

(Provisional Translation)

RECOMMENDATIONS BY THE GOVERNMENT OF JAPAN
TO THE GOVERNMENT OF THE UNITED STATES
REGARDING REGULATORY REFORM AND COMPETITION POLICY

October 24, 2003

FOREWORD

The Deregulation Dialogue under the Enhanced Initiative which continued for four years since 1997, and the first and second year dialogue of the Regulatory Reform and Competition Policy Initiative (“Reform Initiative”) under the “Japan-U.S. Economic Partnership for Growth (“Partnership”)” established by Prime Minister Junichiro Koizumi and President George W. Bush at the Japan-U.S. summit meeting on June 30, 2001, have certainly achieved success in clarifying regulatory and systemic problems of each country and in reducing unnecessary regulations, strengthening competition, and improving market access.

It is also a fact, however, that there remain regulations and systems in the United States that are: 1) unique to the United States and not harmonized with international standards; 2) inconsistent with the principle of free trade; and 3) impeding fair competition. Many of them are imposing unreasonable burdens on Japanese companies conducting business in the United States, thus being their serious concerns. Typical examples are a variety of unilateral measures that the Government of the United States has employed, which are also suspected of inconsistency with the WTO rules.

The Government of Japan also apprehends that the series of changes in policies and reinforcement of regulations by the Government of the United States in several areas such as consular affairs, distributions and export control might impede active and smooth trade as well as movement of peoples between the two countries and mutual visits by both nationals. While the Government of Japan understands that the Government of the United States has been taking these measures pressed by the increasing necessity of national security in fighting against terrorism, it also believes that both Governments, as the two largest economies of the world as well as close allies, should intensify their concerted efforts to prevent these measures from adversely affecting the economic ties between the two countries. For the Government of Japan believes that such efforts will serve the objectives of the Partnership to promote sustainable growth not only in both countries but also of the world economy.

Recognizing the current situation as above, the Government of Japan here presents its recommendations regarding regulatory reform and competition policy to the Government of the United States upon the commencement of the third year dialogue of the Reform Initiative. In course of the dialogue, the Government of Japan will keep urging the Government of the United States to improve its policy and further promote regulatory reform and competition policy by reflecting these recommendations sufficiently.

The Government of Japan strongly hopes that the frank and constructive dialogue with the Government of the United States under the Reform Initiative will greatly contribute toward further strengthening and deepening of the bilateral economic relationship. Japan and the United States should fully recognize that they are leading the growth and harmonization of the world economy as well as the reinforcement of an open and multilateral trading system, and then should demonstrate a model of dialogue and cooperation in this globalized age. The Government of Japan expects that the Government of the United States will seriously consider all the items raised in these recommendations based on the principle of two-way dialogue, and, in order to realize such a productive dialogue, take positive actions for the production of tangible results.

CONTENTS

I. CROSS-SECTORAL ISSUES CONCERNING REGULATORY REFORM AND COMPETITION POLICY	1
1. Consular Affairs	2
2. Distribution	9
3. Trade/Investment Related Measures	13
4. Sanctions Acts	22
5. Competition Policy	25
6. Legal Services and Other Legal Affairs	26
7. Public Construction Works	28
II. TELECOMMUNICATIONS	29
III. INFORMATION TECHNOLOGY (IT)	32
IV. ENERGY	34
V. MEDICAL DEVICES AND PHARMACEUTICALS	36

I. CROSS-SECTORAL ISSUES CONCERNING REGULATORY REFORM AND COMPETITION POLICY

As stated in the foreword, the Government of Japan is seriously concerned about the impact that may be cast upon economic activities by the series of regulatory measures the Government of the United States has taken to reinforce counterterrorism. “The Japan-U.S. Economic Partnership for Growth” articulates that the objective of the Cross-Sectoral Working Group is “to cover thoroughly and conduct in-depth discussions” on “topics that have a widespread impact on the economy.” Recent counterterrorism measures taken by the Government of the United States exactly come under this classification. The Government of Japan hopes that the two Governments will have fruitful discussions on these issues at the Working Group, also attended by the regulatory bodies concerned including the Department of Homeland Security and the Consular Affairs Bureau of the Department of State, in conformity with the spirit of the Partnership.

1. Consular Affairs

As the relationship between Japan and the United States has been deeper than ever, the number of Japanese nationals residing in the United States has reached 315,976 as of October 1¹, 2002, comprising 36 percent of all the Japanese nationals residing overseas. The number of the Japanese nationals who entered the United States in 2002 was 3,651,814², which is the third largest number next to the British and Mexicans. The Government of the United States should enable all of them to smoothly enter, stay at, and take actions necessary in their livings, business and tourism in the United States. The Government of Japan deems it the very basis of the close bilateral relationship.

The Government of Japan therefore requests the Government of the United States to continue its efforts to achieve more effective processing of consular affairs including visas and permission for stay in shorter periods of time. The Government of the United States is also urged to keep immigration officers and local agents of the Federal authorities concerned sufficiently and promptly informed of the establishment, changes and abolition of regulations on consular affairs, in order to eliminate, to the maximum extent, impediments to the livings and actions of foreign nationals residing in the United States.

In this regard, the Government of Japan appreciates that the Government of the United States decided, in the spirit of trust and partnership, the suspension for one year of the non-application of the Visa Waiver Program (VWP) to the holders of non-machine-readable passports on September 24, for twenty-one countries including Japan.

On the recognition above, the Government of Japan requests the followings.

(1) Use of Biometric Identifiers in Immigration Control

(a) Biometric Identifiers on Passports

Section 303 of the Enhanced Border Security and Visa Entry Reform Act of 2002 provides that the United States will suspend the VWP for the countries which have failed to certify to the United States by October 26, 2004 that the said country has a program to issue passports with biometric identifiers. It also stipulates that even the nationals of the countries under VWP must obtain visas if they have passports without biometric information issued after the date.

The Government of Japan is conducting detailed study and investigation from technical and other perspectives for the introduction of passports with biometrics identifiers in an early stage, aiming at enhanced security of passports, namely prevention of counterfeiting and improper use, as well as at contributing to global cooperation for counterterrorism. At the same time, however, identification of persons by biometric

¹ *Statistics on the Japanese national residing overseas, 2002*, Ministry of Foreign Affairs of Japan

² *2002 Yearbook of Immigration Statistics*, United States Department of Homeland Security, table25 (pp106-108)

information is inseparable from the issues of personal information. It is therefore prerequisite for the Government of Japan to fulfill its accountability to and seek understanding from the Japanese on the necessity of the measure and information security prior to the introduction.

From these points of view, the Government of Japan requests the Government of the United States:

- (i) to inform the former when the Government of the United States will examine and announce the details of processes and criteria by which the latter determines whether each country's program for the introduction of biometrics-equipped passports is satisfactory for the country to remain under the VWP, as well as;

to keep the VWP effective even with the holders of non-biometric passports issued after October 26, 2004, once the Government of the United States approves the country of their nationality to have biometric passport program sufficient to remain under the VWP;

- (ii) to confirm the policy of the Government of the United State whether it has decided to use facial information as a biometric identifier and has no intention to adopt fingerprints for the purpose (since the Government of Japan recognizes that the International Civil Aviation Organization (ICAO) suggested the introduction of biometric passports to its Member States in May 2003 and recommended the selection of facial recognition to be globally recorded on passports, while leaving the choices of additional identifiers such as fingerprints and iris to the discretion of each country); and
- (iii) to keep the Government of Japan appropriately informed of the measures concerning biometric identifiers on passports, including information concerning the points above, well in advance of the final consolidation of related arrangements.

(b) Collection of Biometric Information at the Ports of Entry

Prior to the commencement of the measures mentioned in section (a) above, the Department of Homeland Security will collect facial information and fingerprints from all entrants with visas for their authentication in accordance with the United States Visitor and Immigrant Status Indicator Technology (US-VISIT) program, from January 1, 2004 onwards. The Government of Japan requests two points in this regard.

- (i) There remains very limited time before the beginning of this measure in comparison to biometric passports. The Government of Japan therefore urges the Government of the United States to describe the following points as soon as possible:
 - a. specific arrangements the Government of the United States has been making for an adequate control of collected biometric information; and
 - b. specific criteria to limit the sphere of the use of collected information.

