

**SUBMISSION BY THE GOVERNMENT OF THE UNITED STATES TO THE
GOVERNMENT OF JAPAN REGARDING DEREGULATION AND ADMINISTRATIVE
REFORM IN JAPAN**

November 15, 1994

The Government of the United States of America is pleased to submit to the Government of Japan, in the context of the deregulation and competition policy working group under the Joint Statement on the United States-Japan Framework for a New Economic Partnership, the attached paper addressing specific deregulation and administrative reform matters in Japan.

This paper was prepared in response to the invitation of the Government of Japan for interested foreign governments to submit specific requests regarding deregulation matters, based on the recognition that the Government of Japan is in the process of formulating a five-year deregulation action program, which it intends to finalize by March, 1995.

The attached paper is intended as an initial list of proposals and requests made by the Government of the United States. Because deregulation needs to be an ongoing process responsive to the ever-changing marketplace, the United States may submit additional requests or proposals as the Government of Japan continues the process of formulating and implementing the action program.

The Government of the United States looks forward to a constructive dialogue with the Government of Japan on deregulation matters and the deregulation action program, in the context of ongoing consultations in the Framework deregulation and competition policy working group and in other fora as well.

U.S. EMBASSY REFERENCE SERVICE

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I. BASIC PRINCIPLES

The reduction of unduly burdensome regulations in Japan can enhance competition, provide greater market access for foreign goods, services and investment, provide greater benefits to Japanese consumers, producers, and service providers through enhanced efficiency, lower prices and greater product and service choice and availability in the market place, and generally promote the domestic demand-led growth of the Japanese economy. The United States Government urges the Government of Japan to adopt the following principles advocated by major Japanese private sector organizations and study groups, and implement an ambitious program of deregulation based on these principles.

A. Broad & Continuous Review.

All regulations in Japan, whether formal or informal, or whether characterized as social or economic in nature should be reviewed. This review should be conducted on a continuous basis.

B. Freedom from Regulation in Principle, with Regulation as the Exception.

The review of regulations should consider whether the regulations are broader or more burdensome than necessary to achieve their legitimate objectives. Regulations that remain in force should be closely and directly linked to recognized public policy interests such as protection of health, safety, or the environment; protection of national security; or protection of consumers against deception.

C. Enhanced Transparency and Accountability.

Regulations should be based on the principles of transparency and non-discrimination, and regulatory officials should be clearly accountable for their actions. All formal and informal regulations should be in writing and published in publicly-available sources. The specific government entities and officials responsible for the implementation of such regulations should always be clearly identified. Changes to new and existing regulations should be disclosed in advance, with ample opportunity provided for public comment.

D. Prohibition of Informal Delegation of Government Authority.

Indirect, *de facto* regulation by quasi and non-governmental entities, including non-profit organizations, should not be allowed if such regulation is based on informal and non-transparent delegation of government authority unauthorized by the Diet.

E. Non-burdensome Local Regulation.

National government ministries should encourage local governments not to adopt regulations that subvert the efforts at the national level to deregulate.

F. Inclusion of Sunset Provisions.

Sunset provisions, which specify the lifetime of a particular regulation, should be included in newly-issued regulations where appropriate.

G. Promotion of Market Mechanism.

The market mechanism, supplemented by an active and effective antimonopoly enforcement policy, should be relied upon to determine the best and most efficient allocation of resources and the success or failure of individual firms. Private practices that unfairly restrict competition should not be allowed to replace or supplement official regulation.

II. DEREGULATION PROCESS

The five-year action plan should be developed and implemented based on the recognition that deregulation needs to be an ongoing process responsive to the ever-changing marketplace. The United States Government believes that the Government of Japan should develop the five-year action plan with full participation by interested private parties, both domestic and foreign. The United States Government urges the Government of Japan not to deem the drafting of the five-year action plan in March 1995 as the completion of the deregulation process itself. Instead, the Government of Japan should continuously review the implementation of, and where appropriate annually revise on the basis of public comments and other information, the five-year action plan. In this connection, the United States Government urges the Government of Japan to consider the following specific recommendations.

A. Mechanism for Private Sector Participation.

Establish standing working groups consisting of private sector individuals, including representatives of foreign entities, to provide the Administrative Reform Committee with recommendations and feedback on deregulation on a continuous basis. In addition, the Government of Japan should consider including private sector members on the Committee's secretariat staff.

B. Periodic Solicitation of Public Comment.

Seek public comment on a periodic basis in order to ensure transparency with respect to the development, implementation, and review of the five-year action plan. To this end, drafts of the five-year action plan should be published for public comment sufficiently in advance of final decisions to ensure that public comments may be fully considered, and steps should be taken to ensure that public comments are meaningfully and appropriately reflected in the final plan.

C. Directive to Protect Private Firms and Individuals.

Issue a written directive to all ministries instructing such ministries to ensure that the parties who submit such comments will not be treated disadvantageously or subjected to any form of pressure. Such a step would encourage private firms and individuals to submit public comments regarding the five-year action plan.

D. Annual Deregulation Reports.

Issue an annual report which evaluates the progress achieved to support the monitoring of the five-year action plan. A mere counting of the number of regulations relaxed should be avoided in favor of measurements that evaluate the effect in the market resulting from deregulation. Examples of such measurements include the number of actual new entrants, both domestic and foreign, as well as the impact on the large gap between Japan and its trading partners in the prices for goods and services.

III. **SPECIFIC DEREGULATION PROPOSALS**

A. Agricultural-Related.

The United States Government requests the Government of Japan to take steps to deregulate the importation of foodstuffs and other agricultural products. More specifically, the Government of Japan should revise the Food Control Law as well as phytosanitary, sanitary, and food additives regulations. Detailed deregulation measures in this area are currently being discussed by the two Governments in other fora. However, United States Government requests in general include the following:

1. Eliminate excessive regulations that inhibit transparent and expeditious certification by grading and inspection agencies.
2. Ensure that product standards are specifically defined.
3. Review and eliminate excessive regulations pertaining to the manufactured feed sector.
4. Eliminate unduly burdensome phytosanitary requirements in the approval of fruit varieties.
5. Eliminate excessive on-site (in the exporting country) inspection by Japanese phytosanitary inspectors, even for routine items, which could be monitored by exporting country officials.

6. Increase the number of inspectors in Japan who are assigned to inspect imported foodstuffs so that this task can be accomplished expeditiously.
7. Eliminate excessively restrictive requirements regarding pests or insects on fresh fruits and vegetables and cut flowers, including benign or cosmopolitan insects.
8. Expedite the approval process for introduction of new plant products.
9. Review the "positive list" system for acceptable food additives.
10. Expedite the approval process for new food additives.
11. Remove restrictions on the running of foreign-bred thoroughbreds in races in Japan.

B. Automobile and Automotive Parts.

The United States Government requests the Government of Japan to dramatically deregulate the automobile and automotive parts sector. Detailed deregulation measures in this sector are being discussed in the Framework Automobile and Automotive Parts Working Group. However, United States Government requests in general include, among other things, that the Government of Japan:

1. Accept equipment standards for autos and auto parts that are the functional equivalent of Japanese standards, and remove standards which serve no important safety or environmental purpose. Specific steps include, but are not limited to the following:
 - a. Accept the U.S. Environmental Protection Agency certification, and other foreign certifications if appropriate, as the basis for assessing whether a vehicle meets the requirements of the Government of Japan's engine exhaust and emission test.
 - b. Eliminate the catalytic converter overheat warning systems requirement.
 - c. Accept U.S. head restraint designs and certifications, and other foreign designs and certifications if appropriate, as meeting the requirements of the Government of Japan's head restraint test.
 - d. Accept U.S., and if appropriate other foreign, certification standards regarding front turn signal lamps as the functional equivalent of the Government of Japan's requirements regarding the complete on/off function of front turn signal lamps test.

- e. Accept U.S. and if appropriate other foreign vehicle identification number ("VIN") stamping requirements as the functional equivalent of the Government of Japan's VIN stamping requirement.
 - f. Eliminate the requirement for submission of the U.S. Federal Motor Vehicle Safety Standards (FMVSS) 208 data for Type Designation and accept the FMVSS 203 as functionally equivalent to the Government of Japan's steering impact test.
 - g. Eliminate the side-slip test requirement for vehicles imported under Preferred Handling Procedures (PHP).
 - h. Accept the U.S. Society of Automotive Engineering (US SAE) test, and if appropriate other foreign tests, as the functional equivalent of the Ministry of Transport light alloy wheel test.
 - i. Eliminate the rear side marker lamp spacing standard or align the standard with the European Union standard.
 - j. Reduce the emission audit levels for the "Preferred Handling Procedures" to the same level as those used in the "Type Designation System."
 - k. Accept emission testing data and certification of two-wheel drive versions of a vehicle model as fulfilling the data requirements for full-time four-wheel drive versions of the same model.
 - l. Accept U.S. Environmental Protection Agency derived deterioration factors, and other foreign data if appropriate, for "trucks" in cases where those vehicles, for emissions purposes, are classified as cars in Japan.
 - m. Accept the lamp installation requirements of FMVSS 108, and other foreign standards if appropriate, as functionally equivalent to Japan's head lamp spacing requirements.
 - n. Eliminate requirements to type-designate four-lamp headlamp systems and accept headlamps certified to the ECE Regulations.
 - o. Eliminate the minimum seat width requirement.
2. Accept data certified by internationally recognized foreign testing institutes (e.g., U.S.).

3. Eliminate the requirement that repairs by non-certified garages involving the disassembly of critical parts, or the minor modification/alteration of the height, width or length of a vehicle (such as through the addition of a ski rack), be inspected at MOT Land Transport Offices.
4. Permit mailing of motor vehicle inspection certificates to the MOT land office.
5. Ease the regulations that independent repair shops and mechanics must meet to be certified to perform all motor vehicle repairs and "shaken" inspections, including, but not limited to the following:
 - a. Relax the space requirements for certified garages so that certified garages allowed to handle only small-sized motor vehicles under present regulations will be allowed to handle ordinary-sized passenger vehicles as well.
 - b. Revise the tool and equipment requirements for certified garages so that certified garages are required to have only the tools and equipment clearly necessary for safety.
 - c. Reduce to one the number of qualified mechanics required for certified garages.
6. Revise and liberalize regulations regarding repairs for motor vehicles, including, but not limited to the following deregulation steps:
 - a. Eliminate Section 64 of the Road Transport Law, which requires overhaul inspection of vehicles when only minor changes to the vehicle are made, i.e. installation of trailer hitches, shock absorbers or roof carriers.
 - b. For major alterations of vehicle configuration, change regulations to require inspection only of alterations, and eliminate any tax requirement for the inspection. Allow any previous full vehicle inspection to remain valid for its full period despite the alteration.

C. Construction Materials.

The United States Government requests the Government of Japan to expedite deregulation of construction codes and standards. Detailed deregulation proposals relating to building materials and supplies will be submitted to the Ministry of Construction and discussed in parallel with discussions on the Major Projects Arrangements and the 1994 Construction Action Plan. Deregulations objectives covered by the 1990 U.S.-Japan Agreement on Wood Products are under discussion in the context of that Agreement. With regard to wood

products, the United States requests in general include, among other things, that the Government of Japan:

1. On an expedited basis, adopt performance-based building standards for wood products.
2. Modify building and fire codes to broaden authorized uses of wood products, consistent with test data demonstrating acceptable fire and earthquake performance characteristics.
3. Increase procedural transparency for approval of Foreign Testing Organizations (FTO) and expedite processing of FTO applications.

D. Distribution-Related.

The United States Government requests that the Government of Japan take dramatic steps to further deregulate the distribution sector in Japan, including:

1. **Import Processing.**
 - a. Significantly increase parallel processing for all imported products requiring processing by more than one Government of Japan agency, with a view towards using parallel processing for all goods requiring multiple agency approvals.
 - b. Instruct agencies to delegate their authority to process imports to Japanese Customs when their agency's technical expertise is not required (e.g., checking a document but not checking fresh produce for insects); this practice should be the presumed approach.
 - c. Extend the use of computerized processing (currently planned just for agricultural products) to all products as soon as possible, with the aim of achieving "paperless" processing in the near future.
 - d. Adjust airport fees at Kansai airport so that importers will be able to claim their merchandise for reasonable fees (inclusive of tolls and entrance fees) that include only costs directly related to the airport's handling of the goods.
 - e. Increase pre-arrival review by Customs and other Government of Japan agencies, and permit clearance upon arrival for air cargo and small package express.
 - f. Facilitate speedier on-site processing of air cargo at Narita Airport,

including elimination of required use of the Transit Air Cargo Terminal (TACT) at *Baraki*.

- g. Ease entry requirements for importers, including extending to air cargo (through Air-NACCS) the nationwide acceptance of collateral under the comprehensive system of deferred payment of customs duties.
- h. Reduce cargo clearance time at Narita Airport when documents are pre-filed so that such cargo is released faster than cargo for which documentation is presented upon arrival.
- i. Allow submission of customs documentation and communications with Customs officials by telephone, mail or fax.
- j. Simplify and expand inspection services for import clearance of foodstuffs.
- k. Ensure that customs regulations are applied uniformly and are as specific as possible.

2. Standards and Certification.

- a. Extend the planned harmonization of standards and certifications to include a review of all products, based on appropriate international norms.
- b. Implement immediately the Office of the Trade and Investment Ombudsman (OTO) recommendations, and where appropriate take additional steps regarding the list of items related to standards and certification submitted by the United States Government and other organizations.

3. Distribution and Wholesaling.

- a. Reduce significantly the restrictions on entry into the warehouse industry, with the goals of abolishing restrictions, reducing the shortages of storage space, and lowering high fees and minimizing burdens for foreign firms related to the distribution of their products.

4. Freight Transportation.

a. Trucking.

- (1) Harmonize with international standards the weight limits on sea

containers carried by trucks.

- (2) Eliminate restrictions on the use of in-house truck fleets by distributors and retailers.
- (3) Deregulate further the trucking freight rate notification system, including elimination of the requirement for including a cost account statement with the notification.
- (4) Ease continued restrictions on new entry into the trucking industry, including elimination of minimum fleet size requirements.

b. **Maritime.**

- (1) Introduce the seven-day work schedule at major ports to give shippers and customers more flexibility in their transportation logistics and save them costly delays.
- (2) Eliminate fees placed upon shipping lines for weighing and measuring cargo containers. (These are outdated, having been created before cargo was shipped in standardized containers.)
- (3) Ease the requirement that U.S. shipping companies must consult with the Japan Harbor Transportation Association (JHTA) 60 days in advance for "major changes" in ship schedules.

5. **Retail Distribution.**

- a. Reduce restrictions on the operation of large scale retail stores by, among other things, eliminating restrictions and application of notification requirements on the permitted hours of operation and the number of days closed.
- b. Expedite the processing of large scale retail store applications by, among other things:
 - (1) Providing for concurrent processing of store applications by local and prefectural authorities;
 - (2) Reducing the number of licenses required to open new stores;
 - (3) Reduce the amount of time required to begin actual building of a large-scale store, including reducing delays caused by Ministry

of International Trade and Industry (MITI) processing of the notification, and by local prefectural zoning, licensing and traffic regulations.

6. Liquor Distribution.

- a. Review regulations affecting entry and products.

7. Restrictions on Premiums and Sales Promotions.

a. Lotteries and Prize Competitions.

- (1) Revise the Japan Fair Trade Commission's (JFTC) notifications and all fair competition codes to increase to at least 10 million yen the maximum prize that may be offered in open lotteries or prize competitions, and to permit companies, once per 12-month period, to conduct a lottery or prize competition with a maximum prize of up to 100 million yen. Continue liberalization toward complete elimination of any value or frequency restrictions on "open" lotteries and prize competitions.
- (2) Re-define "closed" lotteries and prize competitions to be only those where a purchase is required in order to enter.
- (3) Permit entry in open lotteries by entry forms that can be obtained in newspapers or magazines, through direct mail campaigns, on an outer visible side of product containers or on displays at the point of sale (provided all persons may obtain an entry form by requesting one directly from the sponsor.)

b. Premiums to Consumers.

- (1) Reduce restrictions on premiums to consumers as follows, with a view toward eliminating all restrictions on the offering of premiums to consumers, except those relating to reasonable information disclosure necessary to enable consumers to make an informed choice concerning the purchase of the product being promoted:
 - (a) **Premium Value Limits.** Increase at least 3-fold the limits on the absolute and percentage value of premiums offered to general consumers set out in Paragraph 1 of JFTC Notification No. 5 of March 1, 1977, and

automatically increase these limits each year by an amount corresponding to the percentage increase in inflation over the most recent 1-year period.

- (b) Definition of "in connection with a transaction." Re-define "in connection with a transaction" so that it applies only to cases in which an actual purchase is required to obtain the premium.
- (c) Samples. Permit manufacturers to provide free samples of the smallest size container offered for retail sale to consumers.
- (d) Coupons.
 - i. Revise the JFTC's rules on the offering of coupons to make it clear that:
 - (i) coupons distributed without purchase (other than purchase of a newspaper or magazine containing the coupon) will not be considered a premium if they offer (1) yen or percentage discounts, (2) free samples, (3) "Buy 1, Get 1 Free", or (4) other similar arrangements;
 - (ii) with respect to coupons distributed without purchase, there will be no restrictions on the brand of the promoted product, the number or type of items covered by the coupon or the relation of the promoted product to the issuer or advertiser;
 - (iii) discount coupons (offering yen or percentage discount on the next purchase of a product) distributed with a purchase will be permitted.
 - ii. Ensure that government rules and regulations do not impede the development of coupon redemption systems.
- (e) Accumulation Programs. Clarify that for premium offers and closed lotteries requiring multiple purchases, any applicable premium value limits will be calculated by using the sum of the purchases required to qualify for the

premium offer.

- c. **Premium and other Sales Promotions by Large Retail Stores.**
 - (1) Revoke the JFTC's notification requirement for premium offers by large retail stores.
 - (2) Permit large retail stores to use without restriction premium campaigns and open lotteries to encourage consumers to come into their stores.
- d. **Industry Fair Competition Codes.**
 - (1) Refuse to authorize any new Fair Competition Codes on premiums and lotteries and move toward complete abolition of such Codes. Fully liberalize existing Codes to the general notification levels in the interim.
- e. **Joint Campaigns.**
 - (1) Eliminate any restrictions that would treat joint sales promotions more severely than similar campaigns conducted by an individual company.

E. Energy Production and Delivery.

The United States Government believes that with respect to energy production and delivery (i.e., petroleum and related products, electrical power generation and delivery, natural gas delivery and use), government examination of the changing role of the private sector will result in a corresponding need to re-define the nature and extent of government regulation and interference with those private activities. This process represents an opportunity to alter the nature of that regulation so as to reduce its impact to the minimum required and permit the maximum availability of opportunities associated with energy production and delivery to all parties, domestic and foreign. To this end, the United States Government looks forward to consulting with the Government of Japan regarding specific deregulation measures in Japan related to energy production and delivery.

F. Financial Services.

The Japanese financial markets remain highly segmented and heavily regulated, as evidenced by the variety of laws, administrative regulations, and institutional arrangements governing all aspects of financial activity. Thus, the United States Government has urged the Government of Japan to take steps to deregulate the financial sectors in areas such as pension fund and investment trust asset management, securities underwriting and trading, and

banking. Detailed deregulation measures in the financial services sector are currently being discussed by the two Governments in the Framework Financial Services Working Group. However, the United States Government requests in general include, among other things, that the Government of Japan:

1. Liberalize restrictions on domestic pension fund investment trust management so as to improve fund performance and maximize value for beneficiaries.
2. Limit restrictions on the issuance of securities to the minimum necessary to address appropriate prudential concerns, with the ultimate goal of expanding the definition of "security" under Article 2 of the Securities Exchange Law (SEL) to include all financial instruments that have the characteristics of "investment value and transferability."
3. Reduce restrictions on cross-border capital transactions, with a view toward making all cross-border transactions subject only to ex post notification.

G. Investment-Related.

The United States Government urges the Government of Japan to take aggressive steps to comprehensively review its regulations to encourage foreign direct investment into Japan. Detailed deregulation measures related to foreign direct investment are currently being discussed by the two Governments in the Framework Foreign Direct Investment Working Group. However, the United States Government requests in general include, among other things, that the Government of Japan:

1. Foreign Direct Investment.
 - a. Reduce the number of sectors for which prior approval for foreign direct investment is required;
 - b. Reduce the number of sectors for which approval is required on national security grounds; and
 - c. Expand the positive list for foreign direct investment to include agriculture, petroleum products, insurance, and telecommunications.
 - d. Increase transparency and availability of those requirements for prior approval, regulations, and permit requirements which are retained, as well as public announcements of the reasons for any refusal to grant prior approval to firms.

2. International Contract Notification.

Eliminate the JFTC's discriminatory notification requirements for joint venture arrangements between Japanese and non-Japanese companies.

3. Land Use.

Increase the availability of land in urban areas by taking the following steps:

- a. Reform the land tax system, including land assessment, to discourage holding land as an asset and encourage residential and commercial use.
- b. Apply the October 1991 revisions in the land lease and house lease law to existing leases for commercial property.
- c. Relax regulations governing the land/building ratio and limitations on building heights.

H. Legal Services.

In view of the fact that foreign lawyers play a vital role in facilitating inward transactions and trade into Japan, the United States Government requests that the Government of Japan further liberalize the restrictions applicable to the activities of foreign lawyers in Japan, including restrictions on *Gaikokuho jimubengoshi*. More specifically, the United States Government requests that the Government of Japan:

1. Eliminate all restrictions on the ability of foreign lawyers to represent parties in international arbitrations conducted in Japan.
2. Eliminate the restrictions on partnership or employment arrangements between foreign lawyers and *bengoshi*, and between foreign lawyers and other legal professionals in Japan.
3. Allow foreign lawyers to count all legal experience, regardless of where that experience was obtained, toward the 5-year experience requirement for qualification as a *Gaikokuho jimubengoshi*.

I: Medical/Pharmaceuticals.

The United States Government urges the Government of Japan to take aggressive steps in deregulating the medical/pharmaceutical sector. Specific deregulatory measures are being discussed between the two Governments in the Market-Oriented Sector-Selective (MOSS) talks. The United States Government requests that the Government of Japan, among other things, address the following issues:

1. In-Vitro Diagnostics (IVD) Reagents.

a. Review and revise regulations with respect to IVD reagents for in-vitro diagnostics which are regulated as pharmaceuticals.

- (1) Eliminate requirements that the manufacturer file a partial change registration when introducing new IVDs, or IVD instruments, that involve only minor changes from approved IVDs or IVD instruments not affecting safety or efficacy.
- (2) Accept accelerated stability data and eliminate requirements that the applicant provide data on three lots of product.
- (3) Eliminate requirements that the product registration include the type and concentration of each raw material in the IVD, and that the main ingredients be listed on the label.
- (4) Eliminate requirements that IVD manufacturers/importers have a pharmacist in each sales office.
- (5) Revise regulations that prohibit "outside company" testing of IVDs in connection with a filing for registration of the IVD, and allow such testing after filing for registration.
- (6) Eliminate the requirement that foreign manufacturers maintain lot release quality control records on file both in the foreign country and in Japan.
- (7) Eliminate the requirement that importers of IVDs maintain a quality control laboratory in Japan as well as in the country of production/export.
- (8) Eliminate the requirement that every imported IVD instrument be unpackaged and visually inspected by a registered party prior to commissioning at the customer site, even if the installation is performed by a qualified field engineer. This process is not required for domestic products.

2. Medical Devices.

a. Eliminate certain unduly restrictive and burdensome regulations pertaining to the Highly Advanced Medical Technology Service, and create a quick reimbursement system for high technology products.

Problems include a one year or more review period after license approval to determine qualification for reimbursement; the fact that products are entered at the sole discretion of *chuikyo*; and the fact that during the review period the manufacturer/importer must continually supply the device without any reimbursement.

- b. Revise regulations so that pharmaceutical manufacturers may attend the *chosakai* Expert Committee evaluation of clinical studies.
- c. Clarify the definition of "malfunction" in the "Report of Malfunction for Medical Devices" under the Enforcement Regulation of the Pharmaceutical Affairs Law, Article 62-2, paragraph 2, and provide examples for each product.
- d. Eliminate regulations which classify disinfectant solutions for soft contact lenses as a drug and which require that they be sold only at a pharmacy staffed by a pharmacist.
- e. Change the MHW standards for medical device categories including disposable syringes and needles under Article 42 of the Pharmaceutical Affairs Law, so that the product standards are consistent with those in the United States and Europe.
- f. Change Article 14 of the Pharmaceutical Affairs Law which specifies that "*shonin*" approval is required for import or manufacture of medical devices specified by the MHW. Currently, medical devices whose characteristics are specified in JIS are exempt from *shonin* approval; this exemption should be extended to medical devices manufactured according to ISO or other internationally accepted standards.

3. Contact Lenses.

- a. Modify regulations pertaining to clinical trials for range of lens power in connection to myopia and hyperopia, chemical disinfecting solutions and extended wear lenses, pursuant to the American Chamber of Commerce ((ACCJ) report to the Government of Japan.
- b. Eliminate regulations requiring clinical evaluation of the electronic sphygmomanometers.
- c. Eliminate the requirement that the supplier file a partial change application for packaging, design, and other miscellaneous changes to products which do not significantly affect the intended use, clinical performance, safety and effectiveness of the products, as requested by

the ACCJ in its submission to the Government of Japan.

- d. Eliminate regulations requiring clinical study data for wound care (protective) dressings that are not materially different from approved products.
- e. Harmonize the "Standard for Plastic Suture" with other international standards such as the United States Pharmacopoeia (USP).
- f. Revise regulations pertaining to disinfectants exclusively used for medical devices, equipment and apparatus, which are now classified as drugs, to reclassify them as medical equipment class 1.

J. Telecommunications\Information Systems.

The United States Government believes that an overall approach to deregulation of the Japanese telecommunications sector should emphasize two broad and related topics: (1) transparency and (2) network interconnection issues. These issues figure prominently in nearly all of the specific recommendations in light of their critical role in successfully deregulating modern telecommunications systems. The following provides preliminary recommendations concerning portions of the deregulatory proposal on the telecommunications sector published June 30, 1994, by the Government of Japan. The United States Government looks forward to discussing these issues with the Government of Japan in other fora and in subsequent written submissions. However, United States Government deregulation requests in general include, among other things, that the Government of Japan:

1. Transparency.

- a. Set out clearly all the applicable rules and regulations pertaining to telecommunications, as well as define in public documents the precise processes under which they are interpreted and administered.
- b. Ensure that the regulatory processes are open to participation by all, not just to those invited by the regulatory body and adopt published rules and regulations to prevent abuse of administrative discretion.
- c. Add precise language to the telecommunications regulations and associated directives, notices, and policy statements (such as those in the June 1994 deregulatory package) to replace vague commitments to "reduce" requirements or make them "simpler" which neither precisely state what is actually required nor how it will be accomplished.
- d. Ensure that documents used in the regulation of telecommunications are publicly available in a timely manner, including licenses and the terms

for receiving and maintaining such licenses; applications and supporting documentation; comments regarding documents filed by interested parties and any comments filed by interested parties in response; and other information that will permit the public to assess the operation and results of the regulatory process.

- e. Ensure that groups formed by MPT to address topics (including, for example, access charges, interconnection, or network technology issues) conduct their business in a public forum, and that interested individuals or groups are invited to submit information to the study team.

2. Network Interconnection.

- a. Treat network interconnection issues as a critically important element in developing competitive telecommunications markets, and consider these issues based on the concept of assuring equal access, rather than as a purely technical matter of physically connecting one network to another.
- b. Ensure that the economic conditions for interconnecting networks -- and their economic consequences -- in Japan are truly equal and do not favor one provider over another.
- c. Provide clear definitions of network interconnection points and equal access to, and choice of carriers by, users; ensure unbundled public interconnection and access tariffs; provide for equitable cost allocation methods; and introduce appropriate measures associated with collocation of equipment and other relevant elements.
- d. Ensure active regulation--through formal rules and orders--to maintain competitive and equal access to bottleneck facilities in the telecommunications networks.
- e. Eliminate current restrictions on connecting private leased lines to public networks in Japan.
- f. Extend international points of interconnection to all Type I carriers.

3. Specific Recommendations on the June 1994 Deregulatory Package.

- a. Entry Regulations for Type I Telecommunications Business.
 - (1) Identify which services are affected by new regulations and

define the periods expected for processing applications.

- (2) Eliminate the Ministry of Posts and Telecommunications' (MPT) authority to reject an application on the basis of the demand forecast; identify publicly all terms and conditions that may be considered in evaluating an application.
 - (3) Set out all criteria for judging an application in publicly available documents; ensure that licenses are not negotiated, but instead follow publicly prescribed rules and procedures.
 - (4) Ensure that service authorizations and licensing terms will be publicly available after a license has been granted.
 - (5) Specify the terms under which MPT may revoke licenses for non-performance of the specified, publicly available regulatory criteria.
 - (6) Provide for full public comment on service applications.
- b. **Rate and Service Regulations for Type I Telecommunications Business.**
- (1) Identify which rates are to be subject to the revised processes suggested in the June 1994 package, and how they are to be selected.
 - (2) Broaden the category of rates to be subject to "notification" processes rather than more complex approvals.
 - (3) Expedite rate approval processes (less than 30 days) for Type I carriers with a less than dominant market position (i.e. for carriers without the ability to set market prices); consider reforms of cost-justified tariffs in Japan with the intention of removing tariff requirements in services in competitive markets.
 - (4) Extend rate reforms to all categories of services and consider use of "incentive-based" rate-making methods such as rate "caps" in telephone services.
 - (5) Ensure that there are no *de facto* "minimum" rate floors.
 - (6) Provide for public review of rates and associated regulatory processes for rates not subject to this round of reforms.

- (7) Develop fully unbundled rate structures for carriers with dominant market positions, especially with regard to interconnection-related tariffs and other network competition regulation.
- (8) Base access tariffs and rates on a predefined access cost allocation process with industry disclosure of access costs (networks, operation, and systems) to ensure that rates are not cross-subsidizing noncompetitive products or operations; provide access cost reduction incentives to reduce access charges.
- (9) Prohibit the regulator from imposing interconnection regulations that set limits on network capacity.

c. Network Interconnection Regulations.

- (1) Revise telephone regulations to provide full "equal access" and subscriber choice among carriers.
- (2) Disclose network and network equipment standards, and technical interconnection protocols including for both service level interconnection (voice, data, Virtual Private Network (VPN), etc.) and network signalling (Signalling System #7 [SS#7]) and intelligent network components.
- (3) Establish competitive safeguards to ensure that access and terms of interconnection are truly equal and confer no unfair competitive advantage on one carrier over another; restrain the monopoly local exchange carrier's use of its monopoly position in other markets.
- (4) Streamline regulations with respect to new service features, to permit rapid introduction of new services and real network competition based on service features.
- (5) Require cost-based, unbundled interconnection tariffs; establish a non-discriminatory regulatory appeal process in the event of disputes.
- (6) Provide for resale and shared use of facilities and services, permitting meaningful competition from non-facilities-based carriers.
- (7) Provide a clear schedule for these reforms, with early

completion dates.

- d. **Interconnection of Private Leased Circuits with Public Switched Networks for Voice Service.**
- (1) **Initiate immediately policies to permit interconnection of leased circuits for all services, including voice channels and including SS#7 and operational interfaces equal to those available to NTT, to the public switched telephone network in Japan and at both ends of the circuit, immediately.**
 - (2) **Abolish restrictions on the shared use and resale of services and facilities.**

- e. **Offering of Basic Voice Service/International Value Added Network (VAN) Service.**

Immediately allow offering of basic voice service in connection with international value added network service.

- f. **International Telecommunications, Value-Added Services.**

Eliminate all restrictions affecting interconnection of international value-added network services and use of those services in third countries (i.e., those parts of the service not directly provided by Japanese carriers).

- g. **Response to Convergence of Telecommunications and Broadcasting:**

- (1) **Identify and expand telecommunications services cable operators will be allowed to provide (i.e., local exchange telephone service, data, others).**
- (2) **Examine special provisions needed to offer interactive services.**
- (3) **Ensure that the "equal access" and non-discriminatory network interconnection regime extends to new interactive services**

- h. **Satellite Communications**

- (1) **Allow entities or persons other than Type I carriers to own and operate satellite earth stations.**
- (2) **Open the satellite earth station market to permit earth stations to**

be purchased from sources other than Type I carriers.

- (3) Liberalize standards and standards-setting processes for satellite earth stations so that Japanese standards become comparable to international standards.

K. Other.

In view of the rapidly changing nature of deregulation focus in Japan, the United States Government urges that the Government of Japan add additional sectors, as appropriate, in the future.

IV. ADMINISTRATIVE REFORM RELATED TO DEREGULATION

The United States Government urges the Government of Japan to undertake aggressive administrative reform to enhance the transparency of government practices and to reduce and make transparent the use of informal administrative measures by government officials to direct private sector behavior. The United States Government recognizes that the Government of Japan has begun the process of limiting the use of such tools. However, as long as informal and non-transparent means--such as administrative guidance--are available to Japanese officials, their ability to interfere in private behavior in a discriminatory and unaccountable fashion will be maintained. Thus, the United States Government requests the Government of Japan to take the following steps:

A. Promotion of the Administrative Procedure Law.

The United States Government urges the Government of Japan to undertake an outreach program to further publicize the Administrative Procedure Law (APL) and to familiarize Government of Japan officials, private businesses, trade associations, professional organizations and other interested parties of the rights and procedures provided for by the APL. In addition, the Management & Coordination Agency (MCA) should:

1. Sponsor seminars and similar programs to enhance public awareness and understanding of the APL.
2. Prepare written materials for public dissemination that explain the scope and operation of the APL.
3. Establish a program to review whether the APL is being fully and effectively utilized by private sector entities and individuals. To this end, the MCA should publish an annual report regarding the implementation of the APL.

B. Consideration of Rulemaking Procedures.

The United States Government urges the Government of Japan to request the Administrative Reform Committee to examine the steps necessary to incorporate rulemaking procedures (i.e. procedures requiring, among other things, public comment on regulations before they are adopted) in the APL, as well as expand the law's coverage to all organizations which issue administrative guidance, so as to build on the recommendation issued by the Third Administrative Reform Council. To this end, the Administrative Reform Committee should establish a working group consisting of legal experts to review issues related to the adoption of rulemaking procedures, and publish its findings by the end of FY 1995.

C. Advisory Committees and Study Groups.

The United States Government requests that the Government of Japan take steps to further enhance the transparency of formal and informal advisory committees, such as *shingikai*, *kenkyukai*, *kondankai* and *benkyokai*, which are organized to provide expert advice and recommendations to government agencies on policy matters. The United States Government believes that the public will benefit from the availability of meaningful standards and uniform procedures for the establishment and operation of such committees, as well as greater openness and transparency. To this end, the United States Government requests the Government of Japan to:

1. **Revise "Guidelines Concerning the Management and Other Matters of Advisory Councils" issued on June 24, 1994 to include more specific provisions for keeping the public informed as to the function, purpose, membership and activities of these advisory committees. More specifically, the Guidelines should be amended to:**
 - a. **Expand the scope of their applicability. Amend the Guidelines to apply to committees organized below the director-general level and other committees with substantial official participation.**
 - b. **Require public notice and participation. Open advisory committee meetings to the public and provide public notice sufficiently in advance of meetings so as to permit public participation (subject to specific, narrow, and appropriate exemptions).**
 - c. **Require that ministries define the purpose and seek balance in the membership of the advisory committee. Clearly define a purpose for each advisory committee and include it in a charter made available to the public. Require the relevant ministry to appoint a balanced membership in addition to considering the viewpoint and experience of potential appointees. Include special provisions to support the**

participation of interested foreign firms and individuals.

- d. Require formal documentation of committee proceedings. Include provisions for keeping transcripts, minutes and/or records of all proceedings of committees including the time, date, and place of the meeting, advisory committee members who attended, matters discussed at the meeting and copies of materials presented at the meeting (subject to specific, narrow and appropriate exemptions).
- e. Provide public access to documentation of advisory committee meetings. Information should be made available to the public through each ministry's document section, which also should provide information with regard to the operation of the advisory committees themselves (subject to specific, narrow and appropriate exemptions).

2. Lists of Advisory Committees.

Compile and publish in the *Kanpo* lists of the advisory committees described above including names, charters and details of the membership. Make these documents available at the document sections of the ministries.

D. Information Disclosure.

The United States Government believes that aggressive steps should be taken by the Government of Japan to disclose government information and to enhance the transparency of government-private sector interaction. The United States Government requests that the Government of Japan:

1. Ensure that foreign companies are accorded access to government information and regulatory processes on an equal basis--both legally and practically--to Japanese industry associations, regardless of whether foreign firms are members or non-members of the association.
2. Publish in advance of issuance all administrative guidance issued to industry associations and permit public comment on such guidance before it is finalized.
3. Strengthen the "Interagency Understanding on the Criterion Applicable to Administrative Disclosure System" issued in December 1991, by:
 - a. Revising the Criterion and issuing it as a Cabinet Directive instead of the current "understanding" between ministries.
 - b. Instructing each ministry and agency to compile an annual report on the number of requests it receives and the documents disclosed using the

Criterion.

4. Take steps to adopt the Information Disclosure System by the end of FY1996. To this end, the Government of Japan should:
 - a. Request the Administrative Reform Committee to deliberate on issues related to the adoption of the Information Disclosure Law with a view toward the adoption of a comprehensive information disclosure system.
 - b. Submit to the Diet, by the end of FY1996, legislation on the information disclosure law which will provide the public with an enforceable right of access to records of administrative agencies, subject to specific and appropriate exemptions, the application of which may be reviewed by the courts.

E. Administrative Appeals and Arbitration.

In the new deregulated environment with enhanced consumer responsibility in Japan, the importance of administrative appeals or challenge can be expected to grow. Thus, the United States Government believes that the Government of Japan should strengthen existing mechanisms for such appeals in terms of their availability, speed, and effectiveness. In addition, where appropriate, the Government of Japan should consider establishing new mechanisms to address disputes between private and government or quasi-government entities. To this end, the United States Government requests the Government of Japan to:

1. Administrative Appeals Study. Request the Administrative Reform Committee to establish a working group to prepare a report on the availability and effectiveness of existing review mechanisms to effectively process complaints against administrative entities. The report should include an analysis of the operation and effectiveness of the Administrative Appeals Inquiries Law (*Gyosei fufuku shinsa ho*) (Law No. 160 of 1962) and the Administrative Case Litigation Law (*Gyosei jiken sosho ho*) (Law No. 139 of 1962, as amended).
2. Alternative Dispute Resolution (ADR). Establish an ADR mechanism that could be used in the resolution of disputes between private parties and government agencies. The ADR mechanism should:
 - a. Serve as a forum to resolve disputes between governmental entities and private parties who would be substantially affected by a decision of an entity relating to an administrative approval, guidance, or other action.
 - b. Be a voluntary procedure which supplements rather than limits other available dispute resolution techniques.

- c. Involve neutral persons who function, with respect to an issue in controversy, specifically to aid the parties in resolving their dispute by serving as conciliators, facilitators, mediators, or arbitrators.
 - d. Provide that any neutral person serving as a conciliator, facilitator, mediator, or arbitrator in a dispute have no official, financial, or personal conflict of interest with respect to the issues in controversy, unless such interest is fully disclosed in writing to all parties and all parties agree that the neutral person may serve.
 - e. Provide that decisions rendered by neutral persons serving as arbitrators be binding and enforceable on the parties to the dispute whenever the parties consent thereto.
 - f. Ensure appropriate protection (confidentiality) of communications between the parties and the neutral person serving as conciliator, facilitator, mediator, or arbitrator with the goal of fostering and promoting the use of the ADR mechanism within administrative agencies.
 - g. Be governed by published rules of procedure that adopt internationally recognized principles of due process and grant fair opportunities for private parties with an interest in the matter to present their arguments and supply evidence in support thereof.
3. Arbitration. Enhance mechanisms for arbitration of private disputes between foreign and domestic parties by encouraging the Japan Commercial Arbitration Association (ACCA) to improve its rules and procedures and adopting a new arbitration law.
4. The Office of Trade and Investment Ombudsman. Further strengthen the Office of Trade and Investment Ombudsman.

V. COMPETITION POLICY ENFORCEMENT

In order to ensure that exclusionary private practices are not used to stifle the positive effects of deregulation, the United States Government urges the Government of Japan to implement the following measures related to antimonopoly enforcement:

A. Criminal Enforcement of the Antimonopoly Act.

1. Through the JFTC and Public Prosecutors Office, make utmost efforts to

increase the number of criminal prosecutions of hard-core antimonopoly violations, so as to maximize the deterrent effect that criminal antimonopoly enforcement can have on unlawful anticompetitive activities.

2. Through the JFTC and Ministry of Justice, publicly reconfirm the Government of Japan's intention to apply the criminal provisions of the Antimonopoly Act in an active manner.

B. Investigatory Resources of the JFTC.

1. Increase the staff of the JFTC by at least 200 persons by FY1997, and allot the largest portion of that increase to the investigation department.
2. Authorize the creation of new investigatory sections for the JFTC's main office and its local offices.

C. Enhanced JFTC Enforcement Power.

1. Enhance the enforcement powers of the JFTC by amending the Antimonopoly Act (AMA) to:
 - a. Extend to 3-years the current 1-year limitation contained in section 7 of the AMA on the issuance of elimination measures by the JFTC.
 - b. Empower the JFTC to take enforcement action, including the assessment of surcharge orders, against individuals and trade associations that participate in activities that violate the AMA.
 - c. Increase significantly the criminal penalties for submission of false or incomplete evidence to the JFTC in response to a compulsory request for information pursuant to Sections 40 or 46 of the AMA, including the possibility of imprisonment for intentional false statements or destruction of documents.

D. Upgrade Status of JFTC.

1. Upgrade the status of the JFTC to the level of the National Personnel Office, including converting JFTC Departments ("bu") into Bureaus ("kyoku").

E. Industry Associations.

1. Take all necessary actions to ensure that industry associations do not engage in exclusionary or competition-restricting practices. These actions should include:

- a. Revision of the JFTC's Antimonopoly Guidelines on Trade Association Practices by the end of FY1994,
 - b. Strict and vigorous enforcement of the AMA by the JFTC in accordance with those guidelines; and
 - c. Formal and informal administrative action by ministries with jurisdiction over particular industry associations to prevent any exclusionary or competition restricting practices.
2. Ensure, in particular, that industry associations:
- a. Do not exclude foreign firms from membership nor otherwise discriminate against foreign firms, where such exclusion or discrimination may adversely affect the ability of foreign firms to compete successfully in the Japanese market;
 - b. Provide foreign members access to important association data on the same terms as Japanese members, which should be reasonable.
 - c. Conduct standards and certification processes and rule-makings in an open, transparent and non-discriminatory basis, with full and timely access to, and participation by, foreign firms in such processes.
 - d. Provide non-members with full access to government information in the possession of industry associations and provide foreign firms with access to quasi-governmental processes and procedures conducted by associations that are authorized or delegated to the association by law, regulation or other administrative action.

