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Report Name: China Simplifies Import Procedures for Food and Drug

Substances as Food Ingredients

Country: China - People's Republic of

Post: Beijing

Report Category: Agricultural Situation, MISC-Commodity, Market Development Reports

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Report Highlights:

On December 3, 2025, China announced a pilot measure that simplifies the customs clearance procedures for 30 substances with both food and medicinal use, including American Ginseng, if they are imported as food ingredients. This report contains an unofficial translation of the announcement and a list of food and drug substances subject to the pilot regulatory system.

On December 3, 2025, China introduced a new regulation concerning imported dual-use substances (food and medicine) through a joint announcement (No. 237 of 2025) issued by the General Administration of Customs of China, the National Health Commission (NHC), the State Administration for Market Regulation (SAMR), and the National Medical Product Administration. The regulation, announced as a pilot program initially covering 30 substances, implements new classification rules for imported dual-use substances that link the regulatory requirements directly to the substance's intended use. The list of 30 substances that are subject to the pilot measure, including American Ginseng, is attached to the announcement.

Under the new classification rules, imported dual-use substances are regulated based on their declared purpose. Specifically, if the substances are imported for medicinal use, importers must still submit an "Imported Drug Clearance Form." However, importers do not need to submit the "Import Drug Clearance Form" when the substances are imported as food ingredients. This change means that when imported as food ingredients, dual-use substances are no longer regulated as medicinal substances. A critical requirement for this new system is that the importer must not change the declared purpose of the food and drug substance after it has been imported into China.

This regulatory shift is expected to benefit the import of substances like American Ginseng, as industry sources report it lowers both the associated costs and expands the type of company who can export the substance. Previously, food importers, regardless of their ultimate use for the substance, had to process imports through a pharmaceutical company. Now, food enterprises are permitted to import the listed substances with both food and medicinal use directly, if they are intended for food processing.

China maintains a list of substances considered to be both food and medicine. American Ginseng, which was formerly classified solely as a medicinal substance in China, was officially approved as a "food and drug substance" by NHC and SAMR effective November 9, 2023 (see USDA GAIN report CH2023-0181).

BEGIN UNOFFICIAL TRANSLATION

Announcement No. 237 of 2025 issued by the General Administration of Customs, the National Health Commission, the State Administration for Market Regulation, and the National Medical Products Administration (Announcement on the Pilot Implementation of Classification Management Measures for Imported Substances With Both Food And Medicinal Use)

December 3, 2025

To continue optimizing the port business environment and support the development of imported substances with both food and medicinal use the General Administration of Customs, the National Health Commission, the State Administration for Market Regulation, and the National Medical Products Administration have decided to pilot classified management of imports for certain food and drug substances. The relevant matters are hereby announced as follows:

- 1. A list-based management system for imported dual-use substances (food and medicine) will be implemented on a pilot basis and dynamically updated. For details, please refer to the "List of Imported Substances with Both Food and Medicinal Use Subject to Pilot Classification Regulation" (see attachment).
- 2. Enterprises must strictly operate in accordance with laws and regulations and in good faith for imported dual-use substances subject to pilot implementation. When handling import customs clearance procedures, they should clearly declare the intended use of the products and bear the responsibility of truthfully declaring them in accordance with the law. For commodities in the "List of Imported Substances With Both Food And Medicinal Use Subject to Pilot Classification Regulation," those declared for pharmaceutical use must submit an "Imported Drug Clearance Form," while those declared for other uses are exempt from submitting an "Imported Drug Clearance Form."
- 3. The General Administration of Customs, the State Administration for Market Regulation, and the National Medical Products Administration shall strengthen supervision over imported dual-use substances within their respective responsibilities in accordance with the relevant requirements for import, operation, and processing of food and drug substances, and urge enterprises to operate in accordance with laws and regulations. Except for substances with both food and medicinal use imported for medicinal purposes that can be used as raw materials for health food, importing enterprises shall not change the purpose of the goods or sell them to enterprises or individuals for purposes other than those declared.
- 4. The General Administration of Customs, the National Health Commission, the State Administration for Market Regulation, and the National Medical Products Administration shall establish an inter-agency mechanism for sharing national food safety standards and regulatory information. Those suspected violations of laws and regulations will be held legally responsible.

This announcement takes effect upon issuance.

Attachment: <u>List of Imported Substances With Both Food And Medicinal Use Subject to Pilot Classification Supervision.docx</u>

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No Attachments.