USDA United States Department of Agriculture
Foreign Agricultural Service

GAIN Global Agricultural Information Network

Voluntary Report – Voluntary - Public Distribution **Date:** August 22, 2024

Report Number: CH2024-0110

Report Name: Draft Measures for Entry and Exit Medicinal Materials Notified to the WTO

Country: China - People's Republic of

Post: Beijing

Report Category: FAIRS Subject Report, MISC-Commodity, Trade Policy Monitoring, WTO Notifications

Prepared By: FAS China Staff

Approved By: Adam Branson

Report Highlights:

On July 11, 2024, China notified draft Measures for Supervision and Administration of Quarantine for Entry and Exit Medicinal Materials to the World Trade Organization (WTO) under G/SPS/N/CHN/1314. China's SPS Enquiry Point at sps@customs.gov.cn will accept comments until September 9, 2024. This report contains an unofficial translation of the draft measures. Stakeholders should conduct their own review of the measures and provide comments as necessary.

Summary
On July 11, 2024, China notified the draft Measures for Supervision Administration of Quarantine of Entry and Exit Medicinal Materials to the World Trade Organization (WTO) under G/SPS/N/CHN/1314. China's SPS Enquire Point at sps@customs.gov.cn will accept comments until September 9. 2024.

These revised measures will replace the existing Measures for the Supervision and Administration of Quarantine of Entry and Exit Chinese Medicinal Materials, but the implementation date has not been determined. Notable changes include adjusting the scope of medicinal materials to cover those that are included in national drug standards or that have been approved by the regulatory authorities for drugs at the national, provincial, or municipal levels. Additionally, the draft measures add requirements that GACC will conduct risk analysis on countries or regions that resume export of medicinal materials to China after a suspension. The draft measures eliminate the registration validity period of overseas production enterprises, add requirements for overseas production enterprises to comply with the standards of the exporting country or region, remove pre-inspection requirement in the exporting country or region, and streamline the quarantine requirements for entry and exit medicinal materials in transit and by hand carry or mail.

Interested parties are encouraged to review the draft measures and submit comments in due course.

BEGIN UNOFFICIAL TRANSLATION

Measures for the Supervision and Administration of Quarantine of Entry and Exit Medicinal Materials
(Draft for Comments)

Chapter I General Provisions

Article 1 In order to strengthen the supervision and administration of quarantine of entry and exit medicinal materials, prevent animal contagious diseases, parasitic diseases, and plant pests, weeds, and other harmful organisms (hereinafter referred to as "pests and diseases") from spreading into or out of the country, protect the production of agriculture, forestry, animal husbandry and fisheries, as well as human health and ecological safety, these Measures are formulated in accordance with the laws and regulations such as the Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine and its implementation regulations, the Biosecurity Law of the People's Republic of China, and the Customs Law of the People's Republic of China.

Article 2 The term "medicinal materials" used in these Measures refers to the medicinal parts of medicinal plants and animals that have been collected and initially processed.

Medicinal materials should be varieties included in the national drug standards. Varieties not included in the national drug standards should be medicinal materials approved by the drug supervision and administration departments at the national, provincial, autonomous region, or municipal levels.

Article 3 These Measures apply to the supervision and administration of quarantine of entry and exit medicinal materials.

Article 4 The General Administration of Customs uniformly supervises and administers the quarantine of entry and exit medicinal material at the national level.
The competent customs offices are responsible for the supervision and administration of quarantine of entry and exit medicinal materials within their respective jurisdiction.

Article 5 The General Administration of Customs implements risk management for entry and exit medicinal materials, implements registration management of overseas production, processing, and storage facilities (hereinafter referred to as "overseas production enterprises") that export medicinal materials to China, and implements registration management of production, processing, and storage facilities of exit medicinal materials (hereinafter referred to as "exit production enterprises") according to the requirements of the importing country or region.

Article 6 Enterprises engaged in the production, processing and operation of entry and exit medicinal materials shall comply with laws, administrative regulations, and relevant standards, assume the main responsibility for epidemic prevention, be responsible to the society and the public, ensure the safety of entry and exit medicinal materials, actively accept supervision, and assume social responsibility.

Chapter II Entry Quarantine

Article 7 The General Administration of Customs implements quarantine access management for entry medicinal materials, including product risk analysis, regulatory system assessment and review, determination of quarantine requirements, registration of overseas production enterprises, and retrospective reviews.

