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 VIII

PERFORMANCE OF THE SAFETY STUDY

Study plan

20.—(1) For each safety study, a plan should exist in a written form prior to initiation of the study.

(2) The study plan should be retained as raw data.

(3) All changes, modifications, or revisions of the study plan, as agreed to by the study director, including justifications, should be documented, signed and dated by the study director, and maintained with the study plan.

Content of the study plan

21.—(1) The study plan should contain, but not be limited to, the following information—

(a) Identification of the test and reference substance

(i) a descriptive title,

(ii) a statement which reveals the nature and purpose of the safety study,

(iii) identification of the test substance by code or name (IUPAC, CAS number, etc.),

(iv) the reference substance to be used;

(b) Information concerning the sponsor and the laboratory

(i) name and address of the sponsor,

(ii) name and address of the laboratory,

(iii) name and address of the study director;

(c) Dates

(i) the date of agreement to the study plan by signature of the study director, and when appropriate, of the sponsor and/or the laboratory management,

(ii) the proposed starting and completion dates;

(d) Test methods

reference to OECD test guidelines or other test guidelines to be used;

(e) Issues (where applicable)

(i) the justification for selection of the test system,

(ii) characterisation of the test system, such as the species, strain, substrain, source of supply, number, body weight range, sex, age and other pertinent information,

(iii) the method of administration and the reason for its choice,

(iv) the dose levels and/or concentration, frequency, duration of administration,

(v) detailed information on the experimental design, including a description of the chronological procedure of the safety study, all methods, materials and conditions, type and frequency of analysis, measurements, observations and examinations to be performed;

(f) Records

a list of records to be retained.

Conduct of the safety study

22.—(1) A unique identification should be given to each safety study. All items concerning this safety study should carry this identification.

(2) The safety study should be conducted in accordance with the study plan.

(3) All data generated during the conduct of the safety study should be recorded directly, promptly, accurately, and legibly by the individual entering the data. These entries should be signed or initialled and dated.

(4) Any change in the raw data should be made so as not to obscure the previous entry, and should indicate the reason, if necessary, for change and should be identified by date and signed by the individual making the change.

(5) Data generated as a direct computer input should be identified at the time of data input by the individual responsible for direct data entries. Corrections should be entered separately with the reason for the change, the date and the identity of the individual making the change.