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Standards

Agricultural Genetically Modified Organisms Safety

Administration Regulation

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Report Highlights:

This is an UNOFFICIAL English translation of the People's Republic of China *Agricultural Genetically Modified Organisms Safety Administration Regulation* and should be used as a guide only. Exporters should carefully discuss regulations and their application with Chinese importers to ensure that their interpretation of the regulation is accurate.

Includes PSD changes: No
Includes Trade Matrix: No
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This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Beijing, People's Republic of China for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Summary

The scope of this regulation specifies the management, production, distribution, and use of genetically modified organisms (GMOs) in agriculture. The regulation requires Safety Certification and labeling for all types of domestic or imported GMOs. Text in the regulation is vague and does not provide direction for several procedural measures. This Regulation will be followed by an Implementation Regulation that should clarify some points. The Agriculture Administrative Department of the State Council has statutory authority over this regulation. This department is comprised from representatives from several of China's ministries.

Agricultural Genetically Modified Organisms Safety Administration Regulation

Chapter One: General

Article 1: This regulation is created to strengthen the administration of Agricultural Genetic Modified Organisms (hereafter referred to as Ag GMOs), to safeguard human health and the safety of animals, plants and microorganisms, to protect the ecological environment, and to promote research on Ag GMO technology.

Article 2: Activities of Ag GMO research, testing, production, processing, marketing and imports/exports are subject to the requirements of this regulation.

Article 3: Ag GMOs in this regulation refer to animals, plants, microorganisms, and products with genetic structures that have been modified by genetic engineering technology for the use of agricultural production or processing. Ag GMOs include:

1. Genetically modified animals, plants (including planting seeds, breeding livestock, poultry and fish fry) and microorganisms.
2. Genetically modified animal products, plant products, and microorganism products.
3. Processed products from genetically modified agricultural products.
4. Planting seeds, breeding livestock, poultry, fish fry, pesticides, veterinary medicines, fertilizer and additives with genetically modified animal, plant, or microbe ingredients.

Ag GMO safety, in this regulation, refers to protecting humans, animals, plants, microorganisms, and the ecological environment from risk or potential danger caused by Ag GMOs.

Article 4: The Agricultural Administrative Department of the State Council shall be responsible for nationwide Ag GMO safety, supervision, and administration. The agricultural administrative departments of local people's governments at and above the county level shall be responsible for Ag GMO safety, supervision, and administration

within their jurisdictions. The health administrative departments of local people's governments at and above the county level are, in accordance with relevant regulations of the Law of the People's Republic of China on Foods and Health, responsible for supervision and administration of GMO food safety within their jurisdictions.

Article 5: The State Council has established an Ag GMOs Joint-Ministry Conference System, consisting of responsible officials from Ministries of Agriculture, Science and Technology, Environmental Protection, Health, MOFTEC, and AQSIQ to research and coordinate major problems regarding Ag GMOs.

Article 6. Ag GMO safety is subject to the Classified Administration and Evaluation System of the state. Ag GMOs are classified into Class I, II, III and IV by the nature of their potential danger to humans, animals, plants, microorganisms, and the ecological environment. Detailed standards of classification have been stipulated by the Agricultural Administrative Department of the State Council.

Article 7: Ag GMOs are subject to the Safety Evaluation System of the state, detailed standards and technical rules have been stipulated by the Agricultural Administrative Department of the State Council.

Article 8: Ag GMOs are subject to the Labeling System of the state. The detailed rules for the Ag GMO categories are to be stipulated, adjusted, and announced by the Agricultural Administrative Department after consultation with other relevant departments of the State Council.

Chapter Two: Research and Testing

Article 9: The Agricultural Administrative Department of the State Council shall strengthen the safety evaluation of Ag GMOs research and testing and set up the Ag GMO Safety Committee to oversee the safety evaluations for Ag GMOs. The GMO Safety Committee shall consist of experts in biological research, production, processing, inspection, quarantine, health, and environmental protection.

Article 10: If needed, the Agricultural Administrative Department of the State Council shall entrust technical testing institutes, with appropriate staff and facilities, to test Ag GMOs.

Article 11: Organizations that are engaged in Ag GMO research and testing shall have appropriate safety facilities and measures to ensure the safety of Ag GMO research and testing, and establish an Ag GMO safety group to oversee the safety of the respective Ag GMO research and testing.

Article 12: Organizations that are engaged in class III and IV Ag GMOs research shall report to the Agricultural Administrative Department of the State Council before initiating research.

Article 13: Ag GMO testing normally includes three stages: medium testing, environmental release, and production testing. Medium testing refers to small-scale tests conducted within a controlled system or under controlled conditions. Environmental release refers to medium-scale tests conducted by taking relevant safety measures under natural conditions. Production testing refers to large-scale tests conducted prior to production and application.

Article 14: After finishing Ag GMO laboratory research, if the testing organization wants to proceed to medium testing, the testing organization shall report to the Agricultural Administrative Department of the State Council.

Article 15. If the testing organization wants to proceed to the next stage of Ag GMO testing, the testing organization shall apply to the Agricultural Administrative Department of the State Council. Only after passing the safety evaluation of the Ag GMO Safety Committee shall the Agricultural Administrative Department of the State Council approve the next stage of testing. The testing organization shall provide the following information in the above mentioned application:

1. The Ag GMOs safety classes and the basis for the determination.
2. The inspection report issued by the technical inspection institute of Ag GMOs.
3. The relevant measures on safety control and prevention.
4. The testing report from the previous stage of testing.

Article 16: After finishing the production testing, the Ag GMO testing organizations can apply to the Agricultural Administrative Department of the State Council for the Ag GMO Safety Certificate. The testing organization shall provide the following information in the above mentioned application:

1. The Ag GMOs safety classes and the basis for the determination.
2. The inspection report issued by the technical inspection institute of Ag GMOs.
3. The production testing summary report.
4. Other materials required by the Agricultural Administrative Department of the State Council.

After receiving the application, the Agricultural Administrative Department of the State Council shall arrange for the Ag GMO Safety Committee to conduct a safety evaluation. Only after passing the safety evaluation shall the Ag GMO Safety Certificate be issued.

Article 17: Before the examination, registration, evaluation, and approval formalities are performed, the Ag GMO Safety Certificate shall be obtained for GM planting seeds, breeding livestock, poultry, or fish fry; and pesticides, veterinary medicines, fertilizers and additives containing GM ingredients, as stipulated in Article 16 of this regulation.

Article 18: Joint-venture or solely foreign-owned organizations engaged in Ag GMO research and testing within the territory of the People's Republic of China shall receive approval from the Agricultural Administrative Department of the State Council.

Chapter Three: Production and Processing

Article 19: Any organization that is engaged in the production of GM planting seeds, breeding livestock, poultry, or fish fry shall get a Production Licence from the Agricultural Administrative Department of the State Council. Persons or organizations that apply for the Production Licence of GM planting seeds, breeding livestock, poultry or fish fry shall meet not only relevant laws and administrative regulations, but also the following requirements:

1. They must get an Ag GMO Safety Certificate and pass variety examination.
2. They must engage in production within a designated area.
3. They must undertake appropriate safety administration and prevention measures.
4. They must meet other conditions of the Agricultural Administrative Department of the State Council.

Article 20: Persons or organizations that are engaged in production of GM planting seeds, breeding livestock, poultry, or fish fry shall keep production records that indicate the place of production, gene, genetic source, and method of genetic modification, as well as the location of GM planting seeds, breeding livestock, poultry, or fish fry.

Article 21. Persons or organizations that are engaged in GMO production and processing shall gain approval from the Agricultural Administrative Departments of the State Council or local agricultural administrative department at the provincial, autonomous region, or municipality level. Details shall be stipulated by the Agricultural Administrative Departments of the State Council.

