AMENDMENTS TO THE RELATED LAWS
CONCERNING STANDARDS AND CERTIFICATION SYSTEMS

The following communication, dated 19 May 1983, has been transmitted by the Permanent Representative of Japan to the Director-General.

With reference to my letter of 28 March 1983 addressed to you, I should like to inform you that the Japanese Diet enacted on 18 May 1983 the omnibus law entitled "the law to amend a part of the sixteen related laws to facilitate the obtaining of type approval etc. by foreign manufacturers".

These amendments to the related laws will enable foreign manufacturers to have direct access to certification systems in Japan and thus ensure in terms of legal systems that there be no discrimination between nationals and non-nationals in certification procedures.

The enactment of the omnibus law is an epoch-making undertaking with no precedent elsewhere. The fact that it has been achieved is a concrete demonstration of our active efforts to proceed further, on our own initiative, with the opening up of our market with a view to maintaining and strengthening the free trading system and thus contributing to the revitalization of the world economy.

I enclose in the annex the document describing the outline of the amendments to the related laws.
The Outline of the Amendments to the Related Laws

1. The Consumer Product Safety Law
   A. Registration of foreign manufacturers
      (1) Foreign manufacturers who manufacture the specified products for the purpose of export to Japan will be able to obtain the registration of competent Ministers.
      (2) Regulations concerning the procedures for registration, etc. of domestic manufacturers shall apply to registration by foreign manufacturers as well.
   B. Type approval for foreign manufacturers
      (1) Foreign registered manufacturers will be able to obtain the type approval of the specified products which the manufacturers will produce for the purpose of export to Japan.
      (2) Regulations concerning the procedures for type approval and the obligation of the recipients of the approval (such as the obligation to comply with standards) shall apply to foreign manufacturers.

2. The High Pressure Gas Control Law
   (1) Those who manufacture specified equipment in foreign countries in order to export to Japan will be able to undergo the inspection of the specified equipment.
   (2) Importers will be no longer required to undergo the inspection of the specified equipment when foreign manufacturers themselves undergo such inspection.

3. The Law Concerning the Securing of Safety and the Optimization of Transaction of Liquified Petroleum Gas
   A. Registration of foreign manufacturers
      (1) Those who manufacture class 1 liquified petroleum gas apparatus (hereinafter
referred to as "LPG apparatus"), etc. in foreign countries in order to export to Japan will be able to be registered by the Minister of International Trade and Industry according to the classification of the apparatus.

(2) Regulations concerning the procedures for domestic manufacturers' registration, etc. will apply mutatis mutandis to foreign manufacturers'.

B. Type approval for foreign registered manufacturers

(1) Foreign registered manufacturers will be able to obtain the Minister's approval of the type of the class 1 LPG apparatus to be manufactured and exported to Japan according to the classification of the type.

(2) Regulations concerning the procedures for type approval of domestic registered manufacturers and their obligations (the obligations to comply with the standards, etc.) will apply mutatis mutandis to foreign registered manufacturers.

4. The Law Concerning the Examination and Regulation of Manufacture, etc., of Chemical Substances

A. Notification of new chemical

(1) A foreign manufacturer who intends to produce a new chemical substance for the purpose of export to Japan or a foreign supplier who intends to export new chemical substance to Japan, will be able to notify the name of the new chemical substance and other items to be specified in the relevant Ministerial Ordinances to the Minister of International Trade and Industry and the Minister of Health and Welfare prior to export.

(2) Any person who intends to import a new chemical substance from a foreign manufacturer or supplier will not be required to submit a notice, when the said manufacturer or supplier has received an administrative notice to the effect that
the said chemical substance does not fall into the category of "specified chemical substance".

B. Examination of the new chemical substance

Upon receipt of a notice mentioned in A(1) above, the Minister of Health and Welfare and the Minister of International Trade and Industry must determine, on the basis of already available information concerning the composition, properties, etc., of the new chemical substance mentioned in the notice, whether the new chemical substance falls into the category of "specified chemical substance" or not, and must notify the result within four months from the date of the receipt of the notice.

5. The Measurement Law

A. Pattern approval of measuring instruments for foreign manufacturers

(1) The amendment would enable foreign manufacturers of measuring instruments exporting to Japan to obtain pattern approval by the Minister of International Trade and Industry or Japan Electric Meters Inspection Corporation as well as to take the test performed by the verification bodies.

(2) It will become possible for the foreign manufacturer who obtained pattern approval to affix the pattern approval number to the measuring instruments which belong to the pattern approved according to the method provided by the Ministry of International Trade and Industry Ordinance. Otherwise, it would be forbidden to affix the pattern approval number or any indication which might be mistaken therefor.

B. Designation for business of manufacturing of special containers by foreigners

(1) Any person who is engaged in the business of manufacturing special containers outside Japan will be able to obtain the designation from the Minister of
International Trade and Industry for each factory or workshop.

6. The Electrical Appliances and Materials Control Law

A. Registration of foreign manufacturers

(1) Those in foreign countries who intend to engage in the business of manufacture of the Category A of electrical appliances and materials will be able to obtain registration by the Minister of International Trade and Industry.

(2) Regulations concerning the procedure for registration and so forth of domestic manufacturers shall apply mutatis mutandis to registration of foreign manufacturers.

B. Type approval for foreign manufacturers

(1) Foreign registered manufacturers will be able to receive type approval by the Minister of International Trade and Industry for goods of Category A of electrical appliances and materials which they wish to manufacture and to export to Japan.

(2) Regulations concerning procedure for type approval and the obligation of the recipients of the approval (such as the obligation to comply with standards), shall apply mutatis mutandis to foreign manufacturers.

C. Type authorization regarded as given to importers

When an importer of Category A electrical appliances and materials receives confirmation by the Minister of International Trade and Industry that the type of Category A electrical appliance he wishes to sell belongs to the same type classification and manufactured by the same manufacturer as a type which has already been authorized for other importers, the good in question will be regarded as having obtained type authorization.
7. The Gas Utility Industry Law

A. Registration of foreign manufacturers

Foreign manufacturers producing gas appliances for exportation to Japan will be able to obtain registration by the Minister of International Trade and Industry.

B. Type approval for foreign manufacturers

Foreign registered manufacturers will be able to obtain approval of the Minister of International Trade and Industry for gas appliances to be exported to Japan.

C. Procedure of registration, type approval and so forth for foreign manufacturers

Provisions concerning procedure of registration, type approval and so forth for domestic manufacturers, and similar provisions for manufacturers of class 1 liquified petroleum gas appliances in the Law concerning the Security of Safety and the Optimization of Transaction of Liquified Petroleum Gas shall apply mutatis mutandis to foreign manufacturers.

8. The Fertilizer Control Law

Registration or provisional registration of fertilizer produced outside Japan

(1) The foreign manufacturers who produce ordinary fertilizer to be exported to Japan will be able to get the registration or provisional registration by the Minister of Agriculture Forestry and Fisheries.

(2) Manufacturers who wishes to get the registration or provisional registration according to (1) will be required to designate an agent in Japan.

(3) Manufacturers who have obtained registration or provisional registration according to (1) will be subject to the same obligations as domestic manufacturers. Agents in Japan will be subject to obligations such as keeping of records.
9. The Agricultural Mechanization Promotion Law

A. Application of type inspection by those who live abroad

Those who do not live in Japan will be able to apply for the type inspection of agricultural equipments.

B. Amendments to the provisions on the follow-up inspection

When the Minister of Agriculture, Forestry and Fisheries conducts the follow-up inspection, he will be able to request those who live abroad that the inspection, if necessary, be taken at the sites of operation.

10. The Agricultural Chemical Regulation Law

Registration of foreign made Agricultural Chemicals

(1) Those who manufacture or process agricultural chemicals for the purpose of the export to and the sale in Japan will be able to obtain the registration by the Minister of Agriculture, Forestry and Fisheries.

(2) Those who wish to obtain the registration mentioned in (1) above will be requested to designate an agent who has an address in Japan.

(3) The same obligations imposed for domestic manufacturer will be imposed on those who obtained the registration mentioned in (1) above. Agents in Japan will be subject to obligations such as keeping of records.

11. The Law Concerning Safety Assurance and Quality Improvement of Feed

A. Approval system related to foreign manufacturers

(1) Approval by the Minister of Agriculture, Forestry and Fishery to the testing organization

Should an organization of the Ministry of Agriculture, Forestry and Fisheries or a testing organization designated by the Ministry deem it necessary for the smooth implementation of the test of feed under the
official standard, the foreign manufacturer (for the purpose of this section, the foreign manufacturer is the person who manufactures in foreign countries the feeds for which standards are established for sale in Japan) of the product shall carry out the sampling and place the certification mark on the product with prior approval of the Minister of Agriculture, Forestry and Fisheries, provided that the judgement of whether the said product meets the official standard and other related work are done by the organization of the Ministry or the designated testing organization.

(2) Permission of foreign manufacturer

A foreign manufacturer of a product qualified for a certification mark shall be permitted to indicate said mark on the product as necessary prior to the test when permitted to do so by the Minister of Agriculture, Forestry and Fisheries.

12. The Law Concerning Standardization and Proper Labelling of Agricultural and Forestry Products (JAS Law)

Approval system related to foreign manufacturer

(1) Approval by the Minister of Agriculture, Forestry and Fisheries to the grading organization

Should an organization of the Ministry of Agriculture, Forestry and Fisheries, or a Registered Grading Organization deem it necessary for the smooth implementation of the grading, the foreign manufacturer (for the purpose of this Section, the foreign manufacturer is the person who manufactures or processes in foreign countries the agricultural and forestry products to be exported to Japan) of the product shall carry out the sampling and place the grading indication on the product with the prior approval of the Minister of Agriculture, Forestry and Fisheries, provided that the judgement of whether the said product meets the Japanese Agricultural Standard and other related work are done by the organization of the Ministry or the Registered Grading Organization.
(2) Permission to Foreign Manufacturer

A foreign manufacturer of a product qualified for a grading indication shall be permitted to indicate said grading mark on the product as necessary prior to the grading when permitted to do so by the Minister of Agriculture, Forestry and Fisheries.

13. The Nutrition Improvement Law

(1) Those who wish to affix the mark of enriched foods and foods for special dietary use in foreign countries will be able to obtain approval from the Minister of Health and Welfare.

(2) Those who import foods to which the mark of enriched foods and foods for special dietary use is attached without permit or approval are required to obtain permit of the Minister of Health and Welfare.

14. The Pharmaceutical Affairs Law

(1) The Minister of Health and Welfare will be able to give the manufacture approval of each product on the basis of the application of the foreign manufacturer who intends to manufacture the pharmaceuticals, quasi-drugs, cosmetics or medical devices for the purpose of export to Japan. In that case, the applicant will have to designate an agent who can take measures in Japan to prevent hazards on the public health which may be caused by the use of the said product.

(2) The importer who intends to import the pharmaceutical, etc. for which the foreign manufacturer has already obtained the manufacture approval will not be required to obtain the import approval of that product.

(3) The Minister of Health and Welfare will be able to make the agent provide necessary information such as information on adverse reactions, make his officials conduct on-site inspection or order the agent to take measures to prevent the occurrence or spreading of hazards on the public health.
(4) The foreign recipient of the manufacture approval or the agent will have to provide the information concerning the approval and other necessary information for proper dealing with the pharmaceutical, etc. to the importer who intends to import the related pharmaceutical, etc.

15. The Road Vehicles Act

Foreign manufacturers etc. who manufacture automobile abroad to be exported to Japan will be able to apply for type designation of automobile.

16. The Industrial Safety and Health Law

A. Application etc. by foreign manufacturer of inspection or certification

Those who manufacture the designated machine etc., the machine subject to individual certification etc., and the machine subject to type certification etc., abroad will be able to receive inspection or certification.

B. Accommodation of type certification system

Those who import the machine subject to type certification etc. which has already obtained type certification will not have to obtain type certification again.