THIRD JOINT STATUS REPORT ON THE U.S.-JAPAN ENHANCED INITIATIVE ON DEREGULATION AND COMPETITION POLICY July 22, 2000

On May 3, 1999, the Governments of the United States and Japan issued the Second Joint Status Report on the U.S.-Japan Enhanced Initiative (Second Joint Report) on Deregulation and Competition Policy under the U.S.-Japan Framework for a New Economic Partnership. Based on the reaffirmation of the two governments in the Second Joint Report of their determination to promote further deregulation, they have continued to devote substantial resources to the implementation of the Enhanced Initiative on Deregulation and Competition Policy (Enhanced Initiative), recognizing the importance of actively promoting deregulation and applying an effective competition policy.

The Governments of the United States and of Japan have held meetings of the High-Level Officials Group and of six Expert-Level groups (telecommunications, housing, medical devices and pharmaceuticals, financial services, energy, and structural issues, including competition policy, distribution, and issues related to transparency and government practices) during the third year of the Enhanced Initiative. Consistent with the principles of two-way dialogue and the aim of the achievement of tangible progress, both sides have exchanged views and interests on a wide variety of deregulation items. As part of that effort, both governments provided submissions to each other in October 1999.

The Government of Japan has taken a series of deregulatory measures, the latest and the most significant being the adoption on March 31, 2000 of the final revisions to its Three-Year Programme for Promoting Deregulation. The salient deregulatory and other measures by both governments that relate to the dialogue under the Enhanced Initiative are set out in this Report. Both governments welcomed the progress that has been achieved under the Enhanced Initiative over the past year. The Governments of the United States and Japan share the view that these measures will improve market access for competitive goods and services, enhance consumers' interests, increase efficiency, and promote economic activity. Consistent with international obligations, the measures undertaken under the Enhanced Initiative will provide nondiscriminatory treatment to competitive foreign goods and services.

Both governments reaffirm their determination to further promote deregulation. The two governments, upon the request of either government, will meet at a mutually convenient time to address the measures contained in this report.

DEREGULATION AND OTHER MEASURES BY THE GOVERNMENT OF JAPAN UNDER THE ENHANCED INITIATIVE

I. TELECOMMUNICATIONS

A. Interconnection

- In line with Paragraph B.1.(3) of the First Joint Status Report on the U.S.-Japan Enhanced Initiative on Deregulation and Competitive Policy of May 15, 1998, prior to the introduction of long-run incremental cost (LRIC)-based rates, the Ministry of Posts and Telecommunications (MPT) has promoted the reduction of interconnection rates of NTT regional networks and approved further reductions of interconnection rates for FY 1999 on February 25, 2000, with a total reduction of 177 billion yen over FY 1998. This was the largest annual reduction ever, which included rate reductions of 4.1 percent (GC interconnection, 180 seconds) – 11.2 percent (ZC interconnection, 180 seconds) for analog switch traffic, 27.5 percent (ZC interconnection, 180 seconds) – 32.6 percent (GC interconnection, 180 seconds) for ISDN traffic, and 46.7 percent (1.5 Mbps, within MA) for leased line rates.
- 2. MPT will examine the method of introducing fair and transparent interconnection, in case measures need to be taken to facilitate interconnection between NTT DoCoMo and other carriers, in FY 2000. In the course of MPT's review of the interconnection regime in FY 2000, MPT will determine whether to categorize NTT DoCoMo as a "designated carrier." MPT will provide an opportunity for interested parties to comment on this proceeding.
- 3. In line with Paragraph B.1.(3) of the First Joint Status Report on the U.S.-Japan Enhanced Initiative on Deregulation and Competition Policy of May 15, 1998, the Government of Japan submitted a bill to amend the Telecommunications Business Law to the ordinary session of the Diet on March 31, 2000, which passed on May 12, 2000.
- 4. MPT will amend its ordinances so that reductions of interconnection rates based on "Model Case A" (22.5 percent reduction for GC interconnection, 60.1 percent for ZC interconnection compared with FY 1998) will be phased in over three years. In this regard, MPT welcomes NTT East's and West's plans to frontload the reductions in the first two years by 80 percent for ZC exchange and GC-ZC transmission and 70 percent for GC exchange and other functions, using FY 1999 traffic data. Based on these plans, pending final calculations, GC rates are expected to decline approximately 20 percent by FY 2001, and ZC rates are expected to decline approximately 50 percent by FY 2001, compared with FY 1998 rates.

- 5. MPT welcomes NTT East's and West's plans to apply to implement FY 2000 interconnection rates retroactive to April 1, 2000.
- 6. MPT will launch a study in the autumn of 2000 on revision of "Model Case A," to be completed in CY 2002, including studies of depreciation rates, choice and price of inputs, and the costing of local loops. MPT will decide in CY 2002 on the issue of applying the revised LRIC model as a basis for pricing unbundled local loops and implementing further interconnection rate cuts, with the possibility of retroactive application to April 1, 2002, using FY 2001 traffic data.
- 7. MPT will launch a study in CY 2000 on how to recover non-traffic sensitive (NTS) costs and will decide in CY 2002 whether or not NTS costs should be recovered from the current usage-based interconnection rates. In this process, MPT will pay due consideration so that the revised LRIC model would: 1) cause no disruption of universal service; 2) not prove destructive to business operations of NTT East and West; and 3) garner broad-based public support for the possible shift of cost recovery from usage-based interconnection rates to fixed end-user charges.
- 8. The study group reviewing the LRIC model will use an open and transparent process on a non-discriminatory basis that will include broad participation in the study by interested carriers and will use public comment procedures.
- 9. The Government of Japan will exchange views with the Government of the United States, no later than October 2002, on the timely application of the revised LRIC model.

B. Promotion of Competition and Use of the Internet

The Government of the United States and the Government of Japan initiated a dialogue on competitive carriers' concerns regarding access to subscribers of Internet services and the impact of retail pricing and termination policies on the viability of alternate networks.

C. Unbundling/Co-location

- 1. Unbundling
 - a. MPT will amend its ordinance in CY 2000 to designate Main Distribution Frame (MDF) and I-interface Subscriber Module (ISM) in the communications buildings of NTT East and West as standard interconnection points, so that terms and conditions, such as interconnection rates and technical conditions regarding interconnection with unbundled metal subscriber lines and ISM should be included in the "Articles of Agreement concerning Interconnection" of NTT East and

West in order to promote local competition, including in Internet Services.

- b. To enhance the spread of Digital Subscriber Line (DSL) technology, an MPT Study Group recommended in July 2000 that NTT East and West allow interconnection on a nationwide basis in order to provide DSL services, thereby expanding trial areas and facilitating the introduction of the full range of DSL technologies, whenever feasible. In addition, the study group recommended a seven-working-day target provisioning period for DSL services and a system for the expeditious disclosure by NTT East and West of information needed by competitors to initiate service.
- c. MPT will launch a study in the autumn of 2000, to be completed by the summer of 2001, on issues concerning the necessary rulemaking for unbundling of optical fiber to promote competition.
- 2. Co-location
 - a. MPT amended its ordinance to change the co-location rates of NTT East and West from the market value basis to the book value basis and approved the new rates on February 25, 2000.
 - In approving the FY 1999 "Articles of Agreement concerning Interconnection" of NTT East and West, MPT took steps to prohibit NTT East and West from denying competitors access to co-location space for their equipment based on either NTT East's or West's subjective evaluation that competitors' equipment was not proved necessary for interconnection.
 - To further improve the opportunities for co-location, MPT will amend its c. ordinance to require NTT East and West to stipulate necessary procedures in their interconnection tariffs that 1) permit interconnecting carriers to undertake, on an expeditious basis, construction and maintenance regarding co-located facilities and 2) provide competitors 24-hour access to their equipment co-located in the buildings of NTT East or West. According to MPT's draft ordinance, NTT East and West will also be required to include in their tariffs a standard period for the NTT East and West to reply to co-location requests and do construction for co-location, if they are asked to do so, and procedures for disclosure of information on available space for co-location. MPT consulted with the Telecommunications Council in May 2000 about the amendment. Whether competitors should be allowed to enter the buildings of NTT East and West to see the availability of space for co-location is now being discussed in the Council.

D. Network flexibility

- 1. In order to facilitate understanding among parties interested in constructing telecommunications networks, on December 24, 1999, MPT published the "Manual for the Construction of Networks by Telecommunications Carriers" which compiles the current framework, examples and related matters concerning network construction.
- 2. On December 24, 1999, MPT invited comments on 1) the implementation of the two measures outlined below, 2) issues to be considered when implementing them, such as measures to ensure fair competition and user benefits, and 3) other measures to increase flexibility in the construction of networks. This step was taken with a view to conduct further study to increase flexibility in the construction of networks.
 - a. To allow a Type 1 telecommunications carrier to use telecommunications circuit facilities, procured from another telecommunications carrier on a user tariff basis, as part of its own network, and to operate the whole network as one network for the Type 1 business.

This enables carriers to use capacity-based (including wavelength-based) telecommunications circuit facilities for their operations, procured from another telecommunications carrier.

- b. To eliminate the "separate company requirement" that requires telecommunications carriers to establish separate companies for their Type 1 and Type 2 businesses and instead to allow a Type 1 carrier to operate a Type 2 business or a Type 2 carrier to operate a Type 1 business, as an independent business, in a single entity.
- 3. In order to increase flexibility in the construction of networks by telecommunications carriers, MPT will complete its study on the above two items and take necessary measures by the end of 2000.

