Health Canada Santé Canada

Canada

Pest Management Regulatory Agency

Good Laboratory Practice Requirements for Scientific Studies Supporting Pest Control Products

PMRA Guidance Document

Protecting human health and the environment

Protéger la santé humaine et l'environnement

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Updated	Update/Rationale:
May 2023	Replaces DIR98-01 as part of PMRA's document renewal program.
July 1998	Previous release.

Disclaimer

This document does not constitute part of the *Pest Control Products Act* or its regulations, and, in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

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1.0 Purpose

This Guidance Document informs applicants and other interested groups about Health Canada's Pest Management Regulatory Agency (PMRA) Good Laboratory Practice (GLP) requirements for scientific studies. These studies are sponsored or conducted by applicants to support their application to register a pest control product.

The GLP principles include the organizational process and the conditions under which non-clinical laboratory and field studies are planned, conducted, monitored, recorded, and reported. It promotes the quality and validity of the test data, and improves the international acceptance of data generated in adherence to its principles.

GLP requirements are a component of PMRA's harmonization with other Organisation for Economic Co-operation and Development (OECD) member countries. These requirements improve our ability to share the registration process, through the exchange of reviews based on mutually acceptable studies that are conducted following the GLP principles.

This document is an update to the GLP Regulatory Directive (DIR98-01). This document has been revised and re-formatted to current applicable standards.

2.0 Background

Sections 6 and 8 of the Pest Control Products Regulations require that an application to register or amend the registration of a pest control product must include information that the Minister may require to evaluate the health and environmental risks, and, the value of the pest control product, including the results of scientific investigations. Therefore, the completion of safety related studies in accordance with the acceptable GLP principles is required to support the corresponding data quality.

The adherence to the GLP principles promotes the high quality and validity of test data. It covers the organizational process and conditions under which non-clinical studies are planned, performed, monitored, recorded, and reported.

The OECD has developed Test Guidelines and Principles of the GLP to promote international cooperation. A 1981 OECD Council Decision [C(81)30(Final)] recommended that member countries apply these guidelines and principles in the testing of chemicals. Data generated in an OECD member country in accordance with the OECD Test Guidelines, and the OECD Principles of GLP shall be considered for risk assessment in other member countries.

A 1989 OECD Council Decision-Recommendation [C(89)87(Final)] determined that member countries shall establish procedures for monitoring compliance with the GLP, based on test facility inspections and study audits [Part I, 1(i)]. In addition, Part II of the same Decision-Recommendation limited the 1981 member country mutual acceptance of data requirements to those countries that establish these GLP Monitoring Authorities (GLPMA). Consequently, most OECD countries have implemented the OECD Principles of GLP and the supporting monitoring programs.

3.0 GLP standards

The OECD Principles of Good Laboratory Practice (OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 1, ENV/MC/CHEM(98)17, or subsequent revisions) are adopted as the GLP standard by Health Canada's PMRA. This document is listed as a reference in References: OECD GLP .

Studies that are conducted in accordance with alternative GLP standards and deemed to be consistent with the OECD Principles of GLP, also qualify to be submitted for review by the PMRA.

4.0 Scope

This Guidance Document informs applicants and other interested groups about Health Canada's PMRA GLP requirements for scientific studies that are sponsored or conducted by applicants to support their application to register a pest control product.

The laboratory and field studies done according to the GLP include, but are not limited to:

- mammalian toxicity
- magnitude of residue
- plant metabolism
- rotational crop uptake
- soil metabolism
- soil dissipation
- bioaccumulation
- effects on non-target organisms
- effects on mesocosms

All studies sponsored or conducted by applicants to support their application to register a pest control product and submitted to PMRA must be in compliance with GLP standards. A current list of identifying tests/studies that require GLP compliance by data code is available from the Guidance for Developing Datasets for Conventional Pest Control Product Applications: Data Codes for Parts 1, 2, 3, 4, 5, 6, 7 and 10, and Revised Environmental Data Requirements (PRO2016-01) for Data Codes for Part 8 and 9, available on Canada.ca.

Non-GLP studies that are scientifically sound and have undergone vigorous peer review processes may be accepted to provide supporting information. The use of data from GLP and non-GLP studies is assessed in accordance with the Information Note - Determining Study Acceptability for use in Pesticide Risk Assessments (August 2019), and is available on Canada.ca.

