NOTIFICATION

The following notification is being circulated in accordance with Article 10.4.

1. Party to Agreement notifying: JAPAN

2. Agency responsible:
   (1) Chemical Products Safety Division, Basic Industries Bureau, Ministry of International Trade and Industry;
   (2) Pharmaceuticals and Chemicals Safety Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare;
   (3) Office of Health Studies, Environmental Health Department, Environment Agency.

3. Notified under Article 2.5.2, 2.6.1, 7.3.2, 7.4.1, Other:

4. Products covered (CCCN where applicable, otherwise national tariff heading):
   New chemical substances excluding the chemicals used for the following purposes:
   (1) Foods, food additives, packages, toys, detergents;
   (2) Agricultural chemicals;
   (3) Ordinary fertilizers;
   (4) Feeds, feed additives;
   (5) Drugs, quasi-drugs, cosmetics, medical devices.

5. Title: Establishment of Good Laboratory Practice Standard for Studies on New Chemical Substances.

6. Description of content: To establish the standard (GLP standard) prescribing the matters which testing facilities should obey in principle with a view to ensuring the reliability of test results required for notification of new chemical substances. This standard has its origin in the decision of the council of OECD. The main items of the standard are as follows:
   (1) Purpose and coverage of the standard;
   (2) Organization of personnel; responsibility pertinent to the conduct of a study;
   (3) Design, function, location and control of facilities, equipments and apparatus;
   (4) Handling and storage of test substances, control substances, reagents, etc;
   (5) Operation in testing facilities (standard operating procedure, etc.);
   (6) Designation of quality assurance personnel and its duties;
   (7) Planning and conduct of a study;
   (8) Report of the test results;
   (9) Storage of records, samples and materials.
7. **Objective and rationale:** To ensure the reliability of the test data required for notification of new chemical substances.

8. **Relevant documents:**
   
   (1) Law Concerning the Examination and Regulation of Manufacture, etc. of Chemical Substances;
   
   (2) Order Prescribing the Items of the Tests Relating to the New Chemical Substances.

9. **Proposed dates of adoption and entry into force:** 1 October 1985

10. **Final date for comments:** 10 January 1985

11. **Texts available from:** National enquiry point (x) or address of other body: