

JAPAN

TRADE SUMMARY

U.S. goods exports in 2014 were \$67.0 billion, up 2.7 percent from the previous year. Japan is currently the fourth largest export market for U.S. goods. Corresponding U.S. imports from Japan were \$133.9 billion, down 3.3 percent. The U.S. goods trade deficit with Japan was \$67.0 billion in 2014, a decrease of \$6.4 billion from 2013.

U.S. exports of services to Japan were \$46.3 billion in 2013 (latest data available), and U.S. imports were \$30.0 billion. Sales of services in Japan by majority U.S.-owned affiliates were \$77.6 billion in 2012 (latest data available), while sales of services in the United States by majority Japan-owned firms were \$107.6 billion.

The stock of U.S. foreign direct investment (FDI) in Japan was \$123.2 billion in 2013 (latest data available), down from \$125.3 billion in 2012. U.S. FDI in Japan is led by the finance/insurance, manufacturing, and wholesale trade sectors.

Overview

Japan is a participant in the Trans-Pacific Partnership (TPP) negotiations, through which the United States and 11 other Asia-Pacific partners are working to establish a comprehensive, high-standard, next-generation regional agreement to liberalize trade and investment in the Asia-Pacific. Once concluded this agreement will advance U.S. economic interests with some of the fastest-growing economies in the world; expand U.S. exports, which are critical to the creation and retention of jobs in the United States; set high standards for regional trade and investment that promote U.S. interests and values; and serve as a potential platform for economic integration across the Asia-Pacific region. The United States is proposing to include in the TPP agreement ambitious commitments on goods, services, and other traditional trade and investment matters, and enforceable labor and environment obligations. TPP will also address a range of new and emerging issues of concern to U.S. businesses, workers and other stakeholders in the 21st century. In addition to the United States and Japan, the TPP negotiating partners currently include Australia, Brunei, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam.

In addition to the TPP negotiations, the United States also will continue to address trade-related concerns and issues with Japan through bilateral, as well as other fora.

TECHNICAL BARRIERS TO TRADE / SANITARY AND PHYTOSANITARY BARRIERS

Sanitary and Phytosanitary Barriers

Food Safety

Beef and Beef Products

In December 2003, Japan banned U.S. beef and beef products following the detection of an animal positive for bovine spongiform encephalopathy (BSE) in the United States. Following partial market re-openings in July 2006 and February 2013, the United States is currently eligible to export beef, beef offal, and ground beef from cattle less than 30 months of age. Processed beef products from cattle less than 30 months of age and all products from animals 30 months of age and older remain banned.

U.S. beef exports to Japan have grown significantly since the 2013 market access expansion, reaching \$1.58 billion in 2014. The United States continues to urge Japan to fully open its market, including for products from animals of all ages, consistent with OIE guidelines.

Food Additives

Japan's regulation of food additives has restricted imports of several U.S. food products, especially processed foods. Many additives that are widely-used in the United States and other markets are not permitted in Japan. In addition, U.S. manufacturers have raised concerns about the length of Japan's approval process for indirect food additives (*i.e.*, additives that do not remain in food when consumed, such as solvents).

In 2002, Japan created a list of 46 food additives that would be subject to an expedited approval process. All have been approved, with the exception of four, which the United States understands that Japan is currently reviewing. The United States has urged Japan to complete the reviews and to develop a meaningfully expedited process for reviewing all future requests for food additive approvals.

Gelatin and Collagen

Japan banned the importation of U.S. ruminant-origin gelatin and collagen for human consumption (along with the importation of most other ruminant origin tissues from the United States) following the detection of a BSE-positive animal in the United States in December 2003. In November 2014, Japan revised domestic regulations to allow importation of pharmaceutical grade gelatin from cattle bones. On January 8, 2015, Japan notified the WTO of proposed revisions to regulations on imported ruminant-origin gelatin and collagen for human consumption as well as ruminant-origin bone chips for the production of gelatin and collagen for human consumption. The United States will continue to work with Japan to re-open the Japanese market for U.S. ruminant-origin gelatin, collagen, and bone chips consistent with science and OIE guidelines.

Pre- and Post-Harvest Fungicides

Japan classifies fungicides that are applied pre-harvest as pesticides, and fungicides that are applied post-harvest as food additives; each designation requires a separate review. As a result, registrants of fungicides that may be used both pre- and post-harvest must ensure that two reviews are performed, a process that is redundant and that can take as long as six years to complete. The lengthy review process for post-harvest fungicides deters registrants from pursuing approval for new and safe products. Japan's requirement that post-harvest fungicides be classified as food additives does not have a significant impact on domestic producers, as Japanese farmers do not generally apply fungicides after harvest.

The United States is requesting that Japan streamline the review process for agricultural chemicals, including fungicides, applied both as pesticides (pre-harvest application) and as food additives (post-harvest application). The United States remains concerned that Japan requires products treated with a post-harvest fungicide to be labeled at the point of sale with a statement indicating that they have been so treated. This unnecessary labeling requirement dampens demand for the products.

Maximum Residue Limits

Prior to 2013, Japan refused to accept an application for an import tolerance for a pesticide or fungicide until the agrochemical was approved for use in a major supplier country. This policy caused a significant time lag between U.S. approval of a chemical and Japan's establishment of an import tolerance for that chemical substance. Starting in mid-May 2013, however, Japan began accepting an import tolerance

application for a pesticide or fungicide regardless of whether a maximum residue limit (MRL) for that pesticide or fungicide has been set in the application source country (as long as that country's core risk assessment has been completed). With this change in policy, agrochemical companies submitting registration applications with the U.S. EPA may apply simultaneously for establishment of import tolerances in Japan, moving forward the time of approval by up to 12 months when compared to the previous process.

