SCHEDULE 1

GOOD LABORATORY PRACTICE PRINCIPLES(BASED ON SECTION II OF THE ANNEX TO COUNCIL DIRECTIVE 87/18/EEC,AS AMENDED BY COMMISSION DIRECTIVE 1999/11/EC)

PART V

TEST SYSTEMS

Physical/Chemical

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

(2) The integrity of the physical/chemical test systems should be ensured.

Biological

2.—(1) Proper conditions should be established and maintained for the storage, housing, handling and care of biological test systems, in order to ensure the quality of the data.

(2) Newly received animal and plant test systems should be isolated until their health status has been evaluated. If any unusual mortality or morbidity occurs, the relevant lot should not be used in regulatory studies and, where appropriate, should be humanely destroyed. At the experimental starting date of a regulatory study, test systems should be free of any disease or condition that might interfere with the purpose or conduct of the study. Test systems that become diseased or injured during the course of a regulatory study should be isolated and treated, if necessary to maintain the integrity of the study. Any diagnosis and treatment of any disease before or during a regulatory study should be recorded.

(3) Records of source, date of arrival, and the arrival condition of test sytems should be maintained.

(4) Biological test systems should be acclimatised to the test environment for an adequate period before the first administration or application of the test or reference item.

(5) All information needed to identify properly the test systems should appear on their housing or containers. Individual test systems that are to be removed from their housing or containers during the conduct of the regulatory study should bear appropriate identification, wherever possible.

(6) During use, housing or containers for test systems should be cleaned and sanitised at appropriate intervals. Any material that comes into contact with the test system should be free of contaminants at levels that would interfere with the regulatory study. Bedding for animals should be changed as required by sound husbandry practice. Use of pest control agents should be documented.

(7) Test systems used in field studies should be located so as to avoid interference in the regulatory study from spray drift and from past usage of pesticides.