

Decreto N° 9 de 2001 del MOA sobre “Medidas para la Administración de la Bioseguridad de las Importaciones de OGMs Agrícolas”

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Nota: modificado por Decreto N°38/2004 del MOA y por Aviso N°349/2004 del MOA.

**Decree 9/2002
Measures for the Safety Administration of Ag GMO Imports**

Chapter One: General

Article 1: In order to ensure the safety of Ag GMO imports, these Measures are established in accordance with the Regulations on the Safety Administration of Ag GMOs (hereinafter referred to as "Regulations").

Article 2: These Measures apply to the safety administration for all activities of importing Ag GMOs to the People's Republic of China.

Article 3: The Ag GMO Safety Committee of the State shall be in charge of the safety evaluation of Ag GMO importation. The Ag GMO Safety Administration Office shall be in charge of safety administration of Ag GMO importation.

Article 4: Imported Ag GMOs, for safety purposes, shall be administered under 3 categories in accordance with the Ag GMOs usage, i.e. 1. Testing and Research; 2. Production; 3. Raw Materials.

Chapter Two: Ag GMOs for the Testing and Research

Article 5: If Safety Class I and Safety Class II Ag GMOs are introduced from outside the territory of the People's Republic of China for the purpose of testing and research, the introducer shall apply to the Ag GMO Safety Administration Office and provide the following documents:

- (1) Application documents for qualifications as required by the Ministry of Agriculture;
- (2) Registration Form of Import Safety Administration (see Appendix);
- (3) Certification documents that adequate research has been made on the Ag GMOs introduced from abroad;
- (4) Safety protection measures that the introducer intends to take during the process of introduction.

The Ministry of Agriculture shall grant an Ag GMO import approval document upon passing the examination. The introducer shall provide the approval document to competent authorities and go through relevant procedures.

Article 6: If Safety Class III and Safety Class IV Ag GMOs are introduced from outside the territory of the People's Republic of China for the purpose of testing and research, or if any safety class Ag GMOs are to be introduced for the purpose of medium testing, the introducer shall apply to the Ag GMO Safety Administration Office and provide the following documents:

- (1) Application documents for qualifications as required by the Ministry of Agriculture;
- (2) Registration Form from the Import Safety Administration (see Appendix);
- (3) Certification documents that adequate research has been conducted on the Ag GMOs introduced from abroad;
- (4) Safety protection measures that the introducer intends to take during the process of introduction.

(5) Documents for the relevant stages as specified in the Measures on the Safety Evaluation Administration of Ag GMOs

The Ministry of Agriculture shall grant an Ag GMO import approval document upon completion of the examination. The importer shall provide the approval document to competent authorities and go through the relevant procedures.

Article 7: If Ag GMOs are introduced from outside the territory of the People's Republic of China for the purpose of environmental release and production testing, the introducer shall apply to the Ag GMO Safety Administration Office and provide the following documents:

- (1) Application documents for qualifications as required by the Ministry of Agriculture;
- (2) Registration Form of Import Safety Administration (see Appendix);
- (3) Certification documents that adequate research has been conducted on Ag GMOs introduced from abroad;
- (4) Safety protection measures that the introducer intends to take during the process of introduction.
- (5) Documents for the relevant stages as specified in the Measures on the Safety Evaluation Administration of Ag GMOs

The Ministry of Agriculture shall grant an Ag GMO import approval document upon completion of the examination. The importer shall provide the approval document to competent authorities and go through relevant procedures.

Article 8: If Ag GMOs are introduced from outside the territory of the People's Republic of China for experimental use, the introducer shall apply to the Ministry of Agriculture after each stage of the experimentation, starting with medium testing.

Chapter Three: Ag GMOs for Use in Production

Article 9: Foreign companies that intend to export GM planting seeds, breeding livestock, poultry and fish fry to the People's Republic of China or intend to use GM planting seeds, breeding livestock, poultry, fish fry, pesticides, veterinary medicines, fertilizers and additives made from or containing Ag GMOs in the People's Republic of China shall apply to the Ag GMO Safety Administration Office and provide the following documents:

- (1) Registration Form from the Import Safety Administration (see Appendix);
- (2) Certification documents that the exporting country or region has allowed use of above mentioned products for the same relevant purpose and sells them in its domestic market;
- (3) Documents about the scientific tests by the exporting country or region showing no harm to humans, animals, plants, microorganisms and the environment;
- (4) Safety protection measures that the exporter intends to take during the export process;
- (5) Documents for the relevant stages as specified in the Administration Measures on Ag GMO Safety Evaluation.

Article 10: The above mentioned application shall be made prior to medium testing. Only after approval can the testing materials enter China. Then, the testing materials shall pass the 3 stages of medium testing, environmental release, and production testing and finally enter the application stage for an Ag GMO safety certificate.

After the application for medium testing passes the examination, the Ministry of Agriculture shall issue the Ag GMO import approval document. With this approval document, the foreign company can go through relevant

procedures with the competent authorities. After the applications for environmental release and production testing pass the safety evaluation, the Ministry of Agriculture shall issue the document on examination and approval of Ag GMO safety. With the document on examination and approval the foreign company can go through relevant procedures with the competent authorities. After the application for the safety certificate passes the safety evaluation, the Ministry of Agriculture shall issue the Ag GMO safety certificate. With the Ag GMO safety certificate, the foreign company can go through relevant procedures with competent authorities.

Article 11: Prior to production, the introduced Ag GMOs shall first obtain an Ag GMO safety certificate and then go through the relevant procedures of examination, registration, evaluation and approval under the relevant laws and rules on planting seeds, breeding livestock, poultry, fish fry pesticides, veterinary medicines, fertilizer and additives.

Chapter Four: Ag GMOs for Use as Raw Materials

Article 12: Any foreign company that intends to export Ag GMOs to the People's Republic of China for use as raw materials shall apply for an Ag GMO safety certificate to the Ag GMO Safety Administration Office.

Article 13: When the above mentioned application is made, the following materials shall be provided:

- (1) Registration Form from the Import Safety Administration (see Appendix);
- (2) Safety Evaluation Application (see Appendix V of Measures on the Evaluation Administration of Ag GMOs);
- (3) Certification documents that the exporting country or region has allowed use of above mentioned products for the same relevant purpose and sells them in its domestic market;
- (4) Documents about the scientific tests from the exporting country or region showing no harm to animals, plants or the environment;
- (5) Inspection reports from the technical inspection agency as specified by the Ministry of Agriculture, showing the safety to humans/animals, plants, microorganisms and the environment;
- (6) Safety protection measures that the foreign company intends to take during the export process.

After the safety evaluation is passed, the Ministry of Agriculture shall issue the Ag GMO safety certificate.

Article 14: If those whose application was approved make a subsequent application, the procedure for safety evaluation can be simplified provided that the company and the Ag GMO are the same as the prior application. In this case the following materials are needed:

- (1) Registration Form of Import Safety Administration (see appendix);
- (2) Photocopy of the initial Ag GMO safety certificate issued by the Ministry of Agriculture;
- (3) Safety protection measures that the foreign company intends to take during the export process.

After the examination is approved, the Ministry of Agriculture shall issue the Ag GMO safety certificate.

Article 15: The foreign company shall provide the Ag GMO safety certificate issued by the Ministry of Agriculture and go through relevant procedures with the competent authorities.

Article 16: If the Ag GMOs for the use of raw materials are viable, an import record shall be kept, indicating information about the Ag GMO source, storage, and transportation. In addition, suitable safety control measures shall be taken so that the Ag GMOs do not enter the environment.

Chapter Five: Common Regulation

Article 17: The Ministry of Agriculture shall make a decision of approval or disapproval within 270 days after receiving the application from the applicant and inform the applicant of the decision.

Article 18: Those who import Ag GMOs for the use of production or raw materials shall not sign any contract until the Ag GMO safety certificate issued by the Ministry of Agriculture is obtained.

Article 19: Imported Ag GMOs, without the Ag GMO safety certificate or without relevant approval documents issued by the Agricultural Administrative Department of the State Council or Ag GMOs that do not conform to the certificate or the other documents shall be returned or destroyed.

Article 20: The Ministry of Agriculture shall interpret these Measures.

Article 21: The Measures shall be effective from March 20, 2002.

Appendix: Registration Form of Ag GMO Import Safety Administration

Safety Registration Form for Imported Agricultural Genetically Modified Organisms

General Information on GMO	name			Place of production		
	consignor			consignee		
	Batch number		Article number		Vessel	
	Intended use	1. Research and testing <input type="checkbox"/> 2. Production <input type="checkbox"/> 3. raw material for processing (alive <input type="checkbox"/> not alive <input type="checkbox"/>)				
	Recipient organism	Chinese name			Scientific name	
		Origin or place of origin				
	Target gene	Name			Donor or source	
		Biological function and character				
	Physical state					
	packaging				Manner of storage	
	Safety management measures taken					
	Uses approved by the producing country					
	Approval document of the producing country for the uses			Place of approval		
	Record of failure to obtain approval if any					
General situation of applicant's	country					
	Name of applicant organization					
	Major business activities					
	Communication modes	telephone			Fax	
		e-mail				
Mail address						
Signature of legal representative of the applicant organization	(Signature) (Official seal of the organization)					
Time of application	(Month/ D/ Y)					