In July 2009, the United States and Japan concluded a memorandum of understanding (MOU) on MRLs that changed the way in which Japan handles MRL violations. Pursuant to the MOU, Japan established a mechanism under its import and food monitoring policy for shippers to address violations quickly. While there has been improvement in how Japan handles MRL violations, the United States remains concerned that Japan's procedures still require industry-wide enhanced surveillance of shipments of a product after a single violation by a single shipper.

Plant Health

Fresh and Chipping Potatoes

Starting in 2006, Japan has agreed to allow an expanding scope of imports of U.S. fresh potatoes for the production of potato chips. Currently, potatoes are eligible for importation from 16 states, and shipments may be made over six months (February to July). These shipments may be made to two chipping facilities in Japan. However, because Japan restricts overland transportation of U.S. potatoes, trans-shipments to one facility, in the Kagoshima Port area, cause additional costs, delay, and risk of quality of deterioration.

IMPORT POLICIES

Rice Import System

Japan's highly regulated and nontransparent importation and distribution system for imported rice limits meaningful access to Japan's consumers. Japan has established a tariff-rate quota (TRQ) of approximately 682,000 metric tons (milled basis) for imported rice. The Staple Food Department of the Ministry of Agriculture, Forestry and Fisheries (MAFF) manages imports of rice within the TRQ through periodic ordinary minimum access (OMA) tenders and through simultaneous buy-sell tenders. Imports of U.S. rice under the OMA tenders are destined almost exclusively for government stocks. MAFF releases these stocks exclusively for non-table rice uses, such as industrial food processing or feed sector and for re-export as food aid. U.S. rice exports to Japan in 2014 were valued at over \$271 million, totaling 287,689 metric tons. Only a small amount of this rice reaches Japanese consumers identified as U.S. rice, despite industry research showing Japanese consumers would buy U.S. high quality rice if it were more readily available. The United States continues to monitor Japan's rice imports in light of its WTO import commitments.

Wheat Import System

Japan requires wheat to be imported through the Grain Trade and Operations Division of MAFF's Crop Production Department, which then resells the wheat to Japanese flour millers at prices substantially above import prices. These high prices discourage wheat consumption by increasing the cost of wheat-based foods in Japan. In 2007, MAFF revised its wheat import regime to allow more frequent adjustment to the resale price so that prices more closely reflect international price movements. The United States continues to carefully monitor the operation of Japan's state trading entity for wheat and its potential to distort trade.

Pork Import Regime

Japan is the largest export market for U.S. pork and pork products on a value basis, with shipments valued at nearly \$1.93 billion (468,719 metric tons) in 2014, accounting for nearly one-third of the value of total U.S. shipments to all destinations in that year. The import tariff for chilled and frozen pork is established by a gate price system that applies a 4.3 percent *ad valorem* tariff when the import value is greater than or equal to the administratively established reference price. When the value of imports falls below the reference price, the importer pays an additional specific duty equal to the difference between the import value and the reference price.

Beef Safeguard

In 2014, Japan remained the largest export market for U.S. beef and beef products on both a value and volume basis. Shipments to Japan were valued at \$1.58 billion, totaling 241,128 metric tons. In 1995, as part of the results of the Uruguay Round, Japan was allowed to institute a beef special safeguard (SSG) to protect domestic producers in the event of an import surge. The SSG is triggered when the import volume of beef increases by more than 17 percent from the level of the previous Japanese fiscal year on a cumulative quarterly basis. When triggered, beef tariffs rise to 50 percent from 38.5 percent for the rest of the Japanese fiscal year. Although U.S. exports have increased significantly since further market opening at the start of 2013, the safeguard has not been triggered.

Fish and Seafood Products

Total U.S. fish and seafood exports to Japan in 2014 were valued at \$772 million, a 6 percent increase over 2013. Tariffs on several fish and seafood products remain an impediment to U.S. exports and also pose an impediment for importers who rely on U.S. raw product for their processing operations. Other market access issues include Japan's import quotas on Alaska pollock, cod, Pacific whiting, mackerel, sardines, squid, and Pacific herring, as well as on specific products such as pollock roe, cod roe, and surimi. Although Japan has reduced tariffs, increased import quota volumes, and eased the administrative burdens associated with those quotas, the import quotas impede U.S. exports. The United States is urging Japan to continue to eliminate tariffs on, and remove nontariff obstacles to, U.S. exports of fish and seafood.

High Tariffs on Beef, Citrus, Dairy, Processed Food, and Other Agricultural Products

Japan maintains high tariffs that hinder U.S. exports of agricultural and other food products, including grains, sugar, pork, red meat, citrus, wine, dairy, and a variety of processed foods. Examples of double digit import tariffs include 38.5 percent on beef, 32 percent on oranges imported during the period of December to May, 40 percent on processed cheese, 29.8 percent on natural cheese, 22.4 percent on shredded frozen mozzarella cheese, 20 percent on dehydrated potato flakes, 17 percent on apples, 10.5 percent on frozen sweet corn, 20.4 percent on cookies, up to 17 percent on table grapes during the period of March to October, and 15 percent to 57.7 percent on wine depending on the tariff classification. These high tariffs generally apply to food products that Japan produces domestically. Addressing tariffs and improving market access for these and other products remains a high U.S. priority.

Wood Products and Building Materials

From July 2013 through September 2014, Japan's Forestry Agency administered the Wood Use Point Program (WUPP), with a budget of ¥56 billion (approximately \$574 million), to promote the use of Japanese wood products. Though U.S. Douglas fir and several other non-Japanese species of wood were eventually deemed eligible for WUPP benefits, a cumbersome and time-consuming application process limited the impact of foreign species' eligibility under the program. The United States remains concerned

regarding Japan's use of what appear to be domestic preference subsidy programs to support the Japanese forestry industry and potential discrimination against imported wood products.

