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

Health Canada

1.0 Background

Canada's new *Pest Control Products Act* (PCPA) provides the public with the opportunity to inspect the scientific test data supporting pesticide registration decisions. Companies who want to register a pesticide in Canada must provide test data 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: 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 the test data in the Reading Room, located at the PMRA's National Head Office in Ottawa, Ontario. The data are available for inspection after a final decision is made under the new PCPA to register a product, to amend a registration or to continue a registration after a re-evaluation or a special review is completed. Anyone wishing to inspect the data must submit an application form to identify the data to be inspected 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. There are no fees associated with the inspection of test data.

Providing the public with the opportunity to inspect the 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 it rests. Following a major registration decision for which there was public consultation, the public is encouraged to review the documents in the Public Registry (e.g., evaluation report and decision document) and, if necessary, to inspect the test data in the Reading Room. Anyone who determines there is a scientific basis for reconsidering a registration decision may file a request 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 in the Reading Room. 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 Reading Room visit.

2.0 Availability of Pesticide Information

2.1 Description of Available Information

After 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 not only provides references to the confidential test data submitted by pesticide registrants, but also references any additional information considered in the evaluation.

If a detailed inspection of the confidential test data is desired, members of the public can inspect the test data relevant to the decision in the Reading Room. Since the test data are provided to Health Canada in confidence and are protected from public disclosure under the *Access to Information Act,* the data may be inspected in the Reading Room but cannot be copied or removed from the premises.

The public may inspect the confidential test data supporting a registration when a decision is made under the new 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 test data are available for inspection while the product is still registered.

2.2 What Is Not Available for Inspection

Any personal information or confidential business information (CBI) is removed from the test data before being made available for inspection. The PCPA clearly 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: The *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and Explanatory Note are available in the *Canada Gazette*, Part II, Vol. 139, No. 24, page 2641.

The only information available in the Reading Room is the confidential test data provided by pesticide registrants in support of an application or for the purpose of re-evaluation or special review. Test data are not available for inspection when an application is denied, rejected or withdrawn, or if a registration is cancelled immediately following a re-evaluation or special review.

When evaluating a pesticide, the PMRA may consider additional information other than what was provided by the registrant in support of a registration application, a re-evaluation or a special review. While much of the information is already in the public domain (e.g., scientific publications), some of it is provided to the PMRA in confidence (e.g., unpublished research). In the latter case, the PMRA must respect

confidentiality requirements. An appropriate reference for any additional information considered is provided in the evaluation report so that anyone wishing to obtain a copy can make a request to the provider.

2.3 Timing of Data Availability

The new PCPA, which came into force on 28 June 2006, requires that test data supporting registration decisions be made available for inspection, but only after a decision is made under the new Act. A description of when test data is available in the Reading Room is provided below:

a) Products registered as of 28 June 2006

The 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 new PCPA. Only data relevant to the decision are made available at that time.

b) Products registered or amended after 28 June 2006

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

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 – provided it is not a conditional registration.

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 (i.e., the effective date of cancellation is postponed), the test data are available for inspection until that effective date. However, if a registration is cancelled immediately following a re-evaluation, the test data are not available for inspection in the Reading Room.

c) Conditional Registrations

For products with conditional registrations (i.e., products that are registered on the condition that further data be provided within a specified time period), the evaluation report is published to provide a summary of the data reviewed and the rationale for the regulatory decision, including a description of the data requested. However, the inspection of test data is delayed until:

- the requested data are submitted, evaluated and full registration is supported; or
- the conditional registration is renewed (whichever comes first).

3.0 Submitting an Application to Inspect Confidential Test Data

Those wishing to inspect confidential test data in the Reading Room 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 in the Reading Room, 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 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.

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 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.

A false statement in an affidavit or statutory declaration is also subject to prosecution as 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 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 test data obtained from a prior inspection for purposes described in a).

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

4.2 Notice to Pesticide Registrant

After an application to inspect the 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 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 legislation and will not be extended, applications to inspect the test data in question must be received well in advance of the closing date of the reconsideration period. For more information on the reconsideration of decision process and how to submit a Notice of Objection, consult the PMRA website.

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

5.0 Inspecting Confidential Test Data

5.1 Scheduling an Appointment

Once an application has been processed, Health Canada contacts the applicant by phone or email to schedule an appointment. The Reading Room is situated at: Sir Charles Tupper Building, 5th floor, 2720 Riverside Drive, Ottawa, Ontario. The room is open during normal business hours (8 h 00 to 16 h 00 Eastern Time, Monday through Friday).

5.2 Reading Room Visit

a) Requirements for entry to Reading Room

A valid picture identification (e.g., driver's licence) is required to enter into the building. The applicant's identity is confirmed against the previously submitted affidavit or statutory declaration. As a visitor to the building, the applicant is escorted to the Reading Room situated at the 5th floor Reception area.

b) Protection of data security and copy prevention

Health Canada must ensure that all security concerns are considered and appropriate precautions are taken to prevent the misuse of data inspection. 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 data does not include the right to obtain a copy of it. While photocopying of the 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.

6.0 *Access to Information Act*

The new PCPA does not negate Health Canada's authority and responsibility regarding requests under the *Access to Information Act* (ATIA). Such requests continue to be processed under its terms.

Confidential test data and CBI are both subject to protection from access under the ATIA. Nothing in the PCPA prevents Health Canada from refusing to disclose such information under the ATIA, nor does the right to inspect test data under the PCPA entitle a person to make or obtain a copy of the test data. Because the ATIA protections accorded to third party information continue to exist under the PCPA, the inspection of confidential test data in the Reading Room does not constitute public disclosure and does not compromise the confidentiality of, or proprietary interests in the data. Requests to obtain a copy of the test data and CBI under ATIA must be refused.

For More Information

Please contact the PMRA's Pest Management Information Service.