs to move on from one testing stage to the next testing stage, the organization conducting the test shall make an application to the competent agricultural administrative department of the State Council. The competent agricultural administrative department of the State Council shall grant the approval to the application if the test passes the safety evaluation of the biosafety committee of agricultural GMOs.

When making the application referred to in the preceding paragraph, the organization conducting the test shall provide the following materials:

- (1) The safety class of agricultural GMOs and the justification;
- (2) The testing report issued by a technical inspection body of agricultural GMOs;
- (3) A report about appropriate safety management measures;
- (4) A summary report of the preceding testing stage(s).

Article 16 After the completion of the productive testing, the organization conducting tests on agricultural GMOs may make an application to the competent agricultural administrative department of the State Council for a safety certificate of agricultural GMOs.

When making the application referred to in the preceding paragraph, the organization conducting tests shall provide the following materials:

- (1) The safety class of agricultural GMOs and the justification;
- (2) The testing report issued by a technical inspection body of agricultural GMOs;
- (3) A summary report of the productive testing;
- (4) Other materials required by the competent agricultural administrative department of the State Council.

After accepting the application, the competent agricultural administrative department of the State Council shall arrange for the biosafety committee of agricultural GMOs to conduct the safety evaluation. Only after the safety evaluation has been passed may a safety certificate of agricultural GMOs be granted.

Article 17 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 Article 16 of these Regulations before the examination, registration, evaluation or approval is conducted as provided in 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.

Article 18 Chinese-foreign contractual cooperation, joint venture or sole foreign-funded organizations shall first be approved by the competent agricultural administrative department of the State Council before engaging in research and testing

of agricultural GMOs within the territories of the People's Republic of China.

Chapter III Production and Processing

Article 19 A production license shall be obtained for the commercial production of genetically modified seeds, breeding livestock and poultry, or aquatic fry and seeds from the competent agricultural administrative department of the State Council.

In addition to the conditions provided in relevant laws and administrative regulations, any organization or person applying for the production license of genetically modified seeds, breeding livestock and poultry, or aquatic fry and seeds shall meet the following conditions:

- (1) Having obtained a safety certificate of agricultural GMOs and passed relevant variety registration;
- (2) Planting or raising in the designated areas;
- (3) Having appropriate safety management measures;
- (4) Other conditions required by the competent agricultural administrative department of the State Council.

Article 20 Any organization or person engaged in the production of genetically modified plant seeds, breeding livestock and poultry, or aquatic fry and seeds shall keep clear files of the production places, genes and their sources and methods for genetic modification, as well as the whereabouts of seeds, breeding livestock and poultry, or aquatic fry and seeds, etc.

Article 21 Any organization or person engaged in the production and processing of agricultural GMOs shall obtain approval from the competent agricultural administrative department of the State Council or local agricultural administrative department of province, autonomous region or municipality directly under the Central Government. The implementation regulations shall be formulated by the competent agricultural administrative department of the State Council.

Article 22 Where farmers raise genetically modified animals or plant genetically modified plants, the organizations selling the seeds, breeding livestock and poultry, or aquatic fry and seeds shall, on behalf of the farmers, go through the examination and approval formalities as provided in Article 21 of these Regulations. The examination and approval department and the selling organization shall not charge any fees from the farmers.

Article 23 Any organization or person engaged in production or processing of agricultural GMOs shall arrange the production and processing in accordance with the authorized varieties, scopes, safety management requirements and appropriate technical standards, and regularly report the production, processing, safety management and the whereabouts of the products to the local agricultural administrative department of the people's government at the county level.

Article 24 When any accident happens during the process of production and processing of agricultural GMOs, the organization or person engaged in such production and processing shall immediately take remedial measures and report to the local agricultural administrative department of the people's government at the county level.

Article 25 The organization or person engaged in transportation and storage of agricultural GMOs shall take safety control measures commensurate with the safety class of agricultural GMOs in order to ensure the safety of transportation and storage of agricultural GMOs.

Chapter IV Marketing

Article 26 Any organization or person intending to market genetically modified plant seeds, breeding livestock and poultry, or aquatic fry and seeds shall obtain a marketing license from the competent agricultural administrative department of the State Council.

