Inspection of Confidential Test Data Supporting Pesticide Registration Decisions - Guidance Document

1.0 Background

Canada's *Pest Control Products Act* (PCPA) provides the public with the opportunity to inspect the confidential test data (in other words, test data to which access may be refused under the *Access to Information Act*) supporting pesticide registration decisions or proposed decisions in the case of post-market reviews (re-evaluations and special reviews).

Companies who want to register a pesticide in Canada must provide test data (in other words, scientific or technical information respecting the health or environmental risks or the value of a pest control product) to Health Canada's Pest Management Regulatory Agency (PMRA) for the evaluation of potential risks to human health and the environment as well as to demonstrate the product's value. The data are evaluated by PMRA scientists, who conduct risk and value assessments leading to decisions on whether or not the pesticide can be used in Canada and under what conditions. Data requirements cover a number of areas, such as: toxicology

related to human health, bystander and occupational exposure, food residue trials, environmental toxicology and fate, as well as information supporting the efficacy, crop tolerance and benefits of the pesticide.

Members of the public may inspect confidential test data either in-person in the Reading Room, located at the PMRA's National Head Office in Ottawa, Ontario, or remotely, as part of an ongoing pilot project (see Section 5, Inspecting Confidential Test Data for more information regarding these options). Anyone wishing to provide comments with respect to this pilot project may do so by sending them into the PMRA Reading Room Inbox.

Confidential test data are available for inspection:

- after a final decision is made under the PCPA to:
  - register a product,
  - amend a registration, or
  - continue registration after a post-market review (in particular, a re-evaluation or a special review) is completed;
- as well as at the proposed decision stage for post-market reviews initiated as of 1 January 2022.

Anyone wishing to inspect confidential test data must submit an application form to identify the data they wish to inspect as well as an affidavit/ statutory declaration stating the purpose of the inspection and attesting that the data will not be used or made available to others to register or amend a product registration. The PMRA does not charge a fee to inspect confidential test data.

Providing the public with the opportunity to inspect confidential test data is intended to facilitate transparency and public participation in the regulatory decision-making process. This is particularly important for

anyone who is considering filing an objection to a major registration decision because they must identify the scientific basis on which the objection rests. Following a major registration decision for which there was public consultation, the public is encouraged to review the documents in the Public Registry (for example, evaluation report and decision document) and, if desired, to inspect the related confidential test data. Anyone who raises a scientifically founded doubt as to the validity of the evaluations, on which the decision was based, concerning the health, environmental risk or value of the pest control product, may file an objection and the scientific rationale within 60 days from the regulatory decision date. The PMRA may establish a review panel to examine the regulatory decision in question if the rationale is found to be valid and scientifically based.

The purpose of this document is to provide the public with a description of the policy and procedure for inspecting confidential test data. The document explains what information can be inspected and when it is available. It also provides guidance on how to submit an application and a description of what to expect during the inspection process.

2.0 Availability of pesticide information

2.1 Description of available information

When a pesticide is registered, the public is encouraged to review the published evaluation report and decision document made available on the PMRA website. These documents explain the risk and value assessments supporting a registration decision, along with a summary of the information considered. The evaluation report provides references to all

the data considered in the evaluation, including the confidential test data submitted by pesticide registrants and any other information considered in the evaluation.

If a detailed inspection of the confidential test data is desired, members of the public can inspect the confidential test data relevant to the decision either in person or (as part of an ongoing pilot project), remotely. In addition to domestic legal obligations, Canada has obligations under international law to protect confidential test data from disclosure and unfair commercial use. Consequently, the inspection process includes rigorous controls to fulfil these obligations and to prevent the data from being copied or distributed by the person inspecting it.

Under Section 43 in the PCPA:

> Confidential test data
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> 43 (1) A person who wishes to inspect confidential test data in the Register must submit to the Minister
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> (a) an application in the form and manner directed by the Minister; and
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> (b) an affidavit made under oath or a statutory declaration under the *Canada Evidence Act* made before a commissioner for oaths or for taking affidavits, stating
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> (i) the purpose of the inspection, and
>
> (ii) that the person does not intend to use the test data, or make the test data available to others, in order to register a pest control product in Canada or elsewhere or to amend a registration.

The public may inspect the confidential test data supporting a registration when a decision is made under the PCPA to register a product, amend a registration, or when the registration is continued following a re-evaluation

or special review. If the re-evaluation decision is to phase out the product registration, the supporting confidential test data are available for inspection while the product is still registered.

The confidential test data supporting a proposed post-market decision can also be inspected at the proposed decision stage for re-evaluations and special reviews initiated as of 1 January 2022.

