

JAPAN

TRADE SUMMARY

The U.S. goods trade deficit with Japan was \$82.8 billion in 2007, a decrease of \$5.8 billion from \$88.6 billion in 2006. U.S. goods exports in 2007 were \$62.7 billion, up 5.1 percent from the previous year. Corresponding U.S. imports from Japan were \$145.5 billion, down 1.8 percent. Japan is currently the fourth largest export market for U.S. goods.

U.S. exports of private commercial services (*i.e.*, excluding military and government) to Japan were \$41.3 billion in 2006 (latest data available), and U.S. imports were \$23.9 billion. Sales of services in Japan by majority U.S. owned affiliates were \$53.5 billion in 2005 (latest data available), while sales of services in the United States by majority Japan owned firms were \$28.4 billion.

The stock of U.S. foreign direct investment (FDI) in Japan was \$91.8 billion in 2006 (latest data available), up from \$79.3 billion in 2005. U.S. FDI in Japan is concentrated largely in the finance, manufacturing, wholesale trade, and the professional, scientific, and technical services sectors.

REGULATORY REFORM OVERVIEW

The United States-Japan Regulatory Reform and Competition Policy Initiative

Through the United States-Japan Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative), the U.S. Government seeks changes to regulations and practices in Japan that limit competition, prevent development of innovative products and services, and hinder access for U.S. products and services in Japan's market. The U.S. Government addresses a wide range of issues through this Regulatory Reform Initiative in specific industry sectors, such as information technologies, telecommunications, and pharmaceuticals/medical devices, as well as in other areas that affect multiple sectors, such as competition policy and increased transparency.

The governments of the United States and Japan concluded the Regulatory Reform Initiative's sixth annual Report to the Leaders in June 2007, which documented progress made under the Regulatory Reform Initiative since late 2006. The U.S. Government again presented new, detailed recommendations to Japan in October 2007. After several months of working- and high-level talks, the next Report documenting progress is expected to be completed in the summer of 2008.

The following sections on Sectoral Regulatory Reform and Structural Regulatory Reform outline some of the key reform and market access issues that the U.S. Government continues to seek progress on by Japan under this Regulatory Reform Initiative.

SECTORAL REGULATORY REFORM

Telecommunications

In its 2007 recommendations to Japan under the Regulatory Reform Initiative, the U.S. Government continued to urge Japan to take concrete steps to promote competition and efficiency in the wireless telecommunications sector, streamline regulation of convergent services, and strengthen competitive safeguards on dominant carriers. The U.S. Government also continues to request that Japan ensure the impartiality of its regulatory decision making, including by abolishing the legal

requirement that the government own one-third of the dominant carrier, Nippon Telegraph and Telephone (NTT), and ensuring greater transparency in rulemaking.

Interconnection: Japanese laws and regulations do not prevent NTT's regional carriers from imposing high rates and onerous conditions on their competitors for interconnection. Revisions that Japan's Ministry of Internal Affairs and Communications (MIC) made to its Rules for Interconnection Charges have resulted in modest reductions in interconnection rates, although these rates remain high by international standards. The U.S. Government looks to MIC to ensure that reasonable interconnection terms and conditions and competitive rates are established, particularly as preparations are made to introduce NTT's Internet Protocol (IP) based Next Generation Network to replace the analog network that all carriers use to reach subscribers.

Dominant Carrier Regulation: NTT continues to dominate overwhelmingly Japan's fixed line market. In turn, Japan has been seeking to promote competition in the telecommunications market through its Competition Promotion Program. However, as Japan's broadband users turn from digital subscriber line (DSL) to optical fiber, NTT's competitors fear that NTT may extend its dominant position through control of the fiber-to-the-home (FTTH) market and by bundling NTT fixed services with those of NTT DoCoMo, the dominant wireless operator. In October 2007, MIC issued a revised "New Competition Promotion Program 2010" to address competition concerns as suppliers increasingly offer telecommunications services over IP based networks. The U.S. Government has urged Japan to speed implementation of the plan and will continue to monitor MIC's implementation of the program.

Universal Service Program: Japan approved a scheme beginning in January 2007 for NTT East and West and its competitors to collect a universal service fee of seven yen per month from subscribers of voice services. Based on a routine review, Japan decided to reduce the fee to six yen monthly from January 2008, with subsequent reviews to determine future fees. NTT regional carriers (the only carriers able to benefit from the fund) then receive these fees through the universal service fund to offset costs of providing services in rural areas. The U.S. Government has urged Japan to broaden the base of potential beneficiaries of this fund and ensure that it is implemented in a competitively neutral manner. Cross-subsidization of NTT West by NTT East using interconnection revenue (ostensibly to address NTT West's higher network costs, based on higher number of rural subscribers) further undercuts arguments for the program's need.

Mobile Termination: Like most countries, Japan uses the "Calling Party Pays" system, imposing the entire cost of termination on the calling party (enabling mobile subscribers to benefit from free incoming calls). Although NTT DoCoMo, the dominant mobile incumbent carrier, has lowered its termination rates over the past 10 years, rate reductions have plateaued and remain high. Despite recognizing DoCoMo as a dominant carrier in 2002, MIC has not required DoCoMo to explain how its rates are calculated. With new entrants now in the mobile sector, the U.S. Government will closely monitor actions both by DoCoMo and MIC in addressing such rates to ensure effective competition is possible.

New Mobile Wireless Licenses: Starting in 2005, MIC began to open the market to new mobile providers beyond the three main incumbents by auctioning blocks of spectrum to a limited number of new wireless entrants. In 2007, MIC invited bidding on two additional licenses to offer wireless broadband services and only opened bidding to nonincumbents, awarding licenses in December. Although MIC appears to have made an effort to award the licenses on the basis of objective criteria, the complexity of factors the MIC chose to evaluate raises questions as to whether it achieved its goal. Given the scarcity of spectrum and high demand for new technologies, the U.S. Government has urged MIC to consider alternative means to assign commercial spectrum in a

timely, transparent, objective, and nondiscriminatory manner that adheres to principles of technology neutrality, including through auctions. The U.S. Government has also stressed to Japan the importance of ensuring reasonable “roaming” rates for competitors and Mobile Virtual Network Operators (MVNOs), an area where MIC is making noticeable progress through policies and dispute mediation.

Information Technologies (IT)

Through its October 2007 Regulatory Reform Initiative recommendations, the U.S. Government continues to urge Japan to ensure its regulatory framework for IT and electronic commerce promotes competition and innovation, enhances transparency, and protects users, in addition to taking new steps to protect intellectual property rights (IPR) effectively in the face of challenges posed by globalization and new technologies in a digital era.

IT and Electronic Commerce Policymaking: To augment measures that Japan has taken to promote and support the use of IT and electronic commerce, the U.S. Government has urged Japan to take steps to: ensure transparent policy and rule-making processes are applied to provide interested parties with opportunities to express views and to be aware of and participate in the work of related government-appointed advisory groups; implement laws, regulations, and guidelines to promote choice and competitive market conditions by ensuring that technology providers and users have the flexibility to choose preferred technologies; work cooperatively with the private sector on international standards development and, when appropriate, use established international standards when formulating IT and electronic commerce guidelines and regulations; and ensure its IT and electronic commerce policies and laws are compatible with international practices.

Privacy: With the entry into effect of Japan’s Law on the Protection of Personal Information (Privacy Law) in April 2005, Japan’s ministries and agencies formulated implementation guidelines to ensure its effectiveness. The Cabinet Office reviewed implementation of the Privacy Law and released a report on this review in June 2007. The U.S. Government stressed its view that clear, consistent, and predictable privacy guidelines should be developed across ministries, with separate guideline provisions added as necessary for individual business sectors, and that any recommendations regarding cross-border transfers provide effective protection for individuals’ personal information without unduly restricting the international flow of data.

IPR Protection: The U.S. Government continued to urge Japan to adopt a number of new measures to strengthen IPR protection. These include: extending the term of copyright for sound recording and all other subject matter protected under Japan’s Copyright Law; adopting a statutory damages system that would act as a deterrent against infringing activities; improving the efficacy of the patent application process; and actively working with the United States to develop ways to promote greater protection of IPR worldwide, especially in Asia. (*See also “Intellectual Property Rights Protection” in this chapter.*)

Government IT Procurement: In order to increase the transparency and fairness of Japan’s IT procurements and to stimulate innovation and competition in those procurements, the U.S. Government has urged Japan to: ensure all procuring entities comply with Japan’s Basic Policy for the Public Procurement of Computer Systems (Basic Policy); improve communications with suppliers interested in the implementation of Japan’s government IT procurement policy; apply Japan’s Bayh-Dole system that allows companies to control the intellectual property of inventions they develop under government contracts to all government procurement; allow IT vendors to limit their liability to a level proportionate to the risks they take in government procurement transactions; reduce the use of sole source contracting in IT procurements, including by applying rules on

competitive bidding to independent administrative legal entities, government-sponsored private companies, and local governments; and ensure that contracts are swiftly concluded after winning bidders are chosen and are not backdated.

