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Accessing Confidential Test Data Under Pest Control Products Regulations – Proposed Guidance Document

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Notice to the Reader: The following is a consultation document that informs Canadians, regulated parties, Indigenous organizations, and other interested stakeholders and partners about how Health Canada is considering implementing the proposed regulations on public disclosure of confidential test data, titled "Regulations Amending the Pest Control Products Regulations (Strengthening the Regulation of Pest Control Products in Canada)" and pre-published in the *Canada Gazette,* Part I for consultation on 15 June 2024, available at the following link: https://canadagazette.gc.ca/rp-pr/p1/2024/index-eng.html. Health Canada is seeking feedback on this proposed guidance document, which will inform its finalization should the proposed regulations be adopted by the Governor in Council.

1.0 Background

The purpose of this document is to provide the public with a description of the proposed policy and procedures for accessing confidential test data (CTD) under the proposed amendments to the Pest Control Products Regulations. The document explains what information could be accessed and when. It also provides guidance on how an application may be submitted to access CTD for research and reanalysis purposes, and a description of what may be expected under the proposed regulatory regime.

Under the *Pest Control Products Act*, CTD is scientific or technical information respecting the health or environmental risks or the value of a pest control product to which access may be refused under the *Access to Information Act*.

Under section 43 of the *Pest Control Products Act*, any person can submit an application to Health Canada's Pest Management Regulatory Agency (PMRA) to inspect CTD. To do so, they must include an affidavit or statutory declaration that states the purpose of the inspection of the CTD and that the person does not intend to use the CTD, or make the CTD available to others, to register a pest control product in Canada or elsewhere, or to amend a registration. More information on how to submit an application to inspect CTD under section 43 can be obtained through the PMRA Guidance Document on Inspection of Confidential Test Data Supporting Pesticide Registration Decisions.

PMRA has heard from stakeholders that the conditions regarding the inspection of CTD under section 43 of the *Pest Control Products Act* present challenges for individuals to perform independent research and reanalysis of the evidence underlying PMRA's regulatory decisions. This in turn impacts Canadians' overall confidence in the federal pesticide regulatory system. Further to this feedback, proposed regulations titled "Regulations Amending the Pest Control Products Regulations (Strengthening the Regulation of Pest Control Products in Canada)" were pre-published in the *Canada Gazette,* Part I for consultation on 15 June 2024 to amend Canada's Pest Control Products Regulations. The proposed regulations aim to provide an additional pathway for individuals to access CTD in the Register[1] of Pest Control Products in a manner that would facilitate research and reanalysis.

[1] The Register is a repository of information that is internal to the PMRA; it contains information about pest control products, including information about applications, registrations, re-evaluations and special reviews. The PMRA also maintains an electronic public registry, which contains information from the

The proposed regulatory pathway for access to CTD for research and reanalysis purposes is intended to provide another way for any individual to access CTD, in addition to the existing process under Section 43 of the *Pest Control Products Act*. It does not replace the latter.

Under the proposed pathway, individual members of the public would be able to request access to CTD under the Pest Control Products Regulations by making a request via the PMRA's Public Engagement Portal, as is the case now for requests made further to section 43 of the *Pest Control Products Act*.

The key objectives of this proposed additional process to access CTD are to improve transparency and public participation in the regulatory decision-making process, to increase access to independent data that could be generated from independent research and reanalysis, and to ultimately better inform PMRA decisions and strengthen public trust. This is particularly important for anyone who may consider filing an objection to a major registration decision, as they must identify the scientific basis on which the objection rests.

2.0 Availability of pesticide information

Companies that 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 the PMRA for evaluation. This data, along with data from other sources, is evaluated by PMRA scientists, who conduct risk and value assessments leading to decisions on whether the pesticide can be used in Canada and under what conditions. Data requirements cover a number of areas, depending on the nature of the product and its intended uses, 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.

