

Implementation Regulations on the Safety of Import of Agricultural Genetically Modified Organisms

(Adopted at the 5th Executive Meeting of the Ministry of Agriculture on July 11, 2001, promulgated by Decree No. 9 of the Ministry of Agriculture of the People's Republic of China on January 5, 2002)

Chapter 1 General Provisions

Article 1. These implementation regulations are formulated in accordance with “The Regulations on Safety of Agricultural Genetically Modified Organisms” for the purposes of strengthening the safety administration on imported agricultural genetically modified organisms (hereafter referred to as GMOs).

Article 2. These implementation regulations shall apply to the safety administration of any activity of importing agricultural GMOs and their products into the territories of the People’s Republic of China.

Article 3. The national biosafety committee of Agricultural GMOs is responsible for the safety assessment of imported agricultural GMOs. The office for biosafety administration of agricultural GMOs is responsible for the safety administration of imported agricultural GMOs.

Article 4. To facilitate the safety administration, the imported agricultural GMOs are divided into three groups in accordance with their intended uses: 1) for research and testing, 2) for production and 3) as raw materials for processing.

Chapter 2 Agricultural GMOs for Research and Testing

Article 5. If agricultural GMOs of safety class I or II are planned to be introduced into the People’s Republic of China for research and testing, the introducing institute shall make an application to the office for biosafety administration of agricultural GMOs with the following materials:

- (1) The application qualification documents required by the Ministry of Agriculture;
- (2) The completed safety registration form for imported agricultural GMOs (see the Appendix);
- (3) Documents certifying that related research and testing of the agricultural GMOs in question has been made abroad;
- (4) A plan for safety management measures that the introducing institute intends to take during the process of introduction.

Upon passage of the evaluation, the Ministry of Agriculture shall issue an approval document for the import of the agricultural GMOs, with which the introducing institute shall, in accordance with law, go through the necessary

procedures with relevant departments.

Article 6. If agricultural GMOs of safety class III or IV are planned to be introduced into the People's Republic of China for research, the introducing institute shall make an application to the office for biosafety administration of agricultural GMOs. This provision also applies to the introduction of agricultural GMOs of any safety class into the People's Republic China for the purpose of restricted field-testing. When making the application, the introducing institute shall provide the following materials:

- (1) The application qualification documents required by the Ministry of Agriculture;
- (2) The completed safety registration form for imported agricultural GMOs (see the Appendix);
- (3) Documents certifying that related research and testing of the agricultural GMOs in question has been made abroad;
- (4) A plan for safety management measures that the introducing institute intends to take during the process of introduction.
- (5) Necessary documents for the relevant stages as specified in the Implementation Regulations on Safety Assessment of Agricultural GMOs.

Upon passage of the assessment, the Ministry of Agriculture shall issue an approval document for the import of agricultural GMOs, with which the introducing institute shall, in accordance with law, go through the necessary procedures with relevant departments.

Article 7. If agricultural GMOs are planned to be introduced into the People's Republic of China for enlarged field-testing and/or productive testing, the introducing institute shall make an application to the office for biosafety administration of agricultural GMOs with the following materials:

- (1) The application qualification documents required by the Ministry of Agriculture;
- (2) The completed safety registration form for imported agricultural GMOs (see the Appendix);
- (3) Documents certifying that related research of the agricultural GMOs in question has been made abroad;
- (4) A plan for safety management measures that the introducing institute intends to take during the process of introduction.
- (5) Necessary documents for the relevant stages as specified in the Implementation Regulations on Safety Assessment of Agricultural GMOs.

Upon passage of the evaluation, the Ministry of Agriculture shall issue a safety approval document for the agricultural GMOs, with which the introducing institute shall, in accordance with law, go through the necessary procedures with relevant

departments.

Article 8. If agricultural GMOs are planned to be introduced into The People's Republic of China for testing, the introducing institute shall, starting from the stage of restricted field-testing, make an application to the Ministry of Agriculture for every stage of the testing.

Chapter 3 Agricultural GMOs for Commercial Production

Article 9. Any company outside the territories of China that exports, for the purpose of commercial production and application, to the People's Republic of China genetically modified plant seeds, breeding livestock and poultry, or aquatic fry and seeds shall make an application to the Agricultural GMO safety Administration Office. This provision is also applicable to exporting to China seeds, breeding livestock and poultry, aquatic fry and seeds, pesticides, veterinary medicine and biologics, fertilizers and additives produced by using agricultural GMOs or containing ingredients of agricultural GMOs for the same purposes. When making such an application, the company shall provide the following materials:

- (1) Completed safety registration form for imported of agricultural GMOs;
- (2) Documents issued by the exporting country certifying that the above mentioned products are permitted to be used for the relevant purposes and sold in that country's domestic market.
- (3) Scientific testing data of exporting country or region certifying that the GMO products in question produce no harm to human beings, animals, plants, microorganisms and the environment;
- (4) A plan for safety management measures that the company outside the territories of China plans to take during the process of export;
- (5) Necessary documents for the relevant stages as specified in the Implementation Regulations for Safety Assessment of Agricultural Genetically Modified Organisms.

