

Regulations on Administration of Agricultural Genetically Modified Organisms Safety

Decree No. 304 of the State Council of the People's Republic of China,
Promulgated on May 23, 2001, and effective as of the date of promulgation

Chapter I General Provisions

Article 1 These Regulations are formulated for the purposes of strengthening the administration of agricultural genetically modified organisms safety, safeguarding the health of human bodies and the safety of animals, plants and microorganisms, protecting the ecological environment, and promoting the research into technologies of agricultural genetically modified organisms.

Article 2 The activities of research, experiment, production, processing, marketing, import and export with respect to agricultural genetically modified organisms within the territory of the People's Republic of China must conform to these Regulations.

Article 3 Agricultural genetically modified organism, as 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 drugs, fertilizers, additives and other products containing ingredients of genetically modified animals, plants and microorganisms or their products.

Agricultural genetically modified organisms safety, as referred to in these Regulations, means the protection of human being, animals, plants and microorganisms and the ecological environment against the danger or potential risk arising from agricultural genetically modified organisms.

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

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

The competent public health administrative departments of 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 inter-ministerial joint conference for administration of agricultural genetically modified organisms safety.

The inter-ministerial joint conference for administration of agricultural genetically modified organisms safety shall be composed of responsible persons from the departments of agriculture, science and technology, environmental protection, public health, foreign trade and economic cooperation, inspection and quarantine, and from other relevant departments as well, and shall be responsible for the discussion and coordination of major issues involved in the administration of agricultural genetically modified organisms safety.

Article 6 The State institutes a class-based administration and evaluation system for agricultural genetically modified organisms safety.

Agricultural genetically modified organisms are classified into Classes I, II, III and IV according to the extent of their risks to human beings, animals, plants, microorganisms and the ecological environment. The specific 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 genetically modified organisms.

The standards and technical norms for safety evaluation of agricultural genetically modified organisms are to be formulated by the competent agricultural administrative department of the State Council.

Article 8 The State institutes a labeling system for agricultural genetically modified organisms.

The catalogue of agricultural genetically modified organisms subject to labeling administration shall be determined, adjusted and published by the competent agricultural administrative department of the State Council in consultation with the other relevant departments of the State Council.

Chapter II Research and Testing

Article 9 The competent agricultural administrative department of the State Council shall strengthen the safety evaluation administration of research into and testing of agricultural genetically modified organisms, and set up a bio-safety committee on agricultural genetically modified organisms responsible for safety evaluation of agricultural genetically modified organisms.

The bio-safety committee on agricultural genetically modified organisms shall be composed of the experts who are engaged in biological research, production, processing, inspection and quarantine with respect to agricultural genetically modified organisms, as well as those in the fields of public health and environmental protection, etc.

Article 10 Based on the needs of the safety evaluation of agricultural genetically modified organisms, the competent agricultural administrative department of the State Council may entrust the inspection of agricultural genetically modified organisms to technical inspection bodies with necessary inspecting facilities and capability.

Article 11 Units engaged in research into and testing of agricultural genetically modified organisms shall have facilities and measures commensurate with the safety class so as to ensure the safety of research into and testing of agricultural genetically modified organisms, and shall establish bio-safety groups of agricultural genetically modified organisms which shall be responsible for the safety of the research into and testing of agricultural genetically modified organisms in the units concerned.

Article 12 A unit conducting research into agricultural genetically modified organisms classified as Classes III and IV shall make a report to the competent agricultural administrative department of the State Council prior to the commencement of the research.

Article 13 The testing of agricultural genetically modified organisms shall normally go through three stages, i.e. restricted field testing, enlarged field testing and productive testing.

Restricted field testing means a small-scale test conducted within a controlled system or under controlled conditions.

Enlarged field testing means a medium-scale test conducted under natural conditions with appropriate safety measures.

Productive testing means a large-scale test prior to production and application.

Article 14 Where a testing of agricultural genetically modified organisms needs to move on to the stage of restricted field testing after completion of research in the laboratory, the testing unit shall make a report to the competent agricultural administrative department of the State Council.

Article 15 Where a testing of agricultural genetically modified organisms needs to move on from one testing stage to the next one, the testing unit shall make an application to the competent agricultural administrative department of the State Council; if the testing passes the safety evaluation conducted by the bio-safety committee on agricultural genetically modified organisms, the moving on to the next testing stage shall be approved by the competent agricultural administrative department of the

State Council.