Medical Devices and Pharmaceuticals

The U.S. Government continues to stress the importance for Japan of adopting policies that ensure Japan's regulatory system facilitates the introduction of advanced medical devices and pharmaceuticals and that its reimbursement system appropriately values innovation. Recognizing that innovation can foster economic growth and improved healthcare, the Ministry of Health, Labor and Welfare (MHLW), in its 2007 "Vision" paper, outlined plans to improve the international competitiveness of Japan's pharmaceutical industry. MHLW is preparing a similar paper for the medical device industry. The U.S. Government has urged Japan to implement rapidly the steps set out in the drug Vision paper.

Japan is the largest foreign market for U.S. medical devices and pharmaceuticals, and thus its regulatory and reimbursement policies have a substantial impact on U.S. industry. The U.S. Government, in its 2007 Regulatory Reform Initiative recommendations, urged Japan to facilitate the simultaneous global development of pharmaceuticals, improve the environment for clinical trials, and promote the use of vaccines, among other steps. Regarding devices, the U.S. Government urged Japan to take additional measures, such as speeding approvals of minor product changes, reforming stability testing rules, and eliminating unnecessary data requirements. The U.S. Government is hopeful that Japan's new goals to improve its regulatory system will prove effective, including plans to cut drug approval times by 2.5 years by 2012, more than double the drug review staff by 2010, and increase the device review staff by 30 percent by 2009.

With respect to pricing, Japan is scheduled to revise reimbursement price levels for medical devices and pharmaceuticals on April 1, 2008. The U.S. Government has strongly urged Japan to adopt reimbursement pricing policies that reward development and introduction of innovative medical devices and pharmaceuticals. Such policies will promote the speedy introduction of advanced products that not only help save and improve lives, but also make Japan's healthcare system more efficient by reducing the need for surgeries and cutting the lengths of hospital stays, which are the longest among countries in the OECD.

Regarding drug reimbursement, in the 2007 Report to the Leaders, MHLW noted it would consider industry's views on pricing reforms and ways to improve the reward for innovation. In December 2007, Japan announced its decision on Japan fiscal year 2008 pricing revisions that expanded the use of repricing based on market expansion, albeit with a temporary exception to the rule that lessens its impact on reimbursement prices for new drugs. The U.S. Government continues to urge Japan to abolish repricing based on market expansion because this rule reduces incentives to introduce innovative medicines in Japan. In its December 2007 pricing decisions, MHLW also continued to adhere to the use of biennial, instead of annual, reimbursement rate reviews. The U.S. Government continues to strongly urge Japan to avoid annual reimbursement reviews. Regarding medical device reimbursement, MHLW has agreed to continue to discuss with industry key issues such as the Foreign Average Price (FAP) rule, functional categories, and the system for reimbursement of innovative (C1/C2) technology. The U.S. Government continues to urge Japan to eliminate the FAP rule and to work with U.S. industry to improve the functional category system for devices.

Separately, Japan's 2002 Blood Law established a principle of "self-sufficiency" and included a Supply and Demand Plan (Plan) for the Japanese government to manage supply and demand in the

blood market. The U.S. Government continues to urge Japan to ensure the Plan does not discriminate against foreign blood plasma products and is made consistent with Japan's international trade obligations. The U.S. Government also urges Japan to develop a reimbursement pricing system for blood products that accounts for the industry's unique characteristics and that is not based on Japan's model for drugs.

Nutritional Supplements: While Japan has taken steps, such as streamlining import procedures, to open its \$10.4 billion nutritional supplements market, many barriers to market access remain. Restrictions on health and nutrition claims are a major concern. In Japan, nutritional supplements are classified as food, and only foods approved as Foods for Specific Health Uses (FOSHU) or Foods with Nutritional Function Claims (FNFC) are allowed to have health or nutrition claims. Due to the costly and time consuming approval process for FOSHU and the limited range of vitamins and minerals that qualify for FNFC, however, producers are not able to obtain FOSHU or FNFC approval for a majority of nutritional supplements. This limits the information available to consumers at the point of sale and hinders the ability of producers to differentiate their products. Other concerns include lengthy lead times for food additive applications, high levels of import duties for nutritional supplements compared to duties on pharmaceuticals containing the same ingredient(s), and the potential for opaque development of health food safety regulations or new regulations for health food safety that may not be based on scientific risk assessment principles.

Cosmetics and Quasi-Drugs: Japan is the second-largest market in the world for cosmetics after the United States, yet regulatory barriers continue to limit consumer access to safe and innovative products. Unlike the U.S. over the counter drug monograph system, Japan requires premarket approval for products that are classified as quasi-drugs under the Pharmaceutical Affairs Law. The approval process has requirements that are burdensome, lack transparency, and do not appear to enhance product safety, quality, or efficacy. In addition, many types of advertising claims for cosmetics and quasi-drugs are prohibited, even if scientifically verifiable, denying consumers relevant and important information to help them make sound choices. Other concerns related to cosmetics and quasi-drugs include burdensome paperwork and long lead times for the approval of imported products. The U.S. Government continues to recommend that Japan address these and other issues under the Regulatory Reform Initiative.

Financial Services

As Japan's financial sector becomes increasingly integrated into the global financial system, domestic efforts are underway to improve the international competitiveness of Japan's financial sector. The Financial Services Agency (FSA) published in December of 2007 the "Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets," for example, with a corresponding legislative effort in early 2008. Recent measures taken towards convergence with global practices in accounting and financial reporting standards follow the easing of regulatory barriers to domestic and foreign competition. As a result, foreign financial institutions have gained market share in securities brokerage, asset management, insurance, and banking.

Financial Instruments and Exchanges Law: The Financial Instruments and Exchanges Law (FIEL) of 2006 amended 89 financial laws and consolidated the remainder into a cohesive text. The FIEL was an effort to enhance investor protection and promote the movement of financial assets into securities markets through cross-sectoral rules for investment product sales, management, and disclosure. Given the hundreds of pages of statutes comprising the FIEL and that implementation of the law began September 30, 2007, however, the law's overall impact is still not discernable and

partners are looking to see that FIEL implementing regulations, interpretation, and enforcement are evident, consistent, and predictable.

The transparency and predictability of Japan's financial regulatory system have improved, but further progress is needed. In particular, the FSA could expand the body of written interpretations of Japan's financial laws. While supervision and disclosure have improved, Japan must continue to move forward in establishing transparency in regulation and supervision of financial institutions to bring them in line with international standards and best practices in the support of the government's goal to improve Japan's global financial services competitiveness.

No-Action Letters and Written Interpretations: The FSA has been making some efforts to enhance the effectiveness of the no-action letter system, including the active solicitation of input from U.S. and other foreign firms on how best to improve the system. The use of the system, however, has not materially increased. The U.S. Government has recommended the FSA explore ways to expand use of the no-action letter system, which remains relatively unexploited as a means of seeking administrative guidance. The U.S. Government has also encouraged the FSA to expand the written interpretations it provides through other means, including through active use of its "interpretive letter" system and increasing the number of "reference cases" published on the FSA Internet site.

Agriculture

Japan maintains many tariff and nontariff barriers to trade in the agricultural sector. The U.S. Government's October 2007 submission to Japan under the Regulatory Reform Initiative includes a number of recommendations to enhance the efficiency of the trading environment and the transparency of trade-related rules and regulations. These include: allowing the use of three internationally approved production substances on organic crops and lifting the overly strict zero residue requirement; implementing a Maximum Residue Limits regime that is not more trade restrictive than necessary and treats imports consistently with treatment of domestic products; completing the review of food additives already recognized as safe by a Joint Food and Agriculture Organization/World Health Organization Evaluation Committee; applying science based standards in accordance with World Organization for Animal Health (OIE) protocols on meat; and implementing international standards in plant quarantine. (See also *Standards, Testing, Labeling, and Certification* in this chapter.)

Plant Quarantine Issues: Japan's plant quarantine system is restrictive. Some measures that restrict trade are not based on science. One key impediment to trade is Japan's frequent use of nationwide bans in response to quarantine issues in exporting countries, as opposed to regional bans (*e.g.* states or counties), as recognized by international standards. For example, when a disease or pest outbreak is reported in the United States, Japan has been inclined to impose a nationwide ban on all associated U.S. plant products. This step is unnecessarily trade restrictive. In accord with its WTO SPS obligations, the United States has effective measures to contain the spread of plant disease, and any outbreaks of such diseases are typically limited to a small geographic area. Additionally, it is not apparent that Japan's standards for pest risk analysis are based on international standards, nor that Japan has provided a scientific justification for these measures or articulated how they are a consequence of the level of phytosanitary protection that Japan has determined to be appropriate. The U.S. Government and Japan are working closely through the Regulatory Reform Initiative and in various bilateral fora to facilitate trade and remove restrictions.

