Health Canada
Pest Management Regulatory Agency

Santé Canada
Agence de réglementation de la lutte antiparasitaire

Regulatory Directive

DIR2007-03

Protection of Proprietary Interests in Pesticide Data in Canada

(publié aussi en français)

1 August 2007

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Information Service:
1-800-267-6315 or 613-736-3799
Facsimile: 613-736-3758

Canada

ISBN: 978-0-662-46580-5 (978-0-662-46581-2)
Catalogue number: H113-3/2007-3E (H113-3/2007-3E-PDF)

Table of Contents

1.0 Introduction

In this Regulatory Directive, Health Canada's Pest Management Regulatory Agency (PMRA) describes new provisions for the protection of proprietary interests in data submitted to the PMRA in support of registration, re-evaluation and special review of pesticides, including technical grade active ingredients and their manufacturing concentrates as well as end-use products. This Regulatory Directive replaces the Product-Specific Registration (PSR) provisions found in Trade Memorandum T-1-249, *Product-Specific Registration and Proprietary Rights to Data*, dated 8 July 1987.

On 11 December 2006, the PMRA published for consultation Regulatory Proposal PR02006-03, *Protection of Proprietary Interests in Pesticide Data in Canada*, and comments received from a variety of stakeholders were considered in establishing this Regulatory Directive. A summary of the comments received can be found in Appendix I.

The new provisions will come into effect in two stages. Beginning 1 August 2007, the protection of databases supporting technical grade active ingredients will be implemented. In a second phase, beginning 1 January 2008, the protection of databases supporting end-use products and manufacturing concentrates will follow suit.

The provision of this Regulatory Directive will initially be implemented on a policy basis. However, once experience has been gained with the new provisions under this policy, the PMRA intends to develop regulations under the *Pest Control Products Act* that will prescribe the circumstances and conditions under which the information provided to the Minister is protected and how it may be used or relied upon by others than the initial registrants for applications or registrations.

2.0 Purpose and Context of Directive

This Regulatory Directive sets the Agency's policy for the protection of proprietary interests in pesticide (PPIP) data. It retains many of the elements of the earlier versions of Product-Specific Registration (PSR) as it relies on the principle of chemical or biological equivalency and specifies categories of protected data and duration of data protection. However, in contrast to PSR, the PPIP policy places the onus of determining data value and compensation on the companies involved.

To ensure that the health and environmental risks as well as the value of the pest control products are acceptable, the PMRA requires that applicants submit pertinent scientific data. The Directive describes how data used to support and maintain registration of pest control products are protected and how they could be relied on subsequently by applicants[1] for registration of equivalent technical grade active ingredients, manufacturing concentrates and end-use products.

[1] A new registrant relying on the database of another registrant's equivalent pest control product, in accordance with the provisions of this Regulatory Directive, is also called a generic pesticide registrant.

The PPIP policy is intended to encourage the introduction of new pesticides by protecting the innovator's substantial investment in a supporting database, thereby encouraging the availability of modern, innovative, potentially lower-risk products to Canadian users. On the other hand, the time limited nature of the data protection period will allow for introduction of equivalent products by generic manufacturers, thus enhancing market competition to the benefit of users, including growers. The PPIP policy includes incentives for adding uses primarily, but not exclusively identified on the Minor Use National Priority Listing through extended protection periods.

3.0 Overview of the PPIP Policy

The PPIP policy attempts to create a climate favourable to the introduction of new and reduced-risk pest control products, by protecting the investment in regulatory data made by innovator companies in supporting the registration of their products. This type of limited protection of regulatory data is common throughout the world and is included in international trade agreements such as the North American Free Trade Agreement s.1711 and the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights s.39.3. In addition, the PPIP policy aims to provide favourable conditions for generic pesticide producers to enter the pesticide market and to increase the selection of products available to the user.

The purpose of the PPIP policy is to provide a clear direction for data protection, i.e. which data will be protected, to what degree and for how long they will be protected as well as a process by which generic pesticide producers can gain the right to rely on protected data.

This Regulatory Directive first sets out the primary policy objectives and the principles that guided the development of the revised policy. It also describes which data will be protected, which protection status they will be assigned and for how long they will be protected. It then describes the conditions under which and the mechanism by which the protected data may be accessed by an applicant desiring to rely on data from registrants.

The transition from PSR to the PPIP policy is described as a stepwise progression of the regulatory process that would apply to a request to register a generic product.

