



USCBC Comment on the Section 301 Investigation of China's Implementation of Commitments under the Phase One Agreement

Office of the United States Trade Representative

Docket Number: USTR-2025-0007

The US-China Business Council (USCBC) welcomes the opportunity to submit comments to the Office of the United States Trade Representative (USTR) regarding the initiation of the Section 301 investigation into China's implementation of the Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China ("Phase One Agreement").

USCBC represents about 270 American companies that do business in China. Our membership includes some of the largest and most iconic American brands, in addition to small- and medium-sized enterprises. Our members represent a wide range of industries and sectors, including agriculture, manufacturing, healthcare, technology, and financial services.

When the Phase One Agreement was signed in 2020, USCBC strongly supported the deal as a necessary mechanism to advance a more balanced and mutually beneficial commercial relationship between the United States and China. We viewed the Agreement's structural commitments — specifically those addressing non-tariff barriers and regulatory standards — as essential for correcting long-standing market distortions and enhancing the ability of US companies to compete in China. However, five years following the Agreement's entry into force, significant gaps in implementation persist. While China has made progress in certain areas, it has not fully met its obligations in several critical sectors, creating continued uncertainty and uneven market access for American companies.

USCBC supports the Administration's efforts to ensure American companies can compete on a level playing field. We believe that addressing outstanding trade obligations is essential to establishing a reciprocal commercial relationship that supports American businesses, farmers, and workers. The comments detailed below outline specific areas where implementation of the Phase One Agreement remains incomplete or inconsistent.

Agricultural Commitments

Agricultural Biotech Approvals Process Not Followed

China has not fully implemented a science-based approval mechanism for biotech products. China is non-compliant with its 24-month review commitment. The average monthly approval timeline for US agricultural biotechnology products within China's queue exceeds 5.5 years (69 months), with two products under evaluation for over 9 years. China remains in breach of its Phase One commitments to operate a science-based, timely, and predictable biotechnology import approval process, including its explicit obligation Annex 16 Article 2 to complete food and feed biotech regulatory reviews within an average of 24 months.

China's regulatory delays function as industrial policy, allowing China to dictate the pace of US seed technology adoption, reduce US farm income and jobs, and undermine US agricultural leadership. China also lacks a clear pathway for gene-edited import approvals, enabling regulatory ambiguity that delays US trait commercialization, suppresses US research and development, erodes competitiveness, and allows Chinese firms to commercialize emerging technologies faster and at lower cost. USCBC urges China to uphold the Phase One Agreement and mitigate China's practice of using regulatory approvals as a mechanism for economic and technological advantage.

Beef Plants Not Registered

Starting in early 2025, China failed to fulfill its Phase One commitment in Annex 4 and Annex 7 to update the registrations for dozens of US beef plants, a process typically renewed every five years. While similar delays initially affected US chicken and pork plants, those registrations have since been updated, leaving approximately 400 US beef establishments ineligible, with more scheduled to expire by year-end.

China's recent practice has effectively halted US beef shipments. China has not offered a clear rationale for these lapses, necessitating increased engagement with General Administration of Customs of China (GACC) to seek to restore market access and prevent future disruptions. USCBC requests expedited processing of these renewals to restore market access in accordance with China's Phase One commitment.

US Dairy Treated Unfairly

China's implementation of common food names and facility list updates remains inconsistent. China reversed a common food name by not recognizing the use of "parmesan," which it had previously indicated was not restricted by the EU-China 100 for 100 Geographical Indications (GI) agreement. This negatively impacts US market access by restricting branding and sales for a previously declared unrestricted term. Delays and uncertainty in these areas have impacted market access and created barriers for US dairy exports. USCBC recommends immediate alignment with the common food names provisions in the Phase One Agreement Annex 2 Article 4 to ensure predictable market access.

The Phase One Agreement also commits China to update the list of US dairy facilities registered as eligible to ship to China within 20 business days after receiving the latest copy of the facilities list from the FDA. While China has updated its facility lists, the pace of these updates has not matched that outlined in the Phase One Agreement, introducing further uncertainty into a \$584 million market. USCBC also requests timely dairy facility registrations in accordance with Annex 2 Article 2.

Avian Influenza Protocol Not Followed

On March 23, 2020, the USDA Animal and Plant Health Inspection Service and GACC signed an agreement to adopt a regionalization policy in the event of a High Path Avian Influenza (HPAI)

outbreak in accordance with Annex 3 Article 2 of the Phase One Agreement. This agreement allows states unaffected by HPAI to remain eligible for poultry trade with China. Following the HPAI outbreak in February 2022, GACC initially lifted bans 90 days post-virus elimination for states like Kentucky and Texas.

While the regionalization provisions were initially followed, recent reinstatements of bans reveal a departure from these protocols, limiting market access for US poultry producers. China stopped honoring the agreement for months after former US Speaker of the House Nancy Pelosi visited Taiwan in 2022, relisting only seven states in 2023. Additionally, in early August of this year, GACC reversed its position and reinstated bans for many states.

Without a reliable application of HPAI protocol, US states that have experienced HPAI outbreaks remain banned indefinitely from the Chinese market. USCBC urges a return to the localized restrictions outlined in Annex 3 Article 2 to prevent indefinite and broad market exclusion.

Ractopamine Study Not Released

As a part of the Phase One Agreement Annex 7 Article 5, China agreed to complete an assessment of the safety of ractopamine. This has not happened. We urge China to conduct a study and publish its findings to determine market access standards for US meat products.

