

Regulations on the Safety Administration of Agricultural Genetically Modified Organisms of the PRC

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Chapter I — General Provisions

Article 1 — These Regulations are formulated for the purposes of strengthening the safety administration of agricultural genetically modified organisms, safeguarding human health and the safety of animals, plants,

and microorganisms, protecting the ecological environment, and promoting research on agricultural genetically modified organisms.

Article 2 — Activities involving the research, testing, production, processing, marketing, import, and export of agricultural genetically modified organisms within the territory of the People's Republic of China shall comply with these Regulations. The term "agricultural genetically modified organisms" as used in these Regulations means animals, plants, microorganisms, and their products whose genetic structure has been modified through genetic engineering technology for use in agricultural production or processing, mainly including: genetically modified animals, plants (including seeds, breeding livestock and poultry, aquatic fry and fingerlings), and microorganisms; genetically modified animal, plant, and microorganism products; products directly processed from genetically modified agricultural products; and genetically modified aquatic fry and fingerlings, pesticides, veterinary drugs, fertilizers, additives, and other products containing ingredients of genetically modified animals, plants, microorganisms, or their products.

Article 3 — The administrative department of agriculture under the State Council shall be responsible for the supervision and administration of the safety of agricultural genetically modified organisms throughout the country. The administrative departments of agriculture under the local people's governments at or above the county level shall be responsible for the supervision and administration of the safety of agricultural genetically modified organisms within their respective administrative areas. Other relevant departments of the people's governments at or above the county level shall be responsible for the supervision and administration of the safety of agricultural genetically modified organisms within their respective scopes of duties.

Article 4 — The State shall implement a grading and classification evaluation system for the safety of agricultural genetically modified organisms. Agricultural genetically modified organisms shall be classified into Classes I, II, III, and IV according to the degree of danger they pose to human beings, animals, plants, microorganisms, and the ecological environment. The specific standards shall be formulated by the administrative department of agriculture under the State Council.

Article 5 — The State Council shall establish a joint meeting system for the safety administration of agricultural genetically modified organisms, which shall be composed of responsible persons from the administrative departments of agriculture, science and technology, environmental protection, health, foreign trade and economic cooperation, inspection and quarantine, and other relevant departments under the State Council, to study and coordinate major issues in the safety administration of agricultural genetically modified organisms.

Article 6 — The State shall adopt a system of scientific research, testing, production, processing, marketing, import, and export of agricultural genetically modified organisms on the basis of safety evaluation and upon approval by the relevant competent departments.

Chapter II — Research and Testing

Article 7 — The State shall implement a safety grading administration system for the research of agricultural genetically modified organisms. The administrative department of agriculture under the State Council shall be responsible for formulating the safety grading standards and evaluation norms for the research of agricultural genetically modified organisms. Institutions engaged in the research of agricultural genetically modified organisms shall have facilities and equipment appropriate to the safety grade, adopt corresponding safety management measures, and ensure the safety of agricultural genetically modified organism research.

Article 8 — Institutions engaged in the research of agricultural genetically modified organisms shall establish an agricultural genetically modified organism safety group, which shall be responsible for the safety of the research of agricultural genetically modified organisms of the institution and the examination and supervision of the safety of the intermediary tests and environmental releases of the institution.

Article 9 — Before conducting intermediary tests, the research institution shall report to the administrative department of agriculture under the State Council. After conducting environmental releases and productive tests, the research institution shall apply to the administrative department of agriculture under the State Council for approval.

Article 10 — The safety administration measures for the intermediary tests and environmental releases of agricultural genetically modified organisms shall be examined and approved by the agricultural genetically modified organism safety committee. Those that meet the conditions shall be granted safety certificates. The specific measures for intermediary tests, environmental releases, and productive tests of agricultural genetically modified organisms shall be formulated by the administrative department of agriculture under the State Council.

Chapter III — Production and Processing

Article 11 — An entity engaged in the production or processing of agricultural genetically modified organisms shall obtain a production or processing permit issued by the administrative department of agriculture under the State Council or the administrative department of agriculture of the province, autonomous region, or municipality directly under the Central Government. The administrative department of agriculture under the State Council or the administrative department of agriculture of the province, autonomous region, or municipality directly under the Central Government shall, when entrusting the agricultural genetically modified organism safety committee to conduct a safety evaluation, make a decision on approval or disapproval within a prescribed time limit.