E. Rights of Way and Access to Incumbent Facilities

- 1. In FY 1999, the Government of Japan received complaints with regard to laying of cables, and conducted a review, listening to a broad range of views. The Government of Japan reviewed the circumstances of rights-of-way and access to incumbent facilities and the need for additional means other than those proposed in FY 1998 to improve access to rights-of-way and incumbent facilities. The results of the review were published on March 27, 2000.
- 2. In FY 2000, the Government of Japan will continue to receive complaints with

regard to laying of cables, look into the matters needed within the scope of available cooperation from related entities and then reply to the complaint of applicants in the form of appropriately compiled results. In case problems are clarified through complaints and other means, the Government of Japan will also examine appropriate measures to address those problems.

- 3. In FY 2000, the Government of Japan will continue a review by the Interagency Review Group and also continue to make efforts to facilitate laying of cables by telecommunications carriers and cable television operators.
- 4. By the end of September, 2000, the Government of Japan will research the situation of the measures for improvement taken by the entities concerned in the "Result of the Review of Rights of Way in Japan" issued on March 27, 2000, and will publish the results in October, 2000 through the Ministry of Foreign Affairs Web Site (http://www.mofa.go.jp/mofaj/gaiko/economy/husetsu/index.html).

II. HOUSING

A. Building Regulation and Standards

- 1. The Ministry of Construction (MOC) implemented an interim inspection system for building code enforcement on May 1, 1999. MOC implemented performance-based building standards for the construction of three-story, multi-family wood housing in quasi-fire protection districts on the same date. In June 2000, the revised Building Standard Law (BSL) that introduces performance-based standards became effective. MOC clarified performance-based requirements for fireproof buildings, in accordance with the revised BSL, that allow construction of four-story, multi-family and mixed-use wood-frame buildings that satisfy the requirements. The Governments of Japan and of the United States continue to discuss technically the performance requirements for special use buildings.
- 2. MOC implemented the Public Comment Procedure in developing enforcement orders in February and March 2000 to implement revisions of BSL. It will further implement the Public Comment Procedure in developing future enforcement orders and notifications.
- 3. In December 1999, MOC clarified that sections of a building separated by firewalls meeting the criteria specified in Notification 1059 would be treated as separate buildings for the purpose of calculating permissible floor area.
- 4. MOC implemented in June 2000, a system of recognized/designated evaluation bodies for the nationwide acceptance and evaluation of test data for building methods and materials, and facilitated implementation by providing opportunities

for discussions with potential applicants.

- 5. In June 2000, MOC adopted appropriate ISO testing methods to evaluate the performance of structures and interior finish materials such as noncombustible, quasi-noncombustible, and fire-retardant materials.
- 6. During FY 1999, MOC participated in a number of seminars both in the United States and Japan, aimed at acquainting U.S. and Japanese builders and consumers with ongoing reforms and expanded choices of building methods and materials.
- 7. On July 5, 1999, MOC provided to the United States information on the approval process for aluminum fire-resistant windows. Within six months of submission of all necessary test data from the United States, MOC will authorize the use of U.S. power-driven nails and staples in Japan. MOC is still awaiting certain U.S. test data. MOC is also awaiting the final report from the United States needed to re-evaluate the existing correction factors of Oriented Strand Board (OSB) with the view to applying the existing plywood correction factors to OSB, thereby achieving equivalency.
- 8. In July 1999, the Diet passed an amendment to the Japan Agricultural Standard (JAS) Law to allow testing organizations overseas to function as JAS-registered grading organizations (RGO) and/or JAS-registered certification organizations (RCO). In July 1999, the Ministry of Agriculture, Forestry and Fisheries (MAFF) implemented a revised JAS for structural plywood, which places increased emphasis on performance, including board strength.

B. Housing Policy

- 1. On December 9, 1999, the Diet approved the Law Concerning Special Measures for Encouragement of the Supply of Quality Rental Housing and Other Facilities. The Law, whose implementation was completed on March 1, 2000, revised the Land and House Lease Law by introducing fixed-term lease regimes as an alternative for housing leases. The Law exempts contracting parties (i.e., lessor and lessee) signing fixed-term leases from automatic lease renewal and "justifiable cause" requirements and furthermore allows them to waive their right to claim rent changes with a special clause.
- 2. In May 2000, the City Planning and the Building Standard Laws were amended in order to further promote intensive and effective use of land. The amendment established a new framework to allow a construction site, including a residential building, to utilize unused floor area in commercial districts.
- 3. By December 2000, MOC will initiate assistance to the Real Estate Transaction Modernization Center in strengthening the appraisal system for resale housing so

that maintenance and renovation quality are reflected in price evaluations.

- 4. In December 1999, MOC informed the United States that it had taken necessary measures to ensure that its housing programs do not discriminate against imported products.
- 5. Following the amendment of the Government Housing Loan Corporation Law, the maximum repayment term for resale condominiums meeting certain quality criteria will be extended, within FY 2000, from 30 to 35 years, which is the same as that for newly built houses. Similarly, the maximum repayment term for resale detached houses meeting certain quality criteria will be extended from 20 to 25 years.

III. MEDICAL DEVICES AND PHARMACEUTICALS

- **A. Recognition of Innovation:** Reaffirm the value of innovation of pharmaceuticals and medical devices, so as not to impede the introduction of innovative products which bring more effective and more cost-effective treatments to patients.
 - 1. As the Government of Japan discusses, develops, and implements pharmaceutical pricing reforms, including the treatment of innovative products as well as the treatment of originator products and generic products, with the aim of finalizing measures by April 1, 2002, it will continue to study the pharmaceutical pricing system, the comparitor product selection process, and the scientific basis of product evaluation with related parties, including U.S. industry, with the goals of promoting innovation and increasing the availability of innovative pharmaceutical products. This process will recognize both the value of such products, which bring more effective and more cost-effective treatments to patients, as well as the role of the market.
 - 2. In reforming the by-function system for medical devices, pursuant to *Chuikyo's* March 1, 2000 policy outline, the Government of Japan will take appropriate action based on measures to be discussed by the Subcommittee on Insurance-covered Medical Materials of *Chuikyo*, including multiple prices for the same function, to absorb excessive price changes, so as not to place disproportionate burdens. Such measures would be subject to the approval of *Chuikyo* and implemented in October 2000 with other by-function system reforms. And the Government of Japan will seriously consider incremental functional differences based on clinical benefit in medical device development.

B. Approval Process

1. The Ministry of Health and Welfare (MHW) will continue to coordinate the efforts of the Pharmaceutical and Medical Device Evaluation Center (PMDEC),

the Japan Association for the Advancement of Medical Equipment (JAAME), and the Evaluation and Licensing Division to eliminate redundant work and facilitate the smooth operation of the medical device approval process. The Government of Japan re-categorized the previous categories for device applications into three categories in April 2000: "new medical devices;" "improved devices;" and "metoo devices." The Government of Japan will thereby exempt the applications for "new medical devices" and "improved devices" from equivalence review at JAAME and require them to only be reviewed at PMDEC. The Government of Japan will take measures in which "me-too devices" would be only subject to equivalence review at JAAME in principle. On request reviewers will answer questions from applicants prior to application submission regarding proper device classification. In addition, MHW will start to list items necessary for applicants to determine equivalence of the medical devices in each area of devices through consultations with industry to ensure that MHW Notification 1677, issued on December 1, 1999, will be implemented in a flexible manner, including assurance that data requests do not include asking for proprietary information on other firms' products.

- 2. MHW will consult with U.S. industry regarding biocompatibility testing requirements with the objective of minimizing the data burden on applicants.
- 3. The Government of Japan has taken steps to allow the start of clinical trials for certain radiation therapies.
- 4. In March 2000, MHW issued notifications, including question and answer sections, for pacemakers and orthopedics that are not subject to clinical trials. MHW will decide on future product categories through consulting with industry.
- 5. The speed of the whole New Drug Application (NDA) approval process has been improved recently and review times are decreasing. As agreed in the First and Second Joint Status Reports, MHW has shortened the standard processing period for NDAs to 12 months since April 1, 2000, and to help meet this goal and promote smooth and expeditious NDA approvals, MHW:
 - a. Will encourage improvements in the quality of NDAs through the active use of consultations provided by the Organization for Pharmaceutical Safety and Research (OPSR); and
 - b. Will ensure the consistency of, and adherence to during the review of applications, advice given in prior consultations provided by OPSR, which are based on MHW policy.
- 6. MHW will allow for the submission and review of an NDA for an additional indication while the NDA for the molecule's initial indication is still pending.

- 7. MHW will allow for the submission of an application for partial change for an additional indication while the initial application for partial change is still pending.
- 8. MHW will allow applicants to continue clinical work on a molecule, including work on additional indications, during the NDA review of the molecule's initial indication.
- 9. MHW abolished the Sub-Committees of the Central Pharmaceutical Affairs Council in November 1999 and strengthened a team-review system in the Pharmaceutical and Medical Devices Evaluation Center, that allows for continuous direct communication between the reviewers and the applicant.
- 10. MHW will continue to offer opportunities, as appropriate, for applicants to discuss their NDAs with senior MHW officials.
- 11. MHW has divided the Special Committee on Drugs of the Central Pharmaceutical Affairs Council into two bodies that will meet for up to 16 times-a-year.
- 12. MHW has established a Special Committee to review In-vitro Diagnostics (IVD), including IVD-related devices, and Medical Equipment.
- 13. MHW will maintain dialogue with applicants so that they may have some sense as to how long it will take to process an individual medical device or new drug application.

