Pest Management Regulatory Agency

Information Note: Determining Study Acceptability for use in Pesticide Risk Assessments

28 March 2024 (Amended from 2019 version)

Introduction

All pesticides used in Canada must undergo a rigorous scientific assessment process that provides reasonable certainty that no harm to human health or the environment will occur when pesticides are used according to label directions.

Pesticides are regulated federally under the *Pest Control Products Act* and its regulations, which are administered by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA conducts science-based risk assessments for new pesticides, as well as for registered pesticides that must be re-evaluated on a cyclical basis.

Information considered in the risk assessments may come from scientific test data submitted by pesticide companies, studies published in open peer-reviewed scientific literature, and other sources.

This Information Note explains how the PMRA determines if scientific information is acceptable for use in pesticide risk assessments. It describes the types of studies that the PMRA considers for new registrations and re-evaluations and the criteria for study acceptability and use in risk assessments.

Overall, regulatory authorities from the Organisation for Economic Co-operation and Development (OECD) member countries, including Canada, evaluate the acceptability of scientific test data and open literature studies for use in pesticide evaluations in a consistent manner.

Data sources for pesticide risk assessments

As part of the registration application for a new pesticide, a company must submit a comprehensive set of scientific test data, including exposure and toxicity studies conducted according to internationally accepted guidelines. Typically, hundreds of studies are required to register a new pesticide.

Canada

In addition to the required scientific test data, the PMRA also considers available additional information, including:

- Peer-reviewed studies from scientific journals
    - when review articles are available, the PMRA prefers to assess the referenced primary literature sources that contain the original research
- Reviews from other regulatory bodies
- Incident reports
- Human health and environmental monitoring data.

For a new pesticide, very little or no additional information may be available, particularly if another regulatory body has not registered it. For older pesticides undergoing re-evaluation, additional information is more often available.

Criteria for study acceptability

For both new pesticides and re-evaluations, the PMRA evaluates all available studies against a set of criteria to determine whether they are acceptable for inclusion in the risk assessment. Acceptable studies may have deficiencies and limitations; and if so, these are taken into consideration when using the information from the study. The PMRA's criteria for acceptability of studies is shown in Table 1.

Scientific test data

Most scientific test data submitted by pesticide companies follow specific guidelines designed internationally by scientists and regulators to ensure that the study is scientifically sound. There are hundreds of different types of guideline studies, for example, the OECD Test Guidelines for the Testing of Chemicals.[1] The PMRA scientists compare each study with the appropriate guideline when assessing study acceptability. They also verify that guideline studies were conducted according to Good Laboratory Practices (GLP), a set of principles that assures each study's quality and integrity, for example, PMRA Guidance Document, Good Laboratory Practice Requirements,[2] and OECD Good Laboratory Practice (GLP).[3]

Additional sources of information

Studies from peer-reviewed scientific literature and other sources of data may also be considered for use in risk assessments. The PMRA scientists evaluate these data for scientific validity and acceptability using the same criteria outlined in Table 1, and in a manner consistent with other regulatory organizations.

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[1] Organisation for Economic Co-operation and Development, OECD Test Guidelines for the Testing of Chemicals, http://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm, accessed January 2024.

[2] Health Canada. Pest Management Regulatory Agency, *PMRA Guidance Document, Good Laboratory Practice Requirements for Scientific Studies Supporting Pest Control Products*. 2023. https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/good-laboratory-practice-requirements-scientific-studies-supporting-pest-control-products.html, accessed January 2024.

[3] Organisation for Economic Co-operation and Development. Good Laboratory Practice. http://www.oecd.org/chemicalsafety/testing/good-laboratory-practiceglp.htm, accessed January 2024.

The European Food Safety Authority (EFSA) and the United States Environmental Protection Agency (USEPA) provide guidance for the identification, selection, and evaluation of peer-reviewed scientific literature studies (EFSA Open Literature Guidance[4] and USEPA Open Literature Guidance[5]). The USEPA also provides detailed evaluation guidelines for human[6] and ecological[7] toxicity data from peer-reviewed scientific literature. The PMRA's criteria for assessing study validity and acceptability outlined in Table 1 are consistent with these guidelines.

