

Pest
Management
Regulatory
Agency

Guidance for Registrants and Data Holders for Use or Reliance on Test Data Considered in Support of Re-evaluation and Special Review Decisions Published before 4 December 2023

PMRA Guidance Document



*Protecting human health
and the environment*

*Protéger la santé humaine
et l'environnement*



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1.0 Introduction

On 3 June 2010, the data compensation provisions in the Pest Control Products Regulations came into force (2010 Regulations).¹ This established a regulatory framework by which an applicant may use or rely on test data provided by a registrant in the context of an application to register a pest control product or to amend a registration. These provisions also applied, with any necessary modifications, to a registrant who wished to use or rely on test data of a data holder for the purpose of re-evaluations and special reviews.

Guidance to implement the data compensation provisions in the context of an application to register a pest control product or to amend a registration was published in 2010,² and 2014;³ but these guidance documents did not address the use of or reliance on data holders' test data by registrants for re-evaluations or special reviews.

On 7 June 2023, amendments to the data compensation provisions of the Pest Control Products Regulations were published in the *Canada Gazette, Part II*, and on 4 December 2023 they came into force (SOR/2023-104).⁴

¹ See SOR/2010-119: <https://www.gazette.gc.ca/rp-pr/p2/2010/2010-06-23/pdf/g2-14413.pdf>.

² PMRA, "Regulatory Directive DIR2010-04: Guidelines for Reliance on Proprietary Data Under the Pest Control Products Regulations," 2010, <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/regulatory-directive/2010/dir2010-04-guidelines-reliance-proprietary-data-under-pest-control-products-regulations.html>.

³ PMRA Memo to Registrants, Data Protection Submission Review Process, <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/registrants-applicants/product-application/memo/data-protection-submission-review-process.html>.

⁴ Regulations Amending the Pest Control Products Regulations (Exclusive Rights and Compensable Data): SOR/2023-104 (Canada Gazette, Part II, Volume 157, Number 12, online: <https://www.gazette.gc.ca/rp-pr/p2/2023/2023-06-07/pdf/g2-15712.pdf>).

These amendments are intended to provide clarity regarding data compensation for re-evaluations and special reviews, such as which party can trigger the negotiation and binding arbitration process; when and how to trigger such processes; and when the lists of test data for which compensation may be payable will be made available for re-evaluation and special review decisions published after 4 December 2023. To support the implementation of the amendments related to data compensation for re-evaluations and special reviews, the PMRA published a guidance document⁵ as well as a section 66 Agreement⁶ for re-evaluations and special reviews.

The amendments also aim to clarify the data compensation requirements for applications to register and to amend a registration and to establish consistency with the new data compensation provisions for re-evaluations and special reviews. Some of these amendments address data compensation for use or reliance on foreign test data and on test data for non-equivalent active ingredients subject to exclusive rights. The PMRA also published a section 66 Agreement for pest control product applications to support these amendments.⁷

As the amended data compensation provisions only apply to re-evaluation and special review decisions published after 4 December 2023, the former regulations (in other words, the 2010 Regulations) continue to apply to re-evaluation and special review decisions published prior to that date.

⁵ PMRA Guidance Document, "Guidance for Registrants and Data Holders for Use or Reliance on Test Data Considered In Support Of Re-Evaluation And Special Review Decisions, 2023, <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/guidance-registrants-data-holders-use-reliance-test-data-considered-support-reevaluation-special-review-decisions.html>.

⁶ PMRA, "Agreement for test data compensation under section 66 of the *Pest Control Products Act* for re-evaluations and special reviews," 2023, <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/pest-control-products-acts-and-regulations-en/agreement-test-data-compensation-section66-pest-control-products-act-reevaluations-special-reviews.html>.

⁷ PMRA, "Agreement for test data compensation under section 66 of the *Pest Control Products Act* for pest control product applications," 2023 <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/pest-control-products-acts-and-regulations-en/agreement-test-data-compensation-section66-pest-control-products-act-product-applications.html>.

2.0 Purpose

This guidance supports the interpretation of the former data compensation provisions, and is to be used in conjunction with the *Pest Control Products Act*, the 2010 Regulations, and the Agreement for Test Data Compensation under Section 66 of the *Pest Control Products Act* for Re-evaluation and Special Review Decisions Published before 4 December 2023⁸ (section 66 Agreement).

For the purposes of this guidance document, the term “registrant” applies to the party seeking access to data. The term “data holder” refers to a registrant to whom compensation may be payable in respect of test data.

3.0 Use or reliance on data holder’s test data for re-evaluations and special reviews

The *Pest Control Products Act* and the Regulations set out a regulatory process for data compensation for pest control products. For the purpose of re-evaluations and special reviews, a data holder’s test data can be used or relied on by other registrants, as per *Pest Control Products Act* subsections 16(5) and (5.1) for re-evaluations, and subsections 18(3) and (3.1) for special reviews. As per section 17.8 of the 2010 Regulations, the PMRA will make available to registrants and data holders the list of test data considered by the Minister in support of the final re-evaluation or special review decision for which they will need to enter into an agreement regarding compensation that may be payable.

3.1 Use or reliance on on-hand test data relevant to the equivalent active ingredient under re-evaluation or special review

During a re-evaluation or special review, the PMRA considers relevant test data and other available information from pest control product registrants, published and unpublished scientific reports, reviews, and regulatory decision documents from other regulatory agencies. Here, only relevant test data that is called in and considered by the PMRA for the first time in support of a final re-evaluation or special review decision may be eligible for compensation. The PMRA’s re-evaluations and special reviews may consider “on-hand” (in other words, previously submitted) test data relevant to the pest control product that is under review. If this “on-hand” test data is relevant to the equivalent active ingredient that is subject to the re-evaluation or special review, it will not be considered in the data compensation assessments as it is not eligible for compensation for the purposes of the re-evaluation or special review.

⁸ PMRA, “Agreement for Data Compensation under Section 66 of the *Pest Control Products Act* for Re-evaluation and Special Review Decisions Published before 4 December 2023,” 2024, <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations.html>.

3.2 Use or reliance on on-hand test data relevant to a non-equivalent active ingredient

During a re-evaluation or special review, the PMRA considers all relevant data, including test data on-hand relevant to non-equivalent active ingredients. In other words, the PMRA may consider test data relevant to an active ingredient that is not equivalent to the active ingredient contained in the pest control product that is subject to a particular re-evaluation or special review. If this test data (in other words, on-hand test data relevant to a non-equivalent active ingredient) was considered in a final re-evaluation or special review decision published after 21 September 2017 (2017 Amendments) and was within the compensable period when that re-evaluation or special review decision was made, then as per the 2010 Regulations, as amended on 21 September 2017, compensation may be payable to the data holder for use or reliance on this test data by other registrants. This is being implemented further to Canada's obligations under the Canada-European Union Comprehensive Economic and Trade Agreement (CETA).⁹

3.3 Use or reliance on test data that is called in under subsections 16(3), 18(1), 19(1) of the *Pest Control Products Act*

Under subsection of 17.1 of the 2010 Regulations, test data submitted pursuant to notices delivered to a registrant under relevant subsections 16(3), 18(1) or 19(1) of the *Pest Control Products Act* during re-evaluations or special reviews are eligible for compensation if they are considered by the Minister in support of the re-evaluation or special review decisions. The PMRA may have issued notices under those provisions to registrants for information (in other words, scientific or technical test data) that were considered necessary to conduct the re-evaluation or special review.

The PMRA considers all relevant test data either on-hand at the PMRA or called in from data holders in the context of a particular re-evaluation or special review. However, only test data that is called in, as well as on-hand test data relevant to active ingredients that is not equivalent to the active ingredient that is under re-evaluation or special review may be eligible for compensation; for the latter (i.e., the on-hand test data), compensability will be assessed only for decisions published on or after September 2017.

⁹ For additional context, prior amendments related to CETA include: 2017 amendments to the *Pest Control Products Act* through Bill C-30, "Canada-European Union Comprehensive Economic and Trade Agreement Implementation Act S.C. 2017, c. 6", <https://laws-lois.justice.gc.ca/eng/acts/C-4.8/index.html>, and "Regulations Amending the *Pest Control Products Regulations* (Test Data Protection)", which can be found here: <https://www.gazette.gc.ca/rp-pr/p2/2017/2017-09-07-x1/pdf/g2-151x1.pdf#page=67>.

4.0 General information and approach

4.1 Availability of lists of test data for which compensation may be payable for re-evaluations and special reviews

In accordance with the 2010 Regulations, the PMRA will establish lists of test data for which compensation may be payable for re-evaluations and special reviews that were initiated since 28 June 2006 (the coming into force date of the *Pest Control Products Act, 2002*), and for which a data call-in (DCI) notice was issued under subsections 16(3) or 18(1) or paragraph 19(1)(a) of the *Pest Control Products Act* after 3 June 2010 (the coming into force date of the data compensation provisions in the Pest Control Product Regulations). The PMRA is analysing the decisions with respect to re-evaluations and special reviews published before 4 December 2023, to identify the decisions for which the establishment of lists of compensable test data is required (See Appendix V). PMRA will establish such lists in the following order:

1. Re-evaluation and special review decisions for active ingredients that have ongoing applications to register generic technical grade active ingredient products seeking to use or rely on data holders' test data.
2. Re-evaluation and special review decisions for active ingredients that had recent data compensation assessments completed as a result of a product application.
3. The remaining decisions in chronological order starting with the oldest first.

4.2 Test data requests communicated in writing

The PMRA requested the submission of test data for re-evaluations and special reviews in writing, including via email correspondence or consultation documents. If such test data were used in support of final decisions, they may be eligible for compensation as set out in Section 4.1.

4.3 Eligibility of test data where the compensable protection period ended after the publication of the re-evaluation or special review decisions

Test data may be eligible for compensation if the compensable protection period had not expired by the date of the publication of the final re-evaluation or special review decision under subsection 28(5) of the *Pest Control Products Act*.

4.4 Participating registrants during re-evaluations or special reviews

All technical grade active ingredient registrants who maintained the registrations of their technical grade active ingredient products since the date of the publication of the re-evaluation or special review decision are subject to the data compensation requirements under

the 2010 Regulations. The negotiation and, if necessary, binding arbitration provisions apply to determine whether any compensation is payable for reliance on data holders' test data.

This guidance does not apply to pest control products that were registered after a re-evaluation or special review of the active ingredient contained in that pest control product. Registrations of those products were subject to the application process that took into consideration the test data used in the re-evaluation or special review.

4.5 Compensation requirements if products have since been cancelled

Some registrations of technical grade active ingredients have been cancelled since the date of the publication of the associated re-evaluation or special review decision. In this case, the former registrants of these cancelled products are not required to pay compensation or to participate in the negotiation/arbitration process for access to test data considered in support of the applicable re-evaluations or special reviews.

4.6 Data holders' and other registrants' review of the initial list of test data for which compensation may be payable

An initial list of test data for which compensation may be payable will be sent to the data holders and other registrants whose products are subject to the re-evaluation or special review decision. Data holders and other registrants will have 45 days to provide comments to the PMRA on the scope of the list of test data. Following that, the PMRA will consider all input received and proceed to finalize the list of test data for which compensation may be payable. This list will be made available to all parties referenced above to allow them to initiate negotiations.

4.7 Eligibility criteria for test data for which compensation may be payable for re-evaluations and special reviews

Eligibility criteria for test data that was considered in support of re-evaluation and special review decisions and for which compensation may be payable are outlined in Appendix I of this document.

4.8 Re-evaluation or special review decisions with full cancellation

Registrants are not required to pay compensation if the pest control product registrations subject to the re-evaluation or special review were cancelled as a result of the re-evaluation or special review decision.

4.9 Re-evaluation or special review decisions with cancellation of some uses

A re-evaluation or special review decision may conclude that the risks and the value of a pest control product are acceptable with the amendment of the registration (e.g., to establish additional risk mitigation measures). In the context of a re-evaluation or special review, studies (for example, toxicology or dietary) considered in support of a decision generally apply to all products under review and support the overall decision, including the cancellation of certain uses, or the implementation of additional mitigation measures. Registrants whose products are subject to the re-evaluation or special review decision are required to compensate for the use of or reliance on a data holder's test data that supports a re-evaluation or special review decision, including a decision resulting in the cancellation of certain uses.

4.10 Foreign reviews or foreign regulatory decisions

The PMRA often considers publicly available reviews or regulatory decision documents from other regulatory bodies, such as the United States Environmental Protection Agency (USEPA), European Food Safety Authority (EFSA), or Australian Pesticide and Veterinary Medicine Authority (APVMA), in support of re-evaluation or special review decisions. Foreign reviews or foreign regulatory decision documents considered in support of a re-evaluation or special review decision are not compensable.

However, the PMRA may have reviewed certain underlying studies referenced in foreign reviews or foreign regulatory decision documents to confirm the interpretation or conclusion regarding specific matters addressed in these documents. In this situation, the test data from those underlying foreign studies would have been called in by the Minister under subsections 16(3) or 18(1), or paragraph 19(1)(a) of the *Pest Control Products Act*. If the studies were used to support a final re-evaluation or special review decision, compensation may be payable for the use of or reliance on those called-in underlying foreign studies.

5.0 Negotiation and binding arbitration

Under section 66 of the *Pest Control Products Act*, the Minister is required to determine the terms and conditions of agreements entered into by registrants and data holders for the purposes of determining compensation payable for the use or reliance by registrants on data holders' test data (section 66 Agreement). In accordance with the 2010 Regulations, once a final list of test data for which compensation may be payable is established for a prior re-evaluation or special review, the PMRA will provide the list to the registrant and data holder. Either the registrant wishing to use or rely on the data holder's data or the data holder themselves may deliver the proposed section 66 Agreement to the other party that specifies the test data for which compensation may be payable. On delivery of the proposed section 66 Agreement by either party, the parties must enter into the agreement and begin to negotiate the amount of compensation payable to the data holder.

Under the Regulations, the negotiation period will run for 120 days upon delivery of the proposed agreement but can be extended upon written agreement between the parties. At the end of the negotiation period, if no settlement is reached, either party may trigger binding arbitration by delivering a written notice to the other party. The arbitrator must make an arbitral award within 120 days after the day on which the notice was delivered unless the parties agree to extend that period and provide written notice to the arbitrator or the arbitrator provides written notice of an extension to the parties.

Arbitration is binding on parties and generally an award will be rendered by the Arbitral Tribunal before the end of the proceedings. The award will set out the compensation payable for use or reliance on the data holder's test data and any costs payable by either party to the arbitration.

6.0 Letter of access and renewal of registration

Once a negotiated settlement has been reached or an arbitral award has been issued, the data holder must provide the other registrant with a letter of access (LOA) allowing the registrants to use or rely on the list of test data for which compensation may be payable in Appendix A of the section 66 Agreement as per subsection 17.94(1) of the 2010 Regulations.

If the data holder fails to provide the LOA within the period specified in the negotiated settlement or arbitral award, the registrant may use or rely on the test data without having to continue to comply with the settlement or award as per subsection 17.94(2) of the 2010 Regulations.

At the next registration renewal as per subsection 16(2) of the Regulations following the conclusion of the negotiation or arbitration period, registrants using or relying on the data holder's test data will be required in their renewal applications to provide an LOA, or relevant documents indicating that parties are still in negotiation or arbitration, or that though a negotiated settlement has been reached or an arbitral award issued, the data holder has not provided the registrant with an LOA.

LOAs are to be signed using the attached template in Appendix II.

7.0 Process for determining the list of test data for which compensation may be payable

The process for determining the list of test data for which compensation may be payable is in Appendix III.

8.0 Requests for discontinuation of product registration once the list of test data for which compensation may be payable has been made available to registrants and data holders

There may be circumstances where a registrant is subject to a re-evaluation or special review decision published prior to 4 December 2023, and they notify the PMRA, pursuant to subsection 22(1) of the *Pest Control Products Act*, that they seek to discontinue their product registrations after the PMRA has made available a list of test data for which compensation may be payable. The PMRA will cancel the registration of their products in accordance with subsection 22(3) of the *Pest Control Products Act*. The PMRA may allow for a phase-out period, with timelines consistent with the Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review*.

When a section 66 Agreement has been entered into on delivery, by either party, the terms and conditions of that agreement apply. If a registrant requests to discontinue their product's registration and the Minister cancels their registration under subsection 22(3) of the *Pest Control Products Act*, the terms of the section 66 agreement entered into continue to apply to that party.

Appendix I Eligibility criteria for test data for which compensation may be payable

a) What is eligible for compensation

Pursuant to subsection 17.7(2) of the 2010 Regulations, the following test data are eligible for compensation if considered by the Minister in support of a re-evaluation or special review decision initiated since 28 June 2006:

- Test data that is relevant to an active ingredient that is not equivalent to the active ingredient under the re-evaluation or special review, if the Minister is satisfied that such information is necessary for the re-evaluation or special review decision published on or after 21 September 2017, and
- Test data provided in response to data call-in (DCI) notices issued on or after 3 June 2010 under subsections 16(3), 18(1), or paragraph 19(1)(a) of the *Pest Control Products Act*, for re-evaluations or special reviews.

b) What is not eligible for compensation

Test data and other information that is not eligible for compensation for re-evaluations and special reviews include, but are not limited to, the following:

- Test data where the compensable period or exclusive use period expired prior to the publication date of the final re-evaluation or special review decision.
- Summaries of information (including executive summaries).
- Test data waivers-/scientific rationales.
- Test data in the public domain (for example, data published in the open literature, published foreign reviews or foreign regulatory decision documents).
- Test data in a scientific or technical study that is fully funded by a government or one of its institutions
- Test data that the PMRA deemed to be invalid for regulatory purposes.
- Test data that is on hand and that is relevant to an active ingredient equivalent to the active ingredient under the re-evaluation or special review.
- Test data submitted voluntarily.
- Test data that was received in response to a DCI, issued before 3 June 2010 under subsections 16(3), or 18(1), and or paragraph 19(1)(a) of the *Pest Control Products Act*.
- Test data that was received in response to a DCI issued after 3 June 2010 under subsections 16(3), or 18(1), and paragraph 19(1)(a) of the *Pest Control Products Act* for a re-evaluation or special review initiated before 28 June 2006.
- Test data requested under section 12 of the *Pest Control Products Act*.
- Test data received with an incident report submitted under section 13 of the *Pest Control Products Act*.

Appendix II Letter of Access

[DATA HOLDER COMPANY LETTERHEAD]

Date

Director General,
Registration Directorate

Pest Management Regulatory Agency

Health Canada

Subject: Letter of access to [NAME OF REGISTRANT]

This is to inform you that [NAME OF DATA HOLDER] is granting to [NAME OF REGISTRANT] the right to use or rely on [NAME OF DATA HOLDER]'s test data identified in the Pest Management Regulatory Agency's letter of [DATE], regarding the re-evaluation or special review decision (RVD20XX-XXXX or SRD20XX-XXXX).

Yours truly,

[Data Holder's signature]

[Printed signatory name and contact information]

Appendix III Process for determining the list of test data for which compensation may be payable

Assessments of test data for which compensation may be payable will be carried out for the purposes of subsections 16(5) and (5.1), and 18(3) and (3.1), of the *Pest Control Products Act* and the *Pest Control Products Regulations* (in other words, the 2010 Regulations and the 2017 Amendments). The PMRA will follow the eligibility criteria outlined in Appendix I in assessing the test data for which compensation may be payable. The process for determining the list is set out below.

Step 1 – PMRA establishes initial list of test data for which compensation may be payable

An initial list of test data will be established by considering the eligibility criteria outlined in Appendix 1 and cross-referencing the reference lists in the relevant published re-evaluation or special review documents.

Step 2 – Data holders and other registrants review the initial list of test data for which compensation may be payable

The initial lists of test data for which compensation may be payable will be presented as per the template in Appendix IV, for the active ingredients listed in Appendix V. Data holders and other registrants will be provided with a 45-day period to review and provide written comments to the initial list.

Any written comments must demonstrate how the test data identified meet or do not meet the criteria for compensation set out in Appendix I.

This step is an opportunity for data holders and other registrants to provide input on whether the initial list of test data for which compensation may be payable was established as per the eligibility criteria outlined in Appendix I. It is not an opportunity to question why certain test data was considered or not in support of a decision by the PMRA. Other opportunities were available as part of the re-evaluation and special review processes where data holders and other registrants could comment on the studies considered in support of decisions made prior to 4 December 2023, by the PMRA.

Step 3 – PMRA makes available final list of test data for which compensation may be payable

The PMRA will consider the written comments provided by data holders and other registrants and will finalize the list of test data for which compensation may be payable. The initial list of test data may be revised if deemed necessary. A final list of test data for which compensation may be payable containing the eligible test data considered in support of the Minister's re-evaluation or special review decision will be made available to relevant registrants and data holders using the format in Appendix IV.

Appendix IV List of test data for which compensation may be payable

The initial list and the final list of test data for which compensation may be payable for the re-evaluation or special review of an active ingredient will be presented in the following format:

PMRA No.	Data code (DACO)	Study title	Report number	Report date	Received date	PMRA assessment	Comments

Appendix V

List of identified re-evaluation and special review decisions published before 4 December 2023, where the PMRA may make available lists of test data for which compensation may be payable

Name of active ingredient	PRVD/RVD or PSRD/SRD*
Captan	PRVD2016-13, RVD2018-12
Clodinafop-propargyl	PRVD 2018-16, RVD2020-01,
Chlorimuron-ethyl	PRVD2018-14, RVD2019-02
Clethodim	PRVD2016-11, RVD2017-10
Lambda-Cyhalothrin	PRVD2017-03, RVD2021-04,
Cypermethrin	PRVD2016-18, RVD2018-22
Cymoxanil	PRVD2021-04, RVD2021-09
Cyromazine	RVD2021-08, PRVD2020-02
Dazomet (Preservative in Paints, Coatings and Related Uses)	RVD2022-14, PRVD2020-07
Deltamethrin	PRVD2015-07, RVD2018-27
Difenoconazole	PRVD2021-06, RVD2022-05
Fludioxonil	PRVD2016-03, RVD2018-04
Flucarbazone	PRVD2022-02, RVD2023-03
Folpet (Preservative in Paints and Vinyl Plastics)	PRVD2020-05, RVD2022-16
Florasulam	PRVD2021-03, RVD2022-03
Glyphosate	PRVD2015-01, RVD2017-01
Imidacloprid	PRVD2016-20, RVD2021-05
Imidacloprid (Pollinator Re- evaluation)	PRVD2018-12, RVD2019-06
Isoxaflutole	PRVD2021-02, RVD2022-04
Sodium Omadine (Preservative in Paints, Coatings and Related Uses)	PRVD2020-03, RVD2022-15
Permethrin	PRVD2017-18, RVD2019-11
Chlorothalonil (Agricultural and Turf Uses)	PRVD2011-14, REV2016-06, RVD2018-11
Chlorothalonil (Preservative in Paints)	PRVD2020-06, RVD2022-17
Tebufenozide	PRVD2019-06, RVD2021-01
Trinexapac-ethyl	PRVD2022-01, RVD2022-12
Uniconazole-P	PRVD2019-09, RVD2020-03
Pyrethrins	PRVD2020-08, RVD2023-06
Piperonyl butoxide	PRVD2023-07, PRVD2020-09
Quinclorac	PRVD2016-15, RVD2016-08
Mancozeb	PRVD2018-17, RVD2020-12
Bromoxynil	PSRD2019-01, SRD2019-02
Tetrachlorvinphos	PSRD2019-04, SRD2021-01

* PRVD = Proposed Re-evaluation Decision; RVD = Re-evaluation Decision; PSRD = Proposed Special Review Decision; SRD=Special Review Decision