Article 8 The General Administration of Customs shall conduct risk analysis on medicinal materials that are allowed to enter the country for the first time or resume entry after suspension. Based on the interception of epidemic situations at ports or the dynamics of epidemic situation abroad, a retrospective review can be conducted on varieties of medicinal materials that have been allowed to enter the country, as well as corresponding countries or regions or origin.

Based on the results of risk analysis, assessment and review, the General Administration of Customs may consult with the competent authorities of the exporting country or region to

determine the quarantine requirements and quarantine certificates for medicinal materials exported to China if it is necessary to determine or modify specific quarantine requirements.

The General Administration of Customs is responsible for publishing the list of countries or regions, as well as product types, that are allowed to export medicinal materials to China.

Article 9 The General Administration of Customs implements registration management for overseas production enterprises that export medicinal materials to China. Overseas production enterprises must comply with the relevant laws, regulations, and standards of the exporting country or region, which shall not be lower than the equivalent requirements of relevant laws, regulations, and standards of China.

Overseas production enterprises subject to registration management are recommended to the General Administration of Customs after having been reviewed and approved by the competent authorities of the exporting country or region.

Article 10 After receiving the recommendation materials, the General Administration of Customs reviews and approves the registration of overseas production enterprises in countries or regions that comply with the requirements.

Article 11 When necessary, the General Administration of Customs may conduct a retrospective review on the regulatory system of the exporting country or region and conduct random inspections on overseas production enterprises.

Article 12 Entry medicinal materials subject to approval for entry animal and plant quarantine shall be handled in accordance with relevant provisions on entry animal and plant quarantine approval management.

Article 13 Before or when medicinal materials enter the country, the owner or his agent shall declare to the customs with the following documents:
1) A quarantine certificate issued by the competent authority of the exporting country or region that meets the requirements of the General Administration of Customs
2) A certificate of origin
3) If entry animal and plant quarantine approval is required, a quarantine permit shall be provided.
4) Other materials required by the customs

Article 14 The customs shall review the documents submitted by the owner or his agent and approve them if they comply with the requirements.
If quarantine access is not obtained, registration is required but the owner or his agent fails to do so, there is no valid quarantine certificate issued by the animal and plant quarantine agency of the exporting country or region, or quarantine approval procedures are not carried out in accordance with the law, the goods shall be returned or destroyed.

Article 15 The customs shall implement quarantine on entry medicinal materials in accordance with the requirements of Chinese laws, regulations and mandatory national standards,

requirements specified on the entry animal and plant quarantine permit, and the quarantine requirements determined in Article 8 of these Measures.

Article 16 The Customs shall conduct on-site quarantine according to the following provisions:
1) Whether the goods and documents are consistent.
2) Whether the packaging is intact, whether it contains 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 the Entry and Exit Animal and Plant Quarantine and its implementation regulations as well as the provisions of the supervision and administration measures of quarantine of wood packaging for entry goods.
3) Whether the medicinal materials are corrupt or deteriorated, whether they carry pests and diseases, animal excrement or other animal tissues, or whether there are any animal carcasses, soil, or other prohibited items.
4) Whether it complies with the provisions on product labeling in the quarantine requirements determined in Article 8 of these Measures.
5) Whether it complies with other statutory quarantine requirements.

Article 17 If one of the following circumstances are found during the on-site inspection, the customs shall issue a quarantine treatment notice and notifies the cargo owner or his agent to take the following actions:
1) Goods prohibited from entry by laws and regulations, goods containing prohibited items, goods that do not match the certificates, or goods found to be seriously corrupt or deteriorated shall be returned or destroyed.
2) Goods with damaged packaging shall be repaired by the owner or his agent before unloading from the transport vehicle. Contaminated sites, articles, and equipment shall be quarantined.
3) Goods with pests and diseases, animal excrement, or other animal tissues shall be quarantined in accordance with relevant regulations.
4) Goods contaminated or suspected of being contaminated by pests and diseases shall be sealed and the contaminated goods, loading and unloading tools, and sites shall be disinfected.

Article 18 If pests and diseases or symptoms of pests and diseases are found during on-site quarantine, or if testing and identification are required according to work procedures, the customs shall take samples for testing.

Article 19 Entry medicinal materials will be allowed to enter the country after passing the quarantine inspection.