In addition to the conditions provided in relevant laws and administrative regulations, any organization or person applying for the marketing license of genetically modified seeds, breeding livestock and poultry, or aquatic fry and seeds shall meet the following conditions:

- (1) Having full-time managerial personnel and marketing files;
- (2) Having appropriate safety management measures;
- (3) Other conditions required by the competent agricultural administrative department of the State Council.

Article 27 Any organization or person marketing genetically modified plant seeds, breeding livestock and poultry, or aquatic fry and seeds shall keep clear files of the sources, transportation, storage and the whereabouts of the seeds, breeding

livestock and poultry, or aquatic fry and seeds, etc.

Article 28 Agricultural GMOs listed in the labeling catalogue of agricultural GMOs shall be clearly labeled when they are sold in the territories of the People's Republic of China.

Agricultural GMOs listed in the labeling catalogue of agricultural GMOs shall be labeled by the organization or person producing or repackaging the products. Unlabeled products shall not be sold. When procuring stocks of such products, the organization or person shall check the products and their labels. The organization or person shall re-label the products if their original packages have been opened for sale.

Article 29 The label of agricultural GMOs shall clearly indicate the names of the main raw materials containing genetically modified ingredients in the product. If there are special requirements on marketing scope, the label shall also indicate the scope, and the product shall be sold only within this scope.

Article 30 Advertisements for agricultural GMOs may be published, broadcasted, set and posted only after they have been examined and approved by the competent agricultural administrative department of the State Council.

Chapter V Import and Export

Article 31 When introducing agricultural GMOs into the territories of the People's Republic of China for research and testing, the introducing organization shall make an application to the competent agricultural administrative department of the State Council. The competent agricultural administrative department of the State Council shall give the approval if the application satisfies the following conditions:

(1) A qualified applicant approved by the competent agricultural administrative department of the State Council;

(2) The relevant research and testing of the agricultural GMOs to be introduced has been completed outside the Chinese territories;

(3) Having appropriate safety management measures.

Article 32 Any company outside the Chinese territories that exports to the People's Republic of China genetically modified plant seeds, breeding livestock and poultry, or aquatic fry and seeds shall make an application to the competent agricultural administrative department of the State Council.

This provision also applies to the seeds, breeding livestock and poultry, aquatic fry and seeds, pesticides, animal medicines and biologics, fertilizers and additives produced with agricultural GMOs or containing ingredients of agricultural GMOs.

For those satisfying the following conditions the competent agricultural administrative department of the State Council shall approve the importation of testing materials and the conduction of restricted field testing, enlarged field testing or productive testing in accordance with the provisions of these Regulations:

(1) The exporting country or region has permitted the marketing of the GMOs for the same purpose:

(2) The exporting country or region has verified the safety of the GMOs to human beings, animals and plants, microorganisms and environment through scientific experiments;

(3) Having appropriate safety management measures are in place.

With the completion of the productive testing, only after passing the safety evaluation and obtaining the safety certificate of agricultural GMOs may the formalities of examination, registration or evaluation and approval be gone through in accordance with the provisions of relevant laws and administrative regulations.

Article 33 Any company outside the Chinese territories that exports to the People's Republic of China agricultural GMOs to be used as raw materials for processing shall make an application to the competent agricultural administrative department of the State Council. The competent agricultural administrative department of the State Council shall issue a safety certificate of agricultural GMOs for those passing the safety evaluation and meeting the following conditions:

(1) The exporting country or region has permitted the marketing of the GMOs for the same purpose;

(2) The exporting country or region has verified the safety of the GMOs to human beings, animals and plants, microorganisms and the environment through scientific experiments;

(3) The technical inspection body of agricultural GMOs has confirmed upon experiments that there is no danger to human beings, animals, plants, microorganisms and the environment;

(4) Having appropriate safety management measures are in place.

Article 34 When introducing agricultural GMOs from outside the Chinese territories or exporting agricultural GMOs to the People's Republic of China, the introducing organization or the company outside the Chinese territories shall make a declaration to the exit-entry inspection and quarantine agency at the port with the

relevant documents of approval and a safety certificate of agricultural GMOs issued by the competent agricultural administrative department of the State Council. The introducing organization or the company outside the Chinese territories may make an application to the Customs for relevant formalities only after the agricultural GMO passes quarantine.