Japan's Ministry of Agriculture, Forestry, and Fisheries (MAFF) prohibits the entry of various fresh plant products due to the presence of pests, even though some of these pests are also present in Japan. Japan has a pest forecast system that monitors certain domestic pests and alerts producers to

potential increased pest damage. For decades, the Japanese government has contended that this constitutes official control under the International Plant Protection Convention (IPPC), the international standard setting body for plant protection. According to Japan, it must impose a similar system for imported commodities. Recently the Japanese government took initial steps to harmonize with international standards. In December 2004, Japan notified the WTO of its intent to relax quarantine measures for several plant pests and diseases. In May 2006, five additional cosmopolitan pests were added to the list of pests subject to relaxed quarantine measures. Although the U.S. Government has welcomed these actions, Japan continues to impose measures that are more restrictive than provided for in international standards on dozens more pests in ways that adversely affect U.S. exporters.

STRUCTURAL REGULATORY REFORM

Antimonopoly Law and Competition Policy

Although Japan has made significant positive steps in recent years to bolster its competition regime, cartel activity and bid rigging persist with deleterious effects for the country's economy and government finances. Further measures to combat anticompetitive behavior would improve the business environment. At the same time, further attention must be given to ensuring that antimonopoly enforcement procedures are perceived to be fair and transparent.

Establishing More Effective Deterrence to Anticompetitive Behavior: The Antimonopoly Act (AMA), Japan's primary competition legislation, provides for both administrative and criminal sanctions against violators. However, criminal prosecutions, which would more effectively deter anticompetitive behavior, have been few. From 1990 through October 2007, the Japan Fair Trade Committee (JFTC) initiated 12 criminal prosecutions of alleged AMA violators. While Japanese courts have imposed substantial financial penalties on companies and prison sentences on individuals convicted of violating the AMA, they have consistently suspended prison sentences on individuals even in the case of repeat offenders. The U.S. Government continues to urge Japan to take steps to maximize the effectiveness of AMA enforcement against hard-core violations of that Act, including by increasing the number of criminal prosecutions, strengthening criminal sentences of convicted individuals, and maintaining the system of imposing both administrative surcharges and criminal sanctions on corporate participants in cartel and bid rigging conspiracies.

The lack of sufficient personnel has also hindered the JFTC's ability to enforce the AMA effectively. JFTC's staff totaled 737, including 383 assigned to the Investigation Bureau as of March 31, 2007. JFTC remains relatively weak, however, in the number of staff with post-graduate economics training, a factor which hurts JFTC's ability to engage in the careful economic analysis necessary to properly evaluate noncartel behavior. The U.S. Government continues to urge JFTC to improve its economic analysis capabilities.

Improving Fairness and Transparency of JFTC Procedures: The JFTC introduced a system in January 2006 to allow 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 an order being issued. A similar system was implemented for proposed recipients of public warnings for suspected violations of the AMA or the Premiums and Misrepresentations Act. To ensure further the credibility and transparency of JFTC hearing procedures, however, the U.S. Government has asked the Japanese government to lengthen significantly the two week period during which a company may respond to a draft cease-and-desist or surcharge order from the JFTC, increase the number of JFTC hearing examiners who are outside legal professionals, and strengthen conflict of interest rules with respect to hearing examiners. The

U.S. Government has also requested clarification of conditions under which the JFTC might return to an *ex-ante* hearing system, improved regulations for the standards and procedures used by the JFTC to issue warnings, and recognition of attorney-client privilege in JFTC investigation and hearing procedures.

Broadening Measures to Combat Bid Rigging: In response to frequent and persistent revelations of bid rigging, the Japanese authorities have implemented a series of measures to address the problem. Apart from several cases of invocation by the JFTC of the 2003 law against bureaucrat led bid rigging (so-called *kansei dango*), the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) has strengthened administrative sanctions against companies found by JFTC to have engaged in unlawful bid rigging. MLIT also introduced an administrative leniency program to complement the JFTC leniency program (designed to help encourage individuals and companies to report anticompetitive acts) and put in place a series of measures aimed at ensuring a competitive bidding process for project contracts tendered by the Ministry. In June 2007, the Japanese Diet also passed new legislation aimed at controlling post-retirement employment by its officials in companies they previously helped regulate or were otherwise involved with while in government service, the so-called “descent from Heaven” (*amakudari*), which has been a factor in many bid rigging conspiracies. The U.S. Government has recommended the relevant Japanese authorities increase the standard minimum period of suspension from bidding for companies involved in bid rigging conspiracies, work to prevent conflicts of interest in government procurement, strengthen efforts to eliminate involvement in bid rigging by government officials, and expand the existing administrative leniency programs.

Transparency

Transparency issues continue to be a top concern of U.S. companies that operate in the Japanese market. The U.S. Government has strongly urged Japan to adopt a number of new measures to achieve a higher degree of transparency in governmental regulatory and policy making processes – a critical ingredient necessary to further improve the business and trade environment.

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 councils and study groups often remains opaque and nonmembers are not uniformly offered meaningful opportunities to provide input into these groups’ decision-making processes. The U.S. Government continues to urge Japan to ensure transparency of advisory councils and other government sponsored working groups through new requirements, including those that will ensure ample and meaningful opportunities are provided for all interested parties, as appropriate, to participate in and directly provide input to these councils.

Public Comment Procedures (PCP): U.S. companies remain concerned by the degree to which all Japanese ministries and agencies are fully implementing Japan’s PCP. In particular, concern remains that comment periods are unnecessarily short and that comments that are provided are not adequately being taken into consideration before final decisions are made. The U.S. Government has stressed the need for Japan to ensure its PCP is being fully implemented and to make additional revisions to the system so that truly meaningful opportunities are made available for public input into policy-making and regulatory processes. In addition, the U.S. Government continues to encourage Japan’s ministries and agencies to accelerate the voluntary practice of providing greater opportunities for the public to comment on legislation in the early stages of its formation.

Transparency in Regulation and Regulatory Enforcement: To ensure the private sector has sufficient information about regulations, including interpretations of those regulations, and the

information necessary to comply, the U.S. Government has requested that Japan specifically require its ministries and agencies to make public their regulations and any statements of policy of generally applicable interpretation of those regulations.

Privatization

The Japanese government's effort to reform the Japan Post Group from a public corporation to private business has made important progress. The U.S. Government recognizes that reform, if implemented in a fully market-oriented manner, can have an important positive impact on the Japanese economy by stimulating competition and leading to a more productive use of resources.

The U.S. Government welcomes the ongoing privatization of Japan Post, which has multi-billion dollar banking and insurance businesses in addition to its mail and parcel delivery operations. The U.S. Government continues to monitor carefully the implementation of the Japanese Government's reform efforts, and continues to call on the Japanese Government to ensure all necessary measures are taken to achieve a level playing field between Japan Post and the private sector in Japan's banking, insurance, and express delivery markets.

In the area of express carrier services, the U.S. Government remains concerned by unequal conditions of competition between Japan Post Service and U.S. international express delivery providers. The U.S. Government is strongly urging Japan to create a level playing field, including by ensuring Japan Post Service is subject to similar customs clearance procedures and costs for international express delivery services and that subsidization of Japan Post Service's international express service by revenue from noncompetitive postal services is prevented.

The U.S. Government also has continued to urge the Japanese government to ensure that the process by which this reform proceeds is made fully transparent, including by full and meaningful use of Public Comment Procedures and through opportunities for interested parties to express views to related officials and advisory bodies before decisions are made. The U.S. Government is additionally asking Japan to undertake regular (*i.e.* annual) reviews of the market impacts of the Japan Post reforms that includes the views of other market participants. (*For detailed discussion of Japan Post privatization and the postal insurance corporation, see "Insurance" under the Services Barriers section.*)

Commercial Law

Japan undertook a major reform of its commercial law by enacting a new Corporate Code, which entered into force May 1, 2006. Among other provisions, the code now permits the use of modern merger techniques, including domestic and cross-border triangular mergers. After significant public controversy, however, the Japanese government in April 2007 finalized tax and public disclosure rules for cross border triangular mergers that appear to substantially limit the use of these techniques. Under the new rules, in order for shareholders to defer capital gains on the transaction, the foreign acquiring company, at a minimum, must establish a subsidiary with an office, an employee/executive, and some "business activity" in the Japanese market before the merger. As of December 2007, only one transaction has taken place using these provisions.

Through the Regulatory Reform Initiative, the U.S. Government continues to urge Japan to improve further its commercial law and corporate governance systems to reflect international best practices, promote efficient corporate restructuring and increases in shareholder value. Specifically, the U.S. Government is urging Japan to review impediments to the use of modern merger techniques now

available to investors, including whether the tax rules unduly impede the ability of foreign investors to use triangular merger mechanisms.