Leather/Footwear

Japan continues to apply a TRQ on leather footwear that substantially limits imports into Japan's market, negatively impacting market access for U.S. made and U.S. branded footwear. The United States continues to seek improved market access for U.S. exports in this sector.

Customs Issues

The United States continues to urge Japan to take a variety of steps to improve customs processing and to facilitate expedited treatment of goods at the border. The United States has encouraged Japan to raise the Customs Law *de minimis* ceiling from ¥10,000 (approximately \$84) to a higher level. Strengthening Japan's system for advance rulings would also improve transparency and predictability for U.S. exporters.

SERVICES BARRIERS

Japan Post

The U.S. Government remains neutral as to whether Japan Post should be privatized. However, as modifications to the postal financial institutions and network subsidiary could have serious ramifications for competition in Japan's financial market, the United States continues to monitor carefully the Japanese government's postal reform efforts and to call on the Japanese government to ensure that all necessary measures are taken to achieve a level playing field between the Japan Post companies and private sector participants in Japan's banking, insurance, and express delivery markets.

In the area of express delivery services, the United States remains concerned by unequal conditions of competition between Japan Post and international express delivery suppliers. The United States continues to urge Japan to take action to enhance fair competition by leveling the playing field, including with respect to customs procedures and requirements as well as by prohibiting the subsidization of Japan Post's international express service with revenue from non-competitive (monopoly) postal services.

The United States also continues to urge the Japanese government to ensure that the postal reform process, including implementation of revisions to the Postal Privatization Law, is fully transparent, including by providing full and meaningful use of public comment procedures and opportunities for interested parties to express views to government officials and advisory bodies before decisions are made. Timely and accurate disclosure of financial statements and related notes is a key element in the postal reform process, as is the continued public release of meeting agendas, meeting minutes, and other relevant documents.

On October 1, 2014, the Ministry of Finance (MOF) announced the selection of 11 lead manager securities firms for the initial public offering (IPO) of the Japan Post (JP) Holdings. On December 26, 2014, Japan Post announced that three entities, JP Holdings (the parent company) and its two financial subsidiaries, JP Bank and JP Insurance, would go public at the same time in the "latter half of" Japanese FY2015, which begins April 1. Japan Post Co., the postal service subsidiary, will remain a wholly owned JP Holdings subsidiary. JP Group is expected to submit a preliminary application for the stock listings to the Tokyo Stock Exchange (TSE) in March 2015 with a formal application to be submitted following the JP Group's shareholder meeting in June. Observers anticipate that the IPO will take place in fall 2015.

With issues such as IPO date, percentage of shares to be released, pace of the offerings, continued government ownership, and many other details yet to be determined, the United States will continue to monitor developments and urge that the IPO process proceed in a fully transparent manner.

Insurance

Japan's private insurance market is the second largest in the world, after that of the United States, with direct net premiums of ¥36,743 billion (approximately \$317.7 billion) in Japanese fiscal year 2013. In addition to the offerings of Japanese and foreign private insurers, insurance cooperatives (kyosai) and JP Insurance, a wholly government-owned entity of the JP Group, also provide substantial amounts of insurance to consumers. Given the size and importance of Japan's private insurance market as well as the scope of the obstacles that remain to market access, the United States continues to place a high priority on ensuring that the Japanese government's regulatory framework fosters an open and competitive insurance market.

Postal Insurance

Japan's postal life insurance system remains dominant in Japan's insurance market. At the end of Japanese fiscal year 2013, there were approximately more than 41 million postal life and postal annuity insurance policies in force. In comparison, approximately 138 million life and annuity policies were in force with all other life insurance companies combined. The U.S. Government has long-standing concerns about the postal insurance company's negative impact on competition in Japan's insurance market and continues to closely monitor the implementation of reforms.

The United States continues to urge the Japanese government to take steps to address a range of level playing field concerns in the insurance sector, including differences in supervisory treatment between JP Group's financial institutions and private sector companies, access to the JP network for private providers (including the process of selection of financial products), and cross-subsidization among the JP businesses and related entities. In regard to private suppliers' access to the postal network, there was significant progress during 2013. For example, in July 2013, JP concluded a comprehensive tie-up agreement with a U.S. insurance company, American Family Life Assurance Company of Columbus (Aflac), to increase the number of JP outlets that distribute Aflac's cancer insurance products. As a result, by the end of 2014, the number of postal outlets selling Aflac's cancer insurance products increased from 1,000 to more than 10,100.

The United States continues to urge the Japanese government not to allow the JP Group to expand the scope of operations for its financial services companies before a level playing field is established. The current restraints on the scope of JP Group operations – including the cap on the amount of insurance coverage and limits to the types of financial activities and products JP entities can offer – have helped to limit the extent to which the uneven playing field harms private insurance companies. The U.S. Government welcomed the statement by Deputy Prime Minister Taro Aso on April 12, 2013, that the Japanese government will refrain from approving new or modified cancer insurance and/or stand-alone medical products of JP Insurance until it determines that equivalent conditions of competition with private sector insurance suppliers have been established, and that JP Insurance has a properly functioning business management system in place, which Japan expects will take at least several years to achieve. In addition, before final decisions are made, it is vital that Japan's process for approving new products be transparent and open to all parties, including active solicitation and consideration of private sector views, along with careful analysis and full consideration of actual competitive conditions in the market.

Kyosai

Insurance businesses run by cooperatives (*kyosai*) hold a substantial share of insurance business in Japan. Some *kyosai* are regulated by their respective agencies of jurisdiction (*e.g.*, MAFF or the Ministry of Health, Labor and Welfare) instead of by the Financial Services Agency (FSA), which regulates all private sector insurance and financial services companies. These separate regulatory schemes create a nontransparent regulatory environment, and afford *kyosai* critical business, regulatory, and other advantages over their private sector competitors.

