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 II

QUALITY ASSURANCE PROGRAMME

General

4.—(1) The laboratory should have a documented quality assurance programme to ensure that studies performed are in compliance with the principles of good laboratory practice.

(2) The quality assurance programme should be carried out by an individual or by individuals designated by and directly responsible to management and who are familiar with the test procedures.

(3) This individual or these individuals should not be involved in the conduct of safety study being assured.

(4) This individual or these individuals should report any findings in writing directly to management and to the study director.

Responsibilities of the quality assurance personnel

5.—(1) The responsibilities of the quality assurance personnel should include, but not be limited to, the following functions—

(a) ascertaining that the study plan and standard operating procedures are available to personnel conducting the safety study;

(b) ensuring that the study plan and standard operating procedures are followed by periodic inspections of the laboratory and/or by auditing the safety study in progress. Records of such procedures should be retained;

(c) promptly reporting to management and the study director unauthorised deviations from the study plan and from standard operating procedures;

(d) reviewing the final reports to confirm that the methods, procedures, and observations are accurately described, and that the reported results accurately reflect the raw data of the safety study;

(e) preparing and signing a statement, to be included with the final report, which specifies the dates inspections were made and the dates any findings were reported to management and to the study director.