The U.S. Government also continues to encourage Japan to strengthen further corporate governance mechanisms, including by facilitating and encouraging active proxy voting by institutional investors such as pension and mutual funds, requiring authorization of antitakeover measures by a company committee composed of a majority of truly independent directors, ensuring sufficient protection of minority shareholders in management buy-out and take-over bid situations, and encouraging the major Japanese stock exchanges to adopt listing rules or guidelines that encourage best corporate governance practices.

Article 821 of the new Company Law still has the potential to create burdens for foreign corporations that conduct their primary business in Japan through Japanese branch offices. The U.S. Government has recommended that Japan adopt a simple re-domestication procedure that allows foreign companies to merge or convert into a Japanese corporation, and continues to request that Japan amend Article 821 to prevent adverse effects on the legitimate operation of foreign companies in Japan.

Legal System Reform

Japan continues to impose restrictions on the ability of foreign lawyers to provide international legal services in Japan in an efficient manner. The U.S. Government is urging Japan to further liberalize the legal services market by allowing foreign lawyers to form professional corporations and establish multiple branch offices in Japan whether or not they have established a professional corporation and by counting all of the time foreign lawyers spend practicing law in Japan toward the 3 year experience requirement for licensure as a foreign legal consultant. In addition, the U.S. Government has requested that Japan ensure that Japanese lawyers may become members of international legal partnerships with lawyers outside Japan without restriction. Japan has agreed to continue to examine these issues including by holding further hearings with both the Japanese Bar Association and registered foreign lawyers practicing in Japan. The U.S. Government also is urging Japan to promote arbitration and other alternative dispute resolution (ADR) procedures, including by amending the Foreign Lawyers Law to explicitly permit foreign lawyers to act as neutrals and to represent parties in any international ADR proceedings taking place in Japan.

Distribution and Customs Clearance

The U.S. Government welcomes Japan's efforts to formulate an Authorized Economic Operator (AEO) system in Japan. Under the Regulatory Reform Initiative, the U.S. Government has recommended that Japan apply the following measures to customs brokers with good compliance records: introduce a two-stage declaration of import to allow separation of declaration of shipment acceptance and declaration of tax and duty payment, which would enable express carriers to release import items in a timely way outside of regular business hours; allow customs brokers to make export declarations after export, a system that is effective in the United States and would reduce the impact of airport curfews; allow customs brokers using Nippon Automated Cargo Clearance System (NACCS) to declare express items at any convenient customs office beyond a territory of the Customs Office; and lower overcharge and NACCS charges.

To follow a global trend toward reducing customs workloads while maximizing efficiency, the U.S. Government recommends Japan increase the Customs Law *de minimis* limit from its current 10,000 yen to a level comparable to the \$200 *de minimis* limit.

The U.S. Government welcomes assurances by Japan that distribution vehicles, including those carrying *Yu-pack* and Express Mail Service (EMS) items, will be treated equally with regard to the enforcement of parking laws and traffic regulations. In light of the impact of the revised Road Traffic Law, the U.S. Government has encouraged Japan to take measures that help provide additional parking spaces for distribution vehicles in urban centers where shortages have appeared through the Law's enforcement. The U.S. Government therefore recommends that Japan: (1) increase the number of parking spaces and delivery zones on major streets; (2) coordinate policies among concerned ministries and local authorities to facilitate distribution activities in crowded areas; and (3) ensure equitable application of parking laws for all distribution vehicles.

IMPORT POLICIES

Rice Import System: Although Japan has generally met import volume commitments it made during the Uruguay Round and subsequent negotiations, Japan's highly regulated and nontransparent importation and distribution system for imported rice limits meaningful access to Japanese consumers. U.S. rice exports to Japan in calendar year 2006 were valued just under \$169 million, representing 330,453 metric tons of rice or about 48.5 percent of Japan's minimum access requirement. However, only a small fraction of rice imported from the United States 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 available.

In 1999, Japan established a tariff-rate quota (TRQ) of approximately 682,000 metric tons (milled basis) for imported rice. The Japan Food Department (JFD) of the Ministry of Agriculture, Forestry, and Fisheries (MAFF) manages imports of rice within the TRQ through periodic minimum access (MMA) tenders and through the simultaneous buy-sell (SBS) tenders. Imports of U.S. rice under the MMA tenders are destined almost exclusively for government stocks. The stocks are released exclusively for nontable rice users in the industrial food processing or feed sector, or re-exported as food aid.

Recent increased testing requirements for rice imports have hampered trade of U.S. rice to the Japanese market. In December 2005, MAFF began to impose strict testing requirements on rice imports, ostensibly to ensure compliance with the Japanese Government's new Maximum Residue Limits policy. Rice and wheat, however, are the only commodities for which Japan requires multiple testing, including a test by the rice industry. The result is a disproportionate increase in the cost of bringing U.S. rice to market, particularly for SBS rice because of its smaller import lot size.

Rice Stocks Release Program: On July 29, 2005, in an effort to reduce Japan's government held stocks of rice imported under its WTO MMA commitment, MAFF introduced a new program under which a certain quantity of MMA rice stocks is released to select rice flour users via Japanese rice-flour millers. Although the stated purpose of this policy is to reduce stock levels, the program in effect channels the release of imported rice stocks to displace imports of rice flour bakery/cake mixes, including imports from the United States. Japanese data show that imports of rice flour bakery/cake mixes from the United States during the January-December 2006 period were down 14 percent by quantity and nearly 8 percent by value compared with the same period in 2005. The decline in U.S. imports was similar in 2007. The U.S. Government has strongly urged Japan to address these issues through the United States-Japan Trade Forum and in the context of the WTO Committee on Agriculture. The U.S. Government remains highly concerned about the adverse affect on U.S. exports of prepared mixes and the consistency of the policy with Japan's WTO commitments.

Wheat Import System: Japan requires wheat be imported through MAFF's Food Department, which then resells 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. The U.S. Government remains concerned by the operation of a state trading entity for wheat and its potential to distort trade.

Corn for Industrial Use: Japan's domestic potato starch blending requirement was abolished in April 2007. While the U.S. Government views the decision as a positive step, the reforms do not go far enough to be truly market based. The previous system was replaced by a levy or a surcharge payment arrangement where the quasi-governmental Agriculture and Livestock Industries Corporation collects the difference between the import cost of corn intended for starch production and resale price to Japanese starch manufacturers. The fund created by the pool of collected surcharge is then used to support domestic potato producers. This system mimics the sugar import system. The U.S. Government intends to monitor carefully the administration of this new system for any market distorting effects.

Pork Import Regime: Japan is the world's largest importer of pork, importing a record 725,000 tons in Japan FY 2006, with imports from the United States valued at \$1.15 billion. Japan's pork import system includes a gate price and a safeguard negotiated during the Uruguay Round which automatically raises the gate price if imports are 119 percent or more of the average quantity level of imports during the corresponding period in the previous 3 years.

Beef Safeguard: Once Japan fully opens its beef market, the U.S. Government is concerned about the possibility that Japan's beef safeguards will be triggered, which could hamper the United States' ability to regain historical export levels in the near future (*see the section on "Beef" under the "Standards" heading for context*). Japan has indicated some flexibility in this regard for 2008 imports by applying the 2002-2003 beef import baseline to set its beef safeguard trigger.

Japan's beef safeguard was negotiated during the Uruguay Round to afford protection to domestic producers in the event of an import surge. The safeguard is triggered when imports increase by more than 17 percent from the previous Japanese fiscal year on a cumulative quarterly basis. Once triggered, the safeguard remains in place for the rest of the fiscal year. If triggered, beef tariffs will rise to 50 percent from 38.5 percent. The U.S. Government is seeking a change in the beef safeguard in the Doha Development Agenda negotiations.

Fish Products: Japan has been the most important export market for U.S. fish and seafood products for over 30 years; as recently as 1988, 73 percent of U.S. seafood exports went to Japan. In 2006, however, the European Union surpassed Japan as the most important export market for fisheries products, with only 23 percent of U.S. seafood exports going to Japan. This data should be viewed, however, against the growing trend of U.S. origin seafood being routed through China and Korea for value added processing and/or cold storage holding before being imported into Japan, making actual trade flows harder to follow.

Tariffs on Japanese seafood imports are generally low, but for some products market access is not seamless. Japan maintains several species and product specific import quotas on fish products, including pollock, surimi, Pollock, and cod roe, herring, Pacific cod, mackerel, Pacific whiting, squid, and sardines. Administration of the system has improved considerably over the years, and it is expected that obstacles to Japanese importers and processors will continue to be reduced. While Japan cut tariffs as a result of the Uruguay Round, it did not change its import quotas. As part of ongoing WTO Doha negotiations, Members including the United States and Japan have committed to clarify and improve rules on fisheries subsidies.