- (ii) This measure would require, especially in an early stage, extremely longer immigration processing time at busiest airports than present by collecting biometric information from all the visa-holding entrants. Thus the Government of Japan requests the Government of the United States to explain, without delay, the steps taken, or to be taken, to increase human resources and reinforce equipment at ports of entry in order to avoid such congestion.

(2) Visa Process

(a) Obligatory Personal Appearance upon the Application of Visas

While the Government of Japan understands the rationale for the Government of the United States to introduce this measure, tremendous time and financial burden have been imposed upon the Japanese applicants of U.S. visas since its commencement on August 1, 2003. In this regard, the Government of Japan filed its comments on the proposed revision of rule on July 29, 2003 to the Department of State, and have requested the Government of the United States to seriously consider the comments in a variety of opportunities including the Trade Forum held on July 31.

The Government of Japan hereby reiterates its strong desire for the Government of the United States to realize the following points sincerely:

- (i) drastic limitation of the visa categories for which personal appearance is required; and
- (ii) prioritization of the points below in the practice of the measure:
 - a. to establish a computerized appointment system for the convenience of visa applicants;
 - b. to interview applicants not only at the Embassy in Tokyo and the Consulates-General in Osaka and Okinawa, but also at the U.S. Consulates in Sapporo, Nagoya and Fukuoka; and
 - c. to multiply consular staff to the level sufficient to convince the Government of Japan that applicants' waiting time from application for interview to issuance of visas could be maintained at least at the present level, or less.

The Government of Japan requests the Government of the United States to articulate what actions have been taken to realize the three points above.

(b) Efficient Processing of Visa Revalidation

The Department of State has ceased to revalidate U.S. visas at the Embassy in Tokyo upon application by post from Japanese residents in the United States in September 2002. As a result, those staying in the United States with visas must either apply to the

Department of State or return to Japan to apply to the U.S. Embassy in Tokyo for their visas to be revalidated.

Currently, it usually takes ten to sixteen weeks for visa revalidation at the Department of State, where applicants' passports should be in custody throughout the process. As a consequence, applicants for visa revalidation cannot leave the U.S. territories in the meantime, with little prospect about when their passports with revalidated visas will be returned. Their freedom of movement is thus extremely limited, increasing their discontent about the inconveniences in achieving their objectives in the United States, such as missing important business opportunity.

The U.S. Embassy also forces those applying for visa revalidation on returning to Japan to wait for a couple of weeks, being a serious time burden on them. When they are accompanied by their families, travel cost for all of their family members is still another huge financial burden on them.

The Government of Japan therefore strongly requests the Government of the United States to resume visa revalidation at the U.S. Embassy in Tokyo upon application by post and to extend the validity term of respective types of visas, as fundamental solution for the abovementioned problems. It believes that these measures also alleviate the workload currently borne by the Department of State, thus benefiting both countries.

If it is difficult to take these steps promptly, the Government of Japan should raise the following points as temporary measures.

(i) Revalidation at the Department of State

The Government of Japan requests the Government of the United States:

- a. to remove serious limitation on the freedom of movement of foreign residents arising from their passports being in custody at the Department of State for more than three months;
- b. to establish a standardized term of visa revalidation process so that Japanese residents in the United States could arrange their business and life plan with certainty; and
- c. to enable them to apply for revalidation more than sixty days prior to visa expiration so that Japanese residents in the United States can revalidate their visas in limited opportunities such as summer and new year vacations.

(ii) Revalidation at the U.S. Embassy and Consulates-General in Japan

The Government of Japan requests the Government of the United States:

- a. to ensure the completion of visa revalidation within two weeks after application; and

- b. to promptly increase consular staff at the U.S. establishments in Japan in light of the numerousness of visas issued in Japan.

(c) Regulations on H and L types of visas

Bills have been introduced in the Congress that will reinforce regulations on H and L types of visas by shortening their validity terms or setting floors to the salary earned by the holders of these visas (H.R. 2154, H.R. 2702 and H.R.2849). These bills, when passed and enacted, will affect the economic relationship between the two countries adversely as well as may gravely discourage the Japanese business sector to invest in the United States. The Government of Japan therefore desires these bills to be abandoned.

(3) Social Security Number

(a) Issuance of Social Security Numbers to the Dependents of Employment Visa Holders

The Government of Japan filed its comments on May 13, 2003 on the proposed revision of rule concerning the issuance of Social Security Number (SSN) announced by the Social Security Administration (SSA) on March 26.

In the United States, presentation of SSN is required in principle on various occasions in daily life such as application for a driver's license or a credit card, opening a bank account, and signing a lease contract for housing. As a result, there have been many cases where dependents of Japanese staff working at Japanese firms in the United States, who are legal foreign residents with nonemployment-based visas and thus cannot obtain SSN, are facing inconveniences in the daily life. This is an unnecessary limitation on consumption activities of the dependents of Japanese workers in the United State, and thus depriving the U.S. economy of consumption opportunity for that portion.

The Government of Japan therefore requests the Government of the United States to indicate what actions have been taken since then on the following points made in the comments.

- (i) SSN is virtually the sole measure for identification in the United States. Consequently, the Government of Japan above all requested the SSA to amend the rule so that all legal foreign residents including those with nonemployment-based visas could obtain SSN.
- (ii) Some state governments still require the applicants of driver's license to present SSN. Foreign residents with nonemployment visas in Illinois have faced the most serious obstacles of utter inability to acquire driver's license because of their ineligibility to obtain SSN, since the presentation of SSN is indispensable to apply for driver's license both by regulations and practices in the state. The Government of Japan therefore requested the Government of the United States in the comment to petition that the state governments including Illinois strive to innovate the measures

which are available practically and lightly to all legal foreign residents, in case of introduction of alternative measures for identification.

(b) Shorter Period for SSN Issuance Process

Since the terrorist attacks on September 11, 2001, foreign residents with employment visas have had to wait for more than a month between application for and issuance of SSN. While they must acquire driver's license or open an bank account upon their arrival, such delayed processing of SSN issuance have obliged them to face significant inconveniences at the very beginning of their life in the United States. The Government of Japan therefore requests that the federal government take tangible measures to facilitate smoother and quicker issuance of SSN for legal foreign residents at local agents of the SSA.

(4) Permission for Stay (I-94)

Improper implementation of I-94 extension process has been imposing unnecessary burden on legal foreign residents in the United States, and should be corrected fundamentally. The Government of Japan continues to request the Government of the United States to shorten the processing time of I-94 extension, to rationalize the process and to make the expected time for extension process more predictable for foreign residents.

- (a) The Government of the United States does not accept an application for I-94 extension until the date sixty days prior to its expiration. The Embassy and Consulates-General of Japan in the United States have reported that it takes at least three months for extension in most cases, and six to twelve months in extremely slow cases. Failure to complete extension process before the expiration date obliges foreign residents to overstay during the period between the expiration and the completion of I-94 extension. This is an exorbitantly inadequate situation as well as a sheer incompatibility with the sixty-day rule in application for I-94 extension. The Government of the United States is therefore strongly urged to take either of the following two measures:
- (i) to accept applications for I-94 extension from the date more than two months, namely one year, prior to the expiration, as the majority of extension processing has been taking more than two months; or
 - (ii) to make every necessary arrangement to ensure extension processing completed within two months.
- (b) The Government of the United States offers the Premium Processing Service, by which extension processing within fifteen days is ensured with an additional fee of 1,000 dollars. As a matter of principle, however, extension processing must be completed with certainty before the expiration of effective I-94. In other words, if extension system is implemented in accordance with its intrinsic object, and then there remains very little necessity for the Japanese nationals in the United States to use this service. Due to the very fact that they surely have to wait for more than two months for extension in most cases, Japanese companies stationing in the United States are obliged to pay

1,000 dollars as fixed costs for subsidizing each Japanese employee who needs I-94 extension. The Government of Japan strongly requests the point mentioned in section (a) above also from this perspective.

- (c) The Second Report to the Leaders states “(t)he BCIS is currently in the process of prioritizing work... the United States will provide Japan with updated information on the result of such efforts as appropriate.” The Government of Japan therefore requests the Government of the United States to demonstrate the specific steps taken so far in this regard.

(5) Driver’s Licenses

In some states, driver’s licenses held by foreign residents expire upon the expiration of their visas or I-94. They are sometimes obliged to renew their licenses, which is not necessary at all only if they are eligible to obtain licenses with the same conditions that are applied to the U.S. citizens’, and thus bearing unreasonable burden. Theoretically, state authorities certify the driving ability of holders, which is not relevant to their qualification to stay.