Article 22: Farmers growing GM plants, feeding GM animals, sellers of seeds, breeders of livestock, poultry, or fish fry shall, in accordance with the requirement in Article 21 of this regulation, go through the approval procedure on behalf of farmers. Approval departments and sellers shall not charge farmers for such approval and procedure handling.

Article 23: Persons or organizations engaged in GMO production and processing shall organize production and processing in accordance with the approved varieties, scope, safety control requirements, and relevant technical standards. Persons or organizations shall regularly report production, processing, safety control, and product location to the local agricultural administrative department.

Article 24: If any genetic safety accident happens during production and processing of GMOs, the producer and processor shall take immediate corrective safety measures and report the situation to the local agricultural administrative department of the same county in which the producer is located.

Article 25: Persons or organizations engaged in transportation and storage of Ag GMOs shall take safety control measures appropriate to the safety class so as to ensure the safe transportation and storage of Ag GMOs.

Chapter Four: Marketing

Article 26: Persons or organizations who market Ag GMO planting seeds, breeding livestock, poultry, or fish fry shall obtain a Marketing Licence from the Agricultural Administrative Department of the State Council. Persons or organizations that apply for the Marketing Licence of GM planting seeds, breeding livestock, poultry, or fish fry shall meet not only relevant laws and administrative regulations, but also the following requirements:

1. They must have special managerial personnel and marketing records.
2. They must undertake appropriate safety administration and prevention measures.
3. They must meet other conditions of the Agricultural Administrative Department of the State Council.

Article 27: Persons or organizations engaged in marketing GM planting seeds, breeding livestock, poultry, or fish fry shall keep marketing records that indicate the place of production, genetic source, storage, transportation, and location of GM planting seeds, breeding livestock, poultry, or fish fry.

Article 28: Ag GMOs listed in the Ag GMO category shall be labeled clearly when sold within the territory of the People's Republic of China. Ag GMOs listed in the Ag GMO category shall be labeled by producers, packers, and individuals. Unlabeled products shall not be sold. Marketing organizations and personnel shall check the goods and their labels when procuring such products. Marketing organizations and personnel shall re-label goods if the original packing is opened.

Article 29: The label shall indicate the name of the GM materials. If there are special restrictions on the sale area, the label shall indicate the area where the product will be sold. The product must be sold within that designated area.

Article 30: The publishing, broadcasting, positioning, and posting of advertisements for Ag GMOs shall be subject to examination and approval by the Agricultural Administrative Department of the State Council.

Chapter Five: Imports and Exports

Article 31. Those who introduce Ag GMOs from outside the People's Republic of China for research and testing shall apply to the Agricultural Administrative Department of the State Council and meet the following requirements:

1. They shall be a qualified applicant that meets all regulations created by the Agricultural Administrative Department of the State Council.
2. The Ag GMOs being introduced shall have undergone the relevant research and testing abroad.
3. They shall have established appropriate safety administration and prevention measures.

Article 32: Any foreign company that exports GM planting seeds, breeding livestock, poultry, fish fry, pesticides, veterinary medicines, fertilizers, and additives containing GM ingredients to the People's Republic of China shall apply to the Agricultural Administrative Department of the State Council. Those who meet the following requirements shall be permitted to bring along testing materials and undergo the medium test, environmental release test, and production test under this regulations by the Agricultural Administrative Department of the State Council:

1. The exporting nation or region must allow use of the products for the same relevant purpose, and sell them in their domestic markets;
2. The exporting nation or region must have verified the products' safety for humans, animals, microorganisms, and the environment through scientific testing;
3. The exporting nation or region must have established appropriate safety administration and measures to prevent problems.

After finishing the production testing and receiving the Safety Certificate, traders can go through normal import formalities such as examination, registration, evaluation, and approval.

