



# Trade Facts

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## **Reform Agenda with Japan Yields Results; Important Work Remains**

The United States remains actively engaged with Japan on a broad agenda of regulatory and related reforms to further open Japan's market and help spur greater economic growth and competition through new commercial opportunities and improvements to Japan's business environment.

The focal point for this intensive engagement has been the U.S.-Japan Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative), launched in mid-2001 and now in its eighth year.

A broad array of results has been realized to date through this Initiative, although more work on new and existing issues also remains to be done. The United States and Japan completed the latest round of talks under the Initiative in Tokyo in mid-December 2008.

Work has focused in several key business sectors – including telecommunications, information technologies, and medical devices/pharmaceuticals – as well across a number of cross-cutting issues ranging from regulatory transparency to competition policy. The Regulatory Reform Initiative's comprehensive scope, combined with regular engagement at both working and senior levels, has provided a flexible mechanism to resolve issues, as well as to raise and address new ones as they emerge.

Both Governments exchange recommendations annually each fall and, followed by several months of engagement at working and senior levels, report detailed results in the Initiative's Annual Report to the Leaders.

### **Progress Highlights: U.S.-Japan Regulatory Reform Initiative (2001-present)**

The following summarizes some of the many measures taken by Japan to date under this Initiative:

**Telecommunications.** Eliminated burdensome licensing and notification requirements for firms competing with Japan's large incumbent carrier. Promoted competition by allowing fixed line carriers the right to set retail charges for their customers' calls to mobile networks; introducing mobile number portability to make it easier for consumers to change their mobile carrier; and allowing consumer choices in rate-setting for calls connecting to mobile networks from fixed line phones. Gave priority to new market entrants when allocating new spectrum band for mobile services. Reduced fees charged to consumers for access to incumbent carrier fixed networks.

**Medical and Health-related Industries.** Introduced measures to help reduce Japan's long regulatory approval lag for pharmaceuticals and medical devices, such as creating a new regulatory agency with increased staffing to speed the review process. Improved transparency in Japan's price revision process and continued a commitment to biennial, instead of annual, reimbursement reviews for innovative drugs and devices. Improved government-stakeholder communication to tackle issues necessary to ensure Japanese patients can access the most innovative pharmaceuticals and medical devices, including on a new vision for long-term pricing reform for drugs and new reimbursement approaches for certain highly advanced medical imaging technologies. Adopted measures to improve Japan's clinical trial environment for drugs.

**Transparency and Business Environment Issues.** Established a more meaningful regulatory public comment process and increased information on e-Government websites by posting public comment opportunities and summaries of government policies and administrative procedures. Established a program to translate 200 laws and regulations into English. Promoted the Special Zones for Regulatory Reform system as incubators to test new regulatory approaches, including allowing foreign and domestic companies alike to apply for approval.

**Distribution.** Streamlined customs clearance procedures, including the elimination of customs overtime service charges; the reduction of other customs processing fees; and allowance for authorized customs brokers to file separately for cargo release declarations and for duties/taxes. Simplified vehicle owner information checks and steps to ease registration procedures for transfers of large vehicle fleets. Introduced a new online "One-Stop Service" for motor vehicle registration. Began holding Japan Post Service to similar regulatory treatment of its air/sea/road transportation fleet as that required of private carriers.

**Financial Services/Insurance.** Fully liberalized sales of insurance products through banks, and opened the way for sales of private sector insurance and other financial products through the post office network. Improving the playing field for a more sound banking and insurance market through actions to regulate postal banking and postal insurance business on the same basis as other licensed financial institutions, and to bring under central government supervision previously unregulated insurance cooperatives. Implemented some measures to improve financial regulatory transparency and to modify information sharing restrictions for financial firms.

**Information Technologies (IT).** Approved the World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty, which protects performances and sound recordings in the online environment. Prohibited recording of movies in movie theaters and stiffened related penalties against copyright violators. Promoted health IT systems interoperability and expanded use of these systems, including through the introduction of reimbursement incentives. Improved transparency and communication with stakeholders in areas like government IT procurement.