When making the application referred to in the preceding paragraph, the testing unit shall provide the following materials:

- (1) the safety class of agricultural genetically modified organisms and the justifications therefor;
- (2) the inspection report issued by a technical inspection body of agricultural genetically modified organisms;
- (3) appropriate safety administration and precautionary measures;
- (4) the summary report of the previous testing stage.

Article 16 After the completion of productive testing, the unit engaged in testing of agricultural genetically modified organisms may make an application to the competent agricultural administrative department of the State Council for a safety certificate of agricultural genetically modified organisms.

When making the application referred to in the preceding paragraph, the testing unit shall provide the following materials:

- (1) the safety class of agricultural genetically modified organisms and the justifications therefor;
- (2) the inspection report issued by a technical inspection body of agricultural genetically modified organisms;
- (3) a summary report of the productive testing;
- (4) other materials as provided for by the competent agricultural administrative department of the State Council.

After receiving the application, the competent agricultural administrative department of the State Council shall organize the bio-safety committee on agricultural genetically modified organisms to conduct the safety evaluation; only after the safety evaluation has been passed may a safety certificate of agricultural genetically modified organisms be issued.

Article 17 Before the examination, registration, evaluation or approval is conducted as provided for in relevant laws and administrative regulations, the safety certificate of agricultural genetically modified organisms shall, as provided for in Article 16 of these Regulations, be obtained for genetically modified plant seeds, breeding livestock and poultry, as well as aquatic fry and seeds, and for the seeds, breeding livestock and poultry, aquatic fry and seeds, pesticides, veterinary drugs, fertilizers, additives and others, which are either produced by using agricultural genetically modified organisms or contain ingredients of agricultural genetically modified organisms.

Article 18 Research into and testing of agricultural genetically modified organisms within the territory of the People's Republic of China conducted by means of Chinese-foreign contractual cooperation, joint capital or sole foreign capital shall be approved by the competent agricultural administrative department of the State Council.

Chapter III Production and Processing

Article 19 A production license shall be obtained for the 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 for in relevant laws and administrative regulations, any unit 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 genetically modified organisms and passed variety examination;
- (2) planting or breeding in the designated areas;
- (3) having adopted appropriate safety administration and precautionary measures;
- (4) other conditions provided for by the competent agricultural administrative department of the State Council.

Article 20 Any unit or person producing genetically modified plant seeds, breeding livestock and poultry, or aquatic fry and seeds shall keep production files to clearly record the places of production, 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 unit or person engaged in the production and processing of agricultural genetically modified organisms shall obtain approval from the competent agricultural administrative department of the State Council or the competent agricultural administrative department of a province, an autonomous region and a municipality directly under the Central Government. The specific measures are to be formulated by the competent agricultural administrative department of the State Council.

Article 22 Where farmers breed genetically modified animals or plant genetically modified plants, the units selling 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 for in Article 21 of these Regulations. The examination and approval department and the selling unit shall not charge any fees from the farmers.

Article 23 Any unit or person engaged in the production or processing of agricultural genetically modified organisms shall organize the production and processing in accordance with the approved varieties, scopes, safety administration requirements and appropriate technical standards, and shall regularly report the production, processing, safety administration and the whereabouts of the products to the local competent agricultural administrative department of the people's government at the county level.

Article 24 When any genetic accident happens during the process of production and processing of agricultural genetically modified organisms, the unit or person engaged in such production and processing shall immediately take remedial measures and make a report to the competent agricultural administrative department of the people's government at the county level of the place where it or he is situated.

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

Chapter IV Marketing

Article 26 Any unit 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 for in relevant laws and administrative regulations, any marketing unit 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 adopted appropriate safety administration and precautionary measures;
- (3) other conditions provided for by the competent agricultural administrative department of the State Council.

Article 27 Any unit or person marketing genetically modified plant seeds, breeding livestock and poultry, or aquatic fry and seeds shall keep marketing files to clearly record the sources, transportation, storage and the whereabouts of the seeds, breeding livestock and poultry, or aquatic fry and seeds, etc.

Article 28 Agricultural genetically modified organisms listed in the catalogue of agricultural genetically modified organisms shall be clearly labeled when they are sold in the territory of the People's Republic of China.