The U.S. Government remains concerned about the reversal of progress toward giving FSA supervisory authority over *kyosai* that have insurance operations that are not regulated by the FSA. The 2005 Insurance Business Law revisions would have achieved this by requiring unregulated *kyosai* to come under FSA supervision; the Japanese government, however, has delayed and, in some cases provided exemptions to, implementation.

Policyholder Protection Corporations

The Life and Non-life Policyholder Protection Corporations (PPCs) are mandatory policyholder protection systems created to provide capital and management support to insolvent insurers. In March 2012, the Japanese government extended the existing system of government pre-funding of the PPCs for an additional five years, until March 2017. The United States continues to urge Japan to consider more fundamental changes in the PPC systems, including through full and meaningful deliberations with interested parties, before renewing these measures again.

Other Financial Services

While improvements have been made in Japan's financial services sector, such as the FSA's continued commitment to its Better Markets Initiative, the United States continues to urge reforms in the areas of online financial services, defined contribution pensions, credit bureaus, and sharing of customer information. The FSA continues to enhance its engagement and outreach with both domestic and foreign financial firms operating in Japan, but more improvement in this sector is needed, particularly with respect to transparent practices such as enhancing the effectiveness of the no-action letter and related systems, and providing written interpretations of Japan's financial laws.

Telecommunications

The United States continues to urge Japan to ensure fair market opportunities for emerging technologies and business models, and ensure a regulatory framework appropriate for addressing converged and Internet-enabled services, and maintain competitive safeguards on dominant carriers. The United States also continues to urge Japan to improve transparency in rulemaking and ensure the impartiality of its regulatory decision making.

Dominant Carrier Regulation

The Nippon Telegraph and Telephone Corporation (NTT) continues to dominate Japan's fixed-line market through its control over almost all "last-mile" connections. Although NTT's market share declined by 1 percent from the previous year, it still holds a 71.1 percent share as of the end of June 2014 in the fiber-to-fiber (FTTH) market. NTT's authority to bundle its fixed-line services with NTT DOCOMO's mobile service is also of concern, as it appears to undermine the rationale for structurally separating the companies. NTT plans to start wholesaling its fiber-optic fixed-line services to other companies, including NTT DOCOMO, in February 2015, claiming that it does not violate the Telecommunications Business Act if it

treats all customers equally. However, mobile carriers and CATV companies have expressed concerns that this could result once again in NTT obtaining a dominant market share. The United States will continue to monitor developments.

New Mobile Wireless Licenses

Unlike most advanced economies, Japan does not use auctions to allocate spectrum, and the factors the Ministry of Internal Affairs and Communication (MIC) uses to determine how to evaluate applications have raised questions related to the fairness of the allocation process. In March 2012, Softbank was awarded 900MHz frequencies, and in June 2012, NTT DOCOMO, KDDI, and eAccess (acquired by Softbank in January 2013) were awarded 700MHz spectrum. While Softbank launched its 900MHz networks in 2013, the 700MHz frequencies will not be used until 2015. In July 2013, MIC awarded additional frequencies in the 2,625 MHz to 2,645 MHz bands to UQ Communications, a subsidiary of KDDI, to provide advanced Broadband Wireless Access systems. Although the Japanese government has previously considered introducing legislation that allows for auctions as an option to assign commercial spectrum, it remains unclear whether such legislation will be introduced.

Information Technologies (IT)

Health IT

The United States has urged Japan to improve the quality and efficiency of healthcare by rapidly implementing health IT that is based on international standards, promotes technology neutrality and interoperability, and allows patients greater access to their own health records. Engagement between U.S. and Japanese Government health IT experts continues to address health IT issues of mutual interest.

Privacy

Separate and inconsistent privacy guidelines among Japanese ministries have created an unnecessarily burdensome regulatory environment with regard to the storage and general treatment of personally identifiable information in Japan. The United States has urged Japan to introduce greater uniformity in the enforcement of the Privacy Act across the central government through policy standardization and consistent implementation of guidelines. The Abe Government's Cabinet Secretariat plans to submit a bill to the Diet in 2015 to amend the Privacy Act. The amendment would seek to enhance the use of personal data for business purposes while protecting privacy. The current version of the bill envisions a third party authority similar to the EU's Privacy Commissioner, although the extent of the authority's power is still under deliberation. The United States worked with Japan through the Asia-Pacific Economic Cooperation to facilitate Japan's participation in the Cross Border Privacy Rules (CBPR) system, a voluntary system of commercial data privacy standards. In April 2014, Japan received approval to join CBPR.

Consumption Tax on Online Content from Abroad

In 2012, the Ministry of Finance announced that it intends to begin levying a consumption (value-added) tax on online content from overseas. Such products offered by firms with a physical presence in Japan are already subject to a consumption tax. MOF proposes to introduce a mandatory registration system for foreign firms, modeled on that used in the European Union. MOF had planned to levy the consumption tax on online content from abroad beginning in October 2015, when the consumption tax was scheduled to rise to 10 percent; Prime Minister Abe's decision in November 2014 to postpone the consumption tax increase to April 2017 means that levy of the tax on online content has also been postponed. The United States is continuing to monitor developments.

Legal Services

Japan imposes restrictions on the ability of foreign lawyers to qualify for provision of international legal services in Japan. The United States continues to urge Japan to further liberalize the legal services market. Further, foreign lawyers are prohibited from establishing branch offices in Japan. The United States urges Japan to take important measures, including ensuring that no legal or Bar Association impediments exist to Japanese lawyers becoming members of international legal partnerships and accelerating the registration process for new foreign legal consultants.