**Agriculture.** Streamlined pest quarantine procedures that eased market access to Japan for certain U.S. horticultural products. Approved the use of several food additives already widely accepted throughout the world.

**Competition Policy.** Strengthened deterrence of Antimonopoly Law violations by substantially increasing surcharges and criminal penalties against cartels, giving new criminal investigation powers to the Japan Fair Trade Commission (JFTC), and introducing a leniency program for whistle blowing cartel participants, while ensuring JFTC's independent agency status. Improved JFTC procedural due process. Introduced substantial new measures to deter bid rigging, including increased administrative penalties and leniency programs for whistleblowers, expansion of open bidding, and new laws aimed at preventing government-assisted bid rigging.

**Commercial Law and Legal Services.** Expanded opportunities for cross-border M&A by reducing restrictions on the types of equities companies can issue, permitting cross-border triangular mergers using foreign shares with tax deferral permitted under certain conditions, and introducing measures to ensure anti-takeover measures are not adopted to protect entrenched management. Improved corporate governance by enacting legislation allowing companies to adopt an executive committee board structure with outside directors, strengthening duties of fund managers in exercising proxy votes, and introducing stock exchange requirements and codes of conduct aimed at improving shareholder value. Allowed foreign lawyers to employ or enter into partnership arrangements with Japanese lawyers.

### **Looking Forward:**

The United States submits recommendations to Japan on an annual basis to raise new or continuing issues of concern. The following is a summary of recommendations made to Japan in October 2008 that are currently under discussion between our Governments (a detailed list of the U.S. Government's recommendations to Japan is available at [www.ustr.gov](http://www.ustr.gov)).

**Telecommunications.** Introduce steps to ensure technology decisions are market-based, including technology-neutral licensing regimes. Implement measures to strengthen competitive safeguards on dominant telecommunication carriers. Establish an improved regulatory framework for converged and Internet-enabled services.

**Medical and Health-related Industries.** Take measures to ensure Japan's policies appropriately support the availability of innovative pharmaceuticals and medical devices for Japanese patients. Increase the number of medical device reviewers and make other improvements to the regulatory environment to eliminate the lag in approval of new medicines and medical devices. Allow for simultaneous global development of pharmaceuticals. Improve the regulatory environment for nutritional supplements and cosmetics/quasi-drugs.

**Transparency and Business Environment Issues.** Create new rules to provide predictable access to government advisory groups. Make further improvements to public comment procedures. Ensure transparency in the Japanese Government's interpretation of regulations.

**Distribution.** Ensure equivalent treatment and a level playing field between private sector express carrier services and Japan Post's international express mail service. Reduce airport landing and user fees and promote transparency in the development of these fees. Institute new streamlining measures to promote more efficient import/export processing.

**Financial Services/Insurance.** Modernize Japan's credit information system and make improvements to its defined contribution pension system. Further improve the regulatory inspection process. Ensure that postal insurance and postal banking services are held to strict global best practices for regulation and that equivalent conditions of competition are achieved before expansions in these services are permitted in competition with other market participants.

**Information Technologies (IT).** Further promote healthcare IT and facilitate non-bank payment services for electronic payments. Further improve transparency in government IT procurement. Strengthen copyright enforcement, harmonize Japan's intellectual property rights protection regime with international best practices, and streamline patent procedures.

**Agriculture.** Implement enforcement measures that are the least trade restrictive possible in Japan's import regime for maximum residue levels. Comply with CODEX international standards for organic crop imports and in testing regimes for pre- and post-harvest pesticides.

**Competition Policy.** Improve Antimonopoly Law compliance and deterrence, including through strengthened Japan Fair Trade Commission (JFTC) economic analysis capabilities, while further enhancing due process and transparency in JFTC procedures. Introduce additional measures to stamp out bid rigging.

**Commercial Law and Legal Services.** Expand measures to facilitate cross-border merger and acquisition transactions and corporate reorganizations, including through predictable and appropriate tax deferral rules. Take additional steps to enhance corporate governance. Allow foreign law firms to establish multiple offices in Japan, and ensure no impediments exist for Japanese lawyers to join international partnerships outside of Japan.