2.2 What Is not available for inspection

Any personal information or confidential business information (CBI) is removed from test data before being made available for inspection. The PCPA defines CBI as:

- manufacturing or quality control processes;
- methods for determining the composition of the product;
- monetary value of pesticide sales, and other financial or commercial information; and
- the identity and concentration of formulants and contaminants in a pesticide, other than those considered to be of health or environmental concern.

Note: Information on the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* can be found in "Science Policy Note SPN2020-01, Policy on the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under paragraph 43(5)(b) of the Pest Control Products Act".

The only information available for inspection is confidential test data used to support one of the decisions mentioned in Section 1.0 Confidential test data are not available for inspection when an application is denied, rejected

or withdrawn, or if a registration is cancelled following a re-evaluation or special review; inspection of confidential test data is only applicable for products registered in Canada.

When evaluating a pesticide in the course of a registration application, a re-evaluation, or a special review, the PMRA considers information other than confidential test data provided by the registrant. While much of the information is already in the public domain (for example, scientific publications), some of it is provided to the PMRA in confidence (for example, unpublished research). In the latter case, if the information provided is confidential test data, it can be inspected in the Reading Room. An appropriate reference for any information considered during an evaluation is provided in the published decision document; as such, anyone wishing to obtain a copy of non-confidential business information can seek to access it (for example, by accessing the scientific publication).

2.3 Timing of data availability

The PCPA, which came into force on 28 June 2006, requires that confidential test data supporting registration decisions be made available for inspection, but only after a decision (or proposed decision in the case of re-evaluations or post-market reviews initiated after January 2022) is made under the 2006 Act. A description of when confidential test data is available for inspection is provided below:

a) Products registered as of 28 June 2006

The confidential test data supporting pesticides registered before 28 June 2006 are not available for inspection until a major regulatory decision (major new use, re-evaluation or special review) requiring public consultation is made under the PCPA, 2006. Only data relevant to the decision are made available at that time.

b) Products registered or that have their registrations amended after 28 June 2006

The confidential test data are available for inspection after a final decision is made under the PCPA, 2006.

In the case of applications to register a new active ingredient, a major new use for a registered active ingredient or to amend a registered product, the supporting data are available after the certificate of registration is issued.

For re-evaluations or special reviews where the decision is to continue the registration, the supporting data are available for inspection after the final decision is published on the PMRA website. Where the final decision is to phase out the product registration (in other words, the effective date of cancellation is postponed), the confidential test data are available for inspection until that effective date. However, if a registration is cancelled immediately following a re-evaluation, the confidential test data are not available for inspection.

c) Proposed or final decisions for post-market reviews

The confidential test data supporting a post-market review can also be inspected at the proposed decision stage for re-evaluations and special reviews initiated as of 1 January 2022 (or at the final decision stage, as noted in c), above).

3.0 Submitting an application to inspect confidential test data

Those wishing to inspect confidential test data must submit a completed Application to Inspect Confidential Data form, along with a signed affidavit or statutory declaration.

3.1 Application form

The Application for the Inspection of Confidential Test Data form is found in the Public Engagement Portal.

3.2 Affidavit / Statutory declaration

a) Requirements

In order to inspect confidential test data, the applicant must submit an affidavit made under oath, or a statutory declaration under the *Canada Evidence Act.*

The applicant should contact a Commissioner for the taking of oaths or declarations, a notary public or someone legally authorized to administer an oath. A template of the affidavit/declaration is available on the PMRA's website. The affidavit or statutory declaration must state:

- the purpose of inspecting the confidential test data; and
- that the person does not intend to use the confidential test data, or make the confidential test data available to others, in order to register a pest control product in Canada or elsewhere or to amend a registration.

If the affidavit or statutory declaration is completed outside Canada, it must be sworn or affirmed before a designated official of Canadian embassies, consulates, high commissions or trade commissions or before judicial officials in the foreign country who are authorized to administer, take or receive affidavits or solemn affirmations. A complete list of designated officials is listed in Section 52 of the *Canada Evidence Act.*

b) False statements in affidavits or statutory declarations

The making of a false statement in the affidavit or statutory declaration is an offence under section 43(9) of the PCPA. If found guilty of an offence, a person is liable:

- on summary conviction: to a fine of not more than $200 000 or to imprisonment for a term of not more than six months, or to both; or
- on conviction on indictment, to a fine of not more than $500 000 or to imprisonment for a term of not more than three years, or to both.

Making a false statement in an affidavit or statutory declaration is also an offence under the *Criminal Code* of Canada.

4.0 Processing the application

4.1 Review of application and affidavit / statutory declaration

Health Canada notifies the applicant when the application has been received and the processing has begun.

The application form is reviewed to ensure that all the required information has been provided, and that the requested data set is available for inspection according to the criteria outlined in Section 2.0. If the data being requested do not meet the criteria, the applicant is informed that their application was not accepted.

