



ECONOMIC AND TRADE AGREEMENT BETWEEN THE UNITED STATES OF AMERICA AND THE PEOPLE'S REPUBLIC OF CHINA FACT SHEET

AGRICULTURAL BIOTECHNOLOGY

With China's commitment to implement a transparent, predictable, efficient, science- and risk-based system for the review of products of agricultural biotechnology, the Phase One economic and trade agreement signed by the United States and China on January 15, 2020, will result in improvements to China's regulatory authorization process for agricultural biotechnology products. These changes will result in China completing review of an application for products for animal feed or further processing in an average of no more than 24 months. China will also improve the transparency and timeliness of its process and has agreed to work with importers and the U.S. government in situations of low-level presence (LLP) of genetically engineered materials in shipments.

Market Overview: As incomes rise in China, food, feed, and ingredients derived from biotechnology are increasingly required. Demand for imported products derived from biotechnology is growing at a rapid rate. In recent years, China has become the largest single-nation importer of agricultural products derived from biotechnology. However, product approvals languish in China's regulatory system for five to seven years, stymying U.S. farmers and companies' access to tools and technologies needed to respond to 21st century food and agricultural challenges.

Key Achievements:

China has agreed to:

- Operate a transparent, predictable, efficient, and science- and risk-based regulatory system for products derived from agricultural biotechnology;

- Reduce the application review time for products for animal feed or for further processing to no more than 24 months, on average;
- Base safety evaluation procedures on relevant international standards and recommendations of the Codex Alimentarius Commission and the International Plant Protection Convention;
- Pre-screen each application for regulatory review for completeness and inform the applicant of any deficiencies within five business days;
- Accept complaints from applicants concerning the approval procedure and take corrective action upon receipt of a justified complaint;
- When additional, necessary information is needed by the National Biosafety Committee (NBC) to finalize an evaluation, within 20 business days of such a determination, request all information in writing and provide a written explanation of how the requested information would be relevant to the safety assessment of the product's intended use;
- When additional information has been submitted to the NBC, ensure that the NBC meets as soon as possible and as often as necessary to finalize the NBC's review of the application;
- Extend product authorizations to five years;
- Establish and make public a simplified, predictable, efficient, and science- and risk-based safety assessment procedure for the authorization of food ingredients derived from genetically modified microorganisms;
- Accept product applications on an ongoing, year-round basis and begin review upon receipt of the formal application;
- Not request information unnecessary for assessing the safety of the product for its intended use; and
- For products authorized, issue a biosafety certificate within 20 business days of the conclusion of a NBC meeting.
- In the event of a LLP occurrence, China will:

- Without undue delay, inform the importer of the LLP occurrence and any pertinent information that will be required to assist China to decide on the management of the LLP occurrence;
 - Conduct evaluation on inadvertent or technically unavoidable LLP occurrences on a case-by-case basis to minimize trade disruptions;
 - Provide to the United States a summary of any risk or safety assessment that China conducted in association with the LLP occurrence;
 - Ensure that the LLP occurrence is managed without unnecessary delay; and
 - Consider any relevant risk or safety assessment provided and authorization granted by the United States or any foreign country when deciding how to manage the LLP occurrence.
- Work with the United States to strengthen communication on biotechnology regulation, to increase mutual understanding, and to monitor implementation of this agreement.

Additional Information for Exporters:

- For more information, contact USDA's Foreign Agricultural Service at ChinaAgreement@usda.gov.