Article 20 If the goods fail to pass the quarantine inspection, the customs will issue a quarantine treatment notice and notify the owner or his agent to carry out pest eradication, return or destroy the goods. If the goods pass the pest eradication, they will be allowed to enter the country.

Upon requests to issue a claim certificate, the customs shall issue the relevant quarantine certificate in accordance with the regulations.

Article 21 Transport vehicles and containers carrying entry medicinal materials shall comply with safety and sanitation requirements. If disinfection and quarantine treatment is required, it

shall be carried out under the supervision of the customs at the port of entry. The entry medicinal materials shall not be delivered or unloaded from transport vehicles or containers without the permission of the customs.

Article 22 Domestic cargo owners or their agents shall establish a record system for the entry, sale and processing of medicinal materials, and shall keep relevant records for at least three years. At the same time, they shall be equipped with medicinal material epidemic prevention and safety management personnel and shall establish and strictly implement epidemic prevention and management systems for medicinal materials.

Chapter III Exit Quarantine

Article 23 Exit medicinal materials shall comply with the provisions of the quarantine agreements, protocols, and memoranda signed between Chinese government and the importing country or region, as well as standards of the importing country or region or contract requirements.

Article 24 Exit production enterprises shall meet the relevant requirements of the laws and regulations of the importing country or region and comply with relevant Chinese laws and regulations.

Article 25 Exit production enterprises shall establish a comprehensive epidemic prevention system and traceability management system.

Exit production enterprises shall retain records of procurement and acceptance, production and processing, factory inspection, and warehousing which can reflect the epidemic prevention management and product traceability of exit medicinal materials.
The above records shall be true and kept for no less than three years.

Exit production enterprises shall be equipped with quarantine management personnel and clearly designate persons responsible for epidemic prevention.

Article 26 If the importing country or region requires registration of the production enterprises that export medicinal materials to the country or region, the Customs shall implement the registration. The registration is valid for four years.

Article 27 When applying for registration, an exit production enterprise shall submit the following materials:
1) Registration application form
2) Plant layout plan and photos of key areas
3) Product processing technology

Article 28 An exit production enterprise shall apply for registration to the local customs office.

The local customs of the exit production enterprise shall accept the application and conduct material review and on-site assessment. The customs office directly under the General

Administration of Customs shall decide on granting an administrative permit to the enterprise that meets the registration conditions according to law. If the registration conditions are not met, a decision not to grant an administrative permit shall be made in accordance with the law.

Article 29 If a registered exit production enterprise changes its name, legal representative, product type, storage or production and processing capacity, it shall apply to the local customs office within 30 days after the change and submit the application form and relevant information about the change.

In the case of changing the enterprise name or the legal representative, the local customs office shall review the relevant materials and process the procedures after approval by the customs office directly under the General Administration of Customs.
In the case of changing product types, processing technologies, storage or production and processing capacity, the local customs office shall review the relevant materials and conduct on-site inspection and process the procedures after approval by the customs office directly under the General Administration of Customs.

In the case of enterprise relocation, the enterprise shall apply for registration once again at the local customs office.

Article 30 The customs office directly under the General Administration of Customs shall publish a list of registered exit production enterprises. If the customs office is required to recommend an enterprise for overseas registration, the General Administration of Customs will recommend the enterprise to the competent authorities of the importing country or region after review.

Article 31 The owner of exit medicinal materials or his agent shall truthfully declare to the local customs authority where the exit production enterprise is located.

Article 32 The customs shall implement quarantine supervision on exit medicinal materials according to Article 23 of these Measures.

The customs shall issue relevant quarantine certificates and allow the medicinal materials to leave the country if they have passed the quarantine inspection or pest eradication treatment.

Exit medicinal materials are not to allowed to leave the country if they fail to pass the quarantine inspection or there is no effective method for pest eradication.

Article 33 Based on risk analysis, the customs office may implement classified management on the exit medicinal materials and production enterprises within its jurisdiction in accordance with the relevant requirements of the General Administration of Customs, along with the situation of exit medicinal materials within its jurisdiction, the requirements of the importing country or region, the management capacity and level of production enterprises, the integrity of the production enterprises, risk monitoring, etc.

Chapter IV Supervision and Administration

Article 34 The General Administration of Customs implements animal and plant disease monitoring on entry and exit medicinal materials. The competent customs shall timely handle and report any problems found during the monitoring according to regulations.