4.0 Major Elements of the Policy to Protect Proprietary Interests in Pesticide Data

4.1 Policy Objectives

The objectives of the PPIP policy are as follows:

- A policy that provides fair protection of the proprietary interests in data to encourage the introduction of new and reduced-risk pest control products while providing a predictable, timely process for the introduction of competing generic pesticide products to the Canadian market.

- A policy that encourages registrants to seek registration of a wider range of pesticide uses that have been identified as important to Canadian users[2].
- A policy that confers the determination of data value and compensation to the sphere of business decisions and agreements negotiated between the parties with regulatory guidance but without the direct participation and enforcement by the PMRA.

4.2 Guiding Principles

In establishing this PPIP policy, the PMRA was guided by the following considerations:

- Technical grade active ingredients, manufacturing concentrates and end-use products must be found equivalent before reliance on an innovator registrant's database can be considered.
- Canada's obligations with respect to international agreements on data protection must be fulfilled.
- The PMRA approaches should be in close alignment with the United States Environmental Protection Agency (USEPA) general approaches to data protection and access of generic applicants to protected data.
- Rules and processes for the PPIP policy should be clear and simple, and the process and rules for negotiations should be transparent and predictable.
- Unnecessary, duplicative animal testing should be avoided.
- All registrations must be supported by relevant health, environmental and value data.

4.3 Data Protection

4.3.1 Application of the Policy

The PMRA will apply the PPIP policy when an applicant requests to register or amend the registration of a technical grade active ingredient, manufacturing concentrate or end-use product relying wholly or in part on data of another company with a registered product.

When an applicant copies an end-use product based on a technical grade active ingredient, manufacturing concentrate or an end-use product purchased from a registered source, and this registered source (or affiliated company) confirms this to the PMRA in writing via a Letter of Confirmation of source of supply, the Agency will grant access to the protected database without further consideration of protection status. The PMRA assumes that the access to the protected data and the compensation have been part of the business agreement between the registrant and the applicant.

[2] The Agency needs to further assess the criteria for the addition of those minor uses that will qualify for an extension of the exclusive protection period and will later update the Regulatory Directive accordingly.

4.3.2 Protected / Non-Protected Data

Under the PPIP policy, the proprietary interest in the following data will be protected:

- Data submitted to the PMRA by the first registrant and that formed the basis for registering the technical grade of a new active ingredient and its associated end-use product and/or manufacturing concentrate.
- Data submitted to the PMRA after the first registration of a technical grade active ingredient, an end-use product or a manufacturing concentrate and that formed the basis for additional/amended registration or the maintenance of a registration, i.e. data submitted for use expansions, new formulations, updating of existing data.
- Data requested by the PMRA as a condition of registration and data requested under sections 12(1), 16(3) and 18(1) of the *Pest Control Products Act*, which were part of the data used by the Agency in arriving at re-evaluation or special review decisions. The proprietary interests in these data will be protected for specified periods of time (see Section 4.3.4) and may be relied on by applicants only under specified conditions.
- Studies submitted under Section 13 (incident reporting) once used in support or maintenance of a registration

The following data will not be protected:

- Data that are in the public domain, e.g. data published in the open literature.
- Research and monitoring data generated in Canada by federal and provincial government bodies or by international regulatory bodies such as the World Health Organization.
- Data that the PMRA deemed to be invalid for regulatory purposes.
- Data not requested by the PMRA and not considered for a registration decision.
- Data specific to a tank mix between two or more end-use products that are already part of an existing registration.

4.3.3 Classification and Protection Status of Data

Databases will be assigned a protection status based on their nature, the regulatory context of submission and their use in making registration decisions.

The PMRA will assign a protection status to an entire database rather than to identify and assign a protection status to individual studies within a database. Although a generic pesticide registrant may choose to only negotiate the compensation for those protected studies needed for his specific uses, a letter of access applies to the entire database. A database could only have one of the following protection status.

Exclusive Protection Status
Data submitted to the PMRA and that formed the basis for registering the technical grade of a new active ingredient and its associated end-use product or manufacturing concentrate will be given an exclusive protection status. Also included in the exclusive category will be all data requested as a condition of the first registration through a Section 12 Notice[3, 4].

An exclusive protection status will be given for a specified period during which it cannot be used by an applicant without written consent from the first registrant. During the exclusive protection period, the registrant (owner of an original database) can voluntarily, but is not obliged to, enter into negotiation with an applicant for access to and compensation for a database under exclusive protection.