2.1 Description of available information

When a pesticide is first registered, significantly amended, or undergoes a re-evaluation or special review, the public is able to review the proposed and final decision documents made available on the Decisions and updates page on Canada.ca. These documents explain the risk and value assessments supporting a registration decision, along with a summary of the information relied on to reach the conclusions. The proposed and final decision documents provide references to the data used to make the decisions, including references to the test data submitted by pesticide registrants and applicants and any other information relied on.

Register that the Public may obtain a copy of under the *Pest Control Products Act* and Pest Control Products Regulations, in addition to information on memoranda of understanding between federal government departments, information on international harmonization activities, regulations and proposed regulations, as well as policies, guidelines, and codes of practice.

As with inspections under section 43 of the *Pest Control Products Act*, only CTD that is in the Register would be accessible under the proposed regulatory pathway. Accordingly, CTD would be accessible:

- after a final decision is made under the *Pest Control Products Act* to:
    - register a product,
    - amend a registration, or
    - continue registration after a post-market review (in other words, a re-evaluation or a special review) is completed.
- at the proposed decision stage for post-market reviews initiated as of 1 January 2022.

When evaluating a pesticide in the course of a registration application, a re-evaluation, or a special review, the PMRA considers all information provided by the registrant or applicant (both CTD and information that is not CTD) or obtained elsewhere by the PMRA. While some information is already in the public domain (for example, scientific publications), a portion of it is confidential in nature (for example, certain unpublished research). In the latter case, if the information is CTD and in the Register, it would be accessible as set out under the proposed regulations (in other words, at the final registration decision stage, or in the case of post-market reviews, at the proposed decision stage).

In addition to domestic legal obligations, Canada has international treaty obligations to protect CTD from disclosure and unfair commercial use, in particular through the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights. Consequently, the process to access CTD would include rigorous controls by the PMRA to fulfil these obligations and to prevent the data from being published or disseminated inappropriately.

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 access.

The *Pest Control Products Act* defines CBI as information to which access may be refused under the *Access to Information Act*, that is provided under the *Pest Control Products Act* and is designated as CBI by the person who provided it, and that:

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

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*".

3.0 Identifying CTD

In accordance with the proposed regulations, applicants and registrants would be required to provide sufficient information to enable the PMRA to better identify CTD when submitting any test data after these proposed regulations come into force. While the PMRA would still be responsible for determining whether the test data is CTD, the information provided would help inform the PMRA's determination, mindful of the requirements under the *Access to Information Act* and the *Privacy Act.*

To facilitate this process, it is expected that the following mandatory questions would be included as part of the standard process for registrants or applicants to submit test data to the PMRA:

- Is the information being provided to the PMRA already public, and if so, where can it be found?
- Is it a trade secret?
- Would the disclosure of any non-public information cause prejudice to the applicant, registrant or a third party, and if so, what would be the nature of that prejudice?

In providing this information, "trade secret", "publicly available" and "prejudice" would be understood as:

- A "trade secret" is understood in the same way as it is understood in the Treasury Board Secretariat's Access to Information Manual, which provides guidance on how to interpret the *Access to Information Act*.
- Examples of trade secrets that may be determined to constitute CTD could include certain types of testing methodologies or certain types of aggregated information on a pest control product's safety or efficacy, where such information satisfies the requirements of "confidential test data" under the *Pest Control Products Act*.
- Information may generally be considered to be "publicly available" (see Treasury Board Secretariat's Access to Information Manual) where:
    - it has been published in some form currently available to the public or when it is available in a publicly accessible record or a publicly accessible databank;
    - it is reasonably accessible to the public, not just a select class of persons;
    - it could have been compiled, with little effort, from a number of distinct public records or through a comparison of source documents;
    - it is evident that the information has been made available in a public forum; or,
    - it has been made public by design, that is by law or with the individual's consent, and not by accident.
- "Prejudice" may include financial loss, financial gain to a third party, interference with contractual or other negotiations, or negative effects on the registrant's/applicant's competitive position.