Article 35 The owner or his agent of the entry medicinal materials and the production enterprise of the medicinal materials shall establish an epidemic information reporting system and emergency response plan. Upon discovering any epidemic information, they shall promptly report to the customs and actively cooperate with the customs in epidemic response.

Article 36 The General Administration of Customs issue risk warning information notices based on the risk analysis and the risk information obtained, and decide to take the following control measures according to the circumstances:
1) Restrict entry or exit under certain conditions, including strict monitoring and tightened quarantine.
2) Prohibit entry or exit, destroy on the spot or return.
3) Order relevant enterprises to rectify and suspend the import or export of relevant medicinal materials during the rectification period.
4) Initiate relevant emergency response plans.
The competent custom is responsible for organizing the implementing risk warning and control measures.

Article 37 By referring to the international practices, the General Administration of Customs may directly issue risk warning notices for uncertain risks and take control measures specified in Article 36 of these Measures according to the circumstances. At the same time, the General Administration of Customs shall collect and supplement relevant information and data for risk analysis.

Article 38 Once the epidemic risk of entry and exit medicinal materials has been eliminated or reduced to an acceptable level, the General Administration of Customs shall promptly lift the risk warning notification or notice and control measures.

Article 39 The customs shall handle the epidemics, especially major ones, found during the quarantine inspection of entry and exit medicinal materials in accordance with the emergency response plan for major entry and exit animal and plant epidemics.

Chapter V Legal Liabilities

Article 40 If the owner or agent of entry or exit medicinal materials commits any of the following illegal acts, the customs shall impose penalties according to Articles 39 and 40 of the Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine and Article 59 of the Implementation Regulations for the Law of the People’s Republic of China on Entry and Exit Animal and Plant Quarantine.
1) Fail to declare, fail to go through quarantine approval procedures in accordance with the law, or fail to implement quarantine approval regulations.
2) The declared medicinal materials are inconsistent with the actual ones.

Article 41 For any of the following illegal acts, the customs shall impose penalties according to Article 60 of the Implementation Regulations of the Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine.
1) Unauthorized unloading of entry medicinal materials from transport vehicles or delivery without the permission of the customs
2) Unauthorized opening or damage of animal and plat quarantine seals or marks of the customs

Article 42 Anyone who commits any of the following illegal acts shall be investigated for criminal responsibility in accordance with the law. If the act does not constitute a crime or the crime obviously minor and does not require a penalty in accordance with the law, the customs shall impose penalties according to Article 62 of the Implementation Regulations of the Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine.
1) Causing major animal and plant epidemics
2) Forging or altering animal and plant quarantine documents, stamps, marks, and seals.

Article 43 For production, processing and storage enterprises registered in accordance with the provisions of these Measures, if their entry or exit medicinal materials fail to pass the quarantine inspection, in addition to being returned, destroyed or treated with pests and diseases eradication in accordance with the relevant provisions of these Measures, the customs may cancel their registration in accordance with the Implementation Regulations of the Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine if the circumstances are serious.

Article 44 Customs officers who abuse their power during quarantine inspection, supervision and management of entry and exit medicinal materials, deliberately make things difficult for the parties involved, engage in malpractice for personal gain, falsify quarantine inspection results, or neglect their duties and delay issuing quarantine certificates will be given administrative sanctions according to law. If a crime is constituted, criminal liability will be investigated according to law.

Chapter VI Supplementary Provisions

Article 45 The entry and exit medicinal materials involving wild or endangered animals and plants shall comply with the relevant laws and regulations of China or relevant countries or regions, as well as the requirements of international conventions to which China has acceded.

Article 46 The quarantine of entry and exit medicinal materials in transit and by hand carry or mail 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, as well as relevant provisions.

Article 47 Products that comply with the provisions of Article 2 of these Measures but are not for medicinal purposes shall not apply to these Measures.

Article 48 The supervision and administration of entry and exit medicinal materials shall be implemented in accordance with relevant requirements.

Article 49 The General Administration of Customs shall be responsible for interpreting these Measures.

Article 50 These Measures shall come into force on xx, 2025. The "Measures for the Supervision and Administration of Quarantine of Entry and Exit Chinese Medicinal Materials" (GACC Decree No. 243) shall be repealed simultaneously. In case of any inconsistency between previous regulations on supervision and administration of quarantine of entry and exit medicinal materials and these Measures, these Measures shall prevail.

END UNOFFICIAL TRANSLATION

Attachments:

No Attachments.