- (a) The Government of Japan therefore requests the Government of the United States to convey the points made above to the state authorities, inquire them to clarify the *raison-d’être* of such rules, and petition them to make the expiry date of drivers licenses independent from that of visas.
- (b) A bill has been introduced in the Congress that will create a new federal system similar to existing state-level rules mentioned above (H.R.1121). The Government of Japan apprehends that the bill, if passed and enacted, will oblige foreign residents to face unreasonable inconvenience in their life nationwide. The Government of Japan therefore desires the bill to be abandoned.

2. Distribution

(1) Counter-Terrorism Measures through Promoting Transport Security

The Government of Japan recognizes the importance of, and supports in principle, initiatives launched by the United States to combat terrorism through promoting transport security.

At the same time, however, the Government of Japan requests the Government of the United States to pay due consideration to securing legitimate trade and to ensure that such initiatives do not hinder rapid, smooth and effective distribution. The Government of Japan also believes that the Government of the United States should ensure that specific measures and the application of such initiatives be consistent with the practices of relevant international organizations including the World Customs Organization (WCO), and should aim to build internationally common and unified systems.

With regard to the proposed rule of regulations (published in the Federal Register on July 23, 2003) concerning requirement of advance electronic presentation of cargo information, the Government of Japan requests the United States Bureau of Customs and Border Protection (CBP) to make final rule with due consideration of the filed comments to prevent the regulations from affecting negatively on Japan-U.S. trades and global supply chain. The Government of Japan also requests the CBP to realize benefits to the participants of the Customs-Trade Partnership Against Terrorism (C-TPAT) such as swifter customs clearance and a reduced number of inspections along with the implementation of the proposed rule, or to establish an alliance program in which low-risk traders who meet legitimate guidelines can enjoy benefits similar to those committed under C-TPAT. Further, though the regulations concerning air cargo information will be implemented after ninety days from the date of publication of the final rule, the Government of Japan recommends the CBP to postpone the implementation or set longer moratorium for the related companies to appropriately prepare for the presentation of cargo information. The Government of Japan submitted its comments on the proposed rule, including the points mentioned above, on August 21, 2003, which the Government of Japan urges the Government of the United States to seriously consider.

With regard to the Container Security Initiative (CSI), the Government of Japan hopes that the CBP, the Japanese Customs and Tariff Bureau and all interested parties will continue to exchange their views on the implementation of CSI in order to ensure compatibility between securing safety of containers and legitimate trade.

The Government of Japan requests the Government of the United States to respect international standards such as ISO when establishing electronic management systems of distribution by using information technology and other advanced devices including IC tags, and to utilize advanced technologies appropriately and adequately with a view to reviewing measures to promote transport security when electronic distribution comes into practical use.

Finally, with regard to Automated Commercial Environment (ACE), the Government of

Japan encourages the Government of the United States to introduce it promptly, and to provide the former with information on the details of ACE, current situation of its development, its implementation schedule and on future review of measures to promote transport security along with implementation of ACE.

(2) Customs Liquidation

Sec. 159.11, Title 19 of the Code of Federal Regulations (19CFR159.11) provides in general that “an entry not liquidated within 1 year from the date of entry of the merchandise... shall be deemed liquidated... at the rate of duty, value, quantity, and amount of duties asserted by the importer at the time of filing an entry summary...” In accordance with this provision, the CBP liquidates cargo entering the United States within around 314 days from the date of the entry filing.

Thus the period from an entry filing to liquidation could reach more than ten months in maximum, obliging importers and exporters to choose either refraining from settling accounts throughout the period, waiting duty rates to be consolidated, or prioritizing speediness by settling accounts before liquidation. The former deeply impinges the swiftness of business, while the latter forces either exporter or importer to bear losses. For the latter case, once the account is settled, even if the final duty rates are found to be different from that estimated by importer/exporter upon the settlement, common business practices do not allow either party to claim for *ex post* compensation to the other. In this case, either side has to bare undue burden unilaterally because of the difference.

The Government of Japan therefore requests the Government of the United States to shorten the current long term for liquidation to the sufficiently rational level to reduce uncertainty in trade as mentioned above.

The Government of Japan has repeatedly submitted the following four recommendations to the Government of the United States, which has answered in general that it takes note of Japan’s points in the Reports to the Leaders. The Government of Japan therefore requests the Government of the United States to continue to work in this regard so that the third report to the Leaders to be drafted next year could demonstrate more specific developments on the issues.

(3) Merchant Marine Act of 1920

(a) The Federal Maritime Commission (FMC) is authorized by Sec. 19 (1) (b) of the Merchant Marine Act of 1920 (the Jones Act) to make rules and regulations affecting shipping in foreign trade.

The FMC imposed a unilateral sanction against Japanese carriers in September 1997. Although the sanction was removed in May 1999, the FMC still requires carriers to report to it on the situation of the ports in Japan. The rule (repealed in May 1999) which provided the grounds for unilateral sanctions was a violation of the Treaty of Friendship, Commerce and Navigation between Japan and the United States, which provides each other’s ships with the national treatment and the most-favored-nation

treatment.

The Government of Japan therefore strongly requests the Government of the United States to work even more closely with the FMC in order to ensure that such unilateral measures will not be taken any more.

- (b) Since the repeal of the abovementioned rule, the FMC has required Japanese and U.S. carriers to report to it on the progress of the situation of the ports in Japan.

Efforts have been made and signs of progress have been seen on the situation of the ports in Japan. The “prior consultation system” has improved significantly (and the improved system has been implemented steadily); the revised Port Transportation Business Law abolished the supply-demand adjustment restriction and thus realized new entries into port transport business; progress have also been made toward the introduction of port terminal service operation on the 24-hour/364-day basis. The Government of Japan strongly urges the FMC to have correct understanding of these positive developments.

Despite the significant improvement of port situation in Japan described above, the FMC introduced, in August 2001, a new order which not only increased the number of items to be reported, but also expanded the scope of carriers subject to the reporting requirement. The order includes requirements going beyond the extent deemed appropriate to impose upon carriers, such as directly requiring Japanese carriers to submit translated copies of the Japanese laws and instructions concerned. Thus the order has been causing unfair and excessive burdens on carriers.

If it is the case that the FMC decided to expand the range of the reporting requirements in order to judge whether or not it should impose unilateral sanctions that would violate the Treaty of Friendship, Commerce and Navigation between the United States and Japan, the Government of Japan recognizes it as regrettable and a serious abuse of FMC’s mandates.

The Government of Japan therefore strongly requests the Government of the United States to withdraw the order.

(4) Abolition of Maritime Security Program

The Government of Japan requests the Government of the United States to abolish the Marine Security Program, under which as much as 100 million dollars of maritime subsidy is provided annually for ten years. It is obvious that a provision of such an enormous amount of subsidy distorts conditions for free and fair competition in the international maritime market.

(5) Abolition of Cargo Preference Measures including the Law Lifting the Ban on the Export of Alaskan Oil

The Government of Japan requests the Government of the United States to abolish the Cargo

Preference Measures, such as the requirement to use U.S. vessels for the exports of Alaskan oil which is commercial cargo. These protectionist measures are inconsistent with the principle of national treatment, and are also against the Ministerial Decision on Negotiations on Maritime Transport Services of WTO, which prescribed that the participants should not apply any protectionist measures during the negotiations.

(6) Ocean Shipping Reform Act of 1998

The Ocean Shipping Reform Act of 1998 includes a provision allowing discriminatory treatment of Japanese and other foreign shipping firms by making it possible to impose unilateral regulations on pricing and other practices. As the pricing practice is the foundation of free shipping activity on a commercial basis, unilateral regulations by the FMC on the pricing practice obviously intervenes in free shipping activity, discriminating foreign firms. Furthermore, the amendment to the Act in 1998 explicitly stipulates the right of the Federal Government to make this intervention. The Government of Japan requests the Government of the United States to affirm that in the future the FMC should not impose unilateral regulations on shipping activities on a commercial basis conducted by Japanese and other foreign shipping firms, which do not reflect the reality of the market.

3. Trade/Investment Related Measures

(1) The Federal Buy-American Act and Other Related Rules

The Government of Japan made requests on the federal Buy American Act and other rules of the same purpose in the first, second and third years of the Deregulation Dialogue under the Enhanced Initiative. In light of the absence of tangible improvements achieved by the Government of the United States, the Government of Japan submits anew its recommendations as follows.