Pesticide Data Cooperation Not Initiated

Technical consultations regarding mutually accepted data (MAD) for pesticide registration have not commenced. Specifically, the Phase One Agreement Annex 1 Article 2 states, “The Parties intend to conduct technical consultations with each other on areas of potential cooperation related to pesticides for agricultural use. These consultations may include discussions of the Parties’ pesticide registration data and pesticide trial data, and discussions on the setting of maximum residue levels.” We urge the Ministry of Agriculture and Rural Affairs to initiate consultations with the USDA/EPA regarding pertaining to pesticide registration in China to facilitate US market access for pesticides.

Intellectual Property Commitments

Implementation of pharmaceutical-related IP provisions remains incomplete. In particular, we encourage full adherence to Chapter 1 Articles 1.10, 1.11, and 1.12, paragraph 2(b) of the Agreement. IP right protection is a primary driver of biopharmaceutical innovation, which is not a zero-sum competition. Facilitating responsible development of biopharmaceutical technologies in China supports affordable healthcare and sustainable innovation globally and reinforces the long-term leadership of US biopharmaceutical companies. We believe that China’s partial fulfillment of its IP commitments contradicts the shared objectives of establishing a fair and reciprocal business environment.

Consideration of Supplemental Data

Supplemental data refers to additional experimental evidence collected after an initial patent application and is used to demonstrate the full effect or benefit of a therapeutic compound. Major economies including the United States, the European Union, and Japan routinely accept supplemental data to meet patentability requirements if the technical effect supported by the supplemental data is credible and plausible.

China currently implements a unique “obtainable” standard for accepting supplemental data, requiring that technical effect demonstrated by supplemental data must be “obtainable” from the original specification. Despite revisions to the Patent Examination Guidelines and judicial interpretations clarifying the ability to consider post-filing supplemental data, both the China

National IP Administration and Chinese courts continue considering the “obtainable” requirement as an additional requirement before the acceptance and consideration of supplemental data. As a result, patent holders have faced rejection of supplemental data, enabling third parties to challenge the validity of American invention patents based on flawed reasoning. In addition, China should provide patent protection for “specific therapeutic methods,” consistent with other major drug markets, including the United States.

We believe this practice is inconsistent with Article 1.10, under which China agreed not to impose additional requirements for supplemental data. China should revise its “obtainable” standard for accepting supplemental data, instead applying the same evidentiary standard used for all other forms of evidence for consideration and acceptance of supplemental data under Article 1.10 of the Agreement. This will help better align China’s approach with the fundamental purposes of supplemental data which are to support conventional patentability requirements based on sufficiency of disclosure and enable applicants to protect their inventions appropriately.

Effective Patent Term Extension

In January 2024, China formally introduced a process to grant Patent Term Extensions (PTEs) for eligible pharmaceutical patents. This is an important step toward fulfilling its commitment under Article 1.12, paragraph 2(b). This provision requires China to align with international best practices, extending the term of a patent covering a “new drug” that is approved for marketing when the effective patent term was unreasonably curtailed due to the unreasonably lengthy marketing approval process.

However, the current process uses an excessively narrow and irrelevant definition of “new drug,” limiting eligibility to pharmaceutical products never approved anywhere globally. We believe this definition contradicts Article 1.12 as it only addresses the regulatory status of a pharmaceutical product in China, irrespective of approval or commercialization elsewhere. This definitional issue has made it harder for high-value American pharmaceutical patents and uses that have already been introduced in other markets but are being launched in China for the first time to qualify for PTEs. This limits the economic reward companies can receive for their innovation in the China market.

In addition, China has declined to grant PTEs that cover any authorized uses if they are approved after the approval of the first use. Under the current framework, China only grants PTEs to the first authorized use, excluding all subsequently authorized uses. This approach is inconsistent with Article 1.12, which requires extending protection to “cover all of the exclusive rights, subject to the same limitations and exceptions, of the patent claims” during the PTE period. Therefore, we believe all authorized uses falling within the scope of the compound patent should be covered by the PTE, as mandated under Article 1.12.

To ensure full implementation of Article 1.12, we urge China to grant PTEs for all eligible products regardless of their prior approval in other jurisdictions or the timing of specific authorized uses.

Effective Mechanism for Early Resolution of Patent Disputes

While China has made progress in establishing its early patent dispute resolution mechanism, the current mechanism only includes specific patent categories. We request the inclusion of all applicable patents, including polymorphs and biologics, to fully satisfy Article 1.11 of the Phase One Agreement.

Financial Services Commitments

Electronic Payment Services

China has not fully implemented its commitments in the Phase One Agreement for Electronic Payment Services (EPS). In the Agreement, China committed to accept and make a determination on any application for a Bank Card Clearing Institution (BCCI) license from a US EPS supplier — including any license application of Mastercard, Visa, or American Express, within prescribed time limits and without regard for the applicant’s ownership structure. Full implementation would allow US EPS suppliers to compete in China’s domestic market on equal terms with Chinese [and other US and foreign] companies.

Five years following entry into force, only two US EPS suppliers have secured a BCCI license, while the license application of a third supplier has been pending since 2020. We encourage the administration to prioritize implementation of China’s Article 4.4 commitments, which reflect nearly 25 years of effort to ensure American companies receive fair and reciprocal market access in China.

Conclusion

The Phase One Agreement remains a foundational framework for the US-China commercial relationship. While the Agreement established crucial commitments intended to correct market distortions, the implementation gaps continue to hinder the fair and reciprocal market access originally envisioned.

USCBC believes that resolving these outstanding issues in agriculture, intellectual property, and financial services is imperative for ensuring a level playing field for American companies, farmers and workers. We support the Administration’s efforts to address these outstanding matters through the Section 301 investigation and encourage a targeted approach that addresses specific non-tariff trade barriers and boosts US global competitiveness.

We look forward to working with USTR to advance these priorities and secure concrete outcomes under the Agreement.