C. Acceptance of Foreign Clinical Data

- 1. Regarding acceptance of foreign clinical data for the approval of pharmaceuticals, the Government of Japan provides opportunities for consultation with the Organization for Pharmaceutical Safety and Research (OPSR) and the like to promote the facilitation of acceptance of foreign clinical data based on International Conference on Harmonization (ICH) E5 guidelines.
- 2. MHW notification issued in November 1999 clearly provides protection of rights of natural and legal persons, including protection of business proprietary information, when the data as well as patient records are made public after product approval.
- 3. MHW affirms that on a case-by-case basis, it is possible to submit a bridging data package, as defined by ICH E5 Guidelines, without a new bridging study, in order to obtain product approval, if ICH and Good Clinical Practices-consistent data for extrapolation are available to confirm comparability.

- 4. MHW notification issued in August 1998, based on the International Conference on Harmonization (ICH) guidelines, resulted in the expanded acceptance of foreign clinical test data for the approval of new pharmaceuticals. This progress will continue.
- 5. The Government of Japan has accepted clinical test data for the approval of new medical devices and pharmaceuticals that meet Good Clinical Practices, regardless of origin, whether domestic or foreign. This progress will continue.

D. The Reimbursement Process

- Based on the policy outline adopted at Chuikvo on March 1, the Government of 1. Japan will work to develop prompt, streamlined and transparent reimbursement procedures for medical devices, including written category definitions (e.g., A1 to C2); provisional pricing; written procedures for the creation of new by-function categories that, based on general written principles, have been evaluated to have clinical benefits, including providing an appropriate provisional price, within 4 months in principle, until the new category is implemented; the treatment of "products no longer new to Japan" through the clarification of by-function category definitions; and time-clocks for granting reimbursement, as well as to institute restructured categories and a by-function system for medical devices, and will work to implement these measures simultaneously in October 2000. In doing so, the Government of Japan will seriously take into account of the opinions of related parties, including U.S. industry. The Government of Japan will continue to consider the timing to implement new by-function categories for medical devices as well as the treatment of C2 products, outlined by *Chuikyo* on March 1, with the aim of facilitating the introduction of highly advanced technologies into the Japanese market, taking into consideration the views of interested parties, including U.S. industry, and subject to the approval of *Chuikyo*, after October 2000. Dialogue with the United States Government will continue as necessary.
- 2. An appeals process for medical device and pharmaceutical pricing decisions will be implemented in October 2000. The processes by which judgments will be made will be clearly set out in writing. Judgments will be based on the appropriate and accurate application of pricing rules which are set out in writing.
- 3. On developing and implementing the Drug Pricing Organization and the Special Organization for Insurance-covered Medical Materials, MHW will ensure that the members serving on these bodies have objective scientific expertise and no conflicts of interest, and that membership in these organizations is balanced, seriously taking into account of the opinions of related parties, including U.S. industry. Membership is subject to the approval of *Chuikyo*. MHW, which

calculates prices and is responsible for pricing and appeals decisions, will continue to provide related parties, including U.S. industry, with direct access to MHW.

E. Transparency: To ensure transparency in the consideration of health care policies, foreign pharmaceutical and medical device manufacturers will continue to be provided, upon request, with opportunities to state their opinions in the relevant Councils and relevant study groups on an equal basis with Japanese manufacturers, and to exchange views with MHW officials at all levels. MHW, together with manufacturers, including foreign manufacturers, will make maximum efforts so that such opportunities will be meaningful.

F. Nutritional Supplements

- 1. On March 9, 2000, MHW dropped the requirement that, in order for capsules and tablets of B6, B12, K, Pantothenic acid, Folic acid, Biotin, Zn, Cr(lll), Se, Cu, Mn, Mo, and I to be regarded as food, the daily dosage of each vitamin or mineral preparation must be below a certain amount.
- 2. MHW will continue to institutionalize and implement the measures recommended by the Office of the Trade and Investment Ombudsman on March 18, 1996 to promote liberalization of the Japanese nutritional supplements market, for example, vitamins, herbs, and minerals by:
 - a. Taking existing safety data of excipients that have been used in pharmaceuticals into consideration in the evaluation process of food additives under the Food Sanitation Law; and
 - b. Allowing minerals, vitamins, and herbs to make nutritional and health benefit claims, if there are scientific data and information to support such claims.
- 3. The scope of utilizing foreign data and information to evaluate and approve products in Japan as well as the publication of data required and the criteria by which approvals of herbs, minerals, vitamins, excipients, and nutritional/health benefit claims are judged will be discussed in MHW with opportunities for interested parties, including U.S. industry and the U.S. Government, to offer views and opinions. The progress of these discussions will be reported in the MOSS.
- **G. Services:** The Government of Japan will endeavor to deregulate its health care services sector with an aim to improving the efficiency of the system, including advertising and scope of provided services.

IV. FINANCIAL SERVICES

- A. Specific Measures: The Japanese financial system reform program (the so-called Japanese "Big Bang"), which was started at the initiative of former Prime Minister Hashimoto in November 1996, aims at revitalizing the Japanese financial markets through fundamental financial liberalization and deregulation based upon the principles of "Free, Fair and Global." Up to now, most of its measures have already been implemented.
 - 1. The following measures, in addition to the measures described in the former Joint Status Reports, have already been implemented:
 - a. Establishment of a system to provide data such as base price to private rating institutions so as to improve disclosure by investment trusts in order to allow standardized and accurate comparisons of investment performance (April 1997); The provision of data has been growing to serve as many as 18 rating institutions as of end of November 1999. It is expected that more and more investors will utilize this information on performance assessment when choosing which products to invest in.
 - b. Provision of a public comment period of about 30 days, on all financial services draft measures as required by the "Public Comment Procedure for Formulating, Amending or Repealing a Regulation" (Cabinet Decision of March 23, 1999), with an appropriate period provided to permit public comment on extensive or complex draft measures; The Government of Japan takes seriously the public comments received, and publishes a review of those comments, both those taken and those not accepted, in principle, by the time that a final regulation is issued. For those measures requiring significant changes in operating, administrative, data processing, or other procedures, the government of Japan is committed to providing a sufficient transition period before finalized regulations take effect.
 - c. Implementation of the constant review on the regulations for financial services according to the "Three-Year Program for Promoting Deregulation" (April 1, 1998, its revised version of March 30, 1999 and its re-revised version of March 31, 2000); In keeping with the policy that was established during the "Three-Year Program for Promoting Deregulation," the Japanese government will continually review financial services regulations, and revise those regulations as necessary, taking into consideration comments and requests received from interested parties, both domestic and foreign.
 - d. The Financial Services Agency (FSA) provides in its Guidelines for Supervision, "Responding to Inquiries Concerning the Interpretation of

Laws and Regulations, etc." (Section 0-6), a mechanism for the FSA to respond to inquires on matters under its jurisdiction. These include inquiries on interpretations of laws and regulations, on whether operations, practices and transactions proposed by financial services intermediaries are permitted or otherwise lawful under those laws and regulations, and on whether the FSA staff would recommend taking enforcement actions based on the facts described by the requestor. The FSA may also require requestors to provide a draft response with their inquiry. The FSA under this procedure shall request that inquiries which are deemed to have precedential value be made in writing. The FSA shall respond in writing to all written inquiries, except where the inquiry is incomplete or frivolous or depends on facts or circumstances the FSA cannot verify, or it would otherwise be inappropriate for the FSA to give a response, and shall make publicly available the content of the inquiry and the FSA's response, taking appropriate measures to protect business proprietary and other confidential information. When the FSA declines to respond to an inquiry, it will inform, and provide an explanation to, the requestor within a reasonable period of time. As resources and experience with this system grow, the FSA expects that inquiries under this Guideline will play an increasingly important role in improving transparency and predictability in the regulatory process, similar to that provided by noaction letters and published guidance in other jurisdictions.

- e. Elimination of restrictions on financial company (non-bank) use of proceeds from bond and commercial paper issuance (May 20, 1999);
- f. Elimination of restrictions on the scope of business activities for securities operating subsidiaries of banks and trust banks, and trust bank operating subsidiaries of banks and securities companies (October 1, 1999);
- g. Full liberalization of brokerage commissions (October 1, 1999);
- h. Entry of insurance companies into the banking business (October 1, 1999);
- i. Modification of the provisions concerning the Employee Pension Funds (*kosei nenkin kikin*) and National Pension Funds (*kokumin nenkin kikin*) to allow fund sponsors to directly transfer securities when shifting business from one asset manager, including investment advisory companies, to another (June 1, 2000).
- 2. In addition, the Japanese financial system reform has been proceeding towards its completion by the year 2001. The following measures are on track to be implemented as previously scheduled:

- a. Entry of banks into the insurance business to complete mutual entry between the insurance business and other financial business areas (scheduled to be implemented by March 2001);
- b. Modification of the provisions concerning management of the *Nempuku* successor fund to allow fund sponsors to directly transfer securities when shifting business from one asset manager, including investment advisory companies, to another, and, once guidelines have been set for the successor fund's investment policy, to allow introduction of a new trust scheme (*tokutei shintaku*) as an alternative to the limited partnership scheme for management of the successor fund for *Nempuku* (scheduled to be implemented by April 1,2001);
- c. Regulatory modifications expanding the scope of assets able to be securitized by special purpose companies and improving the convenience of the system (the bill to amend the SPC Law (the Law on Securitization of Specified Assets by Special Purpose Companies) and related laws were approved by the Diet in May 2000, and will take effect as prescribed by government ordinance on a date no later than the end of November 2000.
- 3. Furthermore, the Government of Japan will study:

Possible revision of current regulations, taking investor protection into careful consideration, so that authorized investment advisory companies can invest customers' assets on a co-mingled basis according to the customers' decision.

