

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 V

TEST SYSTEMS

Physical/chemical

14.—(1) Apparatus used for the generation of physical/chemical data should be suitably located and of appropriate design and adequate capacity.

(2) Reference substances should be used to assist in ensuring the integrity of the physical/chemical test systems.

Biological

15.—(1) Proper conditions should be established and maintained for the housing, handling and care of animals, plants, and microbial as well as other cellular and sub-cellular systems, in order to ensure the quality of the data.

(2) In addition, conditions should comply with appropriate national regulatory requirements for the import, collection, care and use of animals, plants, and microbial as well as other cellular and sub-cellular systems.

(3) Newly received animal and plant test systems should be isolated until their health status has been evaluated. If any unusual mortality or morbidity occurs, this lot of test systems should not be used in studies and, when appropriate, humanely destroyed.

(4) Records of source, date of arrival and arrival condition should be maintained.

(5) Animal, plant, and microbial as well as other cellular and sub-cellular test systems should be acclimatised to the test environment for an adequate period before a safety study is initiated.

(6) All information needed to properly identify the test systems should appear on their housing or containers.

(7) The diagnosis and treatment of any disease before or during a safety study should be recorded.