Educational Services

The United States continues to urge the Japanese government to work with foreign universities to find a nationwide solution that grants tax benefits to foreign universities operating in Japan comparable to those provided to Japanese schools and allows them to continue to provide their unique contributions to Japan's educational environment.

In its Economic Revitalization Strategy first issued in June 2013, the government of Prime Minister Abe committed to promoting an educational system that more effectively provides the Japanese people with the skills to compete in the global economy. Consistent with that commitment, Japanese authorities actively engaged in 2014 with American universities operating satellite campuses or extension facilities in Japan to seek a way forward on taxation and other issues. American universities have reported success in being recognized as eligible educational institutions for issuance of visas to foreign students to study at their campuses in Japan. Despite extensive consultations with authorities, however, no American university has yet been able to satisfy all the legal requirements to be granted "educational corporation" ("gakkou houjin") status, which would confer the same tax benefits enjoyed by Japanese universities. The requirement that such corporations be "independently administered" (*i.e.*, not subject to direct administration by the parent university in the home country) is a particularly difficult legal hurdle to overcome. Lack of "gakkou houjin" status means foreign satellite universities are also excluded from participation in new Japanese government grant programs that promote international exchange and provide financial support for students wishing to study abroad.

INTELLECTUAL PROPERTY RIGHTS PROTECTION

Japan generally provides strong intellectual property rights (IPR) protection and enforcement. The United States, however, continues to urge Japan to improve IPR protection and enforcement in specific areas through bilateral consultations and cooperation, as well as in multilateral and regional fora.

The United States also has urged Japan to continue to reduce piracy rates, including by adopting methods to protect against piracy in the digital environment. Police and prosecutors lack *ex officio* authority to prosecute IPR crimes on their own initiative, without a rights holder's complaint. The United States also seeks improvements to Japan's Internet Service Provider liability law to promote cooperation between right holders and Internet service providers.

Japan took steps to revise its Customs Law and Unfair Competition Law in 2011. Japan also revised its Copyright Law in 2012, extending protection for technological protection measures, among other things. The United States continues to urge Japan to further strengthen its laws to provide effective criminal and civil remedies against the unauthorized circumvention of technological protection measures used by rights holders to protect their works, as well as effective criminal and civil remedies against the trafficking in tools used to circumvent such technological protection measures. Furthermore, although Japan provides a 70-year term of protection for cinematographic works, it provides only a 50-year term for other works protected by copyright and related rights. The United States continues to urge Japan to extend the term of

protection for all subject matter of copyright and related rights in line with emerging international trends. Also, while the United States welcomed clarifications to Japan's Copyright Law in 2010 that made clear that the statutory private use exception does not apply in cases where a downloaded musical work or a motion picture is knowingly obtained from an infringing source, the United States continues to urge the Japanese government to expand this limitation on the private use exception to cover all works protected by copyright and related rights.

In its June 2013 Economic Revitalization Strategy the Cabinet announced that Japan would undertake revisions to the Patent Act, Design Act, Trademark Act, and Patent Attorney Act in order to promote the creation, protection, and strategic use of intellectual property. In this connection, Japan amended its Copyright Act in April 2014 to establish new copyright provisions concerning publication rights for digitally published materials (e-books). The new provisions, which became effective as of January 2015, extend copyright protection to material in digital form to address illegal or pirated copies of published materials uploaded to the Internet.

The Ministry of Economy, Trade and Industry and other government agencies are currently working on further legal revisions. These revisions would: (1) amend the Patent Act to provide for enhanced relief measures and to enable the submission of applications in opposition to granted patents; (2) amend the Design Act to allow single applications for patents effective in multiple countries; (3) amend the Trademark Act to grant legal protection to non-traditional trademarks and regional collective trademarks; (4) amend the Patent Attorney Act to clarify the roles and responsibilities of patent attorneys and to expand the scope of their services; and (5) amend the Trade Secret Management Guidelines to clarify a company's role in adequately protecting information that the company wishes to guard as a trade secret and the role of court injunctions to protect such trade secrets.

Japan's Diet passed a bill in June 2014 for the protection of geographical indications (GIs) by means of a *sui generis* system. Enforcement of the new GI regime would begin in June 2015. The MAFF is currently preparing the implementing regulations and implemented a public comment period in February 2015. The United States will continue to engage with Japan during this period to advocate that core principles be addressed in the regulations including the scope of GI protection and GI registration safeguard procedures, protecting the prior rights of owners of existing trademarks, safeguarding the use of generic terms, and ensuring objection and cancellation procedures. The final regulations are expected to come into force in early summer.

GOVERNMENT PROCUREMENT

Japan is a signatory to the WTO Agreement on Government Procurement (GPA). Japan applies a threshold of 15 million SDRs (approximately \$23.98 million) for procurement of construction services by sub-central entities and many government enterprises covered under the GPA, which is three times the threshold applied by the United States and most other GPA Parties.

The United States continues to emphasize the importance of improving the bidding process for government contracts in Japan, including by increasing transparency in tendering decisions and taking steps that facilitate improved opportunities for participation by qualified bidders.

Construction, Architecture, and Engineering

Two bilateral public works agreements are in effect: the 1988 United States-Japan Major Projects Arrangements (MPA, updated in 1991) and the 1994 United States-Japan Public Works Agreement, which includes the Action Plan on Reform of the Bidding and Contracting Procedures for Public Works (Action Plan). The MPA includes a list of 42 projects in which international participation is encouraged. Under

the Action Plan, Japan must use open and competitive procedures for procurements valued at or above the thresholds established in the GPA.

Problematic practices continue to limit the participation of U.S. design, consulting and construction firms in Japan's public works sector, including bid rigging (*dango*), under which companies consult and prearrange a bid winner (see "*Broadening Measures to Combat Bid Rigging*" under the *Anticompetitive Practices* section). The United States continues to press Japan to take more effective action to address this pervasive problem.