F. Prevention of Bid Rigging.

1. Encourage individual procuring agencies, government officials, and private citizens to report evidence of bid rigging or other unlawful activities with respect to public procurements to the appropriate enforcement agency. Public officials who report such evidence should be protected by law from retribution or harassment for their actions.
2. Through the "National Coordinating Committee for Implementation of Public Works Contract Procedures" or other appropriate body, take the following actions to increase administrative sanctions against bid rigging on public procurement:
 - a. Increase to 12 months the minimum period that companies found to

have participated in bid rigging activities will be suspended from bidding on any publicly-funded procurement;

- b. Require that such suspensions from bidding apply to procurement occurring anywhere in Japan; and
 - c. Require any suspended company to repay to the Government its proportionate share of the damages suffered by the Government as a result of the bid rigging, before it may submit bids on future publicly-funded procurements.
3. Through the JFTC, Public Prosecutors Office, and National Police Agency establish and publicize a mechanism by which citizens and government officials can report information about bid rigging and other unlawful activities with respect to public procurement while preserving their anonymity.
4. **Certifications of Non-Collusion**
- a. Require that all bids on publicly-funded procurement be accompanied by a certification, signed by the president of the bidding company, stating that (1) the bid was arrived at independently without any consultation, communication or agreement with any other bidder as to the terms of the bid, and (2) there was no consultation, communication or agreement with any actual or potential bidder as to whether either party would or would not submit a bid.
 - b. Submit legislation making it a crime, punishable with a minimum prison sentence of 60 days, for any person to submit a false certification of the type described in subparagraph (a) above.

G. Elimination of Anticompetitive Market Situations.

1. Through the JFTC, take all appropriate measures, based on aggressive application of all Chapters of the Antimonopoly Act, including Chapter III-II, to remedy market situations or business practices in particular sectors that have the effect of facilitating oligopolistic practices, preventing new entry and stifling competition.
2. Through the JFTC, use the compulsory investigatory powers provided in sections 40 or 46 of the AMA to determine whether producers, agents or distributors in the flat glass industry and in the passenger car industry are engaged in practices that violate the Antimonopoly Act or have otherwise created a market situation that is subject to remedy under the provisions of the AMA.

illegally-priced sales of products ultimately purchased by the plaintiff, or (ii) where the AMA violation excludes or exploits a competitor, the profits earned by the defendant on sales that would otherwise have been made by the plaintiff.

- (5) An industry association shall be jointly and severally liable for damages caused by any conduct it participated in that the JFTC has determined, through a recommendation, recommendation decision or hearing decision, violated Section 8 of the AMA.
- (6) A special filing fee will apply, equal to the level applicable to shareholder derivative suits.
- (7) Courts may enjoin persons and entrepreneurs from continuing to engage in conduct that violates the law.
- (8) The issuance of a surcharge order by the JFTC will be added to the list of JFTC actions in Section 26 of the AMA that constitute a sufficient basis for injured parties to file a private damage action under section 25 of the AMA.

2. Civil Procedure Code Improvements.

a. Amend the Civil Procedure Code so that:

- (1) Plaintiffs have an effective ability to obtain key documents and information needed from the defendant and third parties to successfully pursue their claims.
- (2) Plaintiffs are able to pursue damage actions in an effective and economical manner against tortfeasors that cause relatively small amounts of damages to a large group of persons.

I. Elimination of Antimonopoly Exemptions.

1. Review all systems providing an exemption from the AMA with a view to abolish in principle all such exemptions. The review should cover all relevant laws, including the exemptions contained in the AMA and in the Act Concerning Exemption, Etc. from the AMA (Act No. 138 of 1947).
2. Take, in particular, but without limitation, the following actions:
 - a. Conduct an expedited review of the antimonopoly exemptions applicable in the insurance sector with a view to narrowing or

H. Improved Private Remedies for Consumers

1. Antimonopoly Act Amendments.

a. Amend Article 25 of the AMA to provide that in civil damage actions based on alleged AMA violations, whether filed under the AMA or section 709 of the Civil Code:

- (1) Any conduct that the JFTC has determined, through a recommendation, recommendation decision or hearing decision, violated the AMA will be rebuttably presumed to have caused injury to direct purchaser plaintiffs and to have unreasonably restrained trade.
- (2) Proof that the antimonopoly violation was a material cause of the plaintiff's injury will be sufficient to recover damages. The plaintiff should not be required to demonstrate that there were no other sources of injury other than the unlawful conduct.
- (3) Where a defendant has information in its possession that is relevant to proof of damages or the causal connection between the AMA violation and the alleged damages, the defendant, upon the court's determination that a prima facie case has been established that defendant has violated the AMA, will have an obligation to submit that evidence to the court. If the defendant fails to provide that evidence to the court, the court will be entitled to make inferences adverse to that defendant with respect to proof of such matters.
- (4) Where the court concludes that there is a causal connection between the AMA violation and injury suffered by the plaintiff, the plaintiff shall be entitled to prove, under a lesser burden than the fact that it was damaged, the losses it has suffered as a result of the unlawful conduct. The court may determine the amount of damages suffered by the plaintiff through a just and reasonable estimate based on:
 - (a) direct evidence,
 - (b) data, statistical analyses and/or other indirect evidence that permit inferences of such damages, or
 - (c)(i) where the AMA violation involved an increase in the price of goods or services, the profit earned by the defendant on the

eliminating such exemptions to the greatest extent possible. In particular, complete this process with the view towards eliminating the antimonopoly exemption for rate setting for non-life insurance under the Insurance Association Act and terminating the existing cartel system for the setting of non-life insurance premiums.

- b. Eliminate or substantially limit the antimonopoly exemptions and/or regulated rate systems applicable to freight transportation by the trucking, railroad, maritime shipping and air transport sectors, including the Coastal Shipping Association Act (Act No. 16 of 1957) and the Road Transportation Act.