

**Measures for quarantine supervision and administration of imported and exported
Chinese medicinal materials**

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Chapter I General Provisions

Article 1 These measures are formulated in accordance with the provisions of the law of the people's Republic of China on entry and exit animal and plant quarantine and its implementation regulations and other laws and regulations in order to strengthen the supervision and administration of the quarantine of Chinese medicinal materials entering and leaving the country, prevent the spread of animal and plant epidemics into and out of the country, protect the production of agriculture, forestry, animal husbandry, fishery and human health, and protect ecological security.

Article 2 the term "traditional Chinese medicine" as mentioned in these Measures refers to the raw materials of medicinal plants and animals, which are formed after primary processing after harvesting.

Article 3 these measures are applicable to the quarantine, supervision and administration of imported and exported Chinese medicinal materials declared as medicinal materials.

The inspection, quarantine and supervision and administration of imported and exported Chinese medicinal materials declared for consumption shall be carried out in accordance with the provisions of the General Administration of Customs on imported and exported food.

Article 4 the General Administration of Customs shall be responsible for the unified administration of the quarantine, supervision and administration of imported and exported Chinese medicinal materials throughout the country.

The competent customs is responsible for the quarantine, supervision and administration of imported and exported Chinese herbal medicines in the areas under its jurisdiction.

Article 5 the General Administration of Customs implements the application system for the entry and exit of traditional Chinese medicinal materials. When traditional Chinese medicine materials enter or leave the country, the enterprise shall declare the intended use to the competent customs, specifying "medicinal" or "edible".

Chinese medicinal materials declared as "medicinal" should be listed in the catalogue of medicinal materials in the Pharmacopoeia of the people's Republic of China. Chinese medicinal materials declared as "edible" shall be articles that can be used for food according to national laws, administrative regulations, rules and documents.

Article 6 the General Administration of Customs shall implement risk management on inbound and outbound Chinese medicinal materials; Implement registration management for overseas production, processing and storage units (hereinafter referred to as overseas production enterprises) that export Chinese herbal medicines to China; According to the requirements of the importing country or region, the production, processing and storage units of outbound Chinese medicinal materials (hereinafter referred to as outbound production enterprises) shall be subject to registration management; Implement integrity management for the production and management enterprises of inbound and outbound Chinese medicinal materials.

Article 7 inbound and outbound Chinese herbal medicine enterprises shall engage in production, processing and business activities in accordance with laws, administrative regulations and relevant standards, bear the main responsibility for epidemic prevention, be responsible to the society and the public, ensure the safety of inbound and outbound Chinese herbal medicine, actively accept supervision and bear social responsibility.

Chapter II entry quarantine supervision

Article 8 the General Administration of Customs implements a quarantine access system for imported Chinese medicinal materials, including product risk analysis, evaluation and examination of the regulatory system, determination of quarantine requirements, registration of overseas production enterprises, and entry quarantine.

Article 9 the General Administration of Customs shall conduct product risk analysis and regulatory system assessment on the countries or regions that export Chinese herbal medicines to China for the first time, and conduct a retrospective review on the countries and regions that have already traded.

Based on the results of risk analysis, assessment and examination, the General Administration of Customs shall negotiate with the competent authorities of the exporting country or region to determine the quarantine requirements for the export of Chinese herbal medicines to China, negotiate and sign relevant protocols, and determine the quarantine certificate.

The General Administration of customs is responsible for formulating, adjusting and publishing on the website of the General Administration of customs the list of countries or regions that are allowed to enter the territory of Chinese herbal medicines and the types of products.

Article 10 the General Administration of Customs shall, based on the results of the risk analysis, determine the catalogue of varieties of Chinese medicinal materials that need to be registered by overseas production, processing and storage units, and implement dynamic adjustment. The registration review procedures and technical requirements shall be separately formulated and issued by the General Administration of customs.

The General Administration of Customs shall register the overseas production enterprises of Chinese medicinal materials listed in the catalogue. The registration is valid for 4 years.

Article 11 overseas production enterprises shall meet the requirements of the laws and regulations of the exporting country or region and the mandatory requirements of China's national technical specifications.