The Government of Japan requests the Government of the United States to ensure equal business opportunities for both the U.S. and foreign suppliers, from the viewpoint of fully applying the principle of non-discriminatory treatment in government procurement.

- (a) A matter of particular concern for the Government of Japan is a bill currently under deliberation in the Congress that will further extend discriminatory treatment between U.S. and foreign suppliers in the procurement of the Department of Defense. The Government of Japan is aware that consideration in terms of security is necessary for the procurement of the Department of Defense. If the bill passes, however, it will unreasonably place a restraint on business opportunity of foreign supplies as well as impede the procurement of high-quality, low-cost articles, materials or suppliers by the Department. On this recognition, the Government of Japan desires the bill to be abandoned.
- (b) Another point is the criteria for the procurement of a rolling stock. The rule provides that at least sixty percent of the total cost of parts constituting a rolling stock must be of those manufactured in the United States, and thus hindering efficient procurement of parts by the manufacturers of rolling stocks. The Government of Japan therefore requests the Government of the United States to lower the threshold.

The Government of Japan also apprehends that the rule not only deprives the U.S. citizens of the opportunity to use public transportation services at lower costs but also hinders the extension and improvement railway network, which is the most environment-friendly and energy-saving means of carriage. In other words, the provision impinges the opportunity for the U.S. federal and local governments as well as its citizens to enjoy the forefront railway technology existing in foreign countries including Japan in both terms of transport capacity and energy efficiency. The Government of Japan recommends the improvement of the rule also from this perspective.

(2) Anti-Dumping Measures and Safeguard Measures

- (a) Although anti-dumping measures are proper trade remedies as far as they are operated in a manner consistent with the WTO agreements, there is a possibility that they may unduly limit trade and distort competition once operated in an arbitrary manner, for example, in determining whether a dumping exists or not. Furthermore, the initiation

of anti-dumping investigations itself may discourage exporting companies. From these viewpoints, the Government of Japan urges the Government of the United States to operate its anti-dumping mechanism prudently in a manner fully consistent with the WTO agreements without abusing it for protectionist purposes.

- (b) A number of products have been subject to anti-dumping duties for a considerable period of time. The Government of Japan urges the Government of the United States to strictly examine the necessity of continued imposition of such anti-dumping duties and to take appropriate actions where necessary.
- (c) The United States is one of the major users of anti-dumping measures. A number of countries including Japan have been claiming that some of the U.S. anti-dumping measures are inconsistent with the WTO agreements, because of, for example, the arbitrariness in determining whether a dumping exists or not. In several cases such as "*United States - Anti-Dumping Act of 1916 (DS162)*" and "*United States - Certain Hot-Rolled Steel Products from Japan (DS184)*", the Dispute Settlement Body (DSB) found that the U.S. measures were inconsistent with the WTO agreements. Therefore, the Government of Japan requests the Government of the United States to promptly bring those measures into conformity with the WTO agreements.

In particular, Title VIII of the U.S. Revenue Act of 1916 (the so-called "Anti-Dumping Act of 1916") has already been causing a great amount of actual damages to Japanese firms, including expenses incurred with regard to the judicial proceedings under the Act. With a view to giving a relief to such a respondent Japanese firm, the Government of Japan reiterates its request that the Anti-Dumping Act of 1916 should be abolished and that cases in disputes regarding the Act should be terminated by the retroactive effect of the abolishment.

- (d) The Government of Japan also requests the Government of the United States not to apply, in its future anti-dumping investigations, the methods that have already been found to be inconsistent with the WTO agreements, such as those for anti-dumping margin calculations adopted by the Department of Commerce and for injury determination adopted by the United States International Trade Commission (ITC).
- (e) The Byrd Amendment, which stipulates the distribution of revenues collected from anti-dumping and countervailing duties to U.S. domestic producers who filed or supported the petition for such duties, was found to be inconsistent with the WTO agreements by the WTO panel and Appellate Body. The arbitration has determined that the reasonable period of time (RPT) for the United States to comply with the recommendations and rulings of the DSB will expire on December 27, 2003. Therefore, the Government of Japan continues to request the Government of the United States to urge the Congress to repeal the Byrd Amendment as soon as possible so that the next distribution, scheduled during the RPT, will not be made.
- (f) The Government of Japan requests the Government of the United States to operate its safeguard measures prudently, in a manner fully consistent with the WTO agreements. With regard to the U.S. safeguard measures on imported steel products, which were

invoked in March last year, the Government of Japan is of the view that they are inconsistent with the WTO agreements. The Government of Japan therefore will continue to highlight their illegality in the process of the WTO dispute settlement procedures, while working closely with the other WTO Members concerned, aiming at final withdrawal of these U.S. measures. With the fact that the U.S. measures have triggered a chain reaction of safeguard measures in the steel sector on a global scale, the Government of Japan requests the Government of the United States to withdraw these measures without delay.

- (g) The final point is the proposed revision of the method of anti-dumping duty calculations announced by the Government of the United States, for which it solicited public comments on September 9. The Government of Japan considers that the proposed revision contradicts the core objective of anti-dumping measures to counteract dumping which is causing injury, thus raising a doubt about its consistency with the WTO agreement. Also, it could result to the distortion of the policy goal of safeguard measures due to its unreasonable expansion of the remedy. Therefore, the Government of Japan requests the Government of the United States to consider the former's comments seriously and not to realize the revision.

(3) The Exon-Florio Provision

The Exon-Florio provision (Sec. 721 of the Defense Production Act of 1950) provides a mechanism to review and, if the President finds necessary, to restrict foreign direct investment that threatens the national security of the United States. In general, the Government of Japan fully understands the necessity of regulations for national security reasons. The Government of Japan has concerns, however, about the provision from the following viewpoints:

- (a) the lack of predictability due to ambiguous definition of “national security”;
- (b) the lack of legal stability caused by the possibility that completed transactions can also be subject to future investigation; and
- (c) the lack of due process, illustrated by the fact that even the parties concerned cannot be notified of the reasons for the commencement of investigation nor the final decisions by the President.

The Government of Japan also has concerns that this provision could impede investment activities of Japanese companies beyond the extent necessary for its original purpose. Transparency and predictability of the government regulations are key elements in business's determining investment. They are also prerequisites for competitive businesses to conduct their business under fair conditions. The Government of Japan requests the Government of the United States, in the operation of the Exon-Florio provision, not only to comply with WTO rules but also to take necessary measures to ensure transparency and fairness, to the maximum extent possible, in the process from the notification to the Committee on Foreign Investment in the United States to the final decision by the President.

Although the Government of Japan submitted this request in the second-year dialogue under the Reform Initiative, the situation has not yet been improved. The Government of Japan therefore continues to submit this request.

(4) The Patent System of the United States

The Government of Japan has consistently recommended the improvement of the patent system of the United States. As regards the reexamination system, the Government of Japan appreciates the efforts made to revise the Patent Act in November 2002 that has enabled third persons of *inter partes* reexaminations to appeal to Court of Appeals for the Federal Circuit (CAFC). On other issues, however, there have not been tangible developments. The Government of Japan therefore strongly requests the Government of the United States to further intensify its efforts.

(a) The First-to-Invent System and Interference

The United States is the only country adopting the first-to-invent system. Under this system, when two or more people make inventions separately and file applications respectively, an interference procedure is carried out in order to determine who receives patent rights.

From the point of view of patent applicants, this procedure has problems as follows:

- (i) there is little certainty and predictability in that the position of the right holder may be imperiled *post factum* by the appearance of a prior inventor;
- (ii) the interference procedures requires long periods of time and tremendous cost; and
- (iii) there is a danger of leaking the contents of inventions contained in applications filed or of know-how contained in patents during the interference period.

Another problem is raised when multiple inventors make the same invention independently and multiple patents are granted to some of these inventors. In such a case, there is a possibility that a third person will suffer an unreasonable loss in that he or she may be forced to pay redundant royalties to each right holder, since there is no means for third persons to invalidate the status by themselves.

Therefore, the Government of Japan requests the Government of the United States to switch to the first-to-file system, which is the international *de facto* standard. The Government of the United States is also urged to simplify its interference procedures as a provisional measure until such a switch is made.

(b) The Early Publication System with Exceptions

The United States early publication system, introduced by the revised Patent Act of November 1999, has an exception that allow applicants, by their request, not to publicize applications made in the United States not filed overseas as well as contents of U.S.

applications not included in corresponding foreign applications.

The contents of applications remained unpublicized by request are not disclosed until the granting of patent right is announced on the patent gazette. *Bona fide* third persons may in the meantime redundantly invest in research and development or put an invention to practical use that is identical to one written in the specification. This will certainly damage the predictability of profits and losses in business.

Another problem relating to the U.S. early publication system is the “submarine patent.” If a patent examination is delayed for a long time, an invention identical to one under examination may put into practical and extensive use in the market by *bona fide* third persons. A “submarine patent”, issued after a long term of examinations, could demand huge royalties from those third persons, thus violating their interests which they have obtained in the meantime.

Therefore, the Government of Japan strongly requests the Government of the United States to abolish an article for exceptions included in the early publication system. In this regard, the Government of the United States has already agreed to disclose all applications, excluding those under secret order and those non-pending, within eighteen months after the first date of application in the 1994 agreement under the Japan-U.S. Framework for New Economic Partnership. The Government of Japan reemphasizes that the Government of the United States should sincerely implement the agreement.

(c) The Reexamination System

In the United States, a reexamination system is provided as a means to review the validity of patent rights after granting. The revised Patent Act enacted in November 1999 introduced *inter partes* reexamination, which affords third persons other than patent holders greater opportunity to participate in the process, as an option of the appeal reexamination. Latest revision of the Patent Act in November 2002 further improved the system.

However, the scope of U.S. reexamination system is limited to those based on the existence of prior art documents. It is not allowed to apply for reexamination on the grounds of not meeting the enablement requirement or the description requirement of the specification.

Therefore, the Government of Japan strongly requests the Government of the United States to accept all of the requirement inadequacies prescribed in Article 112 of the Patent Act, excluding the best mode requirement, which is disadvantageous to foreign applicants, as reasons for reexamination request.

(d) Restriction Requirement due to Non-fulfillment of Unity of Invention

When two or more separate inventions are contained in one application, the applicant is requested to select and file only one invention in order to maintain unity of invention. (Only one independent invention should be included in an application.)

The United States standards of decision for unity of invention are more stringent than those of the Patent Cooperation Treaty (PCT). While an invention filed in the United States under the PCT may satisfy the requirement of unity of invention, the same invention may not meet the requirement if the application is filed as claiming priority rights under the Paris Convention for the Protection of Industrial Property.

Those applying for patents in multiple countries prefer considering claims (specified scope of patent contents) in accordance with internationally common standards. It is practically difficult for them to do extra work only for application in the United States, which has peculiar standards on unity of invention in the world.

Another problem is the division of application. Upon specification of a claim to be filed after receiving a request, other claims are automatically opted out from the scope of examination. Therefore, if the applicant wants to maintain such “opt-outs,” he or she needs to file a divisional application before the patent is issued for the remaining claim. Filing divisional applications forces applicants to consume further time and expenses. Nevertheless, extremely stringent standards of unity of invention of the United States expose the applicants to by far larger possibility to be obliged to file divisional applications, thus imposing an excessive burden on them.

Furthermore, the U.S. standards of unity of invention is burdensome to all of parties concerned, namely applicants, right-holders as well as third persons who monitor the patent to avoid conflict. For they are paying costs unnecessary to pay in other countries where multiple inventions that the U.S. authority might deem multiple could be regarded as single.

Therefore, the Government of Japan requests the Government of the United States to ease the requirements for unity of invention.

(e) The Hilmer Doctrine

Article 119 of the U.S. Patent Act provides the priority rights system prescribed by Article 4 of the Paris Convention. Under the provision, an application filed in the United States within twelve months from the first date of corresponding overseas application have the same effects as one filed in the United States on that day.

However, the United States has a unique legal principle called “the Hilmer Doctrine”, which has been causing the following problems:

- (i) According to the Doctrine, precedents and practices have deemed that, among the effects provided under Article 119, the effect of eliminating subsequent applications by third persons on the ground of items on specification being prior art retroacts only to the date of the application in the United States, not to the first date of overseas application; and
- (ii) While applications first filed in the United States have the elimination effects under

both Articles 102(e) and 102(g) of the Patent Law, those afforded to applications made in the United States based on the priority rights of overseas are limited only to the items under 102(g) on subsequent applications within the term of the priority right.

In Japan and Europe, domestic applications based on priority rights of overseas applications retroact to the application date in the first-filing country, and the effects to eliminate subsequent applications applies to all items of the specification. It is unfair that the same treatment is not guaranteed in the United States.

The Government of Japan therefore requests the Government of the United States to improve the system to ensure that all items of the specification could eliminate subsequent applications by third persons, retroacting to the date of first filing overseas.

(5) Metric System

Based both on the dialogue under the Japan-U.S. Enhanced Initiative on Deregulation and Competition Policy and the first- and second-year dialogue under the Reform Initiative, the Government of Japan remains strongly interested in the progress made toward the adoption of the metric system in the United States. In view of the significant impact the U.S. market has on world trade, the Government of Japan continues to urge the Government of the United States to ensure that the metric system (the SI Unit), which is a global standard, is adopted more broadly by the public and private sectors of the United States. The Government of Japan also requests the Government of the United States to exemplify its efforts made in this regard by displaying specific policy measures taken for the spread of the SI Unit in the public sector.

(6) Re-export Control

The Government of Japan appreciates that Government of the United States has introduced some reform measures to reduce the burden of Japanese exporters concerning the U.S. re-export control, reflecting the discussion in the second year of the Reform Initiative. They include the uploading of guidance, in Japanese, on re-export control related to the items of U.S. origin on the website of the Department of Commerce.

However, in the first place, the U.S. re-export control is impermissible under general international law, since it could be an extraterritorial application of the U.S. domestic law. In addition, the Government of Japan controls exports from Japan effectively by, for instance, taking part in all export control regimes and having introduced Catch-all system for weapons of mass destruction and their delivery means. Thus the Government of Japan is convinced that there is little reason to control re-export from Japan, and therefore continues to request the Government of the United States to exempt Japanese importers or re-exporters from the scope of U.S. re-export control.

As transitional measures pending the changes mentioned above, the Government of Japan has already requested the Government of the United States to take steps to reduce the burdens of exporters related to re-export control. In course of the second-year dialogue of

the Reform Initiative, the Government of Japan requested the Government of the United States to oblige U.S. exporters to provide enough information on the export items for Japanese exporters (or re-exporters) and to station experts of export control to the U.S. Embassy and Consulates(-general) in Japan, both of which have not yet been implemented. Whereas the request of uploading Japanese guidance on the U.S. re-export control on the website has been partly satisfied, the contents of the guideline lack practicality, only outlining the regulations.

Accordingly, the Government of Japan requests the Government of the United States to make further efforts to reduce the burden of exporters concerning the U.S. re-export control including the measures specified below:

- (a) to oblige U.S. exporters to provide Japanese importers with enough information including the Export Control Classification Number (ECCN) on the product to be re-exported so that the latter can judge whether the imported items fall under the scope of U.S. re-export control;
- (b) to attach experts on export control to the U.S Embassy and Consulates(-General) in Japan, with whom Japanese exporters can consult about re-export control in Japanese; and
- (c) to improve the contents of Japanese guidance related to the U.S. re-export control on the website for Japanese exporters' more profound understanding of the details of the regulations.

(7) Import Tariff Calculation Method and Labeling Requirements of Origin for Clocks and Watches

(a) Import Tariff Calculation Method for Clocks and Watches

In course of the second-year dialogue under the Reform Initiative, the Government of Japan requested the Government of the United States to simplify the procedure of trade by abolishing the levying of tariffs on each part of clocks and watches, which is currently practiced in the United States, and determining tariff rates on the HS categorization six-digit basis. In light of the absence of improvement in this regard, the Government of Japan continues to request the same point.

The final report issued after the review by the ITC which was concluded in the summer of 2000 does not adequately reflect the "Comments by the Government of Japan on the Draft on Simplification of the Harmonized Tariff Schedule of the United States by the United States International Trade Commission," which was submitted by the Government of Japan in 1999. The Government of Japan continues to urge the Government of the United States to undertake a comprehensive review of the report and to simplify the procedure of trade by abolishing the levying of tariffs on each part of clocks and watches and determining tariff rates on HS categorization six-digit basis.