Article 33: Exports of Ag GMOs as raw materials for processing to the People's Republic of China shall apply to the Agricultural Administrative Department of the State Council. If exporters meet the following requirements and pass the safety evaluation, exporters can obtain a Safety Certificate issued by the Agricultural Administrative Department of the State Council:

1. The exporting nation or region must allow use of the product for the same relevant purpose, and sell the item in its domestic markets;
2. The exporting nation or region must have verified the products' safety for humans, animals, microorganisms, or the environment through scientific tests;
3. Ag GMO technology examination and testing organizations should confirm that the products indeed will not harm humans, animals, microorganisms, or the environment after examination and testing.
4. They must have established appropriate safety administration and prevention measures.

Article 34: Individuals or foreign companies that introduce or export Ag GMOs to the People's Republic of China shall submit the Agricultural Administrative Department of the State Council Safety Certificate and relevant approval documents to the Entry-Exit Inspection and Quarantine Department at the border. Upon passing inspection, Ag GMOs can go through normal Customs procedures.

Article 35: Ag GMO products in transit through China shall apply, in advance, to the Entry-Exit Inspection and Quarantine Department of the State. Upon receiving approval, transit can continue in accordance with relevant laws and administrative regulations of the People's Republic of China.

Article 36: The Agricultural Administrative Department of the State Council and the State Entry-Exit Inspection and Quarantine Departments shall reach their decision of approval or disapproval and inform the applicant within 270 days from the date of receiving the application.

Article 37: If importers require non-GMO certification for the export of agricultural products to foreign countries, the State Entry-Exit Inspection and Quarantine Departments shall examine and test products and issue certification in accordance with the information given by the Agricultural Administrative Department of the State Council.

Article 38: If GMO products arrive for importation without a Safety Certificate issued by the Agricultural Administrative Department of the State Council and the relevant approval documents, or if the goods do not match the Safety Certificate and approval documents, the goods will be rejected or destroyed. If the label is not in accordance with the labeling requirements, the goods can not enter China until the product is re-labeled.

Chapter Six: Supervision and Inspection

Article 39. When Agricultural Administrative Departments implement supervision and inspection, they have the right to:

1. Question researchers, testers, producers, processors, marketers, importers, exporters, and concerned persons or organizations whose products are being inspected, and require them to provide supporting materials or other materials relating to Ag GMO safety;
2. Consult or copy records, accounts and materials relevant to Ag GMOs research, testing, production, processing, marketing, import, or export;
3. Require relevant persons or organizations to answer questions about Ag GMO safety;
4. Charge persons or organizations who violate Ag GMO safety regulations to stop illegal activities;
5. If urgent, Ag GMOs involved in illegal research, testing, production, processing, marketing, import, or export may be detained or sealed.

Article 40: Agricultural Administrative Departments enforcement officers shall present their credentials when implementing inspection or supervision.

Article 41: Relevant persons or organizations shall support and cooperate with enforcement officers and shall not refuse or hamper the implementation of inspection or supervision.

Article 42. If it is determined that Ag GMOs are dangerous to humans, animals, plants, or the ecological environment, the Agricultural Administrative Department of the State Council has the right to prohibit production, processing, marketing, or the importation of relevant Ag GMOs, to revoke the Ag GMO Safety Certificate, and to destroy the dangerous GMOs.

Chapter Seven: Enforcement

Article 43. Those who conduct research and medium testing of class III and IV Ag GMOs without reporting to the

Agricultural Administrative Department of the State Council shall be charged by the Department to stop the research or medium testing and amend their action within a specified time.

Article 44: Those who conduct environmental release and productive testing without permission or who receive permission but fail to take safety control and prevention measures or conduct testing beyond the permitted scope shall be charged by the Agricultural Administrative Department of the State Council or the agricultural administrative department of the province, autonomous region, or municipality to stop testing and pay a fine of 10,000 RMB to 50,000 RMB.

