NOTIFICATION

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

1. Party to Agreement notifying: JAPAN

2. Agency responsible: Plant Protection Division, Agricultural Production Bureau, Ministry of Agriculture, Forestry and Fisheries

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):
   Agricultural chemicals (CCCN: 38.11)

5. Title: Establishment of Good Laboratory Practice Standards for Toxicological Studies on Agricultural Chemicals

6. Description of content: Good Laboratory Practice Standards include following matters:
   (1) Purpose and coverage of the standards
   (2) Organization of personnel; education and training for personnel; responsibility pertinent to the conduct of study
   (3) Designation of quality assurance unit and its duties
   (4) The standard of facilities (animal-care facilities, animal-supply facilities, facilities for handling test and control substances, laboratory operation area, archives, administrative facilities, etc.)
   (5) Design, function, location and control of equipment
   (6) Operation (preparation of standard operating procedure, etc.)
   (7) Determination, handling and storage of test and control substances
   (8) Preparation of protocol and performance of the study
   (9) Preparation of the report and records, storage of the relating materials
   (10) Confirmation taken by the Ministry of Agriculture, Forestry and Fisheries

7. Objective and rationale: For further assuring the quality and integrity of toxicological study data accompanied with the application for agricultural chemical registration

8. Relevant documents: Basic law is the Agricultural Chemicals Regulation Law.
   Good Laboratory Practice Standards have been published through administrative notice.

9. Proposed dates of adoption and entry into force: 1 October 1984

10. Final date for comments: 25 September 1984

11. Texts available from: National enquiry point or address of other body:

84-1737