

Decreto N° 304/2001 del Consejo de Estado sobre “Reglamento sobre la Administración de la Bioseguridad de OGMs Agrícolas”

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Regulation on the Safety Administration of Agricultural GMOs

Chapter 1. General

Article 1. This regulation is promulgated to strengthen the administration of Agricultural Genetic Modified Organisms (hereafter referred to as Ag GMOs), to safeguard the health of humans 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 their products whose genetic structures have been modified by genetic engineering technology for the use of agricultural production or processing. Ag GMOs mainly 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) Products directly processed 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 and microorganisms and the ecological environment from the danger or potential risk caused by Ag GMOs.

Article 4. The Agricultural Administrative Department of the State Council is responsible for nationwide Ag GMO safety supervision and administration. The agricultural administrative departments of local people’s governments at and above the level of county are responsible for Ag GMO safety supervision and administration within their jurisdictions. The health administrative departments of local people’s governments at and above the level of county 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 GM foods 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 the 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 of which 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 consulting with

other relevant departments of the State Council.

Chapter 2. Research and Testing

Article 9. The Agricultural Administrative Department of the State Council should strengthen the safety evaluation of Ag GMOs research and testing and set up the Ag GMO Safety Committee to be in charge of safety evaluations for Ag GMOs. The GMO Safety Committee consists 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 can entrust technical testing institutes, which have appropriate staff and facilities, to test Ag GMOs.

Article 11. Organizations that are engaged in Ag GMO research and testing should have safety facilities and measures appropriate to the safety class, ensure the safety of Ag GMO research and testing, and establish an Ag GMO safety group to be in charge of the safety of their respective Ag GMO research and testing.

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

Article 13. Ag GMO testing normally includes three stages: medium testing, environmental release and productive testing. Medium testing refers to small-scale tests conducted within controlled system or under controlled conditions. Environmental release refers to middle-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 the Ag GMO research in the laboratory, if the testing organization needs to proceed to medium testing, the testing organization shall report to the Agricultural Administrative Department of the State Council.

Article 15. If they need 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 will the Agricultural Administrative Department of the State Council approve movement to the next stage.

When making the above mentioned application, testing organizations shall provide:

- 1) The safety classes of the Ag GMOs and the basis on which the classes are determined.
- 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 productive testing, Ag GMO testing organizations can apply to the Agricultural Administrative Department of the State Council for the Ag GMO Safety Certificate.

When making the above mentioned application, testing organizations shall provide:

- 1) The safety classes of Ag GMOs and the basis on which the classes are determined.
- 2) The inspection report issued by the technical inspection institute of Ag GMOs.
- 3) The summary report of the productive testing.
- 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 when passing the safety evaluation can the Ag GMO Safety Certificate be issued.

Article 17. Before such normal formalities as examination, registration, evaluation and approval are gone through, the Ag GMO Safety Certificate shall be obtained for GM planting seeds, breeding livestock, poultry and 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 that are engaged in Ag GMO research and testing within the territory of the People's Republic of China should get approval from the Agricultural Administrative Department of the State Council.

Chapter 3. Production and Processing

Article 19. Any organization that is engaged in production of GM planting seeds, breeding livestock, poultry or fish fry must 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 should meet not only relevant laws and administrative regulations, but also the following requirements:

- 1) They must get an Ag GMO Safety Certificate and pass the 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 should keep production records which indicate the place of production, gene, genetic source and method of genetic modification, as well as the whereabouts of the GM planting seeds, breeding livestock, poultry or fish fry.

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

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

Article 23. Persons or organizations that are engaged in GMO production and processing should arrange their production and processing in accordance with approved varieties, scope, safety control requirements and relevant technical standards. They should regularly report their production, processing, safety control and products' whereabouts to their local agricultural administrative department.

Article 24. If any genetic safety accident happens during the production and processing of GMOs, the producer and processor shall immediately take remedial 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 that are engaged in transportation and storage of Ag GMOs should take safety control measures appropriate to the safety class so as to ensure the safety of transportation and storage of Ag GMOs.

Chapter 4. Marketing

Article 26. Persons or organizations who market Ag GMO planting seeds, breeding livestock, poultry and fish fry must obtain a Marketing License from the Agricultural Administrative Department of the State Council.

Persons or organizations that apply for the Marketing License of GM planting seeds, breeding livestock, poultry or fish fry should 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 that are engaged in the marketing of GM planting seeds, breeding livestock, poultry or fish fry should keep marketing records which indicate the place of production, genetic source, storage and transportation as well as the whereabouts of the GM planting seeds, breeding livestock, poultry or fish fry.

Article 28. Ag GMOs that are listed in the Ag GMO category must be clearly labeled when sold within the territory of the People's Republic of China. Ag GMOs that are listed in the Ag GMO category shall be labeled by producers, packers and individuals. Unlabeled products shall not be sold. When procuring such products, marketing organizations and persons should check the goods and their labels. Marketing organizations and persons should re-label the goods for sale if they open the original packing.

Article 29. The label should indicate the name of the GM materials. It should also indicate the area in which the product will be sold if there are special restrictions on the area of sale. The product must be sold within that designated area.

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

Chapter 5. Imports and Exports

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

- 1) They must be a qualified applicant that meets all the regulations promulgated by the agricultural administrative department of the State Council.
- 2) The Ag GMOs being introduced must have undergone the relevant research and testing abroad.
- 3) They must have established appropriate safety administration and prevention measures.