Agricultural genetically modified organisms listed in the catalogue of agricultural genetically modified organisms shall be labeled by the unit or person producing or repacking the products. Unlabeled products shall not be sold. When replenishing the stocks of such products, the marketing unit or person shall check the products and their labels. The marketing unit or person shall re-label the products if their original packages have been opened for sale.

Article 29 The label of agricultural genetically modified organisms shall clearly indicate the names of the main raw materials containing genetically modified ingredients in the product. If there are special requirements with respect to the area in which the product can be sold, the area shall also be indi-

cated in the label, and the product in question shall only be sold within such area.

Article 30 Advertisements for agricultural genetically modified organisms 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 genetically modified organisms into the territory of the People's Republic of China for the purpose of research and testing, the introducing unit shall make an application to the competent agricultural administrative department of the State Council; only the application that meets the following conditions may be approved by the competent agricultural administrative department of the State Council:

- (1) having the application qualifications as provided for by the competent agricultural administrative department of the State Council;
- (2) the relevant research into and testing of agricultural genetically modified organisms to be introduced has been completed at abroad (or outside the territory of China);
- (3) having adopted appropriate safety administration and precautionary measures.

Article 32 Any company outside the territory of China that exports to the People's Republic of China genetically modified plant seeds, breeding livestock and poultry, or aquatic fry and seeds, and plant seeds, breeding livestock and poultry, aquatic fry and seeds, pesticides, veterinary drugs, fertilizers and additives produced by using agricultural genetically modified organisms or containing ingredients of agricultural genetically modified organisms, shall make an application to the competent agricultural administrative department of the State Council; where the following conditions are met, the competent agricultural administrative department of the State Council shall approve the importation of testing materials, and the restricted field testing, enlarged field testing or productive testing shall be conducted in accordance with the provisions of these Regulations.

- (1) the exporting country or region has permitted the usage for the same purpose and the putting into market thereof;
- (2) the exporting country or region has, through scientific experiment, proved that they are harmless to human beings, animals and plants, microorganisms and ecological environment;
- (3) having adopted appropriate safety administration and precautionary measures.

With the completion of the productive testing, only after passing the safety evaluation and obtaining the safety certificate of agricultural genetically modified organisms 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 territory of China that exports to the People's Republic of China agricultural genetically modified organisms to be used as raw materials for processing shall make an application to the competent agricultural administrative department of the State Council; for those meeting the following conditions and passing the safety evaluation, the competent agricultural administrative department of the State Council shall issue a safety certificate of agricultural genetically modified organisms:

- (1) the exporting country or region has permitted the usage for the same purpose and the putting into market thereof;
- (2) the exporting country or region has, through scientific experiment, proved that they are harmless to human beings, animals and plants, microorganisms and ecological environment;
- (3) the technical inspection body of agricultural genetically modified organisms has confirmed, upon inspection, that there is no danger to human beings, animals, plants, microorganisms and ecological environment;
- (4) having adopted appropriate safety administration and precautionary measures .

Article 34 When introducing agricultural genetically modified organisms from outside the territory of the People's Republic of China or exporting agricultural genetically modified organisms to the People's Republic of China, the introducing unit or the company outside the territory of China shall make

a declaration for inspection and quarantine to the exit-entry inspection and quarantine agency at the port on the strength of the safety certificate of agricultural genetically modified organisms issued by the competent agricultural administrative department of the State Council and the relevant documents of approval. Only for those passing the quarantine an application may be made to the Customs for going through relevant formalities.

Article 35 When agricultural genetically modified organisms are to be transferred via the territory 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 transfer 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, within 270 days from the date of receipt of the application, make a decision of approval or disapproval, and notify the applicant of the result.

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

Article 38 Agricultural genetically modified organisms that are imported without a safety certificate of agricultural genetically modified organisms issued by the competent agricultural administrative department of the State Council and the relevant documents of approval, or not conforming to the certificate or the documents of approval, shall be rejected or destroyed. Where agricultural genetically modified organisms to be imported are not labeled as required, the goods cannot enter the territory of China until being re-labeled.

