Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version) (Text with EEA relevance)

ANNEX I

THE OECD PRINCIPLES OF GOOD LABORATORY PRACTICE (GLP)

SECTION I

INTRODUCTION

8. Quality assurance programme: means a defined system, including personnel, which...
9. Standard operating procedures (SOPs) means documented procedures which describe how...
10. Master schedule means a compilation of information to assist in...

2.3. Terms concerning the non-clinical health and environmental safety study
1. Non-clinical health and environmental safety study, henceforth referred to simply...
2. Short-term study means a study of short duration with widely...
3. Study plan means a document which defines the objectives and...
4. Study plan amendment means an intended change to the study...
5. Study plan deviation means an unintended departure from the study...
6. Test system means any biological, chemical or physical system, or...
7. Raw data means all original test facility records and documentation,...
8. Specimen means any material derived from a test system for...
9. Experimental starting date means the date on which the first...
10. Experimental completion date means the last date on which data...
11. Study initiation date means the date the study director signs...
12. Study completion date means the date the study director signs...

2.4. Terms concerning the test item
1. Test item means an article that is the subject of...
2. Reference item (control item) means any article used to provide...
3. Batch means a specific quantity or lot of a test...
4. Vehicle means any agent which serves as a carrier used...

SECTION II

GOOD LABORATORY PRACTICE PRINCIPLES

1. Test facility organisation and personnel

1.1. Test facility management's responsibilities
1. Each test facility management should ensure that these principles of...
2. At a minimum it should:
3. When a phase(s) of a study is conducted at a...

1.2. Study director's responsibilities
1. The study director is the single point of study control...
2. These responsibilities should include, but not be limited to, the...

1.3. Principal investigator's responsibilities

1.4. Study personnel's responsibilities
1. All personnel involved in the conduct of the study must...
2. Study personnel will have access to the study plan and...
3. All study personnel are responsible for recording raw data promptly...
4. Study personnel should exercise health precautions to minimise risk to...

2. Quality assurance programme

2.1. General
1. The test facility should have a documented quality assurance programme...
2. The quality assurance programme should be carried out by an...
3. This individual(s) should not be involved in the conduct of...

2.2. Responsibilities of the quality assurance personnel

(**1**) OJ C 85, 8.4.2003, p. 138.

(**2**) Opinion of the European Parliament of 1 July 2003 (not yet published in the Official Journal) and Decision of the Council of 20 January 2004.

(**3**) OJ L 15, 17.1.1987, p. 29. Directive as amended by Commission Directive 1999/11/EC (OJ L 77, 23.3.1999, p. 8).

(**4**) OJ 196, 16.8.1967, p. 1. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

(**5**) OJ L 311, 28.11.2001, p. 1.

(**6**) OJ L 311, 28.11.2001, p. 67. Directive as amended by Commission Directive 2003/63/EC (OJ L 159, 27.6.2003, p. 46).