The United States continues to monitor Japan's public works sector. Specifically, the U.S. Government is paying special attention to certain major projects covered by the public works agreements that are of particular interest to U.S. companies. These include some construction projects for the Tokyo 2020 Olympics; major expressway projects; major public buildings, railroad and railroad station procurements, urban development and redevelopment projects; planned port facilities expansion projects; major private finance initiative projects; and the MPA projects still to be undertaken or completed. The U.S. Government is also monitoring developments related to environmental remediation, "green" building, design, and procurement.

INVESTMENT BARRIERS

Despite being the world's third largest economy, Japan continues to have the lowest inward FDI as a proportion of total output of any major OECD country. According to OECD statistics, FDI stock at the end of 2013 was only 3.5 percent of GDP in Japan, compared to 32.1 percent on average for all OECD members. Inward foreign merger and acquisition (M&A) activity, which accounts for a large portion of FDI in other OECD countries, also lags in Japan.

While the Japanese government recognizes the importance of FDI to revitalizing the country's economy, its performance in implementing domestic regulatory reforms to encourage a sustained increase in FDI has been uneven. In June 2013, the government of Prime Minister Abe announced its goal to double Japan's inward FDI stock by 2020, and reconfirmed this commitment in its revised growth strategy issued in June 2014. The government is pursuing a range of policies intended to promote this target.

Prior to the advent of the Abe Administration, the Japanese government had done little to explicitly encourage inward investment through M&A as a policy priority. After peaking at 309 in 2007, numbers of annual inbound M&A transactions declined to 112 in 2012 but registered a 33 percent increase to 149 in 2013. Despite this uptick, the number of transactions remains low for an economy the size of Japan's, and questions remain about the adequacy of the government's measures if the 2020 target is to be achieved. A variety of factors make inbound M&A difficult in Japan, including attitudes toward outside investors, inadequate corporate governance mechanisms that protect entrenched management over the interest of shareholders, cross-shareholdings, aspects of Japan's commercial law regime (see *Commercial Law* section), and a relative lack of financial transparency and disclosure. A positive development in addressing these issues is the renewed focus on better corporate governance in the government's June 2014 growth strategy. As part of that effort, the FSA and the TSE are jointly drafting a new "Corporate Governance Code of Conduct." While the Code of Conduct will not be legally binding on companies, compliance will become a condition for listing on the TSE. The Code, to be finalized and implemented by June 2015, should contribute significantly to improved corporate governance in Japan.

ANTICOMPETITIVE PRACTICES

Improving Anti-Monopoly Compliance and Deterrence

Japan's Anti-Monopoly Act (AMA) provides for both administrative and criminal sanctions against cartels and administrative sanctions for non-cartel conduct. Criminal prosecutions, which have the strongest deterrent effect against anticompetitive behavior in other countries, have been few, and penalties against convicted company officials have been weak. While the Japanese government has taken some steps to address these concerns, particularly through amendments to the AMA enacted in June 2009 that increased fines for cartel violations, the United States has continued to urge Japan to take steps to maximize the effectiveness of enforcement against cartel violations of the AMA. In addition, the United States has continued to encourage the Japan Fair Trade Commission (JFTC) to make further improvements, including by improving the economic analysis capabilities of JFTC staff, to strengthen its ability to enforce the AMA effectively.

Improving Fairness and Transparency of JFTC Procedures

The JFTC has the authority to make determinations of AMA violations without a prior formal administrative hearing. The JFTC allows companies subject to a proposed cease-and-desist or surcharge payment order to review the evidence relied upon by JFTC staff and to submit evidence and make arguments in their defense prior to issuance of a final order. However, respondents are only afforded the right to seek administrative review of the JFTC decision after the decision is put into place. To address ongoing concerns as to whether the current system provides sufficient due process protections, in December 2013, the Diet enacted an AMA amendment bill to eliminate the *ex post* hearing system and to allow appeals of JFTC orders to go directly to the Tokyo District Court. Under the bill, the JFTC has 18 months to prepare implementing regulations, so the new system will be introduced by June 2015. In December 2014, an advisory panel recommended that the JFTC issue guidelines regarding administrative procedures to enhance the transparency of enforcement proceedings.

Broadening Measures to Combat Bid Rigging

The United States continues to raise concerns with the problem of bid rigging in Japan, and urges that further measures be taken to prevent conflicts of interest in government procurement and improve efforts to eliminate involvement in bid rigging by government officials.

OTHER SECTORAL AND CROSS-SECTORAL BARRIERS

Transparency

Advisory Groups

Although advisory councils and other government commissioned study groups are accorded a significant role in the development of regulations and policies in Japan, the process of forming these groups can be opaque, and nonmembers are too often not uniformly offered meaningful opportunities to provide input into these groups' deliberations. The United States continues to urge Japan to ensure transparency with respect to the formation and operation of advisory councils and other groups convened by the government by adopting new requirements to ensure that ample and meaningful opportunities are provided for all interested parties, as appropriate, to participate in, and directly provide input to, these councils and groups.

Public Comment Procedure (PCP)

Many U.S. companies remain concerned by inadequate implementation of the PCP by Japanese ministries and agencies. Examples include cases where comment periods appear unnecessarily short, as well as cases where comments do not appear to be adequately considered given the brief time between the end of the comment period and the issuance of a final rule or policy. The United States has stressed the need for Japan to ensure additional revisions are made to further improve the system, such as lengthening the standard public comment period for rulemaking.

Commercial Law

Foreign investment into Japan remains constrained by a range of issues, including conditions for using tax-advantaged merger tools for inward-bound investment to Japan, securities law and capital market issues inherent in cross-border stock-for-stock transactions, and corporate governance systems that do not adequately reflect the interests of shareholders. The United States continues to urge Japan to identify and eliminate impediments to cross-border mergers and acquisitions, including the availability of reasonable and clear incentives for many such transactions, and to take measures to ensure that shareholder interests are adequately protected when Japanese companies adopt anti-takeover measures or engage in cross-shareholding arrangements. The United States also continues to urge Japan to improve further its commercial law and corporate governance systems in order to promote efficient business practices and management accountability to shareholders in accordance with international best practices. Areas ripe for improvement include facilitating and encouraging active and appropriate proxy voting, setting minimum requirements for and ensuring the independence of outside directors, augmenting the role of outside directors on corporate boards, strengthening protection of minority shareholders by clarifying fiduciary duties of directors and controlling shareholders, and encouraging the stock exchanges to adopt listing rules and guidelines that improve the corporate governance of listed companies in a manner that protects the interests of minority shareholders.

In June 2014 the Diet passed a bill to amend the Companies Act to require firms to appoint at least one outside director, or to disclose at annual shareholders' meetings why such an appointment would be "inappropriate" (known as the "comply or explain" provision). The amendments also include guidance on multiple shareholder litigation and on voting rights for controlling shareholders. As noted in the "Investment Barriers" section of this report, the Abe Administration followed that legislation with a commitment in its June 2014 Growth Strategy to further strengthen corporate governance by introducing a "Code of Conduct" that will apply to companies listing on the TSE; the new Code is expected to be introduced by June 2015.

Automotive

A variety of nontariff barriers have traditionally impeded access to Japan's automotive market. Overall sales of U.S.-made vehicles and automotive parts in Japan remain low, which is a serious concern. The United States has expressed strong concerns with the overall lack of access to Japan's automotive market for U.S. automotive companies. Barriers include issues relating to standards and certification; transparency issues, including the lack of sufficient opportunities for stakeholder input in the development of standards and regulations; barriers that hinder the development of distribution and service networks; and the lack of equivalent opportunities for U.S. models imported under the preferential handling procedure (PHP) certification program to benefit from financial incentive programs. The United States urges Japan to address these and other barriers in Japan's automotive market. In a positive development, in July 2014 Japanese authorities eased restrictions on maintenance procedures for vehicles using a particular type of air conditioner refrigerant, allowing for importation of new models in which the refrigerant is installed. Also,

in 2013, Japan more than doubled (from 2,000 to 5,000) the number of imported vehicles per type that may use the simplified certification method of PHP.

Medical Devices and Pharmaceuticals

Japan continues to be one of the most important markets for U.S. medical device and pharmaceutical exports. According to Business Monitor International, the Japanese medical device market had an estimated value of \$30.2 billion in 2013 and is projected to expand to \$34.9 billion by 2018. Foreign suppliers have approximately 40 percent of the market. According to the American Medical Devices and Diagnostics Manufacturers' Association, approximately 60 percent of "new medical devices" approved in Japan were from its member companies. The pharmaceuticals market in Japan had an estimated value of \$112.6 billion in 2013 and is projected to expand to \$119.8 billion in 2018. The total market share of U.S.-origin pharmaceuticals in Japan is estimated to be approximately 20 percent if local production by U.S. firms and compounds licensed to Japanese manufacturers are included.

Prime Minister Abe's June 2013 Economic Revitalization Strategy calls for promotion of the pharmaceutical and medical device industries. Among other measures, the strategy includes steps to accelerate regulatory approvals to reduce the so-called "lag" time between application and approval of new products as well as steps to reward innovative medical devices and pharmaceuticals. These and other planned measures should continue to improve opportunities for U.S. medical devices and pharmaceuticals.

The Japanese government has made progress in several areas, including the reduction of lengthy approval periods for medical devices and pharmaceuticals as well as Diet passage in November 2013 of amendments to the Pharmaceutical Affairs Law (PAL). The PAL was further amended and renamed the Pharmaceutical and Medical Devices Law (PMDL) on November 25, 2014. The PMDL will enable further improvements to the regulatory review process, including the establishment of a distinction between the characteristics of medical devices and pharmaceuticals, and the establishment of a new product category for regenerative medicine products. The United States continues to urge Japan to improve performance goals for product reviews by meeting performance targets and to make science-based decisions efficiently and speedily. Also, the United States continues to urge Japan to further harmonize its efforts with other key regulatory agencies on international standards in clinical development, multiregional clinical trials, and risk management.

The United States has urged Japan over the past decade to implement predictable and stable reimbursement policies that reward innovation and provide incentives for companies to invest in the research and development of advanced healthcare products and pharmaceuticals. U.S. stakeholders have raised concerns regarding Japan's proposal to revise reimbursement prices annually, as opposed to the current biennial revision cycle, which it believes will introduce greater uncertainty and administrative burden for the stakeholders in Japan's pricing and reimbursement system. With regard to medical devices, U.S. stakeholders have expressed concerns about Japan's application of, and changes to, the Foreign Average Price (FAP) rule, a mechanism to cut prices of medical devices in Japan based on the simple average of prices for the same or similar products in the United States, Germany, France, the United Kingdom, and Australia.

With regard to pharmaceutical products, the United States welcomes Japan's decision in April 2014 to continue the premium system trial period for an additional two years. The premium, which minimizes downward price revisions on new drugs for which there are no corresponding generic pharmaceutical products, has considerably improved conditions for the development of new pharmaceutical products in Japan. Making this system permanent would increase the predictability and attractiveness of the Japanese market, further reduce lag time for introduction of pharmaceuticals, and promote long-term investment in life sciences. The United States continues to urge the Japanese government to make the system permanent.

Although the level of transparency in Japan's drug and medical device reimbursement decision making processes has improved in recent years, the United States continues to urge Japan to build further on recent improvements to foster a more open and predictable market.

