PROCEDURES FOR ENVIRONMENTAL RISK ASSESSMENT OF PLANT PROTECTION PRODUCTS

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Abstract: In compliance with European legislation, the environmental risk assessment for plant protection products is a very important stage, having as aim to approve and place on the market only those products which meet certain toxicity criteria of some environmental components (such as: birds, aquatic organisms, bees, earthworms, soil microorganisms, useful insects, other than bees). To answer European standards requirements regarding the environmental risks assessment for plant protection products, in the GLP - LECO they have been developed general procedures, quality assurance procedures, and the specific technical and working procedures. Their elaboration was based on OECD Guidelines taking into account the specific conditions of our Institute test facilities that have been developed: 13 General Procedures, 2 Quality Assurance Procedures, and 8 specific Operating Procedures.

Key words: Good laboratory Practice, General procedures, Standard Operating Procedures, Quality Assurance Plan

INTRODUCTION

The substances control legislation is seeking the risks prevention of their potential danger emphasized after they have been tested and assessed. Plant protection products assessment was based on the quality safety data. These demands represent the fundamental principle of this legislation. Good Laboratory Practice Principle (GLP) is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. The OECD Principles of Good Laboratory Practice were first developed by an Expert Group on GLP established in 1978 under the Special Programme on the Control of Chemicals. OECD Principles of a Good Laboratory Practice (Guide no.1) are:

1. Test Facility Organization and Personnel
2. Quality Assurance Plan
3. Facilities
4. Apparatus, Material and Reagents
5. Test systems
6. Test and Reference Items
7. Standard Operating Procedures
8. Performance of the Study
9. Reporting of Study Results
10. Storage and Retention of Records and Materials

Good Laboratory Practice application and implementation to Romania is legalized by some regulation acts presented in the References annex of the study (GD No.63/2002, GD No. 266/2006, GD No. 448/2007) . In order to avoid the introduction of different implementation schemes which could impede the international trade in chemicals, OECD Member countries have pursued international harmonization of test methods and good laboratory practice. Having the advantage created by the different national and international plans opportunities, RDIPP assured the necessary

conditions to carry out some environmental impact studies of plant protection products, in compliance to GLP demands.

Scope

The purpose of these Principles of Good Laboratory Practice should be applied to the non-clinical safety testing of test items contained in different products, including plant protection products. 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 concerning their properties and/or their safety with respect to the environment

MATERIAL AND METHOD

The environmental risk assessment of plant protection products is based on the following testing systems: fish, daphnia, algae, birds, earthworms, bees, other beneficial organisms than bees, soil microorganisms etc. (fig.1). Are followed the working methods described in OECD guides, specific for each testing system.

RESULTS

The demands of the ten OECD principles of GLP implementations, as well as the principles of other plant protection products testing guides for certain biological systems, in the actual conditions of "LECO" test facility and test site working in RDIPP, needed the achievement of a structure including different types of procedures, and providing of an available technical and material support.

The supply with last generation laboratory equipment of performing measurement and control apparatus, it represents a priority condition which is the foundation of the products quality results.

GLP "LECO" test facility frame structure includes the following procedures types: 13 general procedures (GP), 2 quality system procedures (QSP), 8 standard operation procedures (SOP), working procedures (WP), and technical procedures specific for each study (TP), on which is issued the GLP certification for eco-toxicological tests.

These documentations are GLP "LECO" test facility, property of RDIPP and are stored in its sites. The content of each procedure includes: 1) objective, 2) application domain, 3) references documents, 4) terminology and abbreviations, 5) procedures rules, 6) responsibilities, 7) registering, 8) annexes. Each procedure aims the achievement of certain activities representing the scope of it.

GENERAL PROCEDURES (GP)

General procedures are essential GLP Quality System documents, which regulate the implementation modality of each system element. The general procedures are presented as it follows:

1. *GLP quality system procedures elaboration; cod:* GP *-01 GLP*; established the format and the checking out methodology, approval, revision and dissemination of the Procedures used in the GLP studies, as well as the involved personnel responsibilities. All these are applicable at the elaboration, approval, revision and dissemination of all procedures used in GLP "LECO" Test facility of RDIPP.

2. Management analyses; cod: GP *-02 GLP;* established the way how the test site management working GLP test facility will evaluate the activities for ensuring that the phases of the study are conducted according to these GLP principles.

3. Personnel; cod: GP *-03 GLP;* established the study requests and the scheme of organization, as well as the personnel responsibilities involved in the GLP study/testing management.

4. Study Management; cod: GP *-04 GLP;* established supplying of enough qualified personnel operating GLP test facility, needed for GLP studies good working, as well as the personnel responsibilities involved in this activity.

5. Personnel training; cod: GP *-05 GLP;* established the training modality and the responsibilities of the personnel involved in GLP studies.

6. Maintenance and access in the test system facilities; cod: GP *-06 GLP;* established the way of action and maintenance of cleaning in the test facility, the access in the test site, as well as the responsibilities of the involved personnel in this activity.