High Tariffs on Beef, Citrus, Dairy, and Processed Food Products: Japan maintains high tariffs on a number of food products that are important exports for the United States, including red meat, citrus, wine, and a variety of processed foods. Examples of double digit import tariffs include 38.5 percent on beef, 32 percent on oranges, 40 percent on processed cheese, 29.8 percent on natural cheese, 17 percent on apples, and a 15 to 29.8 percent on wine depending on the HTS classification. These high tariffs generally apply to food products where Japan is protecting domestic producers. Tariff reductions are a high priority for the U.S. Government in the Doha Development Agenda agriculture negotiations.

Wood Products and Building Materials: Japan continues to restrict the importation of U.S. manufactured wood products through tariff escalation (*i.e.*, progressively higher tariffs based on the level of processing of the wood product). The elimination of tariffs on wood products remains a long standing U.S. Government objective.

Leather/Footwear: Japan continues to apply a TRQ on leather footwear that substantially limits imports into Japan's market, and establishes these quotas in a nontransparent manner. The U.S. Government will continue to seek elimination of these quotas.

STANDARDS, TESTING, LABELING, AND CERTIFICATION

Japan's enforcement of national standards hinders trade in certain farm, forest, and industrial products. U.S. industry has commented that Japan's stringent testing methods and low tolerances for regulated substances such as pesticides and food additives make it difficult to satisfy import requirements for many products. The U.S. Government is urging Japan to use science based standards and implement risk-based enforcement policies which are the least trade restrictive measures that also satisfy consumer safety concerns.

Standards

Beef: On July 27, 2006, Japan partially reopened its market to U.S. beef. Except for approximately 1 month from December 2005 to January 2006, Japan's market had been effectively closed since the December 2003 detection of a cow with Bovine Spongiform Encephalopathy (BSE) in Washington State.

Japan allows imports of U.S. beef and beef products from animals aged 20 months or younger. This policy, however, has prevented the United States from regaining all but a small portion of its historic level of exports to the Japanese market. Before the ban, Japan was the largest export market for U.S. beef and beef products, totaling roughly \$1.4 billion annually.

The U.S. Government has urged Japan to bring its BSE measures in line with international guidelines set by the World Organization for Animal Health (OIE) by allowing imports of all U.S. beef and beef products derived from animals of all ages deemed safe under OIE guidelines. In May 2007, the OIE determined that the United States is a "Controlled Risk" country for BSE, a determination based on science. The U.S. Government remains highly concerned by Japan's unwillingness to adopt these science based, international guidelines under which beef and beef products can be safely traded and will continue to work vigorously toward achieving a full reopening of Japan's market to U.S. beef in line with OIE guidelines through use of various bilateral and multilateral fora.

Enforcement of Maximum Residue Limits (MRLs): Japanese regulatory requirements specify that foods containing pesticide residues will not be allowed on the Japanese market unless residue levels conform to national Maximum Residue Limit (MRL) standards. These new regulations, known as the “Positive List,” became effective on May 29, 2006. The U.S. Government worked closely with the Ministry of Health, Labor, and Welfare (MHLW) to ensure that potentially trade restrictive measures relating to the new positive list were addressed to minimize disruptions to U.S. agricultural trade with Japan. However, several outstanding issues remain, including MHLW’s MRL enforcement policy that predates the implementation of the new Positive List.

A major U.S. Government concern is that import violations of the MRLs may be treated more harshly than domestic violations. When an MRL violation is detected in a shipment of imported food, MHLW takes action against the entire industry of the country where the food product was sourced; in contrast, violations in a shipment of domestic origin are addressed on a company-by-company basis. Violations in imported food shipments can lead to sanctions that severely affect trade regardless of the level of the violation or the degree of the threat to health. For instance, following only two violations, MHLW can implement 100 percent test-and-hold requirements. The resulting delays can lead to major losses for perishable goods. To address these concerns, the U.S. Government is urging MHLW, through the Regulatory Reform Initiative, to implement a regime that is as minimally trade restrictive as possible, provides national treatment to imports, and is in accordance with international practices.

Restrictive Food Additive List: Japan’s list of food additives restricts imports of several U.S. food products, especially processed foods. The list, which limits the use of specific food additives on a product-by-product basis, is more restrictive than accepted international standards and is without sufficient scientific evidence. For example, the list effectively prohibits imports of light mayonnaise, creamy mustard, or figs containing potassium sorbate, a food additive evaluated and accepted by numerous national and international standard setting organizations, including the Joint FAO/WHO Expert Committee on Food Additives. In spite of this prohibition on imports, Japan in fact allows the use of potassium sorbate in 36 other foods, most of which are traditional Japanese food products not normally produced outside Japan.

U.S. manufacturers have also complained that the process for gaining approval for indirect food additives (that is, additives that do not remain on food, such as solvents) is slow and lacks transparency.

In 2002, Japan created a list of 46 food additives for expedited review. The U.S. Government and many of Japan’s other trading partners have been disappointed by the lack of progress by the MHLW and the Food Safety Commission in finalizing reviews and approving many of these additives, notwithstanding the availability of extensive safety data. In addition, Japan classifies post-harvest fungicides as food additives requiring registration and approval, while the international community, including Codex, classifies them as pesticides. Therefore, products found to have any trace of an unapproved pesticide are prohibited. To address some of these concerns, the U.S. Government has urged Japan through the Regulatory Reform Initiative to complete its review of the remaining 26 food additives in an expedited fashion.

Microbial Content Standards: Japan’s standards under the Food Sanitation Law for microbial content on frozen foods are, in certain instances, impractical and overly restrictive, particularly for foods that require cooking before consumption.

Poultry: Since 2002, Japan has imposed a number of national and statewide bans on the import of U.S. poultry, poultry-meat, and eggs due to the detection of notifiable avian influenza (NAI), both

high pathogenic notifiable avian influenza (HPNAI) and low pathogenic notifiable avian influenza (LPNAI) in U.S. poultry. These bans are not consistent with international guidelines and have disrupted millions of dollars of U.S. poultry trade. According to international guidelines recently revised by the OIE, countries must report to the OIE any findings of NAI in domestic poultry, regardless of its pathogenicity. These guidelines, as well as the WTO SPS agreement, provide for importing countries to impose bans on imports only from affected regions (zones) of the exporting country. While the guidelines support banning certain poultry meat from regions affected by HPNAI, they do not support banning poultry meat from regions affected by LPNAI. As a result of bans based on the reporting of high and low pathogenic avian influenza, as well as other factors, U.S. poultry meat exports to Japan have decreased substantially from roughly \$148 million in 2001 to \$70 million in 2002, ranging from \$39 to \$61 million a year from 2003 through 2006 and down an additional 17 percent in 2007.

Organics: U.S. organic exports to Japan continue to be limited by Japan's ban on three production substances allowed for use on U.S. organic crops: Alkali extracted humic acid, Potassium bicarbonate, and Lignin sulfonate. In addition, Japan's zero tolerance policy for pesticide residues on organic products is not consistent with international standards, is not science based, and is, in practice, more thoroughly enforced for imported organic products.

Marine Craft: Although Japan continues to maintain an inspection regime for new boats and marine engines that is unique in the world in its severity and complexity, Japan's regulatory agencies, MLIT and the Japan Craft Inspection (JCI) Organization, have made a significant shift towards adoption and acceptance of ISO standards, when these ISO standards are determined to provide equivalent or improved safety. The U.S. Government looks to accelerate progress with Japan as quickly as possible to also address Japanese requirements that no other country considers necessary, such as requiring that each imported boat be individually inspected. These unusual rules place an enormous burden on Japanese importers and American boat manufacturers. The U.S. Government will continue to work with relevant organizations and agencies in Japan to urge Japan's acceptance of acceptance of third-party tests of Japanese ISO based standards.

Building Size, Designs, and Wood Products

Japan has adopted and implemented regulations with respect to indoor air quality and chemical emissions, and may be considering additional steps. The U.S. Government will continue to monitor regulatory developments in this area and urge that transparency is ensured in any rule making process that may result. In addition, Japan's fire testing of wood frame assemblies also is subject to standards that are open to interpretation by testing facilities, thereby affecting predictability in meeting Japan's fire testing requirements.

Biotechnology

Japan is the world's largest importer of bioengineered grains and annually imports about 16 million metric tons of U.S. corn and 3.7 million metric tons of U.S. soybeans. In 2006, exports of these commodities alone were worth \$3 billion. As the world's largest exporter and world's largest importer of bioengineered crops, the United States and Japan share a common interest in promoting effective biotechnology approval and regulatory policies.