Nutritional Supplements

Japan's nutritional or dietary supplements market is estimated at ¥1.21 billion (more than \$10 billion) according to research by UBM Media. Japan has taken steps to streamline import procedures and to open this growth market, although many significant market access barriers remain. Burdensome restrictions on health claims are a major concern. Currently, only those products approved as Foods for Specified Health Uses (FOSHU) or Foods with Nutrient Function Claims (FNFC) are allowed to have health or structure/function claims. Producers of most nutritional supplements, however, are unable to obtain FOSHU or FNFC approval due to FOSHU's costly and time-consuming approval process and due to the limited range of vitamins and minerals that qualify for FNFC. These processes apply to both imported and domestic products.

Other concerns include long lead times for food additive applications; difficulties associated with using unregistered food additives (including organic solvents) as processing ingredients for use in nutritional supplements; high import duties for nutritional supplements compared to duties on pharmaceuticals containing the same ingredients; lack of transparency in new ingredient classifications; and lack of transparency in the development of health food regulations.

The Abe Government's Economic Revitalization Strategy issued in June 2013 included plans to implement a new functional health claims (labeling) system for health foods by the end of March 2015. Japan's Consumer Affairs Agency held eight committee meetings on the new functional claim system and published a report on July 30, 2014. Following a public hearing process in which U.S. stakeholders provided comments, the Agency is currently drafting detailed guidelines for implementation of the new system. The guidelines will reportedly reference the U.S. labeling system for dietary supplements; if implemented incorporating global best practices, the system could be a significant step forward in reducing regulatory barriers and expanding the dietary supplement market in Japan by enabling the Japanese consumer to obtain more functional information. The U.S. Government will closely monitor developments.

Cosmetics and Quasi-Drugs

Japan is the world's fourth-largest market (approximately \$39.6 billion in retail sales as projected by Euro Monitor) for cosmetics and quasi-drugs after the United States and China. In 2013, U.S. exports of cosmetics and personal care products to Japan were estimated at 40.3 billion yen (over \$400 million). Despite this market presence by U.S. products, regulatory barriers continue to limit timely consumer access to safe and innovative products, generating unnecessary costs. Unlike the over-the-counter drug monograph system in the United States, Japan requires premarket approval for certain products, such as a category called "medicated cosmetics" that are classified as quasi-drugs under the Pharmaceutical Affairs Law. The quasi-drug approval process includes requirements that are burdensome, lack transparency, and do not appear to enhance product safety, quality, or efficacy. In addition, restrictions on advertising claims for cosmetics and quasi-drugs prevent companies from informing customers of product benefits necessary for making informed choices. Overly complex import notification procedures and a burdensome foreign manufacturer accreditation process act as additional market access barriers for U.S. firms. Enhanced communication between the U.S. and Japanese governments and industries has led to some improvements in the Japanese regulatory system, such as implementation of the on-line customs clearance system as of November 2014.

Proprietary Ingredient Disclosure Requirement for Food and Dietary Supplements

As part of its product classification process for new-to-market food and dietary supplement products, Japan mandates that such products include a list of all ingredients and food additives by name along with content percentages and a description of the manufacturing process. In addition to being burdensome, this process risks the release of proprietary information to competitors.

Aerospace

Japan is among the largest foreign markets for U.S. civil aerospace products. The civil aerospace market in Japan is generally open to foreign firms, and some Japanese firms have entered into long-term relationships with U.S. aerospace firms. The United States continues to monitor Japan's development of indigenous aircraft.

Military procurement by the Ministry of Defense (MOD) accounts for approximately half of the domestic production of aircraft and aircraft parts and continues to offer the largest source of demand in the aircraft industry. Although U.S. firms have frequently won contracts to supply defense equipment to Japan, many contracts for defense equipment are not open to foreign bids. MOD's general preference is that defense products and systems be developed and produced in Japan, and it will often opt for local development and production, even when a foreign option exists that could fulfill the requirements more efficiently, at a lower cost, and with better interoperability with Japan's allies.

Although Japan has considered its main space launch vehicle programs as indigenous for many years, U.S. firms continue to participate actively in those space systems. Japan is also developing a global positioning system navigation satellite constellation known as the "quasi-zenith" satellite system, as well as high-performance Advanced Satellite with New System Architecture for Observation systems. At the conclusion of the second meeting of the United States-Japan Comprehensive Dialogue on Space on May 12, 2014, the United States and Japan released a joint statement welcoming initiatives to enhance bilateral space situational awareness information sharing. The statement also reaffirmed interest in collaboration on evaluating the operational and economic benefits from the use of space for maritime domain awareness.

Japan has been taking steps to bolster aviation operations through the liberalization of regulations and investment in infrastructure. Japan is the United States' largest aviation partner in the Asia-Pacific region, and a bilateral Open Skies regime has been in place since 2010. Operations between the United States and Tokyo's Haneda Airport, however, are limited because Japan strictly controls access to Haneda. Beginning in March 2014, Japanese authorities made limited additional daytime frequencies available for long-haul international flights, and in June 2014 the Ministry of Land, Infrastructure, and Transport (MLIT) released a study outlining options for long-term expansion of capacity at both Haneda and Narita airports. In conjunction with these developments, the U.S. and Japanese governments conducted two rounds of informal consultations regarding Haneda, and the U.S. Government continues to seek a commercially meaningful expansion of daytime access to Haneda that will meet the interests of U.S. airlines.

In the general aviation sector, the United States and the APEC member economies, including Japan, have reached consensus on best practices for the treatment and regulation of international business aviation operations. The U.S. Government will continue to work closely with the government of Japan to promote greater liberalization in the business aviation sector through APEC's Transportation Working Group.