Article 12 when applying for registration in China, the competent authorities of the exporting country or region shall examine the overseas production enterprises, and recommend them to the General Administration of Customs after meeting the relevant provisions of Articles 10 and 11 of these measures, and submit the following materials in Chinese or both Chinese and English:

(1) Relevant laws and regulations on animal and plant epidemics, veterinary health, public health, plant protection, enterprise registration management, etc. in the country or region where they are located, and written materials on the institutional setup and personnel of the competent department in the country or region where they are located, as well as the implementation of laws and regulations;

(2) List of overseas production enterprises applying for registration;

(3) The assessment conclusion of the competent department of the country or region where it is located on the actual situation of epidemic prevention and health control of the enterprise it recommends;

(4) A statement that the enterprise recommended by the competent department of the country or region where it is located meets the requirements of Chinese laws and regulations;

(5) Application for enterprise registration, plan of factory, workshop and warehouse, process flow diagram, animal or plant quarantine prevention and control system documents, photos of epidemic prevention and disinfection treatment facilities, photos of harmless treatment facilities of waste and packaging, etc.

Article 13 after receiving the recommendation materials and passing the written examination, the General Administration of Customs may, after consultation with the competent department of the exporting country or region, send personnel to the exporting country or region to evaluate its supervision system and inspect the overseas production enterprises applying for registration.

The applicant enterprises that meet the requirements after inspection shall be registered.

Article 14 for overseas production enterprises that have obtained registration and need to be renewed, the competent department of the exporting country or region shall apply to the General Administration of Customs in accordance with Article 12 of these measures six months before the expiration of the term of validity. The General Administration of Customs may send personnel to the exporting country or region to review its supervision system and inspect the overseas production enterprises that apply for it.

For countries or regions that meet the requirements in the retrospective review, overseas production enterprises that meet the requirements after inspection shall be registered, and the period of validity shall be extended for 4 years.

Article 15 Where the entry of traditional Chinese medicinal materials requires the approval of entry animal and plant quarantine, the owner or his agent shall obtain the entry animal and Plant Quarantine License of the people's Republic of China in accordance with the provisions of the measures for the administration of entry animal and plant quarantine approval before signing the trade contract.

Article 16 the General Administration of Customs may, according to actual needs, send personnel to the exporting country or region for pre inspection with the consent of the competent government departments of the exporting country or region.

Article 17 before or at the time of the entry of traditional Chinese medicinal materials, the owner or his agent shall apply to the Customs at the port of entry for inspection with the following materials:

(1) The quarantine certificate issued by the authorities of the exporting country or region that meets the requirements of the General Administration of customs;

(2) Certificate of origin, trade contract, bill of lading, packing list, invoice.

Article 18 the customs shall examine the relevant documents submitted by the owner or his agent, and accept the inspection application if it meets the requirements.

If there is no valid quarantine certificate issued by the animal and plant quarantine institution of the government of the exporting country or region, registration is required, registration is not handled as required, or quarantine approval procedures are not handled according to law, the customs may return or destroy them according to the specific circumstances.

Article 19 the customs shall implement quarantine of imported Chinese medicinal materials in accordance with the provisions of Chinese laws and regulations and the requirements of national mandatory standards, the requirements listed in the entry animal and Plant Quarantine License, and the quarantine requirements determined in Article 9 of these measures.

Article 20 the Customs at the port of entry shall carry out on-site quarantine in accordance with the following provisions:

(1) Inquire the time of departure and port, countries or regions passing through, loading list, etc., and check whether the documents are true and valid, and whether the documents are consistent with the name, quantity (weight) of the goods, exporting country or region, shipping mark, mark, name of overseas production enterprise, registration number, etc;

(2) Whether the package is in good condition, whether it has animal and plant packaging and bedding materials, and whether it complies with the provisions of the law of the people's Republic of China on entry and exit animal and plant quarantine and its implementation

regulations, and the measures for the supervision and administration of the quarantine of wood packaging of imported goods;

(3) Whether the traditional Chinese medicine has corruption and deterioration, whether it carries pests, animal excreta or other animal tissues, and whether it carries animal carcasses, soil and other prohibited substances.