Note however that, starting from December 1998, authorized investment advisory companies can be approved to manage investment trusts and can then invest some pension fund assets on a co-mingled basis by, in effect, establishing private offering investment trusts.

B. Insurance

- 1. Improvements in Administrative Procedures and Practices
 - a. The Financial Services Agency (FSA) is undertaking every effort to conduct prompt and efficient processing of all insurance product and rate applications and notifications. Also, the FSA provides guidance, including that regarding insurance product and rate applications and notifications, in writing at the request of insurance providers in accordance with the Administrative Procedure Law (APL), and conducts communications with insurance providers including in writing whenever appropriate from a supervisory standpoint. Recognizing the importance

of transparency, the FSA introduced in August 1999 a voluntary checklist system for use by insurance providers. The purpose of the checklist is both to accelerate the examination of insurance product notifications, and to clarify for insurance providers the examinations standards for insurance products subject to the notification system. Also, as is already commonly practiced in the United States, when processing insurance products and rates, the FSA is, as a general rule, examining insurance products and rates in chronological order according to when they were filed or submitted, although this neither predetermines nor predicts the order in which examinations will be completed.

- b. The Governments of the United States and Japan welcome efforts by the regulatory authorities of both countries to work together to exchange views, experience, and expertise, in the pursuit of superlative regulatory frameworks and operations including efficient approval processes and examination standards in their respective countries. The United States and Japan have common views on the importance of continued appropriate deregulation within the insurance sector and of giving the utmost consideration to prompt and efficient processing of insurance products and rates for the benefit of consumers and providers in both countries, in response to the rapidly changing environment of the worldwide insurance market.
- c. The FSA's recent steps to deregulate concerned most commercial lines, of which in respect to certain commercial lines, once the notification procedure is completed on a specific line, insurance firms can utilize the "free endorsement" system within the scope and objective of the original policy, and/or "free/standard rates," whereby providers are not required to file with or notify the FSA of changes in the products or rates related to that line. Similarly, many U.S. states have adopted and are implementing laws to re-engineer their commercial lines regulatory functions. The U. S. Congress recently passed new legislation, the Gramm-Leach-Bliley Financial Modernization Bill, that encourages further harmonization of state insurance regulation. Among other things, the legislation mandates a national producer licensing system if the states do not improve their current systems. In response to passage of this legislation, the U.S. National Association of Insurance Commissioners (NAIC) adopted a Statement of Intent in March of this year regarding the future of insurance regulation that calls for, among other things, steps to improve speed to market for insurance products and to shift the focus of states away from a prior approval system where appropriate. With similar goals in mind, the FSA has a basic policy to further deregulate the insurance product and rate approval processes and to further shorten in practice examination periods for product and rate applications, and recognizes the need to best utilize

personnel and other relevant resources. The FSA also intends to continue to:

- (1) Study the transition to a notification system for commercial lines, as well as for appropriate personal lines with due consideration for the protection of policyholders, in accordance with the report issued by the Regulatory Reform Committee on December 14, 1999, which stated the study is expected to be completed by the end of FY 2001.
- (2) Review the notification system for commercial lines, including clarification of the examination standards for insurance products, with due consideration for the protection of policyholders and minimization of discretionary factors, in accordance with the report issued by the Regulatory Reform Committee on December 14, 1999, which stated the review is expected to be completed by the end of FY 2000.
- 2. *Kampo* (Postal Insurance)
 - a. The insurance products or riders underwritten or sold on consignment by the Ministry of Posts and Telecommunications (MPT) are to be offered pursuant to law. Approval from the Diet is required to expand or change the insurance products or riders offered by MPT except for limited alterations within the scope of the products or riders authorized by law.
 - b. Regarding the future of the *Kampo*, the Basic Law on the Administrative Reform of the Central Government of 1998 provided for the *Soumusho* and the Postal Services Agency, and later the *Soumusho* and the new public corporation, to take over the management of the system, and to implement the system, reflecting its objective as defined in the Postal Life Insurance Law as well as the basic ideas contained in the Administrative Reform Program adopted by the Cabinet on December 25,1996.
 - c. The Diet passed a law in its 147th session, authorizing post offices to sell on consignment compulsory automobile liability insurance products underwritten by private non-life insurance providers for mopeds and motorbikes with engine displacement of 250 cc or less. MPT currently has no plans to propose legislation to authorize post offices to sell non-life insurance products other than what is already authorized by the Diet.
 - (1) The law enables post offices to sell the products mentioned above for the purpose of expanding the coverage of compulsory automobile liability insurance for mopeds and motorbikes with

engine displacement of 250cc or less.

- (2) The law stipulates that, when the Postal Services Agency is engaged in this business, the Agency will be subject to the relevant provisions of the Insurance Business Law.
- (3) MPT will, at the time of inviting consignors, announce the selection criteria, and at the time of selecting consignors, will treat domestic and foreign insurance providers on a non-discriminatory basis. MPT confirms that in response to requests from private insurance companies, it will meet with those companies to explain the selection criteria to be utilized when choosing a private sector underwriter to be a consignor.
- d. MPT reaffirms the contents of paragraphs IV(4)b and VII of the Measures by the Government of the United States and the Government of Japan Regarding Insurance of October 1994.
- e. MPT confirms that, in response to requests from private interested parties, including foreign insurance providers, it will meet with those parties to explain matters regarding the formulation of proposals to seek from the Diet an amendment to the law to expand, or change, *Kampo* products.

V. ENERGY

- A. Energy Sector Restructuring: The Government of Japan and the Government of the United States exchanged views on Japanese Government plans for energy sector deregulation, as well as the ongoing restructuring of this sector in the United States, and both sides shared the view that the goal of deregulation in the energy sector is the introduction of a more competitive market, which would lead to a more efficient, rational and less expensive supply of energy. The two sides also shared the view that in implementing deregulation in this sector, the two governments should be mindful of its potential effects on public welfare, energy security, and the environment. Based on these shared views, the Government of Japan has taken and will take a series of deregulatory measures in the energy sector.
- **B.** Electricity Sector: Regarding deregulation in the electricity sector, liberalization of retail supply of electricity to extra high-voltage customers was implemented on March 21, 2000, in accordance with the revised Electric Utility Industry Law. To ensure fair and effective competition in the liberalized retail market, the Government of Japan has taken and will take the following measures:
 - 1. After January 2001, the Policy Planning Division of Electricity and Gas Department at the Ministry of International Trade and Industry (MITI) will be

responsible for policy making, while the Electricity Market Division will be responsible for regulation (titles of the divisions are tentative). MITI will implement and enforce rules, regulations and guidelines regarding the newly deregulated electricity market by assigning personnel as appropriate.

- 2. MITI and the Japan Fair Trade Commission (JFTC) will implement and enforce Guidelines on Fair Electricity Transactions that MITI and JFTC jointly established and publicly announced in December 1999 and will expand or clarify, as appropriate, the joint Guidelines, as further experience is gained as to types of activities that may give rise to competition problems.
- 3. MITI will implement and enforce administrative rules on transmission rate calculations, fair, transparent and non-discriminatory access to transmission lines, and other terms and conditions which were established and publicly announced by MITI in December 1999, including reviewing transmission tariffs to be submitted by the electric utility companies hereafter and issuing change orders if they are not drawn up in accordance with the related administrative rules and regulations.
- 4. MITI will implement Guidelines on Information Disclosure on Electricity Tariffs, which were established by MITI in December 1999, in order to make clear information that both MITI and utilities are required to publicly provide, including information regarding transmission tariffs.
- 5. MITI will address complaints that are brought to MITI pertaining to the newly deregulated electricity market in a fair and impartial manner based on the Guidelines on the Settlement of Disputes and its related rules developed by MITI in December 1999 and post to the MITI website issues brought to MITI for dispute resolution.
- 6. The Government of Japan submitted a bill to the Diet, passed on May 12, 2000, that repealed section 21 of the Antimonopoly Act (AMA), thereby eliminating the antimonopoly exemption for the electricity and other sectors.
- 7. JFTC will devote sufficient resources for effective and continuous monitoring of implementation of deregulation in the electricity and gas sectors and will actively promote additional procompetitive regulatory reforms.
- 8. MITI will review the results of the liberalization of retail electricity supply to extra high-voltage customers, roughly three years after the start of the new system.
- C. Gas Sector: Regarding deregulation in the gas sector, the scope of liberalization of retail supply of gas to large-scale customers was expanded on November 19, 1999, in

accordance with the revised Gas Utility Industry Law. To create a competitive gas market, the Government of Japan has taken and will take the following measures:

- 1. The Government of Japan submitted a bill to the Diet, passed on May 12, 2000, that repealed section 21 of the AMA, thereby eliminating the antimonopoly exemption for the gas and other sectors.
- 2. A regulatory framework for fair, transparent and non-discriminatory access to the existing utility-owned gas pipelines was established.
- MITI drew up Guidelines on the Settlement of Disputes on March 23, 2000. MITI and JFTC jointly established Guidelines on Fair Gas Transactions on March 23, 2000.
- 4. MITI will develop methodology for the calculation of fair, transparent and nondiscriminatory transmission rates in a transparent manner.
- 5. MITI will review the results of regulatory reforms in the gas sector roughly three years after the revised Gas Utility Industry Law takes effect.

VI. DISTRIBUTION

A. Customs/Import Processing

- 1. The Government of Japan has taken a number of steps to reduce costs of and to expedite import processing of goods in Japan, including:
 - a. Raising the ceiling for the number of declarations for customs clearance outside of regular working hours that can be cleared in one hour from 20 to 60, whereby high volume importers were able to significantly reduce their overtime expenses.
 - b. Introducing in October 1999, along with Japan Maritime Safety Agency and other related regional seaport authorities, a common electronic format for entry/exit reports for vessels.
 - c. Upgrading Sea-NACCS (Nippon Automated Cargo Clearance System) in October 1999 to allow for import permission to be granted as soon as it is confirmed that imported cargo has entered the customs area.
 - d. Bringing a new electronic system (JETRAS Japan Electronic Open Network Trade Control System) to full operation in April 2000, which allows filing for import-export permits and approvals under provisions of the Foreign Exchange and Foreign Trade Law.

- 2. The Japanese Government will implement measures to further modernize and expedite its customs clearing process, including:
 - a. Introducing the Simplified Declaration Procedure by March 2001 under which an approved importer will be able to have certain cargo released prior to lodging of a declaration for customs duty payment, by separating the import and duty payment declarations. With respect to the designated cargo imported by an approved importer, the new procedures will provide for:
 - (1) A reduction in the amount of information needed to be submitted at the time of release;
 - (2) Deferral of lodging of a declaration for customs duty payment until the end of the following month after release; and
 - (3) Paperless features added to many aspects of import processing.
 - b. Upgrading Air-NACCS in FY2001 in order to further speed customs processing.

B. Retailing and Services

- 1. In order to facilitate consistent, transparent, and predictable implementation of the *Daiten-Ricchi Ho* (Law Concerning the Measures by Large-Scale Retail Stores for Preservation of the Living Environment) (the Law), the Ministry of International Trade and Industry (MITI) has taken or will continue to take the following measures in addition to the measures stated in the Second Joint Status Report:
 - a. MITI established official contact points (*Daiten-Ricchi Ho* Contact Points) on May 23, 2000 within MITI headquarters in Tokyo and at eight regional bureaus to receive and facilitate resolution of complaints from any interested party regarding the application of the Law. MITI published necessary information such as names and addresses of the contact points.
 - b. MITI has explained to relevant local governments the purpose and content of the Law by holding several meetings with prefectures and ordinancedesignated (the 12 largest) cities, and has provided officials of such local governments with technical training. MITI will continue to provide necessary information regarding the implementation of the Law and the role of the contact points.

- c. MITI is encouraging local governments to coordinate closely among their relevant sections and offices on all large-scale retail store environmental issues arising under the new Law. The regional MITI contact officer assists with this coordination.
- d. MITI is working to facilitate a smooth transition from the repeal of the *Daiten-Ho* to the implementation of the *Daiten-Ricchi Ho* within the framework provided by these laws.
- 2. Liquor Stores: With regard to liquor retail licenses, the restriction on the number of licenses issued per a definite population began to be phased out in September, 1998, and will be abolished as of September 1, 2003. The restriction on proximity to existing premises will be abolished on September 1, 2000.

VII. ANTIMONOPOLY ACT AND COMPETITION POLICY

- **A. Anticartel Enforcement:** JFTC is committed to deter and eliminate cartels. From this viewpoint, JFTC will:
 - 1. Make further efforts in FY 2000 to raise its capability for collecting evidence of cartels, including by improving its ability to collect evidence in electronic form and by the submission of a FY 2000 budget, passed by the Diet on March 17, 2000, that will increase the number of staff assigned to the Investigation Bureau;
 - 2. Strengthen training in FY 2000 to improve the effectiveness of investigators in the conduct of searches, in the examination of witnesses both in the investigation stage and in hearing procedures, and in the analysis of evidence;
 - 3. Take more aggressive actions against international cartels; and
 - 4. Actively invoke the provisions of §§92-2, 94, and 94-2 of the Antimonopoly Act (AMA) against activities that illegally obstruct investigations.

B. Measures to Eliminate *Dango*

- 1. The National Police Agency (NPA) has instructed prefectural police departments to vigorously investigate suspected bid rigging activities and is providing necessary assistance for that purpose. NPA will continue to instruct prefectural police departments to actively investigate such activities and to provide necessary assistance to prefectural police departments to investigate suspected criminal bid rigging effectively.
- 2. JFTC and NPA have instituted a liaison mechanism between the agencies and will

begin consultations in FY 2000 on how to improve cooperation on the investigation of bid rigging activities.

3. The Ministry of Justice will continue to take measures to encourage active and strict prosecution of officials found to be disclosing confidential information, including bidding information, or unlawfully aiding bid rigging activities.

C. Improvement of Private Remedies for Antimonopoly Violations

- 1. Last October, the "Study Group on the Civil Remedy System Concerning Antimonopoly Act Violations" organized by JFTC compiled its final report concerning the appropriateness of introducing an injunctive relief system for private antimonopoly actions and concerning methods for improving the AMA §25 damage compensation system. The report contained a number of conclusions, including:
 - a. It would be appropriate to introduce a private injunction system with respect to unfair trade practices (in violation of AMA §19);
 - b. A conclusion on whether violations constituting private monopolization, unreasonable restraints of trade and prohibited acts of trade associations (in violation of AMA §§3 and 8) should be subject to private injunctions should be drawn after further considering the effectiveness of private injunctions and the consistency of the types of violations with those subject to lawsuits under AMA §25;
 - c. It would be appropriate to allow damage compensation lawsuits against prohibited acts by trade associations.
- 2. The Government of Japan submitted a bill to the Diet, passed on May 12, 2000, that permits private parties to:
 - a. Seek and obtain injunction orders from the courts against parties engaged in activities that violate the unfair trade practices provisions of the AMA (§§ 8(1)(v) and 19); and
 - File damage actions against entrepreneurs that violate AMA §6 (prohibition of participation in anticompetitive international agreements or contracts) and against trade associations that engage in acts that violate AMA §8 (1) (prohibited acts of trade associations).

D. Measures for the Promotion of Deregulation

1. JFTC will play an active role in promoting competition in sectors undergoing

deregulation, including in the electricity and gas sectors, among others.

- 2. JFTC's Study Group on Government Regulation and Competition Policy will issue its final report before Fall 2000, which will include advice on how to improve competition in public utility sectors.
- 3. JFTC will actively enforce the AMA against illegal activities which undermine the benefits of deregulation, including activities by dominant firms in partially or fully deregulated industries that exclude or control the business activities of other companies in a manner that violates the AMA.

E. Reduction of Antimonopoly Exemptions

- 1. The Government of Japan submitted a bill to the Diet, passed on May 12, 2000, that repealed §21 of the AMA, thereby eliminating the antimonopoly exemption for the electricity, gas and railroad sectors, as well as other sectors that could be characterized as natural monopolies.
- 2. The Government of Japan affirms that the Industry Revitalization Law (IRL) in no way supersedes the AMA or prejudices JFTC's independence in enforcing the AMA against activities that have been approved by the relevant minister under the IRL.
- 3. JFTC will consider disclosing, on a case-by-case basis, advice it provides on joint applications that it has reviewed pursuant to Article 5 of the IRL and that have been subsequently approved, while preserving business and other confidential information.

F. Improvements in Merger Review

- 1. In order to increase transparency in its merger review process, JFTC will welcome and consider the views of interested third parties concerning a proposed transaction, including those submitted in a timely manner after publication of its reply to a prior consultation.
- 2. In order to improve JFTC's review of mergers, the Government of Japan submitted a FY 2000 budget to the Diet, passed on March 17, 2000, that will increase by 4 persons JFTC's staff responsible for merger reviews.

G. Distribution-Related Measures

1. JFTC will observe the implementation of local government policy related to large-scale retail stores from the standpoint of competition policy and will strictly apply the AMA against anticompetitive collusive practices in the retail sector.

- 2. The Japan Fair Trade Institute, working with JFTC, released on April 28, 2000 a revised and improved Guide for AMA Compliance Programs that will provide companies with a model for ensuring that they have instituted an antimonopoly compliance program that will be effective in preventing practices that may contravene the AMA.
- 3. JFTC will, when requested by companies on a voluntary basis, review the antimonopoly compliance plans of such companies and provide advice on how such plans can be improved to ensure the highest levels of AMA compliance.
- 4. JFTC will take measures to promote an efficient and competitive distribution sector, including surveying and analyzing manufacturer/distributor financial and other interrelationships in the 2000 2001 time frame.
- **H.** JFTC Independence: The Government of Japan confirms that, upon the government reorganization in 2001 that places JFTC within the *Soumusho* (tentative translation: Ministry of General Affairs):
 - 1. It will ensure that JFTC's independence in matters of personnel recruitment, promotion and placement, including at senior levels, and in enforcement decisions or policy, will be preserved after the government reorganization in 2001. In addition, the Government of Japan confirms that the discretion that JFTC currently has within the Prime Minister's Office in connection with procedures for developing its budget, deciding on appropriate expenditures and formulating, coordinating, and conveying its position on legislative matters, will be preserved as well.
 - 2. The Government of Japan will ensure that AMA enforcement activities involving the sectors within the portfolio of the Minister of *Soumusho* are decided upon by JFTC in an independent manner, and that JFTC's present ability to engage in independent competition policy planning and to express its independent views on competition policy issues related to any sector, including through competition advocacy activities, will be fully preserved within *Soumusho*.
 - 3. JFTC will have full and unfettered authority to enforce the AMA against mergers and acquisitions and other business activities in all sectors, including those within the jurisdiction of *Soumusho*.

VIII. LEGAL SERVICES

A. Recognition Concerning Legal Services: The Government of Japan recognizes the importance of adequate legal services in an international financial center and the

concerns expressed with regard to the sufficiency of the infrastructure of legal services capable of meeting the needs of international business.

- **B.** Exchanging Views on the Existing Regime: In order to examine whether there is any problem which calls for further improvement in the existing regime, the Government of Japan, giving appropriate consideration to the concerns set out in paragraph 1 of this section, has started exchanging views with the Japan Federation of Bar Associations (*Nichibenren*) and the Foreign Lawyers' Association of Japan (*Gaikokuho-Jimu-Bengoshi Kyokai*).
- C. Increasing the Number of *Bengoshi*: The Government of Japan has taken the necessary measures to increase the number of successful applicants of the annual Bar Examination, as a result of which the number increased to about 1,000 in FY 1999. In addition, the Government of Japan is conducting research and study of the possibility of increasing the number to about 1,500, as is referred to in "The Three-Year Programme for Promoting Deregulation (revised)," decided by the Cabinet on March 30, 1999. The Judicial Reform Council recognizes the need for an appropriate increase in the number of successful applicants of the Bar Examination.
- **D.** Liberalization of Business-Advertising by *Bengoshi* and *Gaikokuho-jimu-bengoshi*: Taking into consideration various factors, including the request from the Government of Japan which was made in reference to the U.S. Government's submission, the Japan Federation of Bar Associations (*Nichibenren*) amended in March 2000 its regulation so as to lift the ban on business-advertising by *bengoshi* and *gaikokuho-jimu-bengoshi* with certain exceptions, including misleading advertisements. They are now allowed to advertise, for example, their areas of practice, background and fees through newspapers, magazines and the internet.
- E. The Establishment of the Judicial Reform Council: Expecting that the role of the judicial system will become more important as Japanese society becomes more complex, diversified and global in the 21st Century, the Government of Japan considered it necessary to reform the function of the judicial system so as to meet the needs of Japanese society. Based on that recognition, giving appropriate consideration to the concerns set out in paragraph 1 of this section, among other factors, the Government of Japan established the Judicial Reform Council under the Cabinet in order to study and discuss the fundamental policies necessary to build a basis for judicial reform. The Council was established and began its discussions in July 1999, and released its discussion points in December 1999. Among these discussion points were "what a *bengoshi* should be," "recognition of the need for an appropriate increase in the number of successful applicants of the Bar Examination" and "how judges, prosecutors and *bengoshi* should be trained". It will make public its interim report towards the end of October 2000, and, taking into consideration opinions from various groups, submit its final report to the Cabinet by the end of July 2001.

IX. TRANSPARENCY AND OTHER GOVERNMENT PRACTICES

A. Policy Evaluation System

- To improve the transparency of the government, to strengthen the government's accountability to the public and to improve the quality of public administration, the Government of Japan will introduce a government-wide policy evaluation system at the same time as the reorganization of ministries and agencies in January 2001. Under this system, individual ministries and agencies will establish policy evaluation sections and evaluate policies from such viewpoints as need, priority and effectiveness. The policy evaluations will be made public. In addition, the "Soumusho" (the new ministry that will be responsible for the management of the policy evaluation system) will evaluate the policies of the ministries and agencies to ensure the comprehensiveness and strict objectivity of their policy evaluations, and will make necessary recommendations to the ministries and agencies. The Soumusho's policy evaluations will also be made public.
- 2. The Government of Japan is establishing a commission on policy evaluation by government entities and the evaluation of independent administrative institutions (*Seisaku Hyoka Dokuritsu Gyosei Hojin Hyoka Iinkai*), comprised of independent experts, to ensure that the *Soumusho*'s policy evaluation is conducted in a fair and neutral manner.
- 3. The Government will make continuous efforts to enhance and strengthen the policy evaluation system, and will review the system as necessary.

B. Public Comment Procedure

- Since the beginning of FY 1999, the Government of Japan has implemented the "Public Comment Procedure for Formulating, Amending or Repealing a Regulation" (Cabinet Decision). During the first quarter of FY 2000, the Management and Coordination Agency (MCA) conducted a follow-up of the implementation of the Public Comment Procedure in FY 1999 and will publish its findings in July. MCA included the following in its follow-up:
 - a. The length of the public comment period;
 - b. The primary modifications of the draft regulation in response to public comments;
 - c. The reason why ministries and agencies did not use the Public Comment Procedure; and

- d. The cases in which ministries and agencies did not use the Public Comment Procedure, based on the exemption for a special decisionmaking process, such as when an advisory council had used substantially the same procedure.
- 2. MCA will accept comments from the public on the follow-up of the implementation of the Procedure.

C. Administrative Procedures and Practices

- 1. In accordance with the Three-Year Programme for Promoting Deregulation, the Government of Japan continues to promote compliance with the Administrative Procedure Law, and to enhance transparency and clarity in the administrative procedures and administrative guidance pertaining to application processes.
- 2. MCA published "Recommendations based on the Survey on Securing Fairness and Transparency in Administrative Procedures" in June 1999. MCA plans to compile and publish a report regarding measures taken by each government agency in response to the Recommendations.
- **D.** Access to Information Held by Public Corporations (*Tokushuhojin*): The Government of Japan established an "Investigation Committee on Access to Information Held by Public Corporations" (*Tokushuhojin Joho Kokai Kento Iinkai*) under the Administrative Reform Promotion Headquarters in July 1999 to study and make recommendations with regard to legislation that will require the disclosure to the public of information by public corporations (*tokushuhojin*). The Committee will submit its final report around July 2000.

X. MOTORCYCLES

- A. Speed Limit of Motorcycles on National Expressways: The National Police Agency (NPA)'s basic position is to raise the speed limit for mini cars and motorcycles on national expressways from 80km/h to 100km/h by the end of FY 2000, taking into account the results of the studies undertaken in FY 1998 and FY 1999. NPA applied the Public Comment Procedure to its basic position.
- **B.** Motorcycle Tandem Riding on National Expressways and Motorways: NPA has decided to start to study and consider whether or not the ban on motorcycle tandem riding on national expressways and motorways should be lifted, to reach a conclusion as soon as possible.

DEREGULATION AND OTHER MEASURES BY THE GOVERNMENT OF THE UNITED STATES UNDER THE ENHANCED INITIATIVE

I. DEREGULATION, COMPETITION POLICY, AND OTHER MEASURES

A. Trade-Related Measures

- 1. Re-export Controls
 - a. The United States continues to apply both permissive re-export treatment under relevant Department of Commerce regulations, and a *de minimis* rule to Japan, recognizing the effectiveness of Japan's export controls. The U.S. Government also will continue its efforts to ensure that such controls are streamlined and transparent.
 - b. To ensure the transparency of the controls, the Department of Commerce will continue to refine, develop, and expand the re-export guidance offered on its Japanese-language web site, as well as disseminate guidance and clarifications through other media, including Japanese- and English-language pamphlets, and through the United States Foreign Commercial Service personnel at the U.S. Embassy in Tokyo and other locations. Information on the web site includes: *de minimis* rules (preliminary guidance and determination of U.S. content), definition of terms, and guidance on determining the U.S. content ratio of software and technology. The Department of Commerce will review the scope of the information on the Japanese-language web site on a periodic basis to see that Japanese re-exporters can gain sufficient information from the site to understand the U.S. licensing process and their obligations under the Export Administration Regulations (EAR).
 - c. The Government of the United States does not require license authorization if a re-exporter makes the determination via its own calculations that its transaction incorporates less than the *de minimis* amount of controlled U.S. content. See parts 734.4 [*De minimis* U.S. content] and 736.2(b)(2)[General prohibition two] of the Export Administration Regulations (EAR) for further information. The Department of Commerce is willing to discuss this point with the Government of Japan.
 - d. In an attempt to ensure that Japanese re-exporters have access to the appropriate information, the United States has made efforts to increase the level and comprehensibility of the guidance available on U.S. export controls to Japanese re-exporters. The United States will consider how to address the following issues responding to the requests of Japanese re-

exporters: ensuring Japanese re-exporters' access to the specific information necessary to comply with the applicable regulations in individual cases, and how best to streamline and simplify the *de minimis* procedure for technology and software.

- 2. Regulations on Commercial Satellites, Related Items and Technical Information
 - a. The Government of the United States will not routinely apply the strengthened regulation for monitoring of launches of U.S. communications satellites based on PL-105-261 to launches of U.S. satellites in, or by nationals of, a country that is a member of the North Atlantic Treaty Organization (NATO) or that is a major non-NATO ally of the United States, including Japan. The strengthened regulation may nonetheless be applied in some cases, as well as other export controls as appropriate, in furtherance of the security and foreign policies of the United States.
 - b. The Government of the United States will take the following measures to improve the licensing of commercial communications satellites:
 - (1) The Department of State has devised and promulgated a special licensing criterion for commercial satellites and related items, and technical information, which considers requests by the Government of Japan and inputs from the U.S. defense industry. In coordination with the Department of Defense, the Department of State will streamline and simplify the satellite export process for NATO and major non-NATO allies, including Japan. The Department of State will consider specific recommendations offered by the Government of Japan on these processes.
 - (2) "Streamline and simplify," as noted above, includes efforts to reduce the length of the licensing process. In addition, "streamline and simplify" entails efforts to simplify the licensing process for technical data, satellites, and related items (or their equivalent), which U.S. enterprises have furnished to Japanese enterprises in the past, or which Japanese enterprises can obtain easily and without regulation from other NATO and non-NATO allies. "Streamline and simplify" also refers to efforts to reduce the licensing period for technical information related to the export and import of satellites and related items to and from Japanese enterprises, as well as to simplify this licensing process.
 - (3) In addition, ODTC may consider more inclusive license applications that can be handled as a single transaction, provided

the U.S. applicant and its Japanese partner(s) are able to specify, in detail, the complete scope and duration of all technical assistance. Such consideration would also be contingent upon the provision of lists of all technical data due to be provided, as well as of itemized amounts of hardware by quantity, type, and value.

- c. The Office of Defense Trade Controls (ODTC) of the Department of State will evaluate requests by U.S. companies, including those using Japanese contractors, to reconsider and revisit limitations and provisos placed on license approvals which restrict transfer of information and enforce other limitations. These evaluations will be made on a case-by-case basis, and in conjunction with the Department of Defense.
- 3. Import Tariff Calculation Method for Clocks and Watches
 - a. The International Trade Commission (ITC) will continue to consider Japan's comments, including additional data and analysis, in preparing its study of Harmonized Tariff Schedule of the U.S. (HTSUS) provisions related to the import tariff calculation method for clocks and watches. This review will be completed by the summer of 2000.
 - b. The ITC will submit the views and requests of the Government of Japan to Congress along with the final report. The United States will continue its dialogue with the Government of Japan regarding this issue.
- 4. Labeling Requirements of Origin for Clocks and Watches
 - a. In June 1999, the Government of the United States amended the Harmonized Tariff Schedule of the U.S. (HTSUS) to permit an indelible ink marking for the labeling requirement of origin for clocks and watches.
 - b. The International Trade Commission (ITC) will submit the views and requests of the Government of Japan to Congress along with the final report of the study. The United States will continue a discussion with the Government of Japan regarding this issue.
- 5. Customs Regulations Regarding Trademarks: In determining whether or not to adopt as a final rule the proposed amendment to section 19 CFR 141.86(a) of the Customs Regulations regarding the listing of trademarks in entry documentation, the Government of the United States will accord due consideration to the comments submitted by the Government of Japan on December 13, 1999. Once the United States Customs Service (USCS) has reached a final determination on the proposed amendment, it will publish the results in the U.S. Federal Register. If an amendment based on the final determination is implemented, USCS is

willing to respond to Japanese questions regarding that implementation. The amendment, if implemented, should present no unnecessary barriers to trade.

6. NAFTA Rules of Origin for Textile and Apparel Products: The Government of the United States has met with the Government of Japan to discuss Japanese concerns regarding NAFTA rules of origin for textile and apparel products. The Government of the United States has relayed without endorsement, as per Japan's request, Japanese concerns on this issue in meetings with the Governments of Mexico and Canada. The Government of the United States, upon request of the Government of Japan, will hold additional discussions on new issues of concern to the Government of Japan regarding NAFTA rules of origin for textile and apparel products.

B. Regulations on Procurement

- 1. Federal, State, and Local Buy American Legislation: The Government of the United States recognizes that the issue of Buy American provisions is of importance to the Government of Japan and will engage in a continued dialogue with the Government of Japan in this area. The Government of the United States is prepared to meet and exchange views with the Government of Japan and Japanese industry representatives regarding the matter of rolling stock procurement.
- 2. American Automobile Labeling Act
 - a. The Government of the United States, upon request of the Government of Japan, will hold additional discussions on AALA programs, including modifications, if any, of the implementing measures. In the event of such discussions, the Government of the United States will consider the views of the Government of Japan.
 - b. Upon request, the Government of the United States will provide meaningful opportunities to meet and exchange views with interested parties regarding AALA programs, including modifications, if any, of the implementing measures.

C. Corporate Average Fuel Economy (CAFÉ) Regulation

1. The Government of the United States, upon request of the Government of Japan, will hold additional discussions on the CAFÉ regulation, including modifications, if any, of the implementing measures. In the event of such discussions, the Government of the United States will consider the views of the Government of Japan.

- 2. Upon request, the Government of the United States will provide meaningful opportunities to meet and exchange views with interested parties regarding the CAFÉ regulation, including modifications, if any, of the implementing measures.
- **D. Metric System:** The Government of the United States will continue measures to expand and increase the use of the metric system in the private sector and at the federal and local government level. In the meantime, the United States will take the following interim measures:
 - 1. The National Institute of Standards and Technology (NIST) at the Department of Commerce and the National Conference on Weights and Measures (NCWM) will coordinate regarding full implementation of the revised Uniform Packaging and Labeling Regulations (UPLR), which permit metric-only labeling on U.S. consumer products as of January 1, 2000.
 - 2. A bill will be submitted to Congress to update the Fair Packaging and Labeling Act (FPLA) to permit the option of metric-only labeling on products covered by the Act.
 - 3. The United States will publish the 25th Anniversary report on the progress of the "Metric Program" by the end of 2000.
- **E. Patent Issues:** The Government of the United States will continue to ensure full consideration of Japanese requests regarding the shift to a first-to-file system, further improvements of the early publication and re-examination systems, and adoption of the unity of invention rule in compliance with PCT practice.
- F. Sanctions Acts: Regarding the Commonwealth of Massachusetts Burma Sanctions Act, the Government of the United States confirms its position that acts by individual states should be consistent with federal policy in this area. On June 19, 2000, the Supreme Court issued a unanimous decision affirming that the Act is unconstitutional. The Court reached its decision on preemption grounds, finding that the Massachusetts statute conflicts with, and is preempted by, the federal Burma sanctions legislation. The United States believes it is important for the federal government and state governments to coordinate closely on these types of issues.

G. Distribution

- 1. Customs Clearance: The Government of the United States will participate in a Cargo Release Time Survey, to be developed in cooperation with the Governments of Japan and Canada under the auspices of the APEC Subcommittee on Customs Procedures (SCCP).
- 2. Licensing for Sales of Liquor: The Government of the United States will continue

its dialogue with the State of California to ensure that California authorities are aware of relevant WTO and other regulations regarding sales of imported alcoholic beverages, including Japanese "*shochu*".

- **H. Competition Policy:** In an effort to ensure that competitive market forces are allowed to act to the greatest extent possible, the Department of Justice regularly expresses its views on the continued appropriateness of antitrust exemptions, and seeks the elimination of antitrust exemptions where warranted. On March 22, 2000, the Committee on the Judiciary of the U.S. House of Representatives held hearings on a bill, sponsored by Committee Chairman Hyde, that would eliminate the antitrust immunity for ocean shipping carriers. The Department of Justice testified at that hearing in support of the bill.
- I. Legal Services: In the United States, 23 States and the District of Columbia have foreign legal consultant rules. From the viewpoint of facilitating international business, the Government of the United States supports the adoption by the other States of such rules.

J. Consular Affairs

- 1. The Governments of the United States and Japan will continue discussions regarding measures that could address issues of concern related to consular affairs.
- 2. In general, the Government of Japan is welcome to use existing public comment procedures to make its views known regarding specific areas of U.S. immigration rules and regulations. Details may be found on the Department of Justice's Immigration and Naturalization Service web site at www.usdoj.gov.
- 3. The Government of the United States is considering possible measures to improve the process and streamline overall procedures for obtaining H1-B visas. In addition, Congress is currently considering increasing the annual allotment of H1-B visas.
- 4. Regarding Arrival-Departure Records, or "I-94s", the INS is making efforts to reduce the processing period for applications to extend the period of permission to stay. As part of its ongoing Immigration Benefits Re-engineering program, the INS is also making efforts to streamline the processing of applications for extension of stay.
- 5. A 1996 change in Social Security Administration (SSA) policy affected the issuance of Social Security numbers (SSN) to alien residents without employment authorization.
- 6. All lawful aliens, including Japanese aliens, are able to obtain a driver's license in

all U.S. States and jurisdictions, provided they meet a state's driver's license requirements. However, because most states require an applicant to provide a SSN if they have one, an applicant who alleges not to have a SSN may be directed to SSA to apply for a SSN. In those states in which the applicant is ineligible for a SSN, SSA will promptly issue a letter so stating to the alien applicant, which he/she can provide to the state licensing agency in lieu of a SSN.

- 7. SSA and the states will continue to provide information regarding state-specific processes and procedures for obtaining driver's licenses and other documents without a SSN.
- II. HOUSING: The United States has no regulatory jurisdiction in the adoption of test methods for housing products. However, it will continue to encourage local governments and relevant organizations that prepare model codes to consider ISO protocols in the development and refinement of testing methods. The United States will keep Japan informed of developments in this area.

III. TELECOMMUNICATIONS

A. Certification and Licensing Criteria for Foreign Carries' Entry to the U.S. Telecommunications Market

The Government of the United States and the Government of Japan initiated a dialogue relating to the transparency of certification and licensing criteria for entry into the U.S. telecommunications market. In 1999, the Federal Communications Commission (FCC) granted 785 authorizations for international service, more than 200 of which involved carriers with 10 percent or more foreign ownership. 745 of those applications were streamlined (automatically granted after 14 days). Since the Foreign Carrier Order rules went into effect, no applicant has been denied entry into the United States.

B. Benchmarks for International Settlement Rates

The Government of the United States will continue to actively participate in multilateral fora seeking to address the issue of above-cost accounting rates and will contribute to credible efforts to resolve this issue that take into account market realities and that assist developing countries in making the transition to competitive global telecommunications market.

C. State-level Regulation

The Government of the United States facilitated a dialogue between Japan and the National Association of Regulatory Utility Commissioners (NARUC) to discuss Japan's concerns on the diversity of state-level application procedures and request for increased

harmonization. The Government of the United States will continue to facilitate a dialogue on these issues. Concerns expressed by Japan were a topic of discussion by NARUC leadership at the March 2000 NARUC meeting. At that meeting, there was discussion of the appropriateness of assigning as a study issue model reporting requirements. NARUC has established a program whereby foreign regulators can join NARUC as associate members to participate in NARUC and discuss issues of mutual concern.

D. Inter-State Access Charges

On May 31, the FCC ordered access charge reductions in the United States totaling \$3.2 billion. For Regional Bell operating carriers participating in the new access charge regime, access charges for switching and transport are mandated to decline to .55 cents per minute. This rate is approximately one-half the level of the MPT's "Case B" rate developed through the MPT's LRIC model, and is within the range of U.S. LRIC-based models as well. U.S. carriers declining to participate in this new regime will be required to file LRIC studies to form the basis of their access charge rates, to be made effective retroactive to July 1, 2000.

E. Transparency of FCC's Hybrid Cost Proxy Model

The FCC will ensure transparency and the opportunity to comment on future development of any LRIC model including the Hybrid Cost Proxy Model.

F. Access to Calculating Methodology, etc. of Interconnections Rates

The United States has provided the Government of Japan with information on how to electronically access databases of all 50 public utility commissions and the National Regulatory Research Institute (NRRI), which contain a vast range of information regarding interconnection agreements and models.

G. International Charging Arrangements for Internet Services (ICAIS)

At the May 2000 APEC Telecommunications Ministerial, the Government of the United States and the Government of Japan endorsed principles on ICAIS. The Government of the United States, along with the Government of Japan, confirms that "Internet connectivity is an essential element of the global information infrastructure"; "Internet charging arrangements between providers of network services should be commercially negotiated"; but "where there are dominant players or de facto monopolies, governments must play a role in promoting fair competition." In order for APEC to reach consensus on any appropriate recommendations regarding the issue of international charging arrangements for Internet services, the Government of the United States, along with the Government of Japan, will endeavor to make APEC's discussions meaningful.

H. Competitive Environment for the Registration and Administration of Domain

Names

The Government of the United States and the Government of Japan discussed private sector management of the Internet domain name system. The Government of the United States and the Government of Japan share the view that vigorous enforcement of the Network Solutions Inc.(NSI)'s obligations under its agreements with the Government of the United States and the Internet Corporation for Assigned Names and Numbers (ICANN) is necessary to ensure that consumers reap the benefits of robust competition in the market for domain name services. The private sectors of the U.S. and Japan are participating in the new marketplace as competitive domain name registrars and as participants in ICANN's global process. The Government of the United States and the Government of Japan will continue to confer bilaterally and to participate in Governmental Advisory Committee (GAC) and with other GAC members to develop and provide advice on the activities of the ICANN as that relate to concerns of governments.

I. Direct Access to Intelsat

The FCC has taken measures to permit carriers other than Comsat direct access to Intelsat from the United States for international satellite services.

IV. MEDICAL DEVICES AND PHARMACEUTICALS

- A. Good Manufacturing Practices: The Food and Drug Administration (FDA) has been working with the Ministry of Health and Welfare (MHW) through exchanges of information and other activities to develop a cooperative arrangement similar to a mutual recognition agreement regarding Good Manufacturing Practices. The FDA and MHW recognize the importance of these activities. The cooperative process will be pursued and further technical discussion will be continued. In addition, FDA and MHW are working actively in international harmonization fora, such as the International Conference on Harmonization.
- **B. Good Clinical Practices:** FDA will continue cooperative activities regarding Good Clinical Practices (GCPs) especially in the ICH forum, and FDA will continue to respond appropriately to foreign regulatory bodies' requests, including MHW's, for information regarding GCPs.
- **C. Timing of Stability Data:** FDA accepts stability testing data on pilot-plant scale products for New Drug Applications.

V. FINANCIAL SERVICES

A. Abbreviated Exams for Securities Dealers: The Securities and Exchange Commission approved the abbreviated exam proposals for the New York Stock Exchange, National Association of Securities Dealers, Inc., and the American Stock Exchange on January 11,

1996, April 12, 1996, and September 15, 1997, respectively. The NASD, which would administer the abbreviated exams, is working with the Japan Securities Dealers Association (JSDA) on an arrangement to obtain information needed to verify the registration status and disciplinary histories of applicants. If the JSDA and NASD reach agreement, the exchanges listed above will accept abbreviated exams for licensing, allowing Japanese securities representatives to conduct business in the U.S. (although Japanese representatives could not conduct business in municipal securities).

B. Registration Requirements for Newly Issued Foreign Bonds

- 1. The Securities Act of 1933 requires that all offers and sales of securities within the United States be registered with the Securities and Exchange Commission, unless an exemption from registration applies. The Act applies to the securities of foreign governments, as well as the securities of U.S. and foreign corporations. Exemptions from the registration requirement apply to certain types of securities transactions; however, there is no specific exemption from registration for the securities of any foreign government.
- 2. Schedule B of the Act sets out the disclosure requirements for foreign governments making public offerings in the United States. These requirements are relatively limited, and have not evolved into the detailed rules and forms required of commercial, non-governmental issuers. In fact, in order to enhance the market acceptance of their securities, foreign government issuers generally provide additional disclosure beyond the requirements of Schedule B. Although foreign government issuers are not eligible for "shelf" registrations under the SEC's Rule 415, a similar procedure was developed, through SEC interpretive releases, for Schedule B issuers who have registered securities within the past five years and have not defaulted on payments of principal or interest.
- 3. Foreign governments, however, are not required to register their securities if they are issued outside of the United States and are sold in the United States only after a 40-day seasoning period. Foreign governments may also take advantage of exemptions from the registration requirement on certain types of securities transactions specified in the Act. Many foreign governments rely on Section 4(2) of the Act, which exempts from registration "transactions by an issuer not involving any public offering." Many Section 4(2) offerings of foreign government securities are private placements of large blocks of securities with institutional investors.
- C. Citizenship Requirements: Section 72 of the National Bank Act requires that directors of National banks must be citizens of the United States. For a National bank that is a subsidiary or affiliate of a foreign bank, the Comptroller of the Currency may at his or her discretion waive the citizenship requirement in the case of not more than a minority of the total number of directors. The Office of the Comptroller of the Currency will

continue to implement this requirement in such a way as to cause minimal disruption. Many states which have citizenship requirements also (depending on the individual state law) waive such requirements.

- **D. Examination of Foreign Banks:** In October 1999, the federal banking agencies adopted a final rule that authorizes an expanded examination frequency cycle from 12 months to 18 months for certain U.S. branches and agencies of foreign banks. An 18-month examination cycle will reduce regulatory burden for U.S. offices of foreign banks that have total assets of \$250 million or less and meet additional eligibility criteria that are similar to the criteria applied to domestic banks.
- E. Financial Modernization: President Clinton signed the Gramm-Leach-Bliley Act (the Act) on November 12, 1999. Principles of national treatment and equality of competitive opportunity are explicitly adopted in the Act with respect to foreign financial institutions that want to become a financial holding company (FHC). The standards Japanese banks or other foreign banks will need to meet are comparable to those for US banks. Under the Act, the Federal Reserve will apply capital and management standards comparable to those applied to a domestic bank, to a foreign bank that desires to become an FHC. For a foreign bank that is not an FHC, and which has established a Section 20 subsidiary, the Act preserves the underwriting and dealing activities it might have had previously (Section 20 subsidiaries).
- **F. Requested Update on Regulation K:** No action was taken with respect to Regulation K this year other than the adoption of the final rule on the extended examination cycle for certain U.S. offices of foreign banks (discussed above). However, in light of the Gramm-Leach-Bliley Act, it is anticipated that the Federal Reserve Board will take action to adopt revisions to Subpart B of Regulation K in the coming year.