Chapter VI Supervision and Inspection

Article 39 When performing its functions and duties of supervision and inspection, a competent agricultural administrative department has the power to take the following measures:

(1) enquiring the units, individuals, interested parties or witnesses that are being inspected and involved in the research, testing, production, processing, marketing, importation or exportation, and requesting them to provide certifying materials relating to agricultural genetically modified organisms or other materials;

(2) consulting or duplicating the files, account books or materials relating to the research, testing, production, processing, marketing, importation or exportation of agricultural genetically modified organisms;

(3) requesting the units or individuals concerned to make explanations on issues relating to agricultural genetically modified organisms safety;

(4) ordering the units or individuals violating the safety administration of agricultural genetically modified organisms to stop illegal activities;

(5) under emergency circumstances, sealing up or seizing agricultural genetically modified organisms involved in illegal research, testing, production, processing, marketing, importation or exportation.

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

Article 41 The units or individuals 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 according to law.

Article 42 When discovering that agricultural genetically modified organisms endanger human beings, animals, plants or ecological environment, the competent agricultural administrative department of the State Council has the power to make a declaration to prohibit the production, processing, marketing or importation thereof, to take back the safety certificate of agricultural genetically modified or-

ganisms, or to destroy the dangerous agricultural genetically modified organisms in question.

Chapter VII Penalty Provisions

Article 43 Those who, in violation of these Regulations, conduct research into agricultural genetically modified organisms classified as Class III or IV or conduct restricted field testing without making a report to the competent 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, conduct enlarged field testing or productive testing without approval, or with approval but failing to take safety administration and precautionary measures in accordance with the relevant provisions, or conduct testing beyond the approved scope, shall be ordered to stop the testing, and shall be imposed 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 competent agricultural administrative department of the people's government of the province, autonomous region and municipality directly under the Central Government in accordance with their respective functions and powers.

Article 45 Those who, in violation of these Regulations, put agricultural genetically modified organisms into production or application after the completion of productive testing but without obtaining the safety certificate of agricultural genetically modified organisms, shall be ordered to stop the production or application, and shall be imposed 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 into or testing of agricultural genetically modified organisms without the approval of the competent agricultural administrative department of the State Council, shall be ordered by the competent agricultural administrative department of the State Council to stop the research and testing, and to undergo anew examination and approval formalities within the specified time limit.

Article 47 Those who, in violation of these Regulations, produce or process agricultural genetically modified organisms without approval, or conduct the production or processing not conforming to the approved varieties, scopes, requirements for safety administration and technical standards, shall be ordered to stop the production or processing by the competent agricultural administrative department of the State Council or the competent 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 one but not more than five 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 If a unit 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 make and keep production or marketing files, it or he shall be ordered to make corrections and imposed a fine of not less than 1,000 yuan but not more than 10,000 yuan by the competent agricultural administrative department of the people's government at or above the county level in accordance with its functions and powers.

Article 49 If a marketing unit 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, it or he shall be ordered to make corrections and imposed 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, import agricultural genetically modified organisms 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. The imported products and the illegal income shall be confiscated. If the il-

legal income is not less than 100,000 yuan, a fine of not less than one but not more than five 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 genetically modified organisms without making a declaration for inspection and quarantine to the exit-entry inspection and quarantine agencies at the ports, or transfer agricultural genetically modified organisms via the territory 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 agencies at the ports or by the exit-entry inspection and quarantine department of the State by applying mutates mutandis the relevant provisions of the law on the entry and exit animal and plant quarantine.

Article 52 Those who violate the provisions of these Regulations on labeling management of agricultural genetically modified organisms 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 illegally marketed products 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 or sell and buy any relevant certifying documents relating to agricultural genetically modified organisms 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 competent agricultural administrative department of the people's governments at or above the county level in accordance with their respective functions and powers; if a crime is constituted, criminal liability shall be investigated according to law.

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

Article 55 Where the competent agricultural administrative department of the State Council or the competent agricultural administrative department of the people's government of a province, an autonomous region or a municipality directly under the Central Government, in violation of these Regulations, issues licenses, safety certificates of agricultural genetically modified organisms or other documents of approval, or fails to perform the duties of supervision and administration after issuing the licenses, safety certificates of agricultural genetically modified organisms or other documents of approval, the person in charge who has direct responsibility and other direct responsible persons shall be given administrative sanctions according to law; if a crime is constituted, criminal liability shall be investigated according to law.

Chapter VIII Supplementary Provisions

Article 56 These Regulations shall take effect as of the date of promulgation.