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 VII

STANDARD OPERATING PROCEDURES

General

18.—(1) A laboratory should have written standard operating procedures approved by management that are intended to ensure the quality and integrity of the data generated in the course of the safety study.

(2) Each separate laboratory unit should have immediately available standard operating procedures relevant to the activities being performed therein. Published text books, articles and manuals may be used as supplements to these standard operating procedures.

Application

19.—(1) Standard operating procedures should be available for, but not be limited to, the following categories of laboratory activities. The details given under each heading are to be considered as illustrative examples—

(a) Test and reference substances

receipt, identification, labelling, handling, sampling and storage;

(b) Apparatus and reagents

use, maintenance, cleaning, calibration of measuring apparatus and environmental control equipment; preparation of reagents;

(c) Record keeping, reporting, storage and retrieval

coding of studies, data collection, preparation of reports, indexing systems, handling of data, including the use of computerised data systems;

(d) Test system (where appropriate)

(i) room preparation and environmental room conditions for the test system,

(ii) procedures for receipt, transfer, proper placement, characterisation, identification and care of test system,

(iii) test system preparation, observation examinations before, during and at termination of the safety study,

(iv) handling of test system individuals found moribund or dead during the safety study,

(v) collection, identification and handling of specimens including necropsy and histopathol ogy;

(e) Quality assurance procedures

operation of quality assurance personnel in performing and reporting study audits, inspections and final study report reviews;

(f) Health and safety precautions

as required by national and/or international legislation or guidelines.