Health Canada also verifies that the contents of the affidavit or statutory declaration meet the requirements of the PCPA. An application may be denied for the following reasons:

1. the person intends to use the confidential test data or make it available to others, in order to register a pesticide in Canada or elsewhere, or to amend a registration; or

2. the person has used confidential test data obtained from a prior inspection for purposes described in 1.

To manage resources and workload, Health Canada reserves the right to limit the amount of data inspected per inspection.

4.2 Notice to pesticide registrant

After an application to inspect the confidential test data has been approved, Health Canada notifies the registrant who provided the data that someone has been given permission to inspect their data. The identity of the individual is not disclosed; however, the registrant is notified of the individual's affiliation - as stated on the application form. This notification is not intended to delay the inspection or put the registrant in a position to consent or object.

4.3 Timelines

Health Canada places a higher priority on applications to inspect confidential test data associated with a recent major regulatory decision for which the 60-day reconsideration period is still open. Because the timeframe to submit a Notice of Objection is established by the PCPA and will not be extended, applicants who may wish to file such a Notice should submit their application to inspect CTD well in advance of the close of the 60-day period. For more information on the reconsideration of decision process and how to submit a Notice of Objection, consult the Pesticides portion of Canada.ca, Notice of Objection – Public Engagement Portal.

All other applications are processed on a first come, first served basis. To help ensure equal access and participation, Health Canada reserves the right to limit the duration of the inspection or, in the case of in-person inspection, reschedule a visit if necessary.

5.0 Inspecting confidential test data

5.1 Scheduling the inspection

Once an application has been processed, Health Canada contacts the applicant by phone or email to schedule an inspection. The two options for inspecting the confidential test data are 1) an in-person inspection at the PMRA's Ottawa Headquarters, or 2) a remote and secure inspection of the data as part of an ongoing pilot project, i.e., the Virtual Reading Room.

5.2 In-Person inspection (in the Reading Room)

a) Requirements for entry to Reading Room

A valid picture identification (for example, driver's license) is required to enter into the building. The applicant's identity is confirmed against the previously submitted affidavit or statutory declaration.

b) Protection of data security and copy prevention

Health Canada must ensure that security concerns are considered, and appropriate precautions are taken to prevent the misuse of confidential test data. To prevent copying of data, electronic devices such as cell phones, laptops, digital cameras, and personal digital assistants are not permitted in the Reading Room. These items must be left with the receptionist for the duration of the visit. Be aware that visits are monitored.

c) Data format

The confidential test data are available in electronic format on a computer with disabled ports, in order to prevent the attachment of external copying devices. There is no access to the Internet or internal networks.

d) Note-taking

The right to inspect the confidential test data under section 43 of the PCPA does not include the right to make or obtain a copy of it. While photocopying of the confidential test data is not permitted, note-taking is allowed if the applicant provides consent on the application form to having the notes photocopied. At the end of the visit, the notes are photocopied by Health Canada and retained on file for compliance and administrative purposes.

5.3 Remote inspection (virtual Reading Room)

An interim approach is being piloted, where the confidential test data is encrypted to a USB key and shared with the requester for inspection on their Windows System computer. The software encryption prevents copying, sharing, and printing features. Additional digital rights management measures include watermarking, document expiry, environmental controls, verification of document access, and password protection.

Key steps of the pilot project:

1. Once the inspection request has been processed and validated, the PMRA establishes a delivery date with the requester for the USB key, which is sent by courier.
2. The requester then advises the PMRA of the USB key receipt and provides a signed Data Acknowledgement Form to the PMRA. The PMRA Reading Room administrator activates the USB key remotely for the requester, who can start their inspection of the confidential test data.
3. Upon completion of the data inspection, the requester is to return the USB key to the PMRA, as agreed in the Data Acknowledgement Form.

On the expiry date, the PMRA Reading Room administrator deactivates the USB key and the documents remotely.

6.0 Access to Information Act

The PCPA does not replace but complements the rights of Canadians to submit requests for information under the *Access to Information Act* (ATIA). Applicants may seek access under either or both legislation, each offering their own unique procedures, benefits and limitations.

Accessing information through the PCPA may enable applicants access to information that would not otherwise be available or disclosed through the ATIA. The ATIA requires that certain types of confidential commercial information be protected from disclosure when requested under this Act, subject to some exceptions. As a result, requests under the ATIA could result in disclosure of the same or less information than would be accessible through the PCPA, depending on the specific information and circumstances.

Obtaining access under the section 43 of the PCPA does not create a right to make or obtain a copy of the confidential test data under the ATIA.

For More Information

Please contact the PMRA's Pest Management Information Service.

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