

Content

Title :	Regulations for Approving Imports of Designated Plant Regulated Articles <b>Ch</b>
Date :	2024.08.26
Legislative :	1.Promulgated on December 12, 1997 2.Amendment to all Articles promulgated on May 18, 2010 3.Amendment to all Articles promulgated on May 25, 2015 4.Amendment to all Articles promulgated on June 29, 2021 5.Amendment to Article 11-1 promulgated on August 26, 2024
Content :	<p><b>Article 1</b></p> <p>These Regulations are established pursuant to Paragraph 3 of Article 14 of the Plant Protection and Quarantine Act (hereinafter referred to as “the Act” ).</p> <p><b>Article 2</b></p> <p>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:</p> <ol style="list-style-type: none"><li>1.Name, quantity, source, basic information and pest status of designed plant regulated articles to be imported;</li><li>2.Plan of experiments, research, teaching, legal deposit or exhibition plan: the purpose, how it is to be used, post-use treatment and duration for the intended use need to be included. If the use of designed plant regulated articles or other regulated articles which are produced, propagated, or isolated from designed plant regulated articles (hereafter referred to as “derivatives” ), it must be clearly described in the plan;</li><li>3.Post-entry Quarantine management program of the duration of its use: 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;</li><li>4.The routes and means of transportation, both domestically and internationally, and packing methods;</li><li>5.Other related documents and information specified by the central competent authority.</li></ol> <p>If the requisite documents or information of the preceding paragraph are incomplete, the central competent authority shall issue a notice to request a supplementation or correction within a specified time period. If such a supplement or correction is not made or the submitted content remains incomplete within the deadline, the application will not be accepted.</p> <p><b>Article 3</b></p> <p>If the plant quarantine authority deems necessary, it may dispatch inspectors to perform on-site verification of the post-entry quarantine site as stated in Subparagraph 3 of Paragraph 1 of the 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.</p> <p>If the plant quarantine authority performs an on-site verification</p>

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 of Paragraph 1 of the preceding Article 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 Paragraph 1 are 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; the extension period shall not exceed five years. Application for extending the duration of exhibit use may be done three days prior to the expiration date; the extension shall not be longer than the approved exhibition plan.

To apply for an extension under the preceding paragraph, the operation records 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 importer shall import the designed plant regulated articles accompanied by the import permit, and apply for quarantine inspections to the 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 or their derivatives 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. For 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. 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 shall be included;
5. Supporting document showing the importer's agreement to share including the name and quantity of the designed plant regulated articles or their derivatives and the number of import permit;
6. Other relevant documents and information specified by the central competent authority.

For incomplete documents or information of the 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 are 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; the extension shall not exceed five years. Application for extending the duration of exhibit use may be done three days prior to the expiration date; the extension shall not be longer than the approved exhibition plan.

To apply for an extension under the preceding paragraph, the operation records 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 7**

For re-sharing the designed plant regulated articles or their derivatives to other users during the duration of sharing, unless other laws or regulations have other requirements, 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 the 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 2 to 8 of the preceding Article.

#### **Article 8**

During the approved duration of intended use, 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 unless being checked by the inspector dispatched by the plant quarantine authority of the location while it is 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 in accordance with post-entry quarantine management plan.
4. During the duration of the use, designed plant regulated articles or their derivatives and post-entry quarantine site shall be subject to supervision by the plant quarantine authority. Evasion, hindering or denial of such supervision by the importer or user is prohibited. During the duration, the importer or user shall

- take appropriate control measures and notify the plant quarantine authority immediately in case escape of designed plant regulated articles or their derivatives or any pest is found. The costs associated with such measures shall be borne by importer or user.
5. Records of operations shall be made during the use of designed plant regulated articles or their derivatives except for the purpose of exhibition. The description for importation, destruction, sharing or usage needs to be included in the records of operations. If the duration is less than one year, importer or user shall submit records of operations 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 of each year and must be kept for three years.
  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 have any risk for escape of designed plant regulated articles or their derivatives or pest 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 be jointly conducted with the plant quarantine authority and use a sealed or the package which prevents the escape of the pest in the 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 usage of designed plant regulated articles or their derivatives and the status of post-entry quarantine site, and whether any escape or occurrence of pests as follows:

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

#### **Article 10**

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

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

If the risk assessment conducted by the central competent authority indicates potential 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 or sharing permit shall be included in the pertinent reports or literary work of importer or user and be kept for more than one year.

**Article 11-1**

The central competent authority may authorize the plant quarantine authority to handle the matters stipulated in Article 2, Article 4, Article 6, Article 7 and Article 10.

**Article 12**

These regulations become effective on the date of promulgation.

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