Article 21 in case of any of the following circumstances during on-site inspection, the customs shall issue a notice of quarantine treatment and carry out corresponding quarantine treatment:

(1) Those that are prohibited from entering the country by laws and regulations, those with prohibited goods, those with inconsistent cargo certificates, and those found to be seriously corrupt and deteriorated shall be returned or destroyed;

(2) If the package is damaged, the owner or his agent shall be responsible for sorting it out completely before unloading it from the means of transport. The customs shall carry out quarantine treatment on the contaminated sites, articles and instruments;

(3) Those with harmful organisms, animal excreta or other animal tissues shall be subject to quarantine treatment in accordance with relevant regulations;

(4) For those polluted by diseases and pests or suspected of being polluted by diseases and pests, the relevant goods shall be sealed up, and the contaminated goods, loading and unloading tools and sites shall be disinfected.

Article 22 If diseases and insect pests or symptoms of diseases and insect pests are found during on-site quarantine, or laboratory quarantine is required according to relevant working procedures, the customs shall sample the imported traditional Chinese medicinal materials and send them to the laboratory.

Article 23 before obtaining the quarantine certificate, traditional Chinese medicinal materials shall be stored in a place approved by the customs. Without the permission of the customs, no unit or individual may transfer, sell or process them without authorization.

The entry animal and Plant Quarantine License states that the product is subject to quarantine and processing supervision by the destination customs, and the port customs will issue an entry goods transfer notice after verification and inspection and disinfection of the outer package. The consignee or his agent will apply for quarantine at the destination customs within the specified time limit. Without quarantine inspection, it shall not be sold or processed.

Imported Chinese medicinal materials that need entry quarantine approval shall be stored and processed in the designated enterprises listed in the quarantine approval permit.

Article 24 imported Chinese medicinal materials can be sold, used, stored or processed in designated enterprises only after they have passed the quarantine inspection and the Customs has issued the inspection and quarantine certificate of Inbound Goods. The inspection and

quarantine certificate of Inbound Goods shall list the name of the goods, country or region of origin, quantity / weight, production batch number / production date, purpose, etc.

Article 25 If the goods fail to pass the quarantine inspection, the customs shall issue a notice of quarantine treatment, and the owner or his agent shall, under the supervision of the customs, carry out disinfection, return or destruction. Those who pass the disinfection and disinfestation treatment are allowed to enter the country.

If it is necessary for the customs to issue a certificate for claim, the customs shall issue the relevant quarantine certificate in accordance with the regulations.

Article 26 the means of transport and containers for transporting imported Chinese herbal medicines shall meet the safety and health requirements. If it is necessary to carry out epidemic prevention and disinfection, it shall be carried out under the supervision of the Customs at the port of entry. Without the permission of the customs, no inbound Chinese herbal medicines may be unloaded from the means of transport, containers or transported.

Article 27 domestic shippers or their agents shall establish a record system for the import, sale and processing of Chinese herbal medicines, and keep relevant records for at least two years. At the same time, it should be equipped with safety management personnel for epidemic prevention of traditional Chinese medicine and establish a management system for epidemic prevention of traditional Chinese medicine.

Chapter III exit quarantine supervision

Article 28 Chinese medicinal materials leaving the country shall comply with the quarantine agreement, protocol, memorandum and other provisions signed between the Chinese government and the importing country or region, as well as the standards or contract requirements of the importing country or region.

Article 29 an outbound production enterprise shall meet the relevant requirements of the laws and regulations of the importing country or region and comply with the relevant laws and regulations of China.

Article 30 exit production enterprises shall establish a sound epidemic prevention system and traceability management system.

Outbound production enterprises shall establish purchase, acceptance records, production and processing records, ex factory inspection records, warehousing records, etc. of raw materials, packaging materials, etc., and record in detail the epidemic prevention management and product traceability throughout the production and processing of outbound traditional Chinese medicinal materials.

The above records shall be true and the retention period shall not be less than 2 years.

The exit production enterprise shall be equipped with quarantine management personnel, and the person responsible for epidemic prevention shall be clearly defined.

Article 31 Where the importing country or region requires the registration of the outbound production enterprises that export traditional Chinese medicinal materials to it, the customs shall implement registration. The registration is valid for 4 years.

Article 32 when applying for registration, an outbound production enterprise shall submit the following materials:

- (1) Application form for Quarantine Registration of enterprises producing Chinese medicinal materials for exit;
- (2) Plan of the plant area, and provide photos or video materials of key areas;
- (3) Product processing technology.

Article 33 The customs directly under the jurisdiction of the locality shall deal with the applications of exit production enterprises respectively according to the following circumstances:

- (1) If the application materials are complete and conform to the legal form, or the applicant submits all the supplementary and corrected application materials as required, the application shall be accepted;
- (2) If there are errors in the application materials that can be corrected on the spot, the applicant shall be allowed to correct them on the spot;
- (3) If the application materials are incomplete or do not conform to the legal form, the applicant shall be informed of all the contents that need to be supplemented and corrected on the spot or within 5 working days at a time. If the applicant fails to inform within the time limit, it shall be accepted from the date of receiving the application materials.

When accepting or rejecting an application, the customs directly under the customs shall issue a written certificate with the special seal of the administrative organ and a date.

Article 34 The customs directly under the central government shall, after accepting the application, form an evaluation team to conduct on-site evaluation of the outbound production enterprises that have submitted the application. The review team shall submit the review report to the customs directly under it in time after the on-site review.

Article 35 The customs directly under the central government shall, within 20 days from the date of accepting the application, make a decision on whether to approve the registration of the applicant's application; If registration is approved, a registration certificate shall be issued.

If the customs directly under the central government is unable to make a decision within 20 days from the date of accepting the application, it may extend the period by 10 days with the approval of the person in charge of the customs directly under the central government, and shall inform the applicant of the reasons for the extension.

Article 36 If the registered outbound production enterprise changes its name, legal representative, product type, storage, production and processing capacity, it shall submit a

written application to the customs directly under it within 30 days after the change, fill in the application form for Quarantine Registration of outbound Chinese herbal medicine production enterprises, and submit materials related to the change.

If the enterprise name or legal representative is changed, the customs directly under the customs shall directly go through the change procedures after reviewing the relevant materials.

If the product type or production capacity is changed, the customs directly under the central government shall review the relevant materials and organize on-site review. After the review is qualified, the change procedures shall be handled.

If an enterprise relocates, it shall re apply to the customs directly under it for registration.

Article 37 Where it is necessary to recommend registration abroad, the customs directly under the General Administration of Customs shall submit the list of outbound production enterprises that have passed the preliminary examination to the General Administration of customs. The General Administration of Customs shall organize the evaluation, uniformly recommend to the competent departments of the importing countries or regions and handle the relevant procedures.

Article 38 the consignors or their agents of Chinese herbal medicines leaving the country shall apply to the customs of the place where the Chinese herbal medicine production enterprise is located for inspection. When applying for inspection, they shall truthfully declare the intended use of the products and submit the following materials:

- (1) Contract, invoice and packing list;
- (2) Factory certificate issued by the manufacturer;
- (3) A written statement that the product meets the animal and plant quarantine requirements of the entering country or region.

Article 39 The Customs shall, in accordance with the provisions of Article 28 of these measures, exercise quarantine supervision over the exit Chinese herbal medicines.

The customs shall issue relevant quarantine certificates in accordance with regulations and allow the exit of Chinese herbal medicines that have passed the quarantine inspection or the disinfection and disinfestation treatment.

Those who fail to pass the quarantine inspection and have no effective methods for disinfection and disinfestation are not allowed to leave the country.

Article 40 the customs may, according to the relevant requirements of the General Administration of customs, implement classified management on the outbound Chinese herbal medicines and production enterprises under its jurisdiction on the basis of risk analysis, in combination with the outbound situation of Chinese herbal medicines, the requirements of importing countries or regions, the management ability and level of production enterprises, the integrity of production enterprises, and risk monitoring and other factors.

Chapter IV Supervision and Administration

Article 41 The Customs shall exercise quarantine supervision over the production, processing and storage of inbound and outbound Chinese medicinal materials.

Article 42 The General Administration of Customs shall monitor the epidemic situation of animal and plant epidemics of imported and exported Chinese medicinal materials.