Where the initial information provided is not sufficient, applicants or registrants would also be required to provide any additional information that may be relevant to the determination of whether the test data in question is CTD. This could include, depending on the circumstances,

which part of the document the applicant or registrant considers to be CTD. As each situation may be unique, the PMRA may follow up with the applicant or registrant to obtain further information, as needed.

In instances where the PMRA concludes, mindful of the information provided by the applicant or registrant, that the test data submitted is not CTD under the *Pest Control Products Act*, even if the applicant or registrant specifically identified it as such, the PMRA would inform the applicant or registrant accordingly prior to providing access via the new regulatory pathway or section 43 of the *Pest Control Products Act*.

4.0 Submitting an application to access CTD

To request access to CTD under the proposed regulations, an individual would have to make a request via the Public Engagement Portal, as is the case now for requests made further to section 43 of the *Pest Control Products Act*.

4.1 Information to be provided

The individual requesting access to CTD would have to be a resident of Canada, and would have to submit a completed Application to Access Confidential Test Data form, which would be found in the Public Engagement Portal.

In completing the form, the individual would be required to provide their name, residential address in Canada, and email address, along with official government-issued documentation that contains a picture and the address of the individual, so that the PMRA could confirm the identity and residency of the requestor.

The individual would also need to specify what CTD they are requesting access to, the purpose of their research or reanalysis and how the requested CTD is related to it, along with the length of time for which access to CTD is requested, for a maximum of five years.

In the event of any changes to key information provided, the individual would have to update the PMRA as soon as practicable, but in any case within fifteen days of the change.

The PMRA would not require test data submitted as part of an evaluation process to be provided in any specific electronic format. However, the PMRA policy would request registrants or applicants to provide CTD in a format that allows for electronic copying and pasting using commonly available software. This could be done, for example, by providing the data in an Excel spreadsheet, a Word document, a PDF document with copying and pasting enabled, or any other format that allows the copy of data. While the proposed CTD disclosure provisions would apply generally to all CTD in the Register, using an accessible format when submitting CTD would only be applicable to CTD provided after the coming into force of these regulations.

In the proposed regulations, “research” would include scientific or technical inquiry or experimentation, carried out to acquire knowledge or discover new means of applying existing knowledge as relating to the regulation of pest control products under the *Pest Control Products Act*.

“Reanalysis” would include reviewing data and considering/evaluating its validity and quality.

4.2 Acknowledgment of conditions and restrictions

When submitting a request, the individual would have to confirm that they have read and understood the requirements set out in the regulations and that they are aware that the CTD that they have requested may be protected by intellectual property rights. This is to ensure that the individual is aware of the conditions of access and the restrictions on the use of the CTD; non-compliance with the regulatory requirements would amount to a breach of the proposed regulations. Finally, the individual would have to confirm that the information they are submitting is accurate and complete. These prompts would be in the form of a box on which individuals would have to click in order to proceed to submit their application.

4.3 Joint requests

To enable research teams to access the same CTD to conduct their research or reanalysis, it would be possible for individuals to make a joint request. In this case, all members of a joint request would have to make a request for access to CTD with the PMRA and provide the required information; CTD would only be disclosed to those individuals who did so and who meet the proposed regulatory requirements. Members of a joint request that have been explicitly authorized by the PMRA to access CTD would be able to share that CTD among themselves.

5.0 Processing the application

5.1 Review of application

The PMRA would notify the applicant when the application has been received and the processing has begun.

The PMRA would review the application to ensure that all requirements under the regulations have been met, including all documentation provided to verify the identity of the individual making a request, and that they are a resident of Canada.

5.2 Denial of application

Following the review of the application, the PMRA would provide access to the CTD requested by the individual, except in the following instances:

1. the individual is not a resident of Canada; or
2. the application was not complete; or

3. the PMRA has reasonable grounds to believe that:
    a) the individual intends to use the CTD to register a pest control product in Canada or elsewhere or amend a registration, or has used CTD for such a purpose in the past;
    b) the individual intends to make the CTD available to any person for these purposes, or has done so in the past; or
    c) the individual intends to contravene any of the requirements in the regulations, or has done so in the past.