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

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

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

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

- 1) The exporting nations or regions must allow usage of those products for the same relevant purpose, and sell them in their domestic markets;
- 2) Exporting nations or regions must have verified the products' safety for humans, animals, microorganisms and 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. With regard to introduction of Ag GMOs from outside the People's Republic of China or exportation of Ag GMOs to the People's Republic of China, the introducers or foreign companies must submit the Safety Certificate from the Agricultural Administrative Department of the State Council and relevant approval documents to the Entry-Exit Inspection and Quarantine Department at the border. Upon passing inspection, they can go through normal procedures at Customs.

Article 35. Ag GMO products transiting China must apply in advance to Entry-exit Inspection and Quarantine Department of the State. Upon getting approval, such transition can be carried out 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 should make their decision of approval or disapproval within 270 days from the date of receiving the application and inform the applicant.

Article 37. With regard to export of agricultural products to foreign countries, if importers require non-GMO certification, the State Entry-Exit Inspection and Quarantine Departments should examine and test the products and issue such certification according to the information given by the Agricultural Administrative Department of the State Council.

Article 38. With regard to importation of GMO products: if goods arrive without the 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 they are re-labeled.

Chapter 6. Supervision and Inspection

Article 39. When the agricultural administrative departments implement supervision and inspection, they have the right to:

- 1) Question the 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 relating to the Ag GMOs research, testing, production, processing, marketing, import and export;
- 3) Require the concerned persons or organizations to explain the questions about Ag GMO safety;

- 4) Charge the persons or organizations who violate Ag GMO safety regulations to stop their illegal activities;
- 5) If urgent, they may seal or detain the Ag GMOs involved in illegal research, testing, production, processing, marketing, import and export.

Article 40. Enforcers of the agricultural administrative departments should present their credentials when implementing supervision and inspection.

Article 41. Concerned persons or organizations should support and cooperate with enforcers and should not refuse or hamper them when they implement supervision and inspection.

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

Chapter 7. Enforcement

Article 43. Those who conduct the 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 their research or medium test and correct their behaviors within a specific period.

Article 44. Those who conduct environmental release and productive test without being permitted or who get permit but fail to take measures of safety control and prevention 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 the test and pay a fine of RMB 10,000 to 50,000.

Article 45. Those who put Ag GMOs into production and application without getting an Ag GMO Safety Certificate after finishing production test shall be charged by the Agricultural Administrative Department of the State Council to stop production and application and pay a fine of RMB20,000 to 100,000.

Article 46. Those who violate the requirement of Article 18 of this regulation by conducting the research and test of Ag GMOs without being permitted by the Agricultural Administrative Department of the State Council shall be charged by the Department to stop their research and testing until the approval formalies are completed.

Article 47. Those who produce and process Ag GMOs without being permitted or whose production and processing are not in accordance with permitted 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, their products illegally produced or processed and their illegal earnings shall be confiscated. If their illegal earnings exceed RMB100,000, they will be charged to pay a fine 1 to 5 times their illegal earnings. If there are no illegal earnings or illegal earnings are less than RMB100,000, the violator shall be charged to pay a fine of RMB100,000 to 200,000.

Article 48. Persons and organization who are engaged in production and marketing of GM planting seeds, breeding animals, poultry and fish fry, if failing to keep the records on production and marketing as required, shall be charged by the people's government's agricultural administrative department at or above the county level to correct their error and pay a fine of RMB1,000 to 10,000.

Article 49. Sellers of GM planting seeds, breeding animals, poultry and fish fry, if failing 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 correct their error and pay a fine of less than RMB20,000.

Article 50. Those who import Ag GMOs without being permitted by the Agricultural Administrative Department of the State Council shall be charged to stop importation. In this case, the imported products and illegal earnings will

be confiscated. If the illegal earnings exceed RMB100,000, the violator shall be charged to pay a fine 1 to 5 times the illegal earnings. If there are no illegal earnings or illegal earnings are less than RMB100,000, the violator shall pay a fine of RMB100,000 to 200,000.

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 the 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 of this regulation shall be charged by the people's government's agricultural administrative department above the county level to revise the label within specified period. In this case, the products illegally sold and the illegal earnings may be confiscated, and the violator may be fined RMB10,000 to 50,000.

Article 53. If any persons or organizations forge, falsify, transfer, and sell or buy any supporting certificates of Ag GMOs, the certificates shall be confiscated by the people's government's agricultural administrative department at or above the county level and a fine of RMB20,000 to 100,000 shall be imposed. If such behavior constitutes a crime, the concerned party will be held under criminal responsibility.

Article 54. Those whose failure to abide by this regulation causes any genetic safety accident in the course of Ag GMO research, test, production, processing, storage, transportation, sales, import and export shall bear responsibility of compensating for damage caused thereby.

Article 55. If the Agricultural Administrative Department of the State Council or the agricultural administrative department of a province, autonomous region or municipality issues a permit, an Ag GMO Safety Certificate or other approval document not according to this regulation, or fails to perform its duty of supervision and administration after issuing a permit, Ag GMO Safety Certificate or other approval document, the persons directly responsible shall be punished with administrative disciplinary action. If their behavior constitutes criminal activity, they shall bear criminal responsibility as stipulated by law.

Chapter 8. Appendix

This regulation goes into effect from the issuance date.