

Regulations for Approving Import/Export of Transgenic Plant

Promulgated July 7, 2005

Council of Agriculture #0941490342

Article 1

The regulations are established pursuant to the first paragraph of Article 52, Plant Variety and Plant Seed Act (referred as “the Act” hereafter.)

Article 2

Transgenic plants referred to the Art are categorized into two parts based on their intended use:

For propagation or culture use.

For testing or research and development use in laboratories.

Article 3

To import the transgenic plant for propagation or culture use based on Clause 1 Article 2 of the Regulations, the importer shall submit application with following information and documents specified below to the central competent authority. The importer can start the import process only after the import approval is granted.

Required information:

1. Name, phone and address of the importer;
2. The production country, export country and departure port;

Name and quantity of the transgenic plant to be imported; and

Purpose and use of the imported transgenic plant.

Required accompanying documents:

1. The approval documents are pursuant to the second paragraph of Article 52, the Act;
2. Origin of the host plant and information of the host transgenic plant's botanical characteristics, propagation and pollination etc.;
3. Origin of the donor of transgene(s) and information on characteristics and function of the transgene(s);
4. Packaging method and labeling; and
5. Transportation routes, methods and the safeguard measures to be taken during transportation in both the domestic and abroad.

Article 4

To import the transgenic plants for testing or research and development use in laboratories according to Clause 2, Article 2 of the Regulations, the importer should submit application with following information and documents specified below to the central competent authority. The importer can start the import process only after the import approval is granted

Required information:

Name, phone and address of the importer;

The production country, export country and departure port;

Name and quantity of the transgenic plant to be imported; and

Purpose and use of the imported transgenic plant.

Required accompanying documents:

1. Origin of the host plant and information of the host transgenic plant's botanical characteristics, propagation and pollination etc.;
2. Origin of the donor of transgene(s) and information on characteristics and function of the transgene(s);
3. Location and a miniature map of the testing or research and development institution or laboratories;
4. Diagram of facilities and equipments in the testing or research and development institution or laboratories;

Plan of staffing involved in the testing, or research and development;

Organization of a biosafety committee and the list of the committee members;

Biosafety control plan for the transgenic plant imported;

Packaging method and labeling; and

9. Transportation routes, methods and the safeguard measures to be taken during transportation in both the domestic and abroad.

The biosafety committee stated in Clause 6 under Article 4 of the Regulations shall comprise of four to eight members who are experts in biotechnology, crop breeding, biodiversity, plant protection or related fields.

Article 5

To export the transgenic plants, the exporter shall submit application with following information and documents specified below to the central competent authority. The exporter can start the export process only after the export approval is granted.

Required information:

Name, address and phone number of the exporter;

Name and quantity of the transgenic plant to be exported; and

Purpose and use of the exported transgenic plant.

Required accompanying documents:

1. Origin of the host plant and information on the host plant's botanical characteristics, propagation and pollination etc.;
2. Origin of the donor of the transgene(s) and information on characteristics and function of the transgene(s);
3. Packaging method and labeling;
4. Transportation routes, methods and the safeguard measures to be taken during transportation in both the domestic and abroad; and
5. Import approval issued by the import country.

Article 6

In order to verify the nature of imported transgenic plants, the central competent authority shall take samples free of charge from the imported consignments during entrance. The importer of the transgenic plants shall not deny such request.

Article 7

The central competent authority shall grant confidentiality to exporters or importers of transgenic plants who request to the central competent authority for protection of the confidential information about their business

as described important parts in the production method of the transgenic plant.

Article 8

For the approval or rejection of export or import application of transgenic plants, the central competent authority shall make a decision by the following deadlines.

1. For the application case that only implement documents review, the central competent authority shall conclude the application case within 60 days starting from the effective application date. If the central competent authority cannot conclude the application case, the approval or rejection deadline shall be allowed to extend for once and only one time.
2. For an application case that has to sample for verification in addition to documents review, the central competent authority shall conclude the application case within 270 days starting from the effective application date.

Article 9

The central competent authority will announce and publish the format of application forms and other relevant accompanying documents.

Article 10

This Regulations will take into effect from the date it is promulgated.