Article 10. Any company outside the territories of China, when making the aforesaid application, shall submit the application before the start of restricted field-testing. After safety evaluation and approval, the testing materials shall be allowed to enter China and to go through the successive stages of restricted field-testing, enlarged field-testing, productive testing and application for a safety certificate of agricultural GMOs.

After the application for restricted field-testing passes examination, the Ministry of Agriculture shall issue an approval document for the import of the agricultural GMOs,

with which the company can go through the necessary procedures with the relevant departments in accordance with law. After the application for enlarged field-testing or productive testing passes safety evaluation, the Ministry of Agriculture shall issue a safety approval document for the agricultural GMOs, with which the company shall go through the necessary procedures with the relevant departments in accordance with law. With regard to the application for a safety certificate, after passage of safety evaluation, the Ministry of Agriculture shall issue a safety certificate of agricultural GMOs, with which the company shall go through the necessary procedures with the relevant departments in accordance with law.

Article 11. To put the introduced GMOs into commercial production and application, a safety certificate of agricultural GMOs shall be obtained before going through the relevant procedures of examination, registration, evaluation and approval in accordance with the relevant laws and regulations on planting seeds, breeding livestock and poultry, fish fry and seeds, pesticides, veterinary medicine and biologics, fertilizers and additives.

Chapter 4 Agricultural GMOs as Raw Materials for Processing

Article 12. Any company outside the territories of China that exports agricultural GMOs as raw materials for processing shall make an application to the Office for Biosafety Administration of Agricultural GMOs.

Article 13. When making the above application, the company shall provide the following materials:

- (1) The completed safety registration form for imported agricultural GMOs (see the Appendix);
- (2) The completed application form for safety evaluation of agricultural GMOs;
- (3) Documents issued by the exporting country certifying that the above mentioned products are permitted to be used for the relevant purposes and sold in that country's domestic market;
- (4) Scientific testing data of exporting country or region certifying that the GMO products in question produce no harm to human beings, animals, plants, microorganisms and the environment;
- (5) The safety inspection report issued by a technical inspection institute designated by the Ministry of Agriculture, certifying the agricultural GMOs' harmlessness to human beings, animals, plants, microorganisms and the biological environment;
- (6) A plan for safety management measures that the company outside the territories of China plans to take during the process of export.

Upon passage of the safety evaluation, the Ministry of Agriculture shall issue a safety certificate of agricultural GMOs.

Article 14. The application and safety evaluation procedures may be simplified for the company that has previously obtained the approval for exporting the same agricultural GMOs to the People's Republic of China. When applying for repeated export, the same company shall provide the following materials:

- (1) the completed safety registration form for imported agricultural GMOs (see the Appendix);
- (2) A duplicate copy of safety certificate for the same agricultural GMOs previous issued by the Ministry of Agriculture;
- (3) A plan for safety management measures that the company outside the territories of China plans to take during the process of export.

Upon passage of the safety evaluation, the Ministry of Agriculture shall issue a safety certificate of agricultural GMOs.

Article 15. The company outside the territories of China shall, with the safety certificate of agricultural GMOs issued by the Ministry of Agriculture, go through the necessary procedures with the relevant departments in accordance with law.

Article 16. If the imported agricultural GMOs are viable, an import record shall be established, indicating the sources, storage, transportation of such GMOs and other necessary information. Suitable safety control measures shall be taken to ensure that the agricultural GMOs do not enter the environment.

Chapter 5 Basic Provisions

Article 17. The Ministry of Agriculture shall make a decision of approval or disapproval within 270 days after accepting the application and notify the applicant of the decision.

Article 18. Those who import agricultural GMOs for production or as raw materials for processing shall obtain the safety certificate of agricultural GMOs issued by the Ministry of Agriculture before signing the contract.

Article 19. Agricultural GMOs that are imported without a safety certificate of agricultural GMOs issued by the Ministry of Agriculture and the relevant approval documents, or not conforming to the certificate and the relevant approval documents, shall be rejected or destroyed.

Article 20. The Ministry of Agriculture is responsible for the explanation of these

implementation regulations.

Article 21.. These implementation regulations shall enter into force as of March 20, 2002.

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 2. Production 3. raw material for processing (alive not alive)					
	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)					