Article 35 When agricultural GMOs are to be transferred via the territories of the People's Republic of China, the owner of the goods shall in advance make an application to the exit-entry inspection and quarantine department of the State. Such transboundary movement may be carried out only after it has been approved and shall comply with the provisions of the relevant laws and administrative regulations of the People's Republic of China.

Article 36 The competent agricultural administrative department of the State Council and the exit-entry inspection and quarantine department of the State shall make a decision of approval or disapproval and notify the applicant within 270 days from the date of application acceptance.

Article 37 When agricultural products are exported outside the territories of the People's Republic of China and the foreign party requests a certificate of non-GMO agricultural products, the exit-entry inspection and quarantine agency at the port shall undertake detection and issue a certificate of non-GMO agricultural products in accordance with the information of genetically modified agricultural products published by the competent agricultural administrative department of the State Council.

Article 38 Agricultural GMOs that are imported without relevant documents of approval and safety certificate of agricultural GMOs issued by the competent agricultural administrative department of the State Council, or not conforming to the certificate and approval documents, shall be rejected or destroyed. Where agricultural GMOs to be imported are not labeled in accordance with the relevant provisions, they shall not enter the Chinese territories until being re-labeled.

Chapter VI Supervision and Inspection

Article 39 When performing supervision and inspection, the competent agricultural administrative departments have the power to take the following

measures:

(1) Enquiring the organizations and/or persons involved in the research, testing, production, processing, marketing, importation or exportation, interested parties and witnesses and requesting them to provide evidence and other materials relating to agricultural GMOs:

(2) Examining or duplicating the files, account books and/or data relating to the research, testing, production, processing, marketing, or import and export of agricultural GMOs;

(3) Requesting the organizations or persons concerned to make explanations on issues of safety of agricultural GMOs;

(4) Ordering the organizations or persons violating the safety administration regulations of agricultural GMOs to stop illegal activities;

(5) Sealing up or seizing, under emergency circumstances, agricultural GMOs involved in illegal research, testing, production, processing, marketing, import or export.

Article 40 Staff members of the competent agricultural administrative departments shall present their credentials for law enforcement when undertaking supervision and inspection.

Article 41 The organization or persons concerned shall support and cooperate with the competent agricultural administrative departments in their supervision and inspection, and shall not refuse and obstruct the supervision and inspection personnel to perform their duties in accordance with law.

Article 42 When discovering that agricultural GMOs endanger human beings, animals, plants or the environment, the competent agricultural administrative department of the State Council has the power to prohibit the production, processing, GMOs, or to destroy the agricultural GMOs in question.

Chapter VII Penalty Provisions

Article 43 Those who, in violation of these Regulations, conduct research or restricted field testing of agricultural GMOs classified as classes III and IV without making a report to the agricultural administrative department of the State Council shall be ordered by the competent agricultural administrative department of the State Council to suspend the research or restricted field testing, and to make corrections

within the specified time limit.

Article 44 Those who, in violation of these Regulation, arbitrarily conduct enlarged field testing or productive testing without approval, or with approval but fail to take safety management measures in accordance with the relevant provisions, or conduct testing beyond the approved scope, shall be ordered to stop testing and to pay a fine of not less than 10,000 yuan but not more than 50,000 yuan by the competent agricultural administrative department of the State Council or the agricultural administrative department of the people's government of the province, autonomous region or municipality directly under the Central Government in accordance with their respective functions and powers.

Article 45 Those who, in violation of these Regulations, arbitrarily put agricultural GMOs into production or application after the completion of productive testing but without obtaining the safety certificate of agricultural GMOs, shall be ordered to stop the production or application and to pay a fine of not less than 20,000 yuan but not more than 100,000 yuan by the competent agricultural administrative department of the State Council.

Article 46 Those who, in violation of the provisions of Article 18 of these Regulations, conduct research or testing of agricultural GMOs without the approval of the competent agricultural administrative department of the State Council, shall be ordered to stop the research or testing and to take the remedial step of going through the necessary examination and approval formalities within the specified time limit by the competent agricultural administrative department of the State Council.