When the competent customs finds problems in the monitoring, it shall handle and report them in time according to the regulations.

Article 43 the consignors or their agents of imported traditional Chinese medicinal materials and the manufacturers of outbound traditional Chinese medicinal materials shall establish an epidemic information reporting system and an emergency response plan. In case of finding epidemic information, it shall report to the customs in time and actively cooperate with the customs in dealing with the epidemic.

Article 44 The General Administration of Customs shall, based on the obtained risk information and risk analysis, issue a risk early warning information circular and decide to take the following control measures for relevant products:

- (1) Conditionally restrict entry or exit, including strict monitoring and quarantine;
- (2) It is forbidden to enter or leave the country, destroy it on the spot or return it;
- (3) Revoke the registration qualification of the production enterprise;
- (4) Start relevant emergency response plans.

The competent customs is responsible for organizing and implementing risk early warning and control measures.

Article 45 The General Administration of Customs may, with reference to the prevailing international practices, directly issue risk early warning notices for uncertain risks and take the control measures specified in Article 44 of these measures. At the same time, collect and supplement relevant information and data in time for risk analysis.

Article 46 when the epidemic risk of inbound and outbound Chinese herbal medicines has been eliminated or reduced to an acceptable level, the General Administration of Customs shall timely remove the risk early warning notice or risk early warning notice and control measures.

Article 47 the customs shall handle the epidemic situation found in the entry and exit quarantine of Chinese herbal medicines, especially the major epidemic situation, in accordance with the emergency response plan for the major animal and plant epidemic situation at the entry and exit.

Article 48 the customs shall bring the owners or their agents of imported and exported Chinese herbal medicines and domestic and foreign production enterprises under the management of good faith.

Chapter V Legal Liability

Article 49 If the owner or his agent of inbound and outbound Chinese medicinal materials commits one of the following illegal acts, the customs shall punish him in accordance with Article 40 of the animal and plant quarantine law of the people's Republic of China and Article 59 of the regulations for the implementation of the animal and plant quarantine law of the people's Republic of China:

(1) Failing to apply for inspection or go through quarantine examination and approval procedures according to law, or failing to implement the provisions of quarantine examination and approval;

(2) The Chinese medicinal materials applied for inspection are inconsistent with the actual situation.

Article 50 the customs shall punish any of the following illegal acts in accordance with the provisions of Article 60 of the regulations for the implementation of the animal and plant quarantine law of the people's Republic of China:

(1) Unloading or delivering imported Chinese medicinal materials from the means of transport without Customs permission;

(2) Opening or damaging animal and plant quarantine seals or signs without authorization.

Article 51 anyone who commits one of the following illegal acts shall be investigated for criminal responsibility according to law; If the case does not constitute a crime or the circumstances of the crime are obviously minor and do not require criminal punishment according to law, the customs shall punish it in accordance with Article 62 of the regulations for the implementation of the animal and plant quarantine law of the people's Republic of China:

(1) Causing major animal and plant epidemics;

(2) Forging or altering inspection and quarantine documents, seals, marks and seals.

Article 52 any customs staff member who abuses his power in the implementation of quarantine and supervision and administration of inbound and outbound Chinese medicinal materials, deliberately creates difficulties for the parties, engages in malpractices for personal gain, forges inspection and quarantine results, or neglects his duty and delays the issuance of inspection and quarantine certificates shall be given administrative sanctions according to law; If a crime is constituted, criminal responsibility shall be investigated according to law.

Chapter VI supplementary provisions

Article 53 inbound and outbound Chinese medicinal materials involving wild or endangered protected animals and plants shall meet the requirements of relevant laws and regulations of China or relevant countries or regions.

Article 54 the entry and exit of traditional Chinese medicinal materials by international express delivery, mailing and passenger carrying shall comply with the relevant provisions.

Article 55 the quarantine of transit Chinese medicinal materials shall be handled in accordance with the law of the people's Republic of China on the entry and exit animal and plant quarantine and its implementation regulations.

Article 56 The General Administration of customs is responsible for the interpretation of these measures.

Article 57 these Measures shall enter into force as of December 1st, 2015.