

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



*Protecting human health  
and the environment*

*Protéger la santé humaine  
et l'environnement*



## 4 December 2023

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Lignes directrices à l'intention des titulaires et des détenteurs de données concernant la possibilité d'utiliser des données d'essai ou de s'y fier en appui aux décisions de réévaluation et d'examen spécial

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## 1.0 Introduction

On 3 June 2010, the data compensation provisions in the Pest Control Products Regulations came into force. This established a regulatory framework by which an applicant or a registrant may use or rely on test data provided by other registrants in the context of an application to register a pest control product or amend a registration. These provisions also applied, with any necessary modifications, to a registrant who wished to use or rely on test data of another registrant 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 also published in 2010,<sup>1</sup> and updated memoranda were published in 2014,<sup>2</sup> but these guidance documents did not address use or reliance on 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 came into force on 4 December 2023. These amendments provide clarity on data compensation provisions 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 (hereinafter called "the Regulations"). The Regulations are available online in *Canada Gazette, Part II*.<sup>3</sup>

This guidance document explains, in the context of re-evaluations and special reviews, the process for use or reliance by one registrant on another registrant's (in other words, a data holder's) test data under the Regulations. This guidance will apply when a registrant has confirmed they wish to use or rely on a data holder's test data in accordance with the requirements of the *Pest Control Products Act* and the Regulations, including if applicable an Agreement for Test Data Compensation under Section 66 of *Pest Control Products Act* for Re-evaluations and Special reviews entered into by the registrant. This guidance also outlines the Pest Management Regulatory Agency's (PMRA) process and timelines for establishing a list of test data for which compensation may be payable.

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<sup>1</sup> DIR2010-04: Guidelines for Reliance on Proprietary Data Under the Pest Control Products Regulations (<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>)

<sup>2</sup> 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>)

<sup>3</sup> Regulations Amending the Pest Control Products Regulations (Exclusive Rights and Compensable Data): SOR/2023-104 (*Canada Gazette, Part II*, Volume 157, Number 12, also see web link: <https://www.gazette.gc.ca/rp-pr/p2/2023/2023-06-07/pdf/g2-15712.pdf>)

This guidance is to be used in conjunction with the *Pest Control Products Act*, the Regulations, and the Agreement for Test Data Compensation under Section 66 of the *Pest Control Products Act* for Re-evaluations and Special Reviews<sup>4</sup> (section 66 Agreement).

This guidance does not apply where registrants already have a letter of access (LOA) from data holders for the test data they seek to use or rely on in the context of a re-evaluation or special review.

## 2.0 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 data compensation regulatory process 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 18(3) and (3.1) for special reviews. On the day the final decision statement is made public pursuant to subsection 28(5) of the *Pest Control Products Act*, the PMRA will make available the list of test data considered by the Minister in support of the re-evaluation or special review decision for which compensation may be payable.

### 2.1 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, and reviews and regulatory decision documents from other regulatory agencies. 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. Such test data is "on-hand" for the re-evaluation or special review and, if relevant to the equivalent active ingredient that is subject to the re-evaluation or special review, 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.

### 2.2 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

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<sup>4</sup> Agreement for Test Data Compensation under Section 66 of the *Pest Control Products Act* for Re-evaluations and Special Reviews (<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>)

active ingredient is not equivalent to the active ingredient that is subject to a particular re-evaluation or special review. If such test data (in other words, relevant to a non-equivalent active ingredient) are within the periods for exclusive rights or compensable data protection, then as per the Regulations 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).<sup>5</sup>

## 2.3 Use or reliance on test data that is called-in

As outlined in the Regulatory Directive DIR2016-04, Management of Pesticides Re-evaluation Policy,<sup>6</sup> re-evaluation is a step-by-step process including initiation, scoping, information gathering, and review, etc. The process for special reviews is outlined in PMRA Guidance Document, Approach to Special Reviews of Pesticides.<sup>7</sup> The PMRA may issue notices requesting information, also referred to as data call-ins (DCIs), pursuant to subsections 16(3) or 18(1), or paragraph 19(1)(a) of the *Pest Control Products Act*, to registrants for additional information and/or studies that are considered necessary to conduct the re-evaluation or special review.

In general, test data required in the DCIs are selected from the lists of studies submitted by registrants. Certain underlying studies from relevant published foreign reviews or foreign regulatory decision documents may also be required in the DCIs. In some cases, new test data may need to be generated by registrants for a re-evaluation or special review and be submitted to the PMRA within a specified timeline.