Article 47 Those who, in violation of these Regulations, produce or process agricultural GMOs without approval, or conduct production or processing not conforming to the approved varieties, scopes, requirements for safety management and technical standards, shall be ordered to stop the production or processing by the agricultural administrative department of the State Council or the agricultural administrative department of the people's government of the province, autonomous region or municipality directly under the Central Government in accordance with their respective functions and powers. The illegally produced or processed products and the illegal income shall be confiscated. If the illegal income is not less than 100,000 yuan, a fine of not less than 1 but not more than 5 times the illegal income shall be imposed concurrently; if there is no illegal income or the illegal income is less than 100,000 yuan, a fine of not less than 100,000 yuan but not more than 200,000 yuan shall be

imposed concurrently.

Article 48 Any organization or person engaged in the production or marketing of genetically modified plant seeds, breeding livestock and poultry, or aquatic fry and seeds, in violation of these Regulations, fails to establish and keep production or marketing files in accordance with the relevant requirements, shall be ordered to make corrections and to pay a fine of not less than 1,000 yuan but not more than 10,000 yuan by the agricultural administrative department of the people's government at or above the county level in accordance with its functions and powers.

Article 49 Any marketing organization of genetically modified plant seeds, breeding livestock and poultry, or aquatic fry and seeds, in violation of these Regulations, fails to fulfill the obligations of going through the examination and approval formalities on behalf of the farmers or charges fees for such fulfillment, shall be ordered to make corrections and to pay a fine of not more than 20,000 yuan by the competent agricultural administrative department of the State Council.

Article 50 Those who; in violation of these Regulations, arbitrarily import agricultural GMOs without the approval of the competent agricultural administrative department of the State Council, shall be ordered to stop the importation by the competent agricultural administrative department of the State Council and the imported products and the illegal income shall be confiscated. If the illegal income is not less than 100,000 yuan, a fine of not less than 1 but not more than 5 times the illegal income shall be imposed concurrently; if there is no illegal income or the illegal income is less than 100,000 yuan, a fine of not less than 100,000 yuan but not more than 200,000 yuan shall be imposed concurrently.

Article 51 Those who, in violation of these Regulations, import, carry or post agricultural GMOs without making a declaration to the exit-entry inspection and quarantine agency at the port, or transfer agricultural GMOs via the territories of China without the approval of the exit-entry inspection and quarantine department of the State, shall be punished by the exit-entry inspection and quarantine agency at the port or by the exit-entry inspection and quarantine department of the State by applying *mutates mutandis* the relevant provisions of the animal and plant quarantine law.

Article 52 Those who violate the provisions of these Regulations on labeling of agricultural GMOs shall be ordered to make corrections within the specified time limit by the competent agricultural administrative departments of the people's

governments at or above the county level in accordance with their respective functions and powers. The illegal products for sale and illegal income may be confiscated and a fine of not less than 10,000 yuan but not more than 50,000 yuan may be imposed.

Article 53 Those who forge, falsify, transfer, sell or buy the certifying documents related to agricultural GMOs shall have the certifying documents in question confiscated and be imposed a fine of not less than 20,000 yuan but not more than 100,000 yuan by the agricultural administrative department of the people's governments at or above the county level in accordance with their respective functions and powers. In case of a crime, the person(s) involved shall be punished in accordance with the criminal law.

Article 54 Those who, in violation of these Regulations, cause an accident in research, testing, production, processing, storage, transportation, marketing, import or export of agricultural GMOs, thus resulting in any damage, shall bear the liability for compensation in accordance with law.

Article 55 Where the competent agricultural administrative department of the State Council or the agricultural administrative department of the people's government of the province, autonomous region or municipality directly under the Central Government, in violation of these Regulations, issues licenses, safety certificates of agricultural GMOs or other documents of approval, or fails to perform the duties of supervision and administration after issuing the licenses, safety certificates of agricultural GMOs or other documents of approval, the person in charge who has direct responsibility and other direct responsible persons shall be given administrative sanctions in accordance with law. In case of a crime, the person(s) involved shall be punished in accordance with the criminal law.

Chapter VIII Supplementary Provisions

Article 56 These Regulations shall enter into force as of the day of promulgation.