

Draft of Regulations for Approving Imports of Designated Plant Regulated Articles

(In case of any discrepancy between the Chinese text and the English translation thereof, the Chinese text shall govern.)

Article 1

These Regulations are established pursuant to Paragraph 3 of Article 14 of the Plant Protection and Quarantine Act (hereinafter called “the Act”).

Article 2

To import prohibited plant regulated articles pursuant to Subparagraph 1 of Paragraph 1 of Article 14 (hereafter called “designed plant regulated articles”) of the Act, importers shall submit the application with the following documents or information to the central competent authority for approval:

1. Name, quantity, source, basic information and pest status of designed plant regulated articles to be imported.
2. Plan of use: including purpose, the way to use or related experiment, research, teaching, legal deposit or exhibition plan, post-use treatment and duration for the intended use. If the use of designed plant regulated articles or other regulated article produces, propagates, or isolates from designed plant regulated articles (hereafter refer as derivatives), it must be clearly described in the plan.
3. Post-entry quarantine management program: the address, location of post-entry quarantine site and safety operating procedures to avoid the escape of designed plant regulated articles or their derivatives and pests shall be included;
4. The routes and means of transportation, both domestically and internationally, and packing methods;
5. Other relevant documents and information specified by the central competent authority.

If the required documents or information of preceding paragraph are incomplete, the central competent authority shall issue a notice to request a supplement or correction after a specified time period. If such a supplement or correction is not made or the submitted content remains incomplete after the deadline, the application will not be accepted.

Article 3

If the plant quarantine authority deems necessary, it may dispatch inspectors to perform on-site verification of the post-entry quarantine site as de-noted in Subparagraph 3 of Paragraph 1 of preceding Article to confirm that the post-entry quarantine site and post-entry quarantine management program can avoid the escape of designed plant regulated articles or their derivatives and pests.

If the plant quarantine authority performs on-site verification of the post-entry quarantine site and notifies that the improvement shall be done within a specified time period but is not done, the application will not be approved.

Article 4

After being reviewed and approved by the central competent authority and the import permit is issued, the application item of Article 2 shall be imported in accordance with the permit.

The import permit is valid within six months from the day issued.

If the approved plan of use, post-entry quarantine management program, routes and means of transportation, both domestically and internationally, and/or packing methods or related document or information of the first paragraph is changed, the importer shall submit application with the changed document or information to the central competent authority for approval.

The approved duration of designed plant regulated articles or their derivatives shall not exceed five years. The approved duration of the intended use for legal deposit shall not exceed thirty years.

The importer may apply for approval to the central competent authority to extend the duration thirty days prior to expiration date; every extension shall not exceed five years. Application for extending the duration of exhibitive use may be done three days prior to the expiration date; the extension shall not be longer than the exhibition plan.

To apply for an extension under the preceding paragraph, the operation records and the reports of usage, reason of extension, and follow-up safety quarantine

management program shall be submitted. The plant quarantine authority may, if it deems necessary, dispatch inspectors to conduct an on-site verification.

Article 5

The importers shall import designed plant regulated articles accompanied by the import permit and apply for quarantine inspections to plant quarantine authority.

Article 6

Before sharing the designed plant regulated articles or their derivatives to users during approved usage period, the user shall submit the application with the following documents or information to the central competent authority for approval:

1. Name and quantity of designed plant regulated articles to be shared;
2. Plan of use: including purpose, the way to use or related experiment, research, teaching, legal deposit or exhibition plan, post-use treatment and duration for the intended use. If the use of designed plant regulated articles or their derivatives, it must be clearly described in the plan;
3. The routes and means of domestic transportation and packing methods;
4. Post-entry quarantine management program of the duration for having the shared articles: the address, location, post-entry quarantine site and safety operating procedures to avoid the escape of designed plant regulated articles or their derivatives and pests of the shall be included;
5. Supporting document showing the importer's agreement to share including the name and quantity of the designed plant regulated articles and the copy of the import permit;
6. Other relevant documents and information specified by the central competent authority.

For incomplete documents or information of preceding paragraph and the approval of post-entry quarantine site shall proceed according to the Paragraph 2 of Article 2 and Article 3.

For the application stated in Paragraph 1, after being reviewed and approved by the central competent authority and the sharing permit is issued, the application item shall be shared in accordance with the permit.