(b) Labeling Requirements of Origin for Clocks and Watches

In course of the second-year dialogue under the Reform Initiative, the Government of Japan requested the Government of the United States to limit labeling requirements of origin to finished products of clocks and watches only, and to leave the choice of labeling methods, such as carved seals, tags, etc. to the discretion of manufacturers. In light of the absence of improvement in this regard, the Government of Japan continues to request the same point.

In June 1999, the Government of the United States amended the Harmonized Tariff Schedule of the United States to permit an indelible ink marking in addition to a die-stamping on the surface of movements and cases, as a measure to meet the labeling requirement of origin for clocks and watches. The amendment, however, does not sufficiently respond to the abovementioned request by the Government of Japan. It therefore continues to request the Government of the United States to simplify labeling requirements of origin for clocks and watches.

4. Sanctions Acts

The sanctions measures taken by the Government of the United States based on related acts discourage, significantly and unreasonably, incentive of investment into and establishment of economic relations with the countries targeted by those laws, affecting not only U.S. private enterprises but also those all over the world. In legal terms, they constitute an extraterritorial application of domestic laws, which is not permissible under general international law and may cause a problem of inconsistency with the WTO agreements. Moreover, fairness, transparency and predictability have not been observed in their applications. Although the Government of Japan has taken every opportunity, including those available under the Reform Initiative, to urge the Government of the United States to improve the situation from all these perspectives, the latter has not taken actions sufficiently.

The Government of Japan therefore strongly requests the Government of the United States to ensure consistency of these acts with international laws and implement them prudently. Application of the acts to enterprises of third countries is discouraged in particular.

On this recognition, the Government of Japan requests the following points on respective acts.

(1) Iran and Libya Sanctions Act of 1996

It is greatly regrettable that, despite the Government of Japan had repeatedly pointed out the abovementioned problems on various occasions, the Congress approved, without resolving them, the extension of the Iran and Libya Sanctions Act (ILSA) for another five years in August 2001.

The Government of the United States decided in May 1998 that the investment contracts in gas exploitation by three companies of the third countries would be exempted from the application of the Act. Furthermore, on the occasion of the abovementioned decision, the Government of the United States submitted to the Congress a report on this exemption which stated that similar cases would result in like decisions with regard to waivers for the companies of the European Union (EU). This practice has basically continued in relation to other projects in gas and oil exploitation by other foreign companies.

Like this, it is a matter of fact that ILSA has not been applied to a number of investments in Iran by third countries' companies. Under these circumstances, application of ILSA to Japanese companies' investments alone, or higher probability of its application to them in comparison to other countries' cases, would clearly constitute a double standard. Such different treatments cannot be accepted, especially in light of the achievements in international cooperation for nonproliferation and counterterrorism that the Government of Japan has made. The Government of Japan therefore requests the Government of the United States to give Japanese enterprises the level of treatment tantamount to what has been guaranteed to EU enterprises including those stated in the aforesaid report.

(2) Cuban Liberty and Democratic Solidarity Act of 1996

The Government of Japan urges the Government of the United States to fully recognize the fact that the United Nations General Assembly has resolved to express its concern about the Cuban Liberty and Democratic Solidarity Act supported by an overwhelming number of the Member States.

The Government of Japan appreciates the decision made by the Government of the United State on July 16, 2003 to extend the suspension of the implementation of Title 3 of the Act for another six months. From the viewpoint of predictability for potential traders, however, the maximum six-month assurance of the suspension is not yet sufficient. The Government of Japan accordingly requests the Government of the United States to suspend the implementation of the Title 3 of the Act for much longer term, namely one year or more.

(3) *Burmese Freedom and Democracy Act of 2003*

The Government of Japan understands that the United States enacted the “*Burmese Freedom and Democracy Act*” followed by a related Executive Order on July 28, 2003 to illustrate a strong attitude toward the Government of Myanmar in consideration of the present political situation in the country. However, the Government of Japan has concerns about the Act and the Executive Order in the absence of clarity in its implementation.

An issue of particular concern for the Government of Japan is the ban on export and re-export of financial services from the United States to Myanmar. The scope of application of the ban is not yet clearly circumscribed, while the procedure and criteria by which the Department of the Treasury exceptionally licenses financial transactions are not defined. It is apprehended therefore that the rule may discourage enterprises to conduct even those transactions that are out of the scope of the Act, thus hindering appropriate business activities.

For the meantime, the Government of Japan therefore requests the Government of the United States to sufficiently inform the parties concerned regarding the point above as soon as possible, so that companies could make their own judgement on whether respective planned business activities fall within the sphere of the Act or not.

(4) *Sanctions Acts Instituted by Local Governments*

The Government of Japan appreciates the Second Report to the Leaders of the Reform Initiative in stating “(s)hould any new sanctions be proposed, the Government of the United States will make every reasonable effort to work with the governors, attorney generals and government procurement officials of relevant jurisdictions to ensure the consistency of such sanctions with the U.S. constitutional standards.”

On the other hand, the Government of the United States explained in the First Report that it was making efforts to work with the state and local authorities where sanctions initiatives inconsistent with the foreign policy of the United States still exist. The Government of Japan therefore requests the Government of the United States to demonstrate tangible achievements and provide current status of the efforts made by the latter including

cooperative work with the governors, attorney generals and government procurement officials of relevant states.

The Government of Japan also requests the Government of the United States to collect latest information, whenever appropriate, on all effective sanctions acts instituted by the states and local municipalities, and to publish it on any website deemed adequate.

5. Competition Policy

The Government of Japan urges the United States Department of Justice to continue to review and express its views on the appropriate scope and reach of limitations and exemptions of the application of the federal antitrust laws from the viewpoint of active promotion of competition policy, and abolish the limitations and exemptions that have no rationale for their existence. The Government of Japan requests the Government of the United States to actively cooperate with the states concerned in the review process of the antitrust exemptions at the state level as well. The Government of Japan also requests the Government of the United States to make available to the former any public documents relating to the abovementioned work, and to explain the progress that has been made with regard to the work.

6. Legal Services and Other Legal Affairs

(1) Acceptance of Foreign Lawyers as Foreign Legal Consultants

(a) Acceptance of Foreign Lawyers as Foreign Legal Consultant in Every State

In the United States, only twenty-three states and the District of Columbia accept foreign lawyers as foreign legal consultants (FLCs). All other states do not allow foreign lawyers to practice therein, thus restricting the provision of diverse legal services in the United States. The Government of the United States has supported the adoption of rules on FLCs by every state, which the Government of Japan has welcomed, as they facilitate international business. It also requests the Government of the United States to take further positive actions towards the acceptance of foreign lawyers as FLCs in all states.

(b) Reduction of the Period of Practicing Experience Required for Acceptance of Foreign Lawyers as FLCs

As far as the Government of Japan has been aware, practicing experience is necessary for foreign lawyers to be qualified as FLCs in every state and the District of Columbia that accept foreign lawyers as FLCs. The Government of Japan deems that the requirement constitutes a barrier for foreign lawyers to practice in the United States, as the majority of those states require five years of experience, whereas only three years of experience is imperative in Japan in the same regard. The Government of Japan requests the Government of the United States to take necessary measures, such as petitioning the state governments concerned, in order to reduce the period of practicing experience requirement to three years in every state.

(c) Abolition of the Requirement that Only Practicing Experience in the Period Immediately Preceding the Date of Application can be Considered as Practicing Experience

As far as the Government of Japan confirmed, every state and the District of Columbia where foreign lawyers are accepted as FLCs allow only the period of practicing experience immediately preceding the date of application to be considered as that satisfying the requirement. The corresponding system in Japan does not impose such a limitation. The Government of Japan therefore requests the Government of the United States to take necessary steps, such as making suggestions to the relevant state authorities, to eliminate this kind of requirement in qualifying foreign lawyers as FLCs.

(d) Inclusion of the Practicing Experience in Third Countries into the Practicing Experience Requirement for Acceptance of Foreign Lawyers as FLC

As far as the Government of Japan has been informed, there are only two States, namely New York and Indiana, among those accepting foreign lawyers as FLCs, that allow the

inclusion of practicing experience in third countries into the practicing experience requirement. In Japan, the amendment of the Special Measures Law Concerning the Handling of Legal Business by Foreign Lawyers in 1998 has enabled foreign lawyers to include the period of time engaged in legal services in third countries as practicing experience. The Government of Japan urges the Government of the United States to take appropriate actions, including making requests to the state governments, to allow the period of practicing experience in third countries to comprise a part of the entire term of experience required to be FLCs in every state.

