

NAFTA Factsheet

Public Requests for Pesticide Information

Under Canadian and U.S. federal law, the public is entitled to access test data supporting pesticide registrations. The policies by which the public access to data is granted is different between the two countries: the Canadian public may inspect confidential test data in a reading room, whereas in the U.S. the public may obtain a copy of the data.

Pesticide companies submit scientific test data and information to support the registration of a pesticide. While this information must be accessible to the public, any privileged or confidential proprietary business information (CBI), such as trade secrets or commercial or financial information contained within the test data is removed and protected in both Canada and the United States.

Under the authority of the new *Pest Control Products Act* (PCPA) which came into force on June 28, 2006, Health Canada's Pest Management Regulatory Agency (PMRA) must provide the public with the opportunity to inspect confidential test data. A controlled reading room has been chosen as the setting in which such inspections take place. The data are available for inspection after a decision is made under the new Act to register a product, to amend a registration or to continue a registration after completion of a re-evaluation or a special review. The opportunity to inspect the test data is particularly important for anyone planning to file a Notice of Objection to a registration decision since they must identify the scientific grounds on which the objection rests. Such Notices may be filed in relation to major decisions on which the public must be consulted in accordance with the Act.

The U.S. *Freedom of Information Act* (FOIA) allows the public to obtain copies of records in the possession of federal agencies. The Environmental Protection Agency (EPA)'s Office of Pesticide Programs provides the fullest possible disclosure of information to the public unless the information falls into one of the exemptions of FOIA (e.g., personal privacy, Confidential Business Information, trade secrets, etc.). A company submitting studies may specify the information it considers to be trade secrets or commercial or financial information. Such information cannot be released for inspection before the information provider is advised and given the opportunity to oppose such release in a district court action. EPA currently treats pesticide data not claimed as CBI as publicly available subject to limitations imposed by Section 10(g) of the *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA).

Confidential Test Data and Confidential Business Information

The Canadian provisions regarding CBI and confidential test data are similar to those of the United States, with one exception. In Canada, formulants and contaminants of concern identified on a statutory List are not considered as CBI whereas the U.S. requires that List 1 inert appear on the label. A comparison of the PCPA and FIFRA provisions is provided in Table 1.

Table 1. Comparison of Selected Provisions Regarding Public Access

Definitions		
	PCPA	FIFRA
Test Data	<p>Scientific or technical information respecting the health or environmental risks or the value of a pest control product</p> <p>Confidential test data means test data to which access may be refused under the <i>Access to Information Act</i>.</p>	<p>Section 10(d) (1): Information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide (...) or any information concerning the effects of such pesticide on any organism or the behaviour of such pesticide in the environment (...).</p>
Confidential Business Information	<p><i>Pest Control Products Act</i> Information to which access may be refused under the <i>Access to Information Act</i> (ATIA), and meets the requirements of subsection 43(4) or (5) of the new PCPA: (a) manufacturing or quality control processes relating to a pest control product; (b) methods for determining the composition of a pest control product; or (c) the monetary value of sales of pest control products (...) and other financial or commercial information (...). (d) the identity and concentration of the formulants and contaminants in a pest control product, other than those considered to be of health or environmental concern that are identified on a list to be made available to the public (List of Pest Control Product Formulants and Contaminants of Health or Environmental</p>	<p>Section 10 (b) [...] the Administrator shall not make public information which in the Administrator's judgement contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential [...].</p> <p>Note: Section 10(d)(1)(A)-(C) describes data that are not automatically made public. They still have to meet the standard in 10(b) before they are eligible for confidential treatment:</p>

Definitions		
	PCPA	FIFRA
	<p>Concern)</p> <p><i>Access to Information Act</i> Section 20(1): (...) shall refuse to disclose any record requested under this Act that contains:</p> <p>(a) trade secrets of a third party; (b) financial, commercial, scientific or technical information that is confidential information supplied to a government institution by a third party and is treated consistently in a confidential manner by the third party; (c) information the disclosure of which could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, a third party; or (d) information the disclosure of which could reasonably be expected to interfere with contractual or other negotiations of a third party.</p>	<p>Section 10(d): [...] not authorize the disclosure of any information that -</p> <p>(A) discloses manufacturing or quality control processes,</p> <p>(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or</p> <p>(C) discloses the identity of percentage of any deliberately added inert ingredient of a pesticide, unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.</p>

In the U.S., data from studies are not entitled to confidential treatment once the pesticide has been registered (with limited exceptions). While companies submitting studies are authorized to specify what information is CBI, the information is often submitted without any such indication. However, EPA often assumes that such information may be subject to a confidentiality claim and proceeds accordingly. EPA has proposed to clarify its policies on confidentiality claims and on the release of information by the Agency.

In Canada, confidential test data and CBI are subject to protection from access under the *Access to Information Act* (ATIA). Nothing in the PCPA prevents the PMRA 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. Since 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

or proprietary right of the data. Requests to obtain a copy of the test data under ATIA must be refused.

Prior to submitting studies to PMRA for review, the information providers must designate and segregate CBI from the test data. The PMRA verifies that the designated information meets the CBI definition before the pesticide is registered, so that the data are ready for inspection as soon as a regulatory decision is finalized.

Requesting Information

In order to prevent unauthorized use of pesticide data by competitors, Section 10(g) of FIFRA is intended to prevent EPA from providing proprietary data to businesses or other entities who would then use that information to register a pesticide product in foreign countries. The requester must submit a signed “Affirmation of Non-Multinational Status Form” stating that he or she does not intend to, and will not purposefully or negligently deliver the information to foreign national or multinational pesticide producers. Once the information request and affirmation form have been submitted, EPA provides a copy of the pesticide test data or studies to the requester, with the CBI removed.

Anyone wishing to inspect confidential test data in the Canadian reading room must submit an application as well as an affidavit or statutory declaration stating the purpose of the inspection, and attesting that the data will not be used or made available to others in order to register a product or amend a registration in Canada or elsewhere. The application can be denied if the PMRA believes the intent is to use or share data for the purposes of registration, or if a person has breached a previous undertaking. Breach of the affidavit or declaration is a criminal offence and punishable by fine or imprisonment. The PMRA notifies the information provider when someone has been permitted to inspect their data in the Reading Room.

The test data are available for inspection in the Reading Room at the PMRA National Office in Ottawa, Ontario. The visitor is escorted to the Reading room and monitored during the visit. The data are available in electronic format on a computer with disabled ports to prevent the attachment of external copying devices. Photocopying of the test data is not permitted, but note-taking is allowed and a copy of these notes are retained on file.

Weblinks

<i>Pest Control Products Act</i> http://laws.justice.gc.ca/en/P-9.01/92455.html	<i>Federal Insecticide, Fungicide and Rodenticide Act</i> http://www.access.gpo.gov/uscode/title7/cha-pter6_.html
<i>Access to Information Act</i> http://laws.justice.gc.ca/en/A-1/218072.html	<i>Freedom of Information Act</i> www.epa.gov/foia/foiastat.htm
Canada’s Access to Information and Privacy Homepage	EPA’s FOIA Homepage http://www.epa.gov/foia/

http://www.tbs-sct.gc.ca/gos-sog/atip-aiprp/index_e.asp	
How to make Reading Room Request http://www.pmra-arla.gc.ca/english/pubreg/tesdata-e.html	How to make FOIA Request: www.epa.gov/foia/guide.html