Article 12 — An entity engaged in the seed production or commercial-scale livestock and poultry breeding of agricultural genetically modified organisms shall obtain a safety certificate for agricultural genetically modified organisms issued by the administrative department of agriculture under the State Council.

Article 13 — An entity producing genetically modified plant seeds, breeding livestock and poultry, or aquatic fry and fingerlings shall establish production and operation records recording the name of the genetically modified variety, the source of the genetically modified organism, and the location of production.

Article 14 — An entity engaged in the processing of agricultural genetically modified organisms shall clearly mark genetically modified organisms and shall not change the raw materials in the course of processing.

Chapter IV — Marketing

Article 15 — Agricultural genetically modified organisms sold within the territory of the People's Republic of China shall be clearly marked. Agricultural genetically modified organisms sold shall be marked with the name of the genetically modified organism, the main genetically modified traits, and other information. Genetically modified agricultural products sold shall be accompanied by a label indicating the genetically modified ingredients.

Article 16 — Where agricultural genetically modified organisms are put on the market for sale, the seller shall provide the purchaser with relevant safety certificates, production permits, or marketing permits. The seller shall establish a marketing record system to record the sale of agricultural genetically modified organisms.

Article 17 — Agricultural genetically modified organisms shall be advertised only after they have been examined and approved. No false or exaggerated advertising of agricultural genetically modified organisms is permitted.

Chapter V — Import and Export

Article 18 — The import of agricultural genetically modified organisms shall be subject to the approval of the administrative department of agriculture under the State Council. Where agricultural genetically modified organisms are imported for use as raw materials, a safety certificate for agricultural genetically modified

organisms shall be obtained. The import of agricultural genetically modified organisms for research or testing shall be subject to the approval of the administrative department of agriculture under the State Council.

Article 19 — Where agricultural genetically modified organisms are exported, the exporter shall go through the relevant formalities in accordance with the provisions of the State. Where the importing country or region requires certification of the safety of agricultural genetically modified organisms, the exporter may apply to the administrative department of agriculture under the State Council for a certificate.

Article 20 — The entry-exit inspection and quarantine authorities shall conduct quarantine of imported agricultural genetically modified organisms in accordance with the law; where a quarantine certificate has been obtained, the agricultural genetically modified organisms may be used or sold.

Chapter VI — Supervision and Inspection

Article 21 — The administrative department of agriculture under the State Council shall formulate plans for the supervision and inspection of the safety of agricultural genetically modified organisms and organize their implementation. The administrative departments of agriculture under the local people's governments at or above the county level shall be responsible for the supervision and inspection of the safety of agricultural genetically modified organisms within their respective administrative areas.

Article 22 — When performing their supervision and inspection duties, the supervision and inspection personnel may consult or require the party being inspected to provide relevant materials, and the party being inspected shall provide them in a truthful manner. The supervision and inspection personnel shall keep confidential the trade secrets involved in the inspection.

Chapter VII — Legal Liability

Article 23 — Where research, testing, production, processing, marketing, import, or export of agricultural genetically modified organisms is carried out without approval in violation of the provisions of these Regulations, the administrative department of agriculture under the State Council or the administrative department of agriculture of the province, autonomous region, or municipality directly under the Central Government shall, according to its functions and powers, order the cessation of the illegal act, confiscate the illegally sold products and illegal gains, and impose a fine.

Article 24 — Where an entity, in violation of the provisions of these Regulations, produces or processes agricultural genetically modified organisms without a production or processing permit, the administrative department of agriculture shall order it to cease the illegal act, confiscate the illegal gains, and impose a fine. Where the circumstances are serious, the production or processing permit shall be revoked.

Article 25 — Where agricultural genetically modified organisms are sold without labeling in accordance with the provisions, the administrative department of agriculture under the people's government at or above the county level may, according to its functions and powers, order correction, confiscate the illegally sold products and illegal gains, and may concurrently impose a fine.

Article 26 — Where a safety incident involving agricultural genetically modified organisms occurs, and the entity concerned fails to take measures to eliminate the hazard, report to the relevant department, or cooperate with the investigation, the relevant competent department shall order correction and may impose a fine.

Chapter VIII — Supplementary Provisions

Article 27 — The administrative department of agriculture under the State Council shall be responsible for the interpretation of these Regulations.

Article 28 — These Regulations shall take effect as of the date of promulgation.

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