The PMRA would also be able to refuse access in the following limited circumstances where it has determined that:

1. the data requested is not reasonably related to the purpose of the research or reanalysis identified in the application; or
2. it is unreasonable to respond to the request, taking into account:
    a) the scope of the request;
    b) the volume of CTD requested;
    c) the repetitive or systematic nature of the request; and
    d) the impact of the request on departmental operations related to pesticide regulation.

5.3 Prioritization

The PMRA would prioritize applications to access CTD associated with a major regulatory decision referred to in section 28 of the *Pest Control Products Act* which is subject to the reconsideration provisions in the Act. Applicants wishing to participate in the reconsideration process under the Act by filing a Notice of Objection are encouraged to submit their application for access to CTD as soon as possible after the decision in question is published, in order to maximize the time to access the data. For more information on the reconsideration of decision process and how to submit a Notice of Objection, consult the Pesticides and pest management portion of Canada.ca, Notice of Objection – Public Engagement Portal.

All other applications would be processed on a first come, first served basis, and an individual would be notified if their request was put on hold due to a higher-priority request having been made.

5.4 Notice to pesticide registrant

Those who submitted the CTD would be notified if access to their CTD has been granted. This would be automated, and done via email to the extent possible. This notification would occur as soon as access to the CTD has been granted. The identity of the individual accessing the CTD would not be disclosed. This notification would be for information only.

6.0 Accessing confidential test data

6.1 Time periods

Upon receipt and verification of the request for access, the PMRA would disclose CTD to the individual until the earliest of the following, unless the request is denied:

- the end of the period of time for which access is requested;
- the day on which the PMRA has been notified that the research or reanalysis identified in the request is complete and access to the CTD is no longer required; or
- the end of the five-year period from when access to the CTD was granted.

A new request for access would be required, should the individual need to access the CTD beyond the period requested, up to five years.

7.0 Responsibilities of individuals accessing CTD

Individuals accessing CTD under the proposed regulations would be required to use the CTD only for research or reanalysis as further articulated in their request to access CTD submitted to the PMRA (see Section 4.1).

Moreover, individuals would be required to comply with all the requirements set out in the proposed regulations, failure of which would be a contravention of the regulations, and would result in the revocation of their access and denial of future requests to access CTD.

As further set out in the proposed regulations, individuals accessing CTD would be required to:

- be a resident of Canada;
- access the CTD only from within Canada;
- store the CTD in a secure location in Canada; for example, by storing the CTD as a password-protected file on a password-protected USB key or computer, and not “in the cloud”, which could be based in another jurisdiction;
- ensure the CTD remains within Canada. Individuals would not be allowed to bring copies of the CTD outside of Canada; and
- destroy the CTD when the research or reanalysis is completed, the access period has ended, or the access has been otherwise revoked by the PMRA, and notify the PMRA within 15 days that they have done so.

Further, they would not be able to:

- publish the CTD;
- disseminate the CTD to any other entity or person, beyond those who have taken part in a joint request; or
- use the CTD to register a pest control product in Canada or elsewhere, or to amend a registration, or provide the CTD to another person to do so.

In addition, individuals would be required to notify the PMRA of any inadvertent disclosure of personal information in the CTD or as soon as they become aware of unauthorized or possible unauthorized disclosure of the CTD.

It would be possible to publish general findings or conclusions based on the CTD accessed, as long as the CTD cannot be extrapolated from the research.

Enforcement and monitoring

Individuals seeking access to CTD would have to acknowledge that they have read and understood the above restrictions as part of their request to access CTD. Contravention of these requirements would be an offense under the *Pest Control Products Act* and would be subject to the enforcement provisions contained in the Act.

How to get involved

This consultation is open for comment from 17 June to 5 September 2024 (80 calendar days).

Comments from the public, stakeholders and partners can be provided by:

Email at: pmra.regulatory.affairs-affaires.reglementaires.arla@hc-sc.gc.ca

or

Mail at:
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