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Discussion Document

DIS2019-01

# Consultation on Inspecting Confidential Test Data for Post- market Reviews in the Reading Room

*(publié aussi en français)*

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Publications  
Pest Management Regulatory Agency  
Health Canada  
2720 Riverside Drive  
A.L. 6607 D  
Ottawa, Ontario K1A 0K9

Internet: [canada.ca/pesticides](http://canada.ca/pesticides)  
[hc.pmra.publications-arla.sc@canada.ca](mailto:hc.pmra.publications-arla.sc@canada.ca)  
Facsimile: 613-736-3758  
Information Service:  
1-800-267-6315 or 613-736-3799  
[hc.pmra.info-arla.sc@canada.ca](mailto:hc.pmra.info-arla.sc@canada.ca)

Canada 

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The Pest Management Regulatory Agency (PMRA) invites stakeholders and the public to submit written comments on Discussion Document DIS2019-01, *Consultation on Inspecting Confidential Test Data for Post-market Reviews in the Reading Room*.

## 1.0 Purpose of this Consultation

The purpose of this document is to seek input on a proposal to expand access to confidential test data by inviting interested members of the public to inspect this data at the proposed decision stage for post-market reviews (such as, re-evaluations and special reviews).

Presently, confidential test data is prepared for inspection by the public after a final decision is made following a re-evaluation or special review for post-market reviews.

The PMRA is proposing to allow interested parties seeking to understand the scientific basis for a proposed re-evaluation or special review decision to inspect the data used by the PMRA earlier in the process. By viewing this data earlier, comments submitted through the existing consultation process may be more well-informed.

Following the conclusion of the consultation the [Inspection of Confidential Test Data Supporting Pesticide Registration Decisions – Guidance Document](#) will be revised to reflect any changes in policy.

## 2.0 Use of Confidential Test Data for Pesticide Regulation

Before a pesticide can be registered for use in Canada, PMRA reviews available scientific test data to determine whether there are concerns for human health or safety, or the environment, when the product is used according to the label. Some of the data reviewed by the PMRA scientists includes confidential test data.

Confidential test data may include:

- Toxicology related to human health
- Bystander and occupational exposure
- Food residue trials
- Environmental toxicology and fate
- Product efficacy, crop tolerance and benefits of the product
- Other scientific data or studies submitted to, or considered by the PMRA

The PMRA scientists evaluate confidential test data when conducting risk and value assessments. These assessments are an important part of the decision on whether or not the pesticide can be used in Canada, and under what conditions.

Generally speaking, confidential test data is data generated during a scientific study conducted by, or on behalf of, a company applying to register the product under the *Pest Control Products Act*.

The legal definition of confidential test data is provided in the *Pest Control Products Act*, and refers to test data to which access may be refused under the *Access to Information Act*, with section 20 of the *Access to Information Act* being the relevant provision that protects certain third party information.

Confidential test data does not include scientific data that is publicly available (for example, has been published in a scientific journal).

### **3.0 Public Access to View Confidential Test Data**

The [\*Pest Control Products Act\*](#), section 43, provides the public with the opportunity to inspect confidential test data that supports pesticide registration decisions.

The [\*Inspection of Confidential Test Data Supporting Pesticide Registration Decisions – Guidance Document\*](#) describes the current process for the inspection of 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 that the information will not be used to register a pesticide. Confidential test data being inspected at the Reading Room may not be copied or removed from the premises.

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

The PMRA Reading Room is located at the PMRA's National Head Office in Ottawa, Ontario.

### **4.0 Current Proposal**

Providing the public with the opportunity to inspect confidential test data is intended to:

- increase regulatory transparency;
- help interested parties to understand the scientific basis of regulatory decisions; and,
- facilitate more meaningful public participation in the regulatory decision-making process.

The PMRA recognizes that the current approach for post-market reviews (making confidential test data available only after a final decision has been made) may not be meeting expectations of stakeholders and the public.

The proposed change would still require the inspection of confidential test data to take place at the PMRA's National Head Office in Ottawa, Ontario. The PMRA is aware that this may be burdensome for some requestors and is investigating alternative approaches for the future that may allow the inspection of data through other means (for example, satellite reading rooms, secure portals, etc.).

## 5.0 How to Get Involved

The PMRA invites the public to submit written comments on this document up to 60 days from the date of publication.

Please forward your comments to [PMRA Publications](#), and include:

- Your full name and organization;
- Your phone number; and,
- Your complete mailing address or email address.

Comments or questions on this consultation can also be directed to the [Pest Management Information Service](#), by subject.

## 6.0 Reporting to Canadians

Health Canada will make the results of this consultation available on this website. When the consultation has been completed, the PMRA will update the policy pertaining to the Inspection of Confidential Test Data Supporting Pesticide Registration Decisions and publish it on the Pesticides and Pest Management Reports and Publications portion of Canada.ca.

If you have any questions, contact the Pest Management Information Service.

## 7.0 Related Information

*Inspection of Confidential Test Data Supporting Pesticide Registration Decisions – Guidance Document*

- <http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/data-donnes-confid-eng.php>

*Pest Control Products Act*, S.C. 2002, c. 28

- <https://laws-lois.justice.gc.ca/eng/acts/P-9.01/FullText.html>

*Access to Information Act*, (R.S.C., 1985, c. A-1)

- <https://laws-lois.justice.gc.ca/eng/acts/A-1/>