ANNEX I

THE OECD PRINCIPLES OF GOOD LABORATORY PRACTICE (GLP)

SECTION I

INTRODUCTION

Preface

Government and industry are concerned about the quality of non-clinical health and environmental safety studies upon which hazard assessments are based. As a consequence, OECD Member States have established criteria for the performance of these studies.

To avoid different schemes of implementation that could impede international trade in chemicals, OECD Member States have pursued international harmonisation of test methods and good laboratory practice. In 1979 and 1980 an international group of experts, established under the special programme on the control of chemicals, developed the 'OECD principles of good laboratory practice' (GLP), utilising common managerial and scientific practices and experience from various national and international sources. These principles of GLP were adopted by the OECD Council in 1981, as an Annex to the Council Decision on the mutual acceptance of data in the assessment of chemicals (C(81) 30 (final)).

In 1995 and 1996, a new group of experts was formed to revise and update the principles. The current document is the result of the consensus reached by that group. It cancels and replaces the original principles adopted in 1981.

The purpose of these principles of good laboratory practice is to promote the development of quality test data. Comparable quality of test data forms the basis for the mutual acceptance of data among countries. If individual countries can confidently rely on test data developed in other countries, duplicative testing can be avoided, thereby saving time and resources. The application of these principles should help to avoid the creation of technical barriers to trade, and further improve the protection of human health and the environment.

1. Scope

These principles of good laboratory practice should be applied to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms. The purpose of testing these test items is to obtain data on their properties and/or their safety with respect to human health and/or the environment.

Non-clinical health and environmental safety studies covered by the principles of good laboratory practice include work conducted in the laboratory, in greenhouses, and in the field.

Unless specifically exempted by national legislation, these principles of good laboratory practice apply to all non-clinical health and environmental safety studies required by regulation for the purpose of registering or licensing pharmaceuticals, pesticides, food and feed additives, cosmetic products, veterinary drug products and similar products, and for the regulation of industrial chemicals.

2. Definition of terms

2.1. Good laboratory practice

Good laboratory practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

2.2. Terms concerning the organisation of a test facility

1. Test facility means the persons, premises and operational unit(s) that are necessary for conducting the non-clinical health and environmental safety study. For multisite studies, those which are conducted at more than one site, the test facility comprises the site at which the study director is located and all individual test sites, which individually or collectively can be considered to be test facilities.

2. Test site means the location(s) at which a phase(s) of a study is conducted.

3. Test facility management means the person(s) who has the authority and formal responsibility for the organisation and functioning of the test facility according to these principles of good laboratory practice.

4. Test site management (if appointed) means the person(s) responsible for ensuring that the phase(s) of the study, for which he is responsible, are conducted according to these principles of good laboratory practice.

5. Sponsor means an entity which commissions, supports and/or submits a non-clinical health and environmental safety study.

6. Study director means the individual responsible for the overall conduct of the non-clinical health and environmental safety study.

7. Principal investigator means an individual who, for a multisite study, acts on behalf of the study director and has defined responsibility for delegated phases of the study. The study director's responsibility for the overall conduct of the study cannot be delegated to the principal investigator(s); this includes approval of the study plan and its amendments, approval of the final report, and ensuring that all applicable principles of good laboratory practice are followed.

8. Quality assurance programme: means a defined system, including personnel, which is independent of study conduct and is designed to assure test facility management of compliance with these principles of good laboratory practice.

9. Standard operating procedures (SOPs) means documented procedures which describe how to perform tests or activities normally not specified in detail in study plans or test guidelines.

10. Master schedule means a compilation of information to assist in the assessment of workload and for the tracking of studies at a test facility.

2.3. Terms concerning the non-clinical health and environmental safety study

1. Non-clinical health and environmental safety study, henceforth referred to simply as ‘study’, means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities.

2. Short-term study means a study of short duration with widely used, routine techniques.

3. Study plan means a document which defines the objectives and experimental design for the conduct of the study, and includes any amendments.

4. Study plan amendment means an intended change to the study plan after the study initiation date.

5. Study plan deviation means an unintended departure from the study plan after the study initiation date.

6. Test system means any biological, chemical or physical system, or a combination, thereof used in a study.

7. Raw data means all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognised as capable of providing secure storage of information for a time period as stated in section 10 below.

8. Specimen means any material derived from a test system for examination, analysis, or retention.

9. Experimental starting date means the date on which the first study-specific data are collected.

10. Experimental completion date means the last date on which data are collected from the study.

11. Study initiation date means the date the study director signs the study plan.

12. Study completion date means the date the study director signs the final report.

2.4. Terms concerning the test item

1. Test item means an article that is the subject of a study.

2. Reference item (control item) means any article used to provide a basis for comparison with the test item.

3. Batch means a specific quantity or lot of a test item or reference item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such.

4. Vehicle means any agent which serves as a carrier used to mix, disperse, or solubilise the test item or reference item to facilitate the administration/application to the test system.