Compensable Protection Status
Data submitted to the PMRA subsequent to the first registration of a new technical grade active ingredient, and its accompanying end-use product or manufacturing concentrate, are assigned a compensable protection status. These are data that formed the basis for an additional/amended registration or maintenance of a registration, i.e. data submitted for use expansions, new formulations, data requested under sections 12(1), 13, 16(3) and 18(1) of the *Pest Control Products Act* submitted to and considered by the PMRA in the context of re-evaluation and special review.[4]

It should be noted that a database's compensable protection status starts only once the exclusive protection status of a database has lapsed and the compensable data will only benefit from the remaining protection time.

A compensable protection status will be given for a specified period of time during which an applicant can gain the right to rely on a registrant's database by entering into a negotiated commercial agreement that addresses the issue of data access and compensation of the owner of those data.

The owner of the compensable database will be obliged to negotiate with an applicant and, if necessary, binding arbitration may be used for a final resolution of access and compensation issues.

Non-Protected / Generic Status
The PMRA will consider any database that does not meet the criteria for exclusive or compensable protection status, or whose exclusive or compensable protection status has lapsed, to be without protection.

---

3 An exclusive protection period will not be granted to the technical grade active ingredients that were given registration status through a "grandfathering" process and that are supported with only minimal or no data.

4 Evolving science will lead to new scientific approaches and studies that are not part of the Agency's data requirements, but that can become an integral part of the scientific data supporting the registration of a pesticide. These new studies will receive compensable protection status.

4.3.4 Protection Periods—Start and Duration

A database that qualifies for an exclusive protection status will be given 10 years of exclusive protection from the date of first registration of a technical grade active ingredient. In order to encourage and to set a regulatory climate favourable to adding minor uses, it will be possible to extend this period incrementally up to five years, with the addition of minor uses that are of significant benefit to Canadian users. However, the comments received from stakeholders raised a number of questions that must be addressed before these provisions are implemented. The Agency will further analyze the different proposals and intends to finalize the eligibility criteria in 2008. Products that are registered in the mean time will remain eligible for an extension once the final provisions are in place.

Data from a database that qualify for a compensable protection status will be given 12 years of compensable protection from the date of the original application for a use expansion or a change of formulation, and from the date of submission when providing data in response to a PMRA request under sections 12(1), 16(3) and 18(1) of the *Pest Control Products Act* in support of reevaluation or special review decisions. Protection period for data provided under Section 13 will start once it has been cited in an application or used in a re-evaluation.

The compensable protection period cannot be extended by providing new data comparable to previously submitted data.

Once a registrant has granted an applicant the right to rely on a database under exclusive or compensable protection, this right cannot be revoked. This right extends only to the database comprising those studies identified by the registrant and the PMRA prior to the negotiation period. Future data that might be added will not be covered under this right to access.

4.4 Access to Protected Data

4.4.1 Negotiation/Arbitration

During the period of exclusive and compensable data protection, an applicant can acquire the right to rely on a protected database through negotiation with the owner of the database. Applicants can also submit data comparable to the protected data, but such data would not be granted protection exceeding that of the original protection period.

Negotiation of access to a database under exclusive protection status will be strictly voluntary on the part of the owner of the data. The PMRA will allow for submission of an application to establish equivalency, but will take no further part in these commercial negotiations and will consider an application for registration only upon receipt of a written communication of the business agreement giving the right to rely on the protected database.

Negotiation of access to a database with compensable protection status will be mandatory. The *Pest Control Products Act* sections 66(1) and 66(2) require that the Minister determine the terms and conditions of agreements to be entered into by registrants and applicants for the purpose of determining compensation payable for the right to use or rely on information provided by

registrants to the Minister under the Act. Section 66(2) further requires that such an agreement be arrived through negotiation and binding arbitration, in accordance with regulations made under section 67(1)(h). The Act further stipulates that for the purpose of the regulation the Commercial Arbitration Act shall be used.

The PMRA intends to implement these provisions of the *Pest Control Products Act* and will develop a regulation within a reasonable time. The regulation will set out the principal parameters for negotiation and binding arbitration. The Agency also intends to develop a guidance document that will identify general principles and major considerations to be taken into account in arbitration.

The Agency will develop an on-line database of protected studies for the direct use by generic pesticide producers and registrants. Until such an on-line database has been made available, the PMRA will assist the registrant(s) in identifying which data are included in the compensable database, but will take no part in the negotiations between applicant and registrant(s). A final list of protected data will be made available to the registrant and the applicant. It should be noted that although a complete list of protected data will be identified, the two parties may negociate for a subset of the data. However, the PMRA will not enforce this agreement on behalf of the registrants. It is expected that both parties will be actively monitoring compliance with their business agreements.

If there is more than one registrant of an equivalent technical grade active ingredient, the applicant must obtain access to a complete set of data required by the Minister through negotiation with either one registrant with a complete set of protected data or a combination of registrants each having subsets of the protected data.

Once the PMRA has established the equivalency and has identified which data are protected, the applicant and registrant(s) will be required to enter into mandatory negotiation for data access and compensation. The time allocated for negotiation will be 120 days. The Agency will consider extension to the negotiation period at the request of both parties. If, after the initial 120-day negotiation period, a negotiated settlement appears to be unachievable, either party may initiate binding arbitration.

It should be noted that the PMRA will not get involved in the negotiation process per se. The PMRA will continue the registration process only upon receipt of a written confirmation granting the applicant the right to access the registrant’s data or upon receipt of a commitment from the applicant to enter binding arbitration and pay the amount awarded by the arbitrator. The applicant must commit to provide to the PMRA within one year a letter of access. Non receipt of a letter of access at the end of the one year period will result in cancellation of the generic registration.

In the case of failure of a registrant to participate in the negotiation or arbitration, or refusal to comply with the terms of the arbitration, the PMRA will rely on the registrant’s data in support of the applicant’s petition.

If an applicant fails to report back after the 120-day period, the Agency will consider the application to have been withdrawn.

4.4.2 Start of Registration

The time limited mandatory negotiation and the binding arbitration process are designed to ensure resolution of data compensation issues within a reasonably short-time period. Therefore, the PMRA will register a generic pest control product when its equivalency has been established, the protected data have been identified and the negotiation has been completed or the binding arbitration process has been initiated.

4.5 Transition From PSR II to the PPIP Policy

The new PPIP policy will not revoke any proprietary interest protection of data previously granted under PSR II. These data will continue to be protected and the new protection periods will be applied under PPIP. However, with the inception of this Regulatory Directive, data submitted voluntarily will only be protected if the data are needed by the Agency for the continuing support of a current registration.

Special provision for data protection may apply on a case-by-case basis in some situation where there are agreements already in place for data generated and submitted by a task force.

Once the eligibility criteria have been established and this Regulatory Directive updated, registrants will be able to extend an existing exclusive protection period by supporting minor uses as described in Section 4.3.4.

Applications by generic manufacturers to register pest control products in reliance on a protected database submitted prior to the inception of the PPIP policy will be processed according to Trade Memorandum T-1-249 (PSR II). The Agency will consider requests to apply the new policy to these applications as long as the Agency has not yet progressed to the stage of establishing chemical equivalency.

4.6 Re-evaluation and Special Review

4.6.1 New Registrations

Applications to register a new technical grade active ingredient, manufacturing concentrate or end-use product based wholly or in part on data of an already registered pest control product while that product is under re-evaluation or on a special review provides a particular challenge to the protection of data ownership.

Once the re-evaluation of a pesticide has been initiated, an applicant, having obtained access to the protected data through negotiation/arbitration with one or several registrants, will also have to satisfy all data requirements that may be imposed on the original registrant(s) as condition of continued registration.

4.6.2 Existing Registrations

For re-evaluation and special review purposes, it is assumed that all registrants either had to provide their own data, or had to gain access to another registrant's database in order to be granted registration. Therefore, the PMRA uses all available data and applies them to all registrants for evaluating their acceptability for continued registration.

However, it is frequent that part of the data has been submitted by only some of the registrants to support specific uses or claims for some, but not all products. If other registrants, or an applicant, wish to rely upon these data in order to add new uses or claims to his product, they would need to negotiate with the original submitter of these data to gain access.

If the PMRA requires new data as a condition of continued registration, these requirements will have to be satisfied by all relevant registrants. Registrants may develop the data individually, together with others, or they may gain access to another registrant's data as per Section 4.4 of this Regulatory Directive.

4.6.3 Re-evaluation Program—Program I

The USEPA Reregistration Eligibility Documents (REDs) are frequently used by the PMRA in support of re-evaluation decisions under Program I as per Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*. REDs are based on data submitted to the USEPA. The actual studies are not submitted to the PMRA, but are considered to have been relied on and may be subject to data protection.

The data identified in the USEPA RED will be protected in the context of a new registration if the following criteria are met:

- The active ingredient is or was re-evaluated under Program I.
- The data are considered relevant to the Canadian use pattern.
- The data have no equivalent in the PMRA's database.
- The registrant can demonstrate ownