SCHEDULE 1

PRINCIPLES OF GOOD LABORATORY PRACTICE (BASED ON ANNEX 2 TO THE DECISION OF 12TH MAY 1981 OF THE COUNCIL OF THE OECD ON THE MUTUAL ACCEPTANCE OF DATA FOR THE EVALUATION OF CHEMICAL PRODUCTS)

PART III

FACILITIES

General

6.—(1) The laboratory should be of suitable size, construction and location to meet the requirements of the safety study and minimise disturbances that would interfere with the validity of the safety study.

(2) The design of the laboratory should provide an adequate degree of separation of the different activities to ensure the proper conduct of each safety study.

Test system facilities

7.—(1) The laboratory should have a sufficient number of rooms or areas to ensure the isolation of test systems and the isolation of individual projects, involving substances known or suspected of being biohazardous.

(2) Suitable facilities should be available for the diagnosis, treatment and control of diseases, in order to ensure that there is no unacceptable degree of deterioration of test systems.

(3) There should be storage areas as needed for supplies and equipment. Storage areas should be separated from areas housing the test systems and should be adequately protected against infestation and contamination. Refrigeration should be provided for perishable commodities.

Facilities for handling test and reference substances

8.—(1) To prevent contamination or mix-ups, there should be separate areas for receipt and storage of the test and reference substances, and for the mixing of the test substances with a vehicle.

(2) Storage areas for the test substances should be separate from areas housing the test systems and should be adequate to preserve identity, concentration, purity, and stability, and ensure safe storage for hazardous substances.

Archive facilities

9. Space should be provided for archives for the storage and retrieval of raw data, reports, samples and specimens.

Waste disposal

10.—(1) Handling and disposal of wastes should be carried out in such a way as not to jeopardise the integrity of studies in progress.

(2) The handling and disposal of wastes generated during the performance of a safety study should be carried out in a manner which is consistent with pertinent regulatory requirements. This includes provision for appropriate collection, storage and disposal facilities, decontamination and transportation procedures, and the maintenance of records related to the preceding activities.