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 X

STORAGE AND RETENTION OF RECORDS AND MATERIAL

Storage and retrieval

25.—(1) Archives should be designed and equipped for the accommodation and the secure storage of—

(a) the study plans;

(b) the raw data;

(c) the final reports;

(d) the reports of laboratory inspections and study audits performed according to the quality assurance programme;

(e) samples and specimens.

(2) Material retained in the archives should be indexed so as to facilitate orderly storage and rapid retrieval.

(3) Only personnel authorised by management should have access to the archives. Movement of material in and out of the archives should be properly recorded.

Retention

26.—(1) The following should be retained for the period specified by the appropriate authorities—

(a) the study plan, raw data, samples, specimens and the final report of each safety study;

(b) records of all inspections and audits performed by the quality assurance programme;

(c) summary of qualifications, training, experience and job descriptions of personnel;

(d) records and reports of the maintenance and calibration of equipment;

(e) the historical file of standard operating procedures.

(2) Samples and specimens should be retained only as long as the quality of the preparation permits evaluation.

(3) If a laboratory or an archive contracting facility goes out of business and has no legal successor, the archive should be transferred to the archives of the sponsor of the safety study.