Japan's regulatory system is complex and compliance is costly. Japan's independent Food Safety Commission conducts risk assessments in support of product evaluations by the Ministry of Health, Labor and Welfare and Ministry of Agriculture, Forestry and Fisheries. The regulatory burden is such that only large multinational companies or governments can typically afford to complete the

approval process, even for bioengineered traits that are relatively well known. Further, a surge in new biotechnology applications is expected in coming years that will strain this regulatory system. There is also the real possibility of trade disruptions from an unapproved bioengineered variety showing up in trace amounts in imported grain or processed foods. To avoid disrupting trade, the U.S. Government is encouraging Japan's regulatory agencies to take a risk based, case-by-case approach when dealing with unapproved varieties.

In addition to Japan's national regulatory system, 11 prefectural and local governments have rules, generally not based on science, which further limit the cultivation of bioengineered crops. These rules, combined with local regulations and public pressure on research institutions, have made it increasingly difficult for technology companies to secure sites for field trials, which are mandated under the national government's approval process.

Although Japan is the largest importer of bioengineered crops, no consumer-ready foods with recognizable bioengineered ingredients are sold in Japan. One factor that keeps bioengineered foods out of the supermarket is Japan's labeling requirement. As yet, no Japanese food manufacturer or retailer has been willing to test the market for a genetically modified organism labeled, consumer-ready food.

The U.S. Government will continue to encourage Japan to address these issues and continue to participate in discussions on biotechnology policy advancement and regulation in international fora (*i.e.*, the WTO, the Codex Alimentarius Commission, the OECD, and the APEC forum) and through international agreements dealing with international movement of bioengineered crops.

Labeling

Proprietary Ingredient Information Disclosure Requirement for Import: As part of its product classification process for new-to-market food and dietary supplement products, Japan mandates that all ingredients and food additives be listed by name, along with content percentages, and include a description of the manufacturing process. In addition to being overly burdensome, this process runs the risk that proprietary information may be obtained by competitors.

Labeling of Beef: In 2007, the Ministry of Agriculture, Forestry, and Fisheries adopted labeling guidelines for "wagyu" beef. Although presented as voluntary standards, the guidelines bar use of the term "wagyu" on cattle not born and raised in Japan. The U.S. Government is concerned by the regulation and is monitoring this situation closely.

GOVERNMENT PROCUREMENT

Japan is a Signatory to the WTO Agreement on Government Procurement (GPA). For procurement of construction services by sub-central and government enterprises covered under the GPA, Japan applies a threshold of approximately \$22 million, which is three times the threshold applied by the United States.

Construction, Architecture, and Engineering

Even though Japan has the second largest public works market in the world (\$149 billion in 2007), U.S. companies annually obtain far less than 1 percent of projects awarded. 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 included 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. Public works issues are raised in the Expert-Level Meeting on Public Works under the United States-Japan Trade Forum.

Problematic practices that continue to limit the participation of U.S. design/consulting and construction firms in Japan's public works sector include bid rigging (*dango*), under which companies consult and prearrange a bid winner. The prevalence of *dango* is evidenced by the recent Defense Facility Agency procurement, in which 58 major construction companies were implicated in *dango*. The U.S. Government continues to stress the need for Japan to effectively address this pervasive problem.

Another concern is Japan's use of excessively narrow Japan-specific qualification and evaluation criteria that preclude U.S. firms from competing for projects. The U.S. Government has asked Japan to develop procedures to simplify the qualification process for foreign firms that have relevant experience outside of Japan, as well as to ensure that all of the qualification requirements for a project are made public, as required by the GPA and the bilateral agreements. For example, the Action Plan requires that definitive criteria be published so that firms can determine if they qualify for a project. Other concerns with Japan's procurement practices include the imposition of unreasonable restrictions on the formation of joint ventures, extremely low design fees, and excessive and costly documentation requirements for design bids.

The U.S. Government has also urged Japan to increase the use of Construction Management and Project Management in its public works to create greater opportunities for U.S. firms, which have extensive expertise in these areas. Construction and Project Management involve advanced project delivery and management systems that maximize the efficiency of projects.

The U.S. Government is paying special attention to several major projects covered by the public works agreements of particular interest to U.S. companies with the expectation that they will provide important opportunities for U.S. firms. These projects include Okinawa Institute of Science and Technology; Haneda Airport development and expansion; Kansai International Airport; Central Japan International Airport; Kyushu University Relocation Project; Gaikan Expressway Project; Metropolitan Expressway Shinagawa Route Projects; Japan Post's Post Office Projects; major public buildings, large-scale hospital building projects, urban development, and redevelopment projects; major PFI projects; and the MPA projects that have not yet been undertaken or completed.

INTELLECTUAL PROPERTY RIGHTS (IPR) PROTECTION

The U.S. Government continues to pursue its IPR protection agenda with Japan through bilateral consultations and cooperation as well as in multilateral and regional fora. For its part, Japan continues to make progress in improving the protection of IPR. In addition to increasing our bilateral cooperation, the U.S. Government has identified a number of areas in Japan's IPR protection regime where further action by Japan is needed.

Patents

The U.S. Government has urged Japan to adopt a 12 month patent application filing grace period, similar to that provided under U.S. law, to harmonize the two systems and provide U.S. innovators with an appropriate measure of protection against loss of rights when seeking to obtain patent protection in Japan. The U.S. Government also continues to urge Japan to implement procedures to

avoid a piecemeal approach to patent examinations that results in unnecessarily lengthy delays in granting patents.

In 2005, Japan established an Intellectual Property High Court staffed with judges and judicial research officials conversant with IPR cases, which the Japanese government reports has reduced the average length of litigation. The U.S. Government welcomes this reduction in the average length of litigation as helping to address longstanding concerns, and will continue to monitor the implementation and impact of Japan's reforms on the cost, length, and effectiveness of IPR related litigation.

Copyrights

Adequate protection of intellectual property, including copyrights and neighboring rights, is critical for the continued development and competitiveness of content related industries such as entertainment software, music, film, literary works, and software, and is a vital component to advancing electronic commerce and a well-functioning digital economy. The U.S. Government remains concerned that Japan's Internet service provider liability law does not provide adequate protection for the works of right holders on the Internet or the appropriate and necessary balance of interests among telecommunications carriers, service providers, rights holders, and website owners. The law could be improved by, among other things, including a requirement for more expeditious notification to right holders in the "notice and takedown" system.

The U.S. Government continues to monitor Japan's efforts to promote digital content distribution and urges that as technology advances to distribute content, the international framework of the exclusive rights of authorship and the incentives to create be preserved.

The U.S. Government is also urging Japan to continue efforts to reduce piracy rates, including piracy on the Internet, and is recommending that Japan amend its Civil Procedures Act to provide for the availability of statutory damages for infringement, at the election of the right holder, as an alternative to actual damages. Police and prosecutors should be given *ex officio* authority to enable them to investigate and prosecute IPR crimes on their own initiative, without the requirement of right holder consent. To develop Japan's digital communication networks, Japan's Copyright Law should better protect the technological adjuncts to copyright protection such as strengthening the remedies for trafficking in the tools used to circumvent access controls. Japan also does not forbid copyright infringement in government operations through a public decree or the issuance of regulations.

The U.S. Government is also concerned about the scope of the personal use exception, both as it applies to the Internet and to book piracy in the educational context, and is encouraging Japan to: make clear in its law that the otherwise infringing use of copyrighted works over peer-to-peer networks is not excused by the personal use exemption; and address the fact that Japan's personal use exception appears to allow students to copy entire textbooks for personal use.

The U.S. Government also continues to strongly urge Japan to extend the term of protection for all the subject matter of copyright and neighboring rights to life plus 70 years, or where the term of protection of a work (including a photographic work), performance, or phonogram is calculated on a basis other than the life of a natural person, to 95 years.

Japan's government is coordinating an ongoing discussion among stakeholders of these and other related issues and plans to revise Japanese laws in the near term. The U.S. Government welcomes

this process and encourages Japan to ensure it is open, inclusive, and transparent, and offers all stakeholders fair opportunities to express views.

Border Enforcement

Border enforcement is a critical component of effective IPR protection. The U.S. Government notes steps taken by Japan to strengthen its own border enforcement as well as to provide assistance to improve the border enforcement of key trading partners. The U.S. Government also welcomes revisions to the Customs Tariff Law, which went into force in 2007, including expanding the list of prohibited goods for export to include items that infringe copyrights and neighboring rights, and strengthening the penalty clauses for customs offences. It is important for Japan to continue its aggressive interdiction of infringing articles and to vigorously apply the new provisions of the Customs Tariff Law. The U.S. Government also welcomes Japan's international efforts to enhance IPR enforcement in fora such as the G-8, APEC, and the WTO TRIPS Council, as well as in the *ad hoc* Japan-China-Korea trilateral Customs dialogue.

SERVICES BARRIERS

Insurance

Japan's private insurance market is the second-largest in the world, after that of the United States, with direct net premiums of an estimated 36.8 trillion yen (over \$300 billion) in Japan fiscal year (FY) 2006. In addition to the offerings of Japanese and foreign private insurers, substantial amounts of insurance are also provided to Japanese consumers by the National Public Health Insurance System, a web of insurance cooperatives (*kyosai*), and the Kampo life insurance company (a wholly government owned entity of the Japan Post Group). Given the size and importance of Japan's private insurance market as well as the scope of the obstacles that remain, the U.S. Government continues to place a high priority on ensuring that the Japanese government's regulatory framework fosters an open and competitive insurance market.

Kampo Insurance: The Japan Post Group's insurance business, Kampo, continues to be the largest player in Japan's insurance market. In Japan FY 2006, there were approximately 64 million life and annuities insurance policies issued by Kampo in force compared to 126 million issued by all private life insurance companies combined. The U.S. Government has long standing concerns about Kampo's impact on competition in Japan's insurance market. It remains vital that Japan create a level playing field between Kampo and private sector insurers to cultivate competition, encourage more efficient allocation of resources, and stimulate economic growth.

The U.S. Government is closely monitoring the privatization of Japan Post and implementation of related reforms. The Japan Post reform framework established by Japan's Diet in 2005 includes a number of key measures that, if implemented fully, will represent long awaited progress in areas of concern to U.S. and insurers in the market. Importantly, the legislation also included establishment of equivalent conditions of competition between Japan Post and the private sector as a basic principle of the reforms.

In addition to ensuring equal supervisory treatment between Kampo and private sector companies, the U.S. Government continues to seek for Japan to take the steps necessary to achieve a level playing field. Among those steps, the U.S. Government urges that adequate measures are implemented to ensure that cross-subsidization does not take place among the newly created Japan Post businesses and related entities, including by ensuring Japan Post's strict compliance with the Insurance Business Law's arms-length rule and requiring adequate financial disclosures to

demonstrate that cross-subsidization is in fact not occurring. The U.S. Government also continues to emphasize the importance of ensuring the new company established to manage Japan's post office network will transparently and without discrimination select insurance products of private providers for distribution throughout the network.

The U.S. Government continues to call on Japan to ensure that a level playing field is created between the postal insurance company and private insurers before the postal insurance institutions are permitted to underwrite and introduce new or altered insurance products. Approval of any proposed new products by the new postal insurance company has shifted to a new process whereby decisions are made by the Prime Minister (with the Commissioner of the Financial Services Agency acting as proxy) and Minister of Internal Affairs and Communications, after hearing the opinion of an appointed government advisory body. This new process should be transparent and open to all parties. It is also critical that the process include careful analysis of, and full consideration given to, actual competitive conditions in the market and that private sector views are actively solicited and considered before decisions are made.

As modifications to the postal financial system could have serious ramifications to competition in Japan's insurance market, adequate transparency in implementation of the reforms passed by the Diet is essential. The U.S. Government has urged Japan to continue to take a variety of steps that ensure transparency, including: providing meaningful opportunities for interested parties to exchange views with related government officials as well as members of government-commissioned advisory committees and groups before decisions, including those on new products, are made; and fully utilizing public comment procedures with respect to drafting and implementing regulations, guidelines, Cabinet Orders, and other measures.

Kyosai: Insurance businesses run by cooperatives, or *kyosai*, hold a substantial market share of insurance business in Japan. Some *kyosai* are regulated by their respective agencies of jurisdiction (the Ministry of Agriculture, Forestry and Fisheries, or the Ministry of Health, Labor and Welfare, for example) instead of by the FSA, while others have been allowed to operate without any regulatory supervision at all. These separate regulatory schemes undermine the ability of the Japanese government to provide companies and policyholders a sound, transparent, regulatory environment, and afford *kyosai* critical business, regulatory, and tax advantages over their private sector competitors. The U.S. Government believes all *kyosai* must be subject to the same regulatory standards and oversight as their private sector counterparts to ensure a level playing field and to protect consumers.

The Japanese government took some important steps in 2006 to bring more oversight scrutiny to unregulated *kyosai*. Under these regulatory reforms, previously unregulated *kyosai* will be supervised by the FSA and held to some of the same regulatory standards as private sector insurers. *Kyosai* that do not comply with FSA regulations will be forced to shut down their operations. As the Japanese government implements this new system and reviews its operation as required under the amended law, the U.S. Government urges additional steps be taken to hold *kyosai* to the same regulations and FSA supervision as are applied to private companies.

With respect to *kyosai* regulated by ministries and agencies other than the FSA, the U.S. Government remains concerned by their continued expansion in Japan's insurance market and continues to call on Japan to bring these *kyosai* under FSA supervision.

Policyholder Protection Corporations: The Life and Non-life Policyholder Protection Corporations (PPCs) are mandatory policyholder protection systems created in 1998 to provide capital and management support to insolvent insurers. Japan's Diet passed legislation in 2005 to renew the

PPC system. While some improvements were made, the PPC system continues to rely upon prefunding by its members, instead of adopting a system of funding to follow an insolvency that results in a draw of funds from the PPC (post-funding). The U.S. Government continues to urge Japan to adopt more fundamental changes in the PPC systems, including the post-funding approach, when the next renewal of the system is enacted.

Bank Sales: The U.S. Government welcomes the decision taken by the Japanese government in December 2007 to liberalize fully the range of products eligible to be sold through the bank sales channel. As meaningful liberalization of the bank sales channel is critical for Japanese and foreign stakeholders alike, regulation of the channel should avoid arbitrary *ex-ante* restrictions that would effectively minimize the benefits of liberalization. Equally important is that restrictions on sales in the channel not unreasonably limit sales of first or third-sector products.

Professional Services

U.S. and other foreign firms and individuals are hampered in providing professional services in Japan by a complex network of legal, regulatory, and commercial practice barriers. U.S. professional services providers are highly competitive. Their services also help facilitate access for U.S. exporters of other services and goods, and contribute valuable expertise to the economies they serve. The availability of such services can be a key factor in U.S. firms' decisions whether to invest and thus is central to improving the environment for foreign direct investment in Japan.

Accounting and Auditing Services: U.S. providers of accounting and auditing services face regulatory and market access barriers in Japan that impede their ability to serve this important market. Only Certified Public Accountants (CPAs) or Audit Corporations (made up of five or more Japanese CPAs) can offer accounting services. Foreigners must pass a national examination to qualify and this examination is offered annually. The U.S. Government will continue to urge Japan to remove restrictions on accounting services.

Medical Services: Restrictive regulation limits foreign access to the medical services market. In our bilateral Regulatory Reform Initiative, the U.S. Government has recommended that Japan allow commercial entities to provide full service, for-profit hospitals in Japan's special economic zones as a first step to opening this sector to foreign capital affiliated providers.

Educational Services: Excessive regulation has discouraged foreign universities from operating branch campuses in Japan, presenting obstacles in the form of both administrative requirements and restrictions on pedagogical choices. Under the United States-Japan Investment Initiative, the Japanese government established a new category of "Foreign University - Japan Campus" for foreign accredited institutions of higher education. This designation provides these campuses with benefits similar to those accorded Japanese educational institutions (for example, student eligibility for student rail passes and student visas), but does not confer tax benefits enjoyed by Japanese institutions and their students. The U.S. Government continues to urge Japan's Ministry of Education, Culture, Sports, Science and Technology to work with these foreign universities to find a nationwide solution that grants tax benefits comparable to Japanese schools and allows them to continue to provide their unique contributions to Japan's educational environment.

INVESTMENT BARRIERS

Despite being the world's second-largest economy, Japan continues to have the lowest inward FDI as a proportion of total output of any major OECD country. Inward foreign mergers and

acquisitions (M&A) activity, which accounts for up to 80 percent of FDI in other OECD countries, also lags in Japan, even though it is on an upward trend.

The Japanese government has recognized the importance of FDI to revitalizing the country's economy. In September 2006, the Japanese government set a goal of doubling the stock of FDI in Japan by 2010 to the equivalent of 5 percent of Gross Domestic Product (GDP). Japan has also taken several recent steps to improve the FDI environment, including revision of the Corporate Code to permit the use of triangular stock swaps for international M&A deals. With only one cross-border stock transaction occurring under the new rules as of October 2007, however, the long term impact of the liberalization of M&A rules is still unclear.

Cross-border M&A is more difficult in Japan than in other countries, partly because of attitudes toward outside investors and partly because of differing management techniques and the relative lack of financial transparency and disclosure. There is also growing concern among foreign investors about the impact of recent court rulings related to allowable defensive measures by listed companies against unsolicited takeover bids.

The United States-Japan Investment Initiative, co-chaired by the U.S. Department of State and Japan's Ministry of Economy, Trade and Industry (METI), has worked to promote policy changes that improve the overall environment for foreign (and domestic) investment since 2001 and to focus on specific barriers in certain sectors, including educational and medical services.

Anticompetitive Practices

Law against Unjustified Premiums and Misleading Representations: Despite nominal changes to the Law against Unjustified Premiums and Misleading Representations over the past two decades, the law itself and JFTC's enforcement of its provisions block many common sales techniques such as product giveaways and lotteries. In March 2007, however, the JFTC did revise the maximum amount that a business may offer as a nonprize premium from one-tenth to two-tenths of the purchase price. Nevertheless, fair trade councils (essentially, private trade associations) set their promotion standards through self-imposed fair competition codes that are recognized by the JFTC. These codes frequently impose additional standards that effectively protect vested manufacturing and retailing interests to the detriment of new entrants to the market. As of November 2007, there were still 38 JFTC authorized premium codes.

(For detailed discussion on other anticompetitive practices and Antimonopoly Act enforcement, see the section above titled "Structural Regulatory Reform.")

OTHER BARRIERS

Autos and Automotive Parts

A variety of nontariff barriers have traditionally impeded access to this market, and overall sales of North American made vehicles and parts in Japan remain low. Even as U.S. automakers have invested in Japanese automobile manufacturers, there has not been a corresponding level of increase in sales in Japan's market. The Japan Automobile Importers Association (JAIA) reports that sales of U.S. produced motor vehicles in Japan decreased in 2006 to 16,290 units.

Through the Regulatory Reform Initiative, the U.S. Government continues to address crosscutting structural and regulatory reform issues with Japan that affect the automotive sector, including

urging Japan to take steps that help expand the opportunities for foreign investment, strengthen competition policy, and increase transparency in rule making.

Aerospace

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

Military procurement by the Ministry of Defense (MOD) accounts for over 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 (over 90 percent of the annual foreign defense procurement is from the United States), the MOD has a general preference for domestic production or the licensing of U.S. technology for production in Japan to support the domestic defense industry.

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, including Japan's primary space launch vehicle, the HII-A. The U.S. Government has welcomed Japan's plans to develop a supplementary GPS navigation satellite constellation known as the "quasi-zenith" system. The U.S. Government is working very closely at the technical level with Japanese counterparts to ensure the Japanese system remains compatible with the U.S. system and anticipates that U.S. companies will have the opportunity to supply major components.

Business Aviation

Japan's regulatory framework coupled with infrastructure shortages impedes the development of business aviation, as well as the ability of business aviation interests from other countries to use facilities in Japan.

Regulations for commercial airline safety, maintenance, and repair issues administered by the Japan Civil Aviation Bureau (JCAB) of the MLIT also apply to business aircraft. The current regulatory environment greatly raises the costs of qualification, operation, and maintenance of business aircraft to uneconomical levels. As a result, most business aircraft in Japan are registered in the United States. Landing business aircraft in Japan is difficult due to rules that hamper flexible scheduling, especially in the Tokyo area. Current regulatory burdens mean Japanese companies, foreign companies in Japan, and foreign companies interested in doing business with Japan cannot use business aviation effectively and economically. U.S. aircraft manufacturers note further that the regulatory situation has greatly limited sales of their airplanes to Japanese clients.

Severely restricted hours for landings and take-offs at Haneda and the lack of services at Narita and Haneda significantly limit travel on business aircraft to and within Japan. On a more positive note, certain airports in the Chubu and Kansai regions are more open to business aircraft and are attempting to provide many of the same services that business aircraft operators receive in the United States and Europe. Since April 2005, regional (nondesignated) airports may also accept landings of international charter and business aviation flights with 3 days' notice, provided that customs, immigration, and quarantine are available. These forward looking measures are not sufficient, however, to overcome other obstacles impeding business aircraft use in Japan.

Based on the growing needs of business aircraft owners and operators, the U.S. Government has been urging JCAB to reexamine the application of airline-specific civil aviation regulations to business aviation and develop appropriate regulations specific to the business aviation industry. These regulations should, to the greatest degree possible reflect a regulatory approach consistent with the treatment of business aviation in the North America, Europe, and several other parts of the world. The U.S. Government also encourages JCAB to consider the regulatory reform requests submitted by U.S. and Japanese industry. In advance of the opening of the additional runway at Haneda planned for 2010, the U.S. Government urges Japan to make immediate improvements in the overall regulatory framework. In the past year, JCAB has taken positive steps, such as participating in business aviation events in the United States and Japan. JCAB also created a team to study business aviation and is in the process of conducting research on conditions impacting business aviation in other countries.

Civil Aviation

Market access for U.S. air carriers in Japan improved significantly with a 1998 bilateral agreement and additionally with a new bilateral agreement reached in September 2007 (pursuant to comity and reciprocity pending formal conclusion). U.S. carriers, however, remain constrained by restrictions on traffic rights, operational flexibility, and pricing, and some of the world's highest airport costs.

The September 2007 agreement provides nonincumbent cargo carriers with the ability to serve additional points in Japan and beyond. Restrictions and limitations on same country code-sharing arrangements were mostly removed with some notable exceptions. This agreement also relaxed the pricing regime from "double approval" to "country of origin." It fell short, however, of the standard "double disapproval" regime for pricing liberalization. On a related note, U.S. industry has reported cumbersome and time-consuming filings are still required for fare changes. Key U.S. concerns include the continuing disparity between the rights of "incumbent" and "nonincumbent" airlines, restrictions on change-of-gauge, and pricing inflexibility. Limitations on same country code-sharing have been lessened, but remain more restrictive than the open code-sharing framework in U.S. agreements with most other countries. The September 2007 agreement provided two U.S. nonincumbent cargo carriers the ability to service an additional point in Japan, coupled with new fifth freedom (onward connection) rights.

Narita International Airport ("Narita") operates below its potential capacity. The U.S. Government encourages Japan to take steps that would increase capacity and reduce congestion at one of the world's most important airports. An extension of Narita's second runway that will facilitate more long haul flights is currently underway, although there are concerns about the project's financing – specifically that already high user fees may be increased. Recently lowered landing fees at Narita were offset in part by other new or increased fees. The issue of high landing fees at Narita, Kansai, and Central Japan International Airport (Centrair) airports continues to be raised in the Regulatory Reform Initiative and in bilateral aviation discussions.

Both Narita and Haneda Airports are undergoing ambitious expansion projects set to be completed by 2010. The planning processes for these airport projects have not been fully transparent. Concerns include the procedures by which new slots at Narita airport will be allocated, and prospective rules at Haneda that could adversely impact the competitiveness of U.S. carrier operations in the long term. While these issues will be addressed in United States-Japan Civil Aviation Talks set to resume by the summer of 2008, the U.S. Government urges Japan to ensure that, through a timely and transparent consultative process, non-Japanese carriers have meaningful opportunities to comment. The ultimate decisions regarding these issues will significantly affect the traveling public and the movement of cargo in the Tokyo Metropolitan Area, and throughout the

Asia Pacific region. Connections between airports in the Tokyo metropolitan area remain difficult and time-consuming. The weak connectivity harms the efficiency of the airports and carriers serving Tokyo. The U.S. Government encourages Japan to improve transit access between Haneda and Narita Airports.

Consistent with its longstanding policy to promote competition and market access in civil aviation, the U.S. Government will continue to press Japan for further liberalization.

Transport/Ports

The U.S. Government continues to hold longstanding concerns over the barriers to entry to and the competitiveness of Japanese ports. Foreign shippers servicing Japan are locked into long-term relationships with specific Japanese stevedoring companies, which reportedly collude within the industry association to keep newcomers out and costs high. Foreign companies have indicated that a lack of transparency in Japanese laws and regulations related to ports creates a barrier to entry. Foreign owned and run stevedoring businesses do not exist at major Japanese ports, and even major Japanese companies have been prevented from being directly involved in the stevedoring business. As part of the Regulatory Reform and the Initiative, we have made recommendations on transparency that could apply to the rulemaking process. Japanese laws and regulations could be reviewed with an eye to facilitating new entrants and outside competition in the stevedoring business.

Japan amended its Port Transportation Business Law (effective November 2000) to eliminate the need for new entrants to prove there is surplus demand. Charges for harbor services in nine large ports are subject to a prior notification requirement, and there is an approval requirement for other ports by the MLIT.

Since 1999, the U.S. Government has continued to express concern that reforms have not lessened the Japan Harbor Transportation Association (JHTA)'s ability to deter new entry and restructuring in the ports sector. The Port Transportation Business Law introduces new requirements that run counter to the need for efficient port operations and discriminate against new entrants wishing to offer port services. In addition, MLIT has not addressed concerns about the prior consultation process conducted by the JHTA nor about the apparent threat of illegal strikes against foreign carriers who obtain permission to operate their own container terminals. The U.S. Government continues to note that the Japanese government has failed to implement important aspects of the wide-ranging port deregulation promised in 1997.