Article 45: Those who, after finishing the production test, put Ag GMOs into production and use without receiving an Ag GMO Safety Certificate shall be charged by the Agricultural Administrative Department of the State Council to stop production and use and pay a fine of 20,000 RMB to 100,000 RMB.

Article 46: Those who violate Article 18 requirements by conducting research and testing of Ag GMOs without permission by the Agricultural Administrative Department of the State Council shall be charged by the Department to stop their research and testing until approval formalities are completed.

Article 47: Those who produce and process Ag GMOs without permission or whose production and processing are not in compliance with approved varieties, scope, safety control requirement, and technical standard shall be charged by the Agricultural Administrative Department of the State Council or the agricultural administrative department of the province, autonomous region or municipality to stop production or processing. In this case, the products produced or processed illegally and the illegal earnings shall be confiscated. If the illegal earnings exceed 100,000 RMB, the producers or processors shall be charged a fine 1 to 5 times the illegal earnings. If there are no illegal earnings or the illegal earnings are less than 100,000 RMB, the violator shall be charged a fine of 100,000 RMB to 200,000 RMB.

Article 48: Persons and organization engaged in production and marketing of GM planting seeds, breeding animals, poultry, or fish fry, that fail to keep production and marketing records as required, shall be charged by the people's government's agricultural administrative department at or above the county level to amend the error and pay a fine of 1,000 RMB to 10,000 RMB.

Article 49: Sellers of GM planting seeds, breeding animals, poultry, or fish fry, that fail to perform their obligation of handling approval formalities on behalf of farmers or charging farmers for such handling, shall be charged by the Agricultural Administrative Department of the State Council to amend the error and pay a fine no more than 20,000 RMB.

Article 50: Those who import Ag GMOs without permission from the Agricultural Administrative Department of the State Council shall be charged to stop importation. In this case, the imported products and illegal earnings shall be confiscated. If the illegal earnings exceed 100,000 RMB, the violator shall be charged a fine 1 to 5 times the illegal earnings. If there are no illegal earnings or the illegal are less than 100,000 RMB, the violator shall pay a fine of 100,000 RMB to 200,000 RMB.

Article 51: Those who import, carry, or mail Ag GMOs without declaring them to the port Entry-Exit Inspection and Quarantine Department, or whose Ag GMOs transit China without a permit from the Entry-Exit Inspection and Quarantine Department of the State shall be fined by the port Entry-Exit Inspection and Quarantine Department or the

Entry-Exit Inspection and Quarantine Department of the State by reference to the relevant regulations in this Law and the regulations for Entry and Exit Inspection and Quarantine of Animals and Plants.

Article 52: Those who violate the Ag GMO labeling requirement in this regulation shall be charged by the agricultural administrative department of the people's government above the county level to amend the label within a specified period. In this case, the products sold illegally and the illegal earnings may be confiscated, and the violator may be fined 10,000 RMB to 50,000 RMB.

Article 53: If any person or organization forge, falsify, transfer, sell, or buy any supporting certificates of Ag GMOs, the certificates shall be confiscated by the agricultural administrative department of the people's government at or above the county level and be fined 20,000 RMB to 100,000 RMB. If such behavior constitute a crime, the concerned party shall be held liable under criminal responsibility.

Article 54: Those whose failure to abide by this regulation causes a genetic safety accident in the course of Ag GMO research, testing, production, processing, storage, transportation, sale, import, or export shall bear compensatory responsibility.

Article 55: The persons directly responsible for issuing a permit, an Ag GMO Safety Certificate, or other approval documentation that is not in accordance to this regulation or the persons who fail to perform the required supervisory or administrative duty after issuing a permit, Ag GMO Safety Certificate, or other approval documentation shall be punished using administrative disciplinary action. If the behavior constitutes criminal activity, the persons shall bear criminal responsibility as stipulated by law.

Chapter Eight: Appendix

This regulation shall be effective from the date it is published.