7. Archive; cod: GP-*07 GLP;* established the way of storage and preservation of the study documents, registrations and materials, as well as the responsibilities of the personnel involved in this activity.
8. Control and maintenance of the storage areas; cod: GP *-08 GLP;* established the way of control and maintenance of the storage areas, as well as the responsibilities of the involved personnel in this activity.
9. Protection and control measures for the human health and environment; cod: GP *-09 GLP;* established the means of control and protection for the personnel and environment health, and responsibilities for the personnel involved in this activity.
10. Third party services contracting; cod: GP-*10 GLP;* established the external services contracting modality and conditions, subcontracting of some adherent studies respectively, and the responsibilities of the personnel involved in this activity.
11. Materials, equipments and reagents supply; cod: GP-*11 GLP;* established the modality and conditions of materials, equipments and reagents provision, and the responsibilities of the personnel involved in this activity.
12. Testing systems supply; cod: GP-*12 GLP;* established the testing biological systems supply modality for GLP studies, as well as the responsibilities for the personnel involved in this activity.
13. Testing systems facilities and materials supply; cod: GP *-13 GLP;* established the testing system materials and facilities way of provision existing in the test facility, as well as the responsibilities for the personnel involved in the activity.

QUALITY ASSURANCE PROCEDURES (QAP) - the test facility should have a documented QA Plan to assure that the performed studies are in compliance with the Principles of GLP
1. Quality Assurance Plan; QAP-01 GLP; established the Quality Assurance Plan way of operating, and the responsibilities for the personnel involved in this activity.
2. Contractors' audit; QAP-02 GLP; established the GLP test facility contractors' assessment modality, and the responsibilities for the personnel involved in the activity.

STANDARD OPERATION PROCEDURES (SOP)

Standard operation procedures are documents approved by test facility management intended to ensure the quality and integrity of the generated data by that test facility. Revisions of these SOPs should be approved by test facility management. SOPs are as follow:
1. Materials and equipments; SOP-*01 GLP;* established the quality and quantity general methodology, ensure machines and equipment control, calibration and maintenance for GLP study, as well as the responsibilities for the personnel involved in this activity.
2. Reagents and solvents control; SOP-*02 GLP;* established the quantity and quality control general methodology for study reagents.
3. Testing systems control and maintenance; SOP-*03 GLP;* established the control and maintenance general methodology in GLP studies, as well as the responsibilities for the personnel involved in these activities.
4. The characterization and identification of testing and reference substances; SOP-*04 GLP;* established the testing and reference substance characterization and identification methodology in GLP studies, as well as the responsibilities for the personnel involved in these activities.
5. Documents checking out; SOP-*05 GLP;* established the checking out rules for the documents included in the GLP quality control system, and the responsibilities for the personnel involved in this activity.
6. Study plan; SOP-*06 GLP;* established the Study Plan preparation modality, and the responsibilities for the personnel involved in this activity. Each Study Plan should be approved by dated signature of the Study Director, test facility management, and sponsor, and verified for GLP compliance by the QA personnel
7. Study report; SOP-*07 GLP;* established the way of Study Report design, and the responsibilities for the personnel involved in this activity.
8. Recording control; SOP-*08 GLP;* established the rules regarding the GLP study quality control registrations, and the responsibilities for the personnel involved in this activity.

WORKING PROCEDURE (WP)

Working procedures are documents describing an activity or a measure equipment procedure operated by a single person for the determination of same limitative parameters in a restricted domain and number of determinations. The working procedure achieved: weighing (WP-01 GLP); pH measurement (WP-02 GLP); solved oxygen concentration measurement (WP-03 GLP); humidity measurement (WP-05 GLP); testing substrate preparation (WP-06), etc.

TECHNICAL PROCEDURE (TP)

These procedures are documents describing the working actions on a plant protection product testing during the performance of the study, complying to the OECD method, including the technical information on the study process, containing table format where are gathered the rude primary data, and the observations upon the study. This type of procedure is carried out at the initiation of each study.

CONCLUSIONS

The present procedures are complying with the GLP demands and adjusted with the actual conditions achieved in LECO GLP test facility from RDIPP.

They have been elaborated: 13 General Procedures, 2 Quality Assurance Plan, 8 Standard Operation Procedures, Working procedures and instructions for Measuring and Control Equipment.

The achieved procedures are the property of LECO test facility; the consulting of the documents is allowed only by the Study Management approval.

GLP LECO Test Facility has been supplied with modern and performing technical and material equipment of the last generation in order to enable the achievement of a high quality testing data.

For the testing methods used in plant protection products risk assessment it is compulsory to have a GLP certification.

REFERENCES

Government Decision No. 63/2002 regarding the Good Laboratory Practice Principles approval.
Government Decision No. 266/2006 amending and completing the Government Decision No. 63/2002
Decision No. 448/2007.05.16 amending the Government Decision No. 63/2002 regarding the Good Laboratory Practice Principles approval, as well as the inspection and control of the decision observance on chemical substances testing.
OECD guideline series regarding the GLP principles and conformity monitoring; GLP OECD Principles (revised in 1997)
OECD guidelines for testing of chemicals

Fig.1 Testing biological systems