5.0 Compliance monitoring

The 1989 OECD Council Decision-Recommendation [C(89)87(Final)] identified the requirement for a national authority, or authorities, to monitor compliance to GLP principles and recommended further guidance documents as the basis for developing and implementing like procedures:

- The OECD Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals, 12 May 1981 - [C(81)30/Final], amended on 26 November 1997 - [C(97)186/Final] ("OECD Decision") with its Test Guidelines ("OECD Test Guidelines") and Principles of Good Laboratory Practice ("OECD GLP Principles")
- The OECD Council Decision-Recommendation on Compliance with Principles of Good Laboratory Practice, 2 October 1989, [C(89)87/Final] ("OECD Decision Recommendation") with its Revised Guides for Compliance Monitoring Procedures for GLP; the Revised Guidance for the Conduct of Laboratory Inspections and Study Audits; and, the Guidance for the Preparation of GLP Inspection Reports

The purpose of the OECD Principles of Good Laboratory Practice is to promote the development of quality non-clinical test data.

Part I of the 1989 OECD Decision-Recommendation requires a Member country, in which the testing of chemicals for the purposes of assessment are related to the protection of health and the environment being carried out; is pursuant to the principles of good laboratory practice that are consistent with the OECD GLP Principles; to establish national procedures for monitoring compliance with OECD GLP Principles based on laboratory inspections and study audits; and, to designate an authority to discharge the functions required by the procedures for monitoring compliance to these Principles.

Part II of the 1989 OECD Decision-Recommendation requires a Member country to recognize the assurance by another Member country that the test data have been generated in accordance with GLP Principles, if other like Member country complies with this Part and Part I of the Decision-Recommendation.

Health Canada recognizes the importance of the Standards Council of Canada (SCC)'s role as the Monitoring Authority in their GLP Compliance Program for pest control products since 1998, and for pharmaceuticals, radiopharmaceuticals, and biologic drugs since 2010.

Health Canada has cooperated with the Standards Council of Canada (SCC)[11] to establish a GLP Compliance Program. The Council serves as a Good Laboratory Practice

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[1] The Standards Council of Canada is a Crown Corporation whose mandate is to foster and promote standardization to advance the national economy; to benefit the health, safety and welfare of the public; to facilitate domestic and international trade; and, to further international cooperation in the field of standards.

Monitoring Authority (GLPMA) in accordance with the 1989 OECD Council Decision. It operates in a manner consistent with the OECD document, "Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice" (OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 2 (revised), Monograph #110, 1995, or subsequent revisions).

The program functions on a fee-for-service basis between the applying test facility and the SCC, with the resulting recognition being based upon inspections and study audits. These inspections and audits are conducted in accordance with the OECD document, Revised Guidance for the Conduct of Test Facility Inspections and Study Audits (OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 3 (revised), Monograph #111, 1995 or subsequent revisions).

The objective of the inspection is to determine whether a facility complies with the OECD GLP principles and requirements, and consists of both a facility inspection and audits of selected ongoing and/or completed relevant studies.

The GLPMA recognizes GLP compliance by issuing formal documentation to successful test facilities that support the validity of their study GLP compliance statements and the acceptability of these studies in the OECD member countries. Then, the GLPMA updates its list of inspected facilities to identify the facility, area(s) of expertise, the dates/type of inspection and compliance status, and, provides this information to Health Canada following each revision.

Typically, routine inspections occur on a two-year cycle.

SCC administers a GLP compliance program for studies (i.e., "GLP Recognition Program") which designates GLP criteria.

The successful compliance is evidenced as a "GLP certificate of recognition".

The "GLP certificate of recognition" will be recognized by Health Canada that the test data has been generated in accordance to GLP Principles and is acceptable for data submission to authorize the eventual marketing of the drug or pest control product in Canada.

The Council's Conformity Assessment Division[2] can be contacted for a detailed description of the SCC GLP Compliance Program, including application instructions and the fee schedule.

