STATUTORY INSTRUMENTS

1997 No. 654

HEALTH AND SAFETY

The Good Laboratory Practice Regulations 1997

Made - - - -	*6th March 1997*
Laid before Parliament	*7th March 1997*
Coming into force	*1st April 1997*

THE GOOD LABORATORY PRACTICE REGULATIONS 1997

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 I — LABORATORY ORGANISATION AND PERSONNEL

1. The management's responsibilities
2. The study director's responsibilities
3. Personnel responsibilities

PART II — QUALITY ASSURANCE PROGRAMME

4. General
5. Responsibilities of the quality assurance personnel

PART III — FACILITIES

6. General
7. Test system facilities
8. Facilities for handling test and reference substances
9. Archive facilities
10. Waste disposal

PART IV — APPARATUS, MATERIALS AND REAGENTS

11. Apparatus
12. Materials
13. Reagents

PART V — TEST SYSTEMS

14. Physical/chemical
15. Biological

PART VI — TEST AND REFERENCE SUBSTANCES

16. Receipt, handling, sampling and storage
17. Characterisation

PART VII — STANDARD OPERATING PROCEDURES

18. General
19. Application

PART VIII — PERFORMANCE OF THE SAFETY STUDY

20. Study plan
21. Content of the study plan
22. Conduct of the safety study

PART IX — REPORTING OF SAFETY STUDY RESULTS

23. General
24. Content of the final report

PART X — STORAGE AND RETENTION OF RECORDS AND MATERIAL

25. Storage and retrieval
26. Retention

SCHEDULE 2 — INSPECTION PROCEDURES AND STUDY AUDITS (BASED ON ANNEX B TO THE GLP INSPECTION AND VERIFICATION DIRECTIVE)

PART I — INSPECTION PROCEDURES

1. Pre-inspection
2. Starting conference
3. Organisation and personnel
4. Quality assurance programme
5. Facilities