- (e) The Second Report to the Leaders of the Reform Initiative states, “[a]t the next meeting of the U.S.-Japan Regulatory Reform and Competition Policy Initiative, the Government of the United States will inform the Government of Japan whether it has received from the ABA (*American Bar Association*) any formal response by State authorities to the Japanese request, and the content of any such response.” The Government of Japan therefore requests the Government of the United States to inform the former of whether the ABA has conveyed Japan’s request to state authorities, which state authorities have made responses as well as their contents.

(2) Product Liability Law

Product Liability Law in the United States constitutes a heavy burden for Japanese and U.S. companies doing business in the U.S. The Government of Japan appreciates the U.S. Supreme Court decision in April 2003, which found that excessive punitive damage award might violate constitutional due process. However, Product Liability Law still constitutes a heavy burden for companies. The Government of Japan therefore requests the Government of the United States to encourage the reforms currently underway in various states to limit product liability, and to promote reform of product liability law at the federal level such as putting certain limits to the amount of damages and shortening the statute of limitations, which has already been attempted in such form as the submission of relevant bills to the Congress.

7. Public Construction Works

Facilitation of Dispute Settlement in Construction Works Ordered by State and Municipal Governments

Disputes between placers and receivers of public construction orders are often caused by the former's mistakes in design and occurrence of additional cost caused by unforeseen technical difficulties. Such disputes are better settled through neutral arbitration by experts of technicalities than at court.

While the federal government of the United States is equipped with such neutral measures for dispute settlement, or alternative dispute resolution (ADR), majority of state and municipal governments have not introduced those systems yet. Contractors are therefore obliged to appeal to court once they find disputes over contracts. Some Japanese construction companies have already spent a great amount of time and money with additional works resulting from such lawsuits.

In Japan, in contrast to the U.S. situation described above, the Construction Disputes Committee has been working under the Construction Business Act as a means of dispute settlement, under which as much as 500 disputes in construction work contracts are resolved annually in a simple, swift and proper manner. Also, the Standard Contract Form for Public Works provides that disputes be resolved at the Committee, based on which most of public construction works are contracted by commissioning entities of national and local governments.

As discussed in course of the second-year dialogue of the Reform Initiative, the Government of Japan is of the view that the dispute settlement concerning public construction works should be further facilitated in the United States. The Government of the United States is therefore encouraged to request the state and municipal authorities to adopt dispute settling systems similar to ADR, which has already been introduced in federal construction works. The Government of Japan believes that it will serve not only Japanese companies operating in the United States but also U.S. construction business itself.

In this regard, the Second Report to the Leaders states "(t)he Government of the United States will continue to exchange information with the Government of Japan on this issues, including development at state and local levels." The Government of Japan therefore requests the Government of the United States to inform the former, whenever appropriate, of the works that the latter has done with local and municipal governments in response to this request.

II. TELECOMMUNICATIONS

1. Restrictions on Foreign Investment in the Licensing of Radio Stations

Section 310 of the Communications Act of 1934 (hereinafter referred to as “the 1934 Act”) stipulates, as a criterion of licensing, that ratio of foreign direct investment in radio stations shall be limited to 20 percent. This restriction makes it impossible for Japanese carriers to directly obtain licenses to establish earth stations in the United States to provide services such as international communications between Japan and the United States by satellite. As a result, they are faced with difficulties in creating flexible networks.

The Government of Japan has already abolished the restriction on foreign investment ratio in licensing radio stations for telecommunications activities. Thus, it continues to request the Government of the United States to take the same action in licensing telecommunications business stipulated in Section 310 of the 1934 Act.

2. Certification and Licensing Criteria for Foreign Carriers’ Entry into the U.S. Telecommunications Market

Section 214 and Section 310 (b)(4) of the 1934 Act provides several certification and licensing criteria for foreign carriers’ entry into the U.S. telecommunications market. Among them, the criteria of “trade concerns” and “foreign policy” could be applied to refuse issuance of certification or licenses as reasons that are irrelevant to telecommunications policy. The Government of Japan therefore requests the Government of the United States to abolish them.

The Government of Japan also requests the Government of the United States to clarify and publish guidelines under which the criteria of “very high risk to competition” will be applied.

The Government of Japan further requests the Government of the United States to clarify guidelines under which the dominant carrier regulation in Sec.63, Title 47 of the Code of Federal Regulations (47CFR63) is applied to carriers providing international communications services.

The Government of Japan requests the Federal Communications Commission (FCC) to amend the rules including those mentioned above, based on proposals in the staff reports regarding the biannual review of FCC rules, accommodating proposed rulemaking.

3. State-Level Regulations

In the United States, the federal institutions delegate applications of various kinds of regulations on telecommunications to states’ decisions. Due to the differences in applications of regulations among states, telecommunications carriers are facing obstacles in the development of their inter-state level businesses. The Government of Japan requests the

Government of the United States to enable smooth management of those wide-area businesses by ensuring unified or harmonized applications among states of federal regulations and their amendments on telecommunications.

The priorities are two-fold.

- (1) In the United States, carriers are obliged to file reports on business information including their earnings to all individual states where they are providing services. As there is no standardized filing form that is common among the states, an excessive burden has been placed on carriers in reporting. Although the Government of Japan requested the Government of the United States to simplify and standardize request forms in the second-year dialogue of the Reform Initiative, there is no indication of improvement. Accordingly, the Government of Japan maintains the same request.
- (2) On August 21, 2003, the FCC published “Review of the Section 251 Unbundling Obligations of Incumbent Local Exchange Carriers (*ILECs*)” (Triennial review). This order grants states with the authority to determine whether an ILEC has an unbundling duty as for certain network element, and to define the geographical scope of the market to which the same duty is applied. The Government of Japan is concerned that the authority given to states will delay the implementation of the connecting rule and, by fragmenting the market, impose undue burdens and inefficiency on related companies. Therefore, the Government of Japan requests the FCC to ensure uniformity, efficiency, and promptness in state-level application of federal rules.

4. Access Charges

There are three different kinds of access charges in the United States: reciprocal compensation, intra-state access charges, and inter-state access charges, which are imposed depending on, for instance, the types of accessing carrier. The Government of Japan requests the FCC to eliminate or at least reduce disparity and inconsistencies among them.

5. Procedures for Processing Export Licenses and TAA Approval of Commercial Satellites

- (1) Companies have to undergo a series of tests by the Department of State to obtain permission for the export of commercial satellites and transfer of technical information concerning these satellites. In this regard, the Government of Japan is encouraged that the Directorate of Defense Trade Controls of the Department of State is developing an electronic “paperless” licensing system, which is expected to accelerate approval processing. The Government of Japan requests that the Government of the United States provide, whenever appropriate, the schedule for the establishment of the electronic licensing system and information related to the progress of the system.
- (2) On the other hand, criteria of export licensing and transfer of related technical information are not clear. Moreover, exporters are not provided with essential information such as documents on test procedures nor reports on non-performance on the manufacturing process. As a result, satellite communications companies of Japan have had long-lasting concerns over business activities. The Government of Japan therefore requests the

Government of the United States to clarify the standards required to obtain permission for the export of commercial satellites and transfer of technical information, and to limit the types of unopened information to the minimum.

- (3) The Government of the United States restricts disclosure of certain types of information in satellite trades. As a consequence, when a U.S. satellite purchaser puts out a tender, Japanese satellite makers can only obtain related documents later than U.S. makers do. The Government of Japan is concerned that Japanese makers will be at a disadvantage in competition, and thus requests the Government of the United States to ensure fair competition for satellite communications businesses in the procurement of U.S. satellites.

6. The 1990 Exchange of Letters on Network Channel Terminating Equipment (NCTE)

Considering the rapid change in the market environment, the Government of Japan requests the 1990 Exchange of Letters on Network Channel Terminating Equipment (NCTE) to be terminated with a view to promoting speedy development of businesses and putting in place an appropriate circumstances under which competition can be facilitated.

III. INFORMATION TECHNOLOGY

Given the current situation that copyrighted works are freely distributed across the borders due to the wide use of the Internet and the development of digital technologies, it is vital to ensure protection of copyright and related rights in an internationally harmonized manner.

From this viewpoint, the Government of Japan requests the Government of the United States to ensure clear and reliable protection of items which are not fully protected in the United States, such as the right of making available, the rights concerning live performances, the moral rights, the right of rental concerning video games, organizations, and the unfixed works. The Government of Japan also requests the Government of the United States to work with the former to explore and consider possible ways of cooperation to combat piracy of digital content under the Reform Initiative.