The sharing permits valid within six months from the day issued.

If the approved plan of use, post-entry quarantine management program, routes and means of domestic transportation, and packing methods or related documents or information of the permit of the third Paragraph is changed, the user shall submit application with the changed document or information to the central competent authority for approval.

The approved duration of the sharing designed plant regulated articles or their derivatives shall not exceed five years.

The user may apply for approval to the central competent authority to extend the duration thirty days prior to expiration date; every extension shall not exceed five years. Application for extending the duration of exhibitive use may be done three days prior to the expiration date; the extension shall not be longer than the exhibition plan.

To apply for an extension under the preceding paragraph, the operation records and the reports of usage, reason of extension, and follow-up safety quarantine management program shall be submitted. The plant quarantine authority may, if it deems necessary, dispatch inspectors to conduct an on-site inspection.

Article 7

For re-sharing the designed plant regulated articles or their derivatives to other users during the duration period of sharing, the other users shall submit the application with the documents or information in accordance with Subparagraphs 1 to 4 and 6 of Paragraph 1 of preceding article, supporting document showing the user's agreement to share and the copy of sharing permit to the central competent authority for approval and shall proceed according to the process mentioned in Paragraph 4 to 8 of preceding Article.

Article 8

The importer or user shall comply with the following safety control measures after the designed plant regulated articles or their derivatives are approved for import or sharing:

1. The approved designed plant regulated articles or their derivatives shall be sealed by the plant quarantine authority and then escorted by the plant quarantine authority or transported domestically by the importer or user; the importer or user shall provide transportation vehicles or bear the expenses for the transportation.
2. It shall not be opened and used before being checked by the inspector dispatched by the central competent authority of the location being transported to the post-entry quarantine site.
3. It shall be utilized according to the intended purposes in the post-entry quarantine site as approved by the central competent authority and maintenance of the post-entry quarantine site to avoid the escape of designed plant regulated articles or their derivatives and pests from the post-entry quarantine site in accordance with post-entry quarantine management program.
4. During the duration period of intended use, designed plant regulated articles or their derivatives shall be subject to supervision of their use by the plant quarantine authority. Evasion, hindering or denial of such supervision by importer or user is prohibited. During the duration period of intended use, the importer or user shall take appropriate control measures and notify the plant quarantine authority immediately in case any pest is found. The costs associated with such measures shall be borne by importer or user.
5. Operation records shall be made during the duration period of the use of designed plant regulated articles or their derivatives except for the purpose of exhibition. If the duration is less than one year, importer or user shall submit operation records to the plant quarantine authority within thirty days after end of use of designed plant regulated articles or the expiration date. If the duration is more than one year, importer or user shall provide the operation records of the last year to the plant quarantine authority before March 31 each year.
6. Containers, tools, package materials, cultivation media, plants or plant products and other articles used by or in contact with designed plant regulated articles or their derivatives shall be subject to proper treatment or be destroyed after the usage.

7. When re-exporting designed plant regulated articles or their derivatives, it shall conduct jointly with the plant quarantine authority and use a sealed or the package which avoids the escape of the pest in package during transport.

Article 9

During the use of designed plant regulated articles or their derivatives, the plant quarantine authority shall send personnel to inspect the status of post-entry quarantine site, plant growth and the occurrence of pests as follows:

1. For experiment, research, teaching or exhibition purpose: at least once every three months.
2. For legal deposit purpose or other designed purpose by applying from the central competent authority: at least once per year.

Article 10

Upon the expiration date, end of use of designed plant regulated articles or their derivatives, or violation of the safety measures of Article 8 and correction or improvement not done after being noticed by the plant quarantine authority within a time limit, the designed plant regulated articles and their derivatives shall be re-exported or destroyed jointly with plant quarantine authority.

Except for the application for exhibition use, importer or users may apply to central competent authority to lift the re-export or destruction and safety measures of Article 8 thirty days prior to expiration date.

If the risk assessment conducted by central competent authority indicate invasive or pest risk, the application pursuant to the preceding paragraph will not be approved.

Article 11

After the designed plant regulated articles or their derivatives are approved for import or sharing, the reference numbers of the import permit shall be included in the pertinent reports or literary work of importer or user and be kept for more than one year.

Article 12

This Regulations become effective on the date of promulgation.