PMRA use of information in risk assessments

The PMRA uses studies that are acceptable (that is, acceptable and acceptable with limitations) in its risk assessments, when they are relevant to the Canadian context.

Study deficiencies and limitations are taken into account when evaluating data, and when making risk conclusions and regulatory decisions. These studies may be used in the risk assessment if they are reasonably scientifically sound and consistent with results of other studies. Confidence in the information increases with consistency across multiple studies. If study limitations or the study design provide results that are unsuitable for use in quantitative risk calculations, the study may still contain useful qualitative information. The PMRA may use a weight-of-evidence approach[8] in its risk assessments and conclusions, which includes considering all acceptable information while taking into account any study limitations or deficiencies and the consistency of the information.

Public access to data

The Canadian public is consulted on all proposed major registration decisions, including new registrations and re-evaluations. Consultation documents that outline the major findings of the evaluations and proposed decisions are available to the public in the Pesticides and Pest Management Consultations section of Canada.ca. Only the studies that were included in the risk assessments and regulatory decisions are referenced in the PMRA's published documents. Confidential test data referenced in published PMRA documents that support pesticide regulatory decisions are available for inspection at the PMRA's Reading Room upon request.

For more information, please refer to the Pesticides section of Canada.ca at Canada.ca/pesticides. If you have any comments or questions, contact the Pest Management Information Service.

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[4] European Food Safety Authority. *Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009* (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092. http://www.efsa.europa.eu/en/efsajournal/pub/2092, accessed January 2024.

[5] United States Environmental Protection Agency. Guidance for Identifying, Selecting and Evaluating Open Literature Studies. https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-identifying-selecting-and-evaluating-open, accessed January 2024.

[6] United States Environmental Protection Agency. Office of Pesticide Programs. *Guidance for Considering and Using Open Literature Toxicity Studies to Support Human Health Risk Assessment*. 2012. https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-considering-and-using-open-literature, accessed January 2024.

[7] United States Environmental Protection Agency. Office of Pesticide Programs. *Evaluation Guidelines for Ecological Toxicity Data in the Open Literature*. 2011. https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluation-guidelines-ecological-toxicity-data-open#memo, accessed January 2024.

[8] Health Canada. Weight of Evidence: General Principles and Current Applications at Health Canada. 2019. https://www.canada.ca/en/health-canada/services/publications/science-research-data/weight-evidence-general-principles-current-applications.html, accessed January 2024.

Table 1 Classifications and criteria for study acceptability

Study acceptability classification	Classification terms typically used by OECD countries	Criteria
Acceptable	• Acceptable • Fully reliable • Quantitative	• Scientifically sound study design • For guideline studies, fully complied with the specified guideline • For guideline studies, Good Laboratory Practices were followed • Raw data available • Study provides valid endpoints that may be used in a quantitative risk assessment or endpoints or other information that may be used in a qualitative weight-of-evidence risk assessment
Acceptable with limitations	• Acceptable with limitations • Reliable with restrictions • Qualitative/quantitative • Supplemental • Informative	• Scientifically sound study design; there may be some limitations • For guideline studies, may not have fully complied with the specified guideline but the study still provides reliable and useful information • For guideline studies, there may be some deviations from Good Laboratory Practices but the study still provides reliable and useful information • Raw data may or may not be available • Study provides valid endpoints that may be used in a quantitative risk assessment or endpoints or other information that may be used in a qualitative weight-of-evidence risk assessment, taking into account the limitations of the study
Unacceptable	• Unacceptable • Not reliable • Invalid	• Major study design flaws • For guideline studies, does not comply with the specified test guideline and does not provide any reliable or useful information • Study provides no valid endpoints and no information that may be useful or informative for the risk assessment