IV. ENERGY

The Comprehensive Energy Bill including the repeal of the Public Utility Holding Company Act (PUHCA) has been deliberated in the Congress. While the Government of Japan welcomes this development, the bill has not yet been approved by the Congress. In order to realize a dynamic electricity market throughout the United States by reducing business risks and barriers, the Government of Japan believes that it is beneficial to take the following measures under the leadership of the Federal Government as soon as possible.

1. The Power Outage in the Northeast of North America and the Improvement of Network Reliability

The large-scale power outage in the northeast of North America this summer has been raising concerns about stable supply of electric power in the United States. Accordingly, the Government of Japan recommends that the Government of the United States thoroughly investigate the cause of the power outage and take necessary measures to improve network reliability in order not to have such a serious accident take place again. Also, the Government of Japan recommends the Government of the United States articulate its views on the incident in the context of the ongoing reform of electricity industry system in the United States.

2. Improving the Two-Layer Structure of Federal and State Regulations and Disparity among States

In the United States, both the federal and state governments regulate the electricity sector, obliging new entrants to learn and research the regulations of respective states in addition to those of the federal government. The diversity in the scopes and structures of market liberalization among states impedes market participants developing their business smoothly. Regulating authorities also remains split between the federal and states governments: the wholesale market is under the Federal Energy Regulatory Commission (FERC) while the retail market is regulated by the State Public Utility Commissions.

Moreover, the state authorities have not yet clarified whether each of them has liberalized the retail market and, if so, its schedule, thus hindering competitors entering the retail market.

The Government of Japan continues to recommend the measures be implemented rapidly to resolve the problem of two-layer structure of federal and state regulations and the their disparities among states.

3. The Prompt Approval of the Comprehensive Energy Bill including the Repeal of the PUHCA

The Government of Japan recognizes that the Comprehensive Energy Bill deliberated in the

Congress is essential for the improvement of energy infrastructure and the reinforcement of energy security. The Bill also includes the repeal of the PUHCA, and the Government of Japan expects the Bill to be approved particularly in this regard, for it has prevented business activities of the retail suppliers operating in multiple states by requiring them to comply with complex approval procedures and other. Accordingly, the Government of Japan recommends that the Government of the United States intensify its efforts to ensure the early approval of the Bill including the repeal of the PUHCA.

4. Review on Publicly-Owned Entities

Regarding review on publicly-owned entities (POEs), the Second Report to the Leaders states “(t)he Government of the United States continues to assess the impact of Publicly Owned Entities (POEs) on fair competition in a liberalized market.” The Government of Japan recommends that the Government of the United States complete such assessment promptly and examine future policies on POEs, such as mandatory participation of local public distributors in the liberalized market similarly to investor-owned electric companies, in accordance with the progress of competition in the electricity market.

5. Standard Market Design (SMD)

The Government of Japan appreciates the reference in the Second Report to the Leaders that “(t)he Government of the United States further clarified that SMD inherently aims to ensure coordinated development of generation and transmission facilities.” However, tangible measures of such coordination have not yet been demonstrated. The Government of Japan therefore continues to pay attention to future progress in this regard. The Government of Japan recommends the Government of the United States to continue to ensure coordinated development of generation and transmission facilities in designing the system, in extending the SMD to the national level in future.

6. Clarification of the Market Regulation Policies and Measures of the Federal Energy Regulatory Commission (FERC)

Regulatory policies and measures of the FERC for wholesale and other markets have problems in terms of predictability. For example, it takes extremely long time to issue final rules after publication of draft rules (Notice of Proposed Rulemaking: NOPR), as well as in its finalization process rules are subject to fundamental changes at their core policies. Due to such concerns, business entities planning to enter the U.S. wholesale market have faced obstacles of little predictability about regulations and administrative decisions in developing their business. Accordingly, the Government of Japan recommends that the FERC make draft rules after hearing sufficiently from the state governments and other parties interested or concerned at technical conferences to produce more feasible NOPRs. It will certainly enhance the predictability about the final rules for business sector as well as facilitate their smooth implementation.

7. Price Cap Regulation in Wholesale Market

The Federal Government has price cap regulations on the electricity wholesale trade in some

states, which would prevent market participants from recovering their investments. Whereas the Second Report to the Leaders clarifies that the FERC “will trigger such caps only to prevent the abusive exercise of market power,” measures to accomplish that purpose are not limited to price cap regulation but *ex post* approach may also serve it. Consequently, the Government of Japan recommends the Government of the United States to verify that price cap regulation is the most effective and efficient measure for the prevention of the abusive exercise of market power.

V. MEDICAL DEVICES AND PHARMACEUTICALS

The Government of Japan expects to have productive and beneficial discussions with the Government of the United States on the followings recommendations, with participation by the officials of the United States Food and Drug Administration (FDA), both at the sessions held in Tokyo and Washington, D.C. of the Working Group on Medical Devices/Pharmaceuticals (Japan-U.S. MOSS Follow-up Meeting),

1. Acceptance of Data Obtained by Means of the Harmonized Pharmacopoeial Test

Pharmaceutical companies in Japan usually employ test methods described in the Japanese pharmacopoeia (JP) when they prepare data for new drug application. In this field, the related authorities of Japan, the United States and the EU have already been working cooperatively to harmonize pharmacopoeial monographs. The FDA, however, still requires applicants of new drugs to re-conduct drug tests in accordance with the method described in the U.S. pharmacopoeia (USP), even for the drugs which have already tested by the internationally harmonized method. Hence the Government of Japan requests the Government of the United States to treat data obtained from the internationally harmonized test method equally with those obtained in accordance with the USP.

2. FDA's Regular Meeting with Foreign Industry

The Government of Japan requests the Government of the United States to provide foreign pharmaceutical and medical device industry operating in the United States, including those Japanese, with continuous as well as meaningful opportunities to exchange views with the FDA on the U.S. regulations concerned.

The Government of Japan also requests the Government of the United States to provide similar opportunities extensively to Japanese industry as well when they visit the United States.

3. Simplification of Data Requirements for Investigational New Drug Application

The FDA requires excessive amount of data on drugs in the investigational stage, Chemistry, Manufacturing and Controls (CMC) data in particular, in comparison to those required in Japan. While it is surely important to guarantee the quality of investigational drugs once they be given to the human body, the data requirement should be minimized for investigational new drugs in the process of manufacturing, where production process has not been optimized.

4. Compliance with ICH Guidelines

The Government of the United States has not fully implemented some of the guidelines of the International Conference on Harmonization (ICH). In a certain case, for example, the FDA required twelve-month chronic toxicity testing in non-rodents, although the corresponding

period that the ICH guideline provides is nine months. Since such a disregard of harmonized guidelines has merely negative impact on both applicants and the FDA, the Government of Japan requests the Government of the United States to observe the agreed ICH guidelines.

5. Immediate Implementation of the Agreements in GHTF

The Government of the United States has not yet fully implemented some of the agreements at the Global Harmonization Task Force (GHTF) including the Essential Requirement. The Government of Japan therefore requests the Government of the United States to implement all the GHTF agreements without delay.

6. Mutual Recognition on Good Manufacturing Practices of Pharmaceutical Products and Medical Devices

In December 2000, the Ministry of Health and Welfare (present Ministry of Health, Labour and Welfare (MHLW)) of Japan and the FDA exchanged letters regarding cooperation in the exchange of pharmaceutical inspection reports and other pharmaceutical surveillance information. The Government of Japan requests the Government of the United States to further enhance this cooperative relation and to initiate more substantial discussion with the former toward the mutual recognition on Good Manufacturing Practices (GMPs) of pharmaceutical products. The Government of Japan believes that it will facilitate the process of confirming the quality management of production as well as reduce the burden of inspections conducted by the Government of the United States to the Japanese manufacturers exporting products to the United States.

The Government of Japan also encourages the Government of the United States to launch more essential consultations toward the mutual recognition on GMPs of medical devices as well.

7. Mutual Recognition on Good Clinical Practices

The Government of Japan requests the Government of the United States to exchange information on GCP inspection more actively, and to embark on substantial consultations with the former toward the mutual recognition on Good Clinical Practices (GCPs). The Government of Japan is convinced that it will facilitate the processing of GCPs conformity assessment of application dossiers, and subsequently will reduce the time currently required for MHLW's review of new drug application.