[2] The SCC can be contacted through the following options, current at the time of publication: Telephone: +1 (613) 238-3222 Facsimile: +1 (613) 995-4564 Internet: www.scc.ca. The program document and corresponding GLP application/checklists are available from the Council as CANP-1583 and CAN-P-1584, respectively.

6.0 PMRA GLP study compliance

6.1 Recognition of compliance

It is emphasized that the GLPMA is only involved in the recognition of compliance to the principles of GLP. It does not assess the suitability of the study's design, objectives, test system, or the interpretation of results that are functionally inherent to the regulatory role of the PMRA.

A PMRA study acceptability evaluation, as it relates to use in pesticide risk assessment, is assessed in accordance with the Information Note - Determining Study Acceptability for use in Pesticide Risk Assessments (August 2019) available on Canada.ca.

6.2 Non-GLP supported test facilities

If a compliance statement is not supported by a GLPMA recognition of the test facility, the PMRA may refuse to consider the study as reliable for the purposes of supporting an application for a research permit, or registration. Studies to which the principles of GLP apply, but do not comply with these principles, must be accompanied by a waiver request at the time of submission. This waiver request is reviewed by PMRA to assess acceptability with respect to non-conformance to the principles of GLP. The PMRA's acceptance/rejection decision is based upon the rationale provided, and the relative significance and potential impact of the study.

6.3 Statement of false compliance

Submission of a false compliance statement may form the basis for cancellation, suspension, or modification of the research permit or registration; or, denial or rejection of an application for a research permit or registration.

7.0 Storage and retention of records and materials

All records and materials pertaining to a study shall be stored in archives in accordance with the OECD Principles of GLP. Archive conditions shall protect the contents from untimely deterioration.

These retention periods shall be observed:

7.1 Submissions in support of an application

When the results are submitted to the PMRA in support of an application for a research permit or registration, all documentation, files, and raw data shall be kept at least until the review of the submission has been completed.

7.2 Grant of permit or registration

When a research permit or registration has been granted, all documentation, files, and raw data shall be kept as long as the sponsor or its successor holds the pertinent research permit or registration.

7.3 Retention of specimens, test and control substances

Specimens and samples of test and control substances, and special preparations shall be kept only as long as the quality of the preparation permits re-analysis. The date, reasons, and authority for disposal shall be specified in the archive.

7.4 Transfer to study sponsor (archives)

If a test facility or an archive contracting facility goes out of business and has no legal successor, the archive shall be transferred to the archives of the sponsor of the study. This is the responsibility of the sponsor. Additionally, in the case of a sponsor going out of business, the archive shall be transferred to its legal successor.

8.0 Glossary

The Glossary contains a listing of PMRA abbreviations referenced in this Guidance document.

8.1 PMRA abbreviations

GLP - Good Laboratory Practice

GLPMA - Good Laboratory Practices Monitoring Authority

OECD - Organisation for Economic Cooperation and Development

SCC - Standards Council of Canada

9.0 References: OECD GLP documents

These documents are derived from the OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring.[3] They provide further guidance on GLP implementation and are current as of the publication date of this Guidance Document:

Document	Title
Number 1	OECD Principles on Good Laboratory Practice (ENV/MC/CHEM(98)17)
Number 2	Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice (Environment Monograph No. 110)
Number 3	Revised Guidance for the Conduct of Laboratory Inspections and Study Audits (Environment Monograph No. 111)

[3] At the time of this Guidance Document publication, these reference documents were available on the Internet in Portable Document Format (PDF) at https://www.oecd.org/chemicalsafety/testing.

Number 4	Quality Assurance and GLP (ENV/JM/MONO(99)20)
Number 5	Compliance of Laboratory Suppliers with GLP Principles (ENV/JM/MONO(99)21)
Number 6	The Application of the GLP Principles to Field Studies (ENV/JM/MONO(99)22)
Number 7	The Application of the GLP Principles to Short-Term Studies (ENV/JM/MONO(99)23)
Number 8	The Role and Responsibilities of the Study Director in GLP Studies (ENV/JM/MONO(99)24)
Number 9	Guidance for the Preparation of GLP Inspection Reports (Environment Monograph No. 115)
Number 10	The Application of the GLP Principles to Computerized Systems (Advisory Document No. 17)
Number 11	The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP (ENV/MC/CHEM(98)16)