All registrants who receive DCI notices are required to respond to the notice with the information in the form and within the timelines established in the DCI notices. The following options are available to registrants during a re-evaluation or special review to address the DCI requirements.

- Option 1: Provide the required test data, or acceptable scientific rationales, or provide an LOA to the test data listed in the DCI notice that will be submitted by other registrants; or
- Option 2: Confirm that you wish to use or rely on another registrant's test data that will be provided in response to this notice and later considered by the

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<sup>5</sup> For additional context, prior amendments related to the CETA including: 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>.

<sup>6</sup> Regulatory Directive DIR2016-04, Management of Pesticides Re-evaluation Policy (<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/regulatory-directive/2016/management-pesticides-evaluation-policy-regulatory-directive-dir2016-04.html>)

<sup>7</sup> PMRA Guidance Document, Approach to Special Reviews of Pesticides (<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/approach-special-reviews-pesticides.html>)

Minister in support of the re-evaluation or special review decision. Your use or reliance on the test data will be in accordance with the requirements of the *Pest Control Products Act* and the Regulations and, if applicable, an Agreement for Test Data Compensation under Section 66 of the *Pest Control Products Act* for Re-evaluations and Special Reviews<sup>8</sup> entered into with other registrants to determine the compensation payable; or

- Option 3: Provide notice of your intent to discontinue the registration of your product (in other words, a notice under subsection 22(1) of the *Pest Control Products Act*). The PMRA will take steps to cancel the registration under subsection 22(3) of the *Pest Control Products Act*. Cancellation of a registration would terminate your right to sell the product as of the date indicated in the cancellation letter.

Failure to meet the requirements of the DCI notice may result in cancellation or amendment of the product's registration as per paragraph 20(1)(a) of the *Pest Control Products Act*.

Registrants may wish to collaborate on generating the test data jointly as per paragraphs 16(5)(a) and 18(3)(a) of the *Pest Control Products Act*. Further, to the extent possible, the data compensation program encourages the use or reliance on existing test data over duplication of studies. Unnecessary, duplicative animal testing should be avoided.

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 called in, as well as on-hand test data relevant to active ingredients not equivalent to the active ingredient that is under re-evaluation or special review, may be eligible for compensation.

## 3.0 General information and approach

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

As required by the Regulations, the PMRA will make available to data holders and other registrants a list of test data for which compensation may be payable, on the date the final re-evaluation decision or special review decision is published.

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<sup>8</sup> Agreement for Test Data Compensation under Section 66 of the *Pest Control Products Act* for Re-evaluations and Special Reviews (<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>)

## **3.2 Data holders and other registrants review of the initial list of test data for which compensation may be payable**

Although not required by the Regulations, the PMRA will consider input from data holders and other registrants when establishing the list of test data for which compensation may be payable. After the consultation period for a proposed re-evaluation or special review decision is closed and before the final decision is published an initial list of test data for which compensation may be payable will be sent to both the data holders and other registrants. Registrants will have 30 days to provide comments to the PMRA. 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 when the final re-evaluation and special review decision is published.

## **3.3 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.

## **3.4 Re-evaluation or special review decisions with full cancellation**

There are no data compensation requirements if the pest control products subject to the re-evaluation or special review are cancelled as a result of re-evaluation or a special review.

## **3.5 Re-evaluation or special review decisions with cancellation of some uses**

A re-evaluation or special review decision may find that the risks and the value of a pest control product under review are acceptable with the amendment of the registration. In the context of a re-evaluation or special review, studies (for example, toxicology, dietary) considered in support of a decision generally apply to all products under review and support the overall decision, including cancellation of certain uses, or the implementation of additional mitigation measures. Registrants will be required to compensate for use 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.

## **3.6 Consideration of 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 need to review certain underlying studies referenced in foreign reviews or decision documents to confirm the interpretation or conclusion on specific matters addressed in these documents. If required, the specific studies will be identified by the Minister and included in a DCI notice. In this situation, the test data from those underlying foreign studies will be called in by the Minister as per subsections 16(3) or 18(1), and paragraph 19(1)(a) of the *Pest Control Products Act* and compensation may be payable.

## 4.0 Negotiation and binding arbitration

Under section 66 of the *Pest Control Products Act*, the Minister determines 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). Under the Regulations, either the registrant wishing to use or rely on the data holder's data or the data holder themselves may deliver a proposed section 66 Agreement to the other party that specifies the test data that the registrant wishes to use or rely on. Parties will have 60 days after the final re-evaluation or special review decision is published under subsection 28(5) of the *Pest Control Products Act* to deliver the proposed section 66 Agreement to the other party. When a section 66 Agreement is entered into, parties must begin to negotiate the amount of compensation payable to the data holder.

Under the Regulations, the negotiation period will run for 120 days after the final decision statement is published under subsection 28(5) of the *Pest Control Products Act*, 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 prior to 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. Following issuance of the award, the registrant has 30 days to decide to pay the compensation amount or to choose to discontinue their registration pursuant to subsection 22(1) of the *Pest Control Products Act*. If choosing to discontinue their registration, the registrant will still need to pay any costs of the arbitration as determined by the Arbitral Tribunal. Requests for discontinuation will be administered by PMRA in accordance with the *Pest Control Products Act* and as set out in Section 7 of this guidance document below.

## 5.0 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 other registrants with an LOA allowing them to use or rely on the data listed in Appendix A of the section 66 Agreement as per subsection 17.17(1) of the 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 17.17(2) of the Regulations.

At the next registration renewal following a re-evaluation or special review decision, registrants using or relying on the data holder's test data will be required in their renewal applications to provide an LOA, or as per subsection 16(2) of the Regulations, 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 for an LOA in Appendix II.

## 6.0 Process of 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 found in Appendix III.

## 7.0 Requests for discontinuation of product registration following the re-evaluation or special review decision

Following the publication of a final re-evaluation or special review decision, registrants who wished to use or rely on a data holder's test data may notify the PMRA pursuant to subsection 22(1) of the *Pest Control Products Act* that they seek to discontinue their product registrations. The PMRA will cancel the registration of their products under subsection 22(3) of the *Pest Control Products Act*. Depending on the outcome of the re-evaluation and special review decision, the PMRA may allow for a phase-out period, with timelines consistent with the re-evaluation or special review decision and the Regulatory Directive DIR2018-01, Policy on Cancellations and Amendments Following Re-evaluation and Special Review.

Where an end-use product contains a technical grade active ingredient that has been cancelled, the PMRA will communicate with the registrant of the relevant end-use product on the next steps, including the option of changing technical grade active ingredient source.

## 8.0 Effective date of the Regulations

The Regulations came into force on 4 December 2023 (**180 days** after the day published in the *Canada Gazette, Part II*, on 7 June 2023). These Regulations apply to ongoing re-evaluations and special reviews, if the final re-evaluation decisions or special review decisions are not published prior to 4 December 2023.

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

### a. Test data eligible for compensation

As per subsection 17.12 (1) of the Regulations, the following test data are eligible for compensation if considered by the Minister in support of the re-evaluation or special review decision for the period specified in subsection 17.12(2):

- 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, and
- Test data provided in response to data call-in (DCI) notices issued under subsections 16(3), 18(1), or paragraph 19(1)(a) of the *Pest Control Products Act*.

### b. Test data 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 data period or exclusive rights expires prior to the publication date of the final decision.
- Test data summaries (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 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 such as during representations or consultation period
- Test data that was received in response to a data call-in notice issued before June 3, 2010 under subsections 16(3), 18(1), and 19(1) of the *Pest Control Products Act*
- 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

[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 (RVD202X-XXXX or SRD202X-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 Regulations. The PMRA will follow the eligibility criteria outlined in Appendix I in assessing the test data for which compensation may be payable.

### Step 1 – Initial list of test data

An initial list of test data will be established by considering the eligibility criteria outlined in Appendix 1 and reference lists in the relevant published documents such as the proposed regulatory decision.

### Step 2 – Data holders and other registrants' review of 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. A letter accompanying the list will be sent to the relevant parties after the publication of the proposed re-evaluation decisions or the proposed special review decisions and the consultation period is closed. Data holders and other registrants will be provided with a 30-day period to review and provide written comments on the PMRA's initial list.

Any written comments must provide proof explaining 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 are being considered or not in support of a decision by the PMRA. Other opportunities are available as part of the re-evaluation and special review processes where data holders and other registrants can comment on the studies being considered in support of a decision by the PMRA.

### Step 3 – 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 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 decision will be made available to relevant registrants on the day of the publication of the re-evaluation or special review decision using the format in Appendix IV.

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

Attachment: Initial list of test data for which compensation may be payable for the re-evaluation or special review of pest control products that contain (active ingredient name)

PMRA Number	DACO	Study Title	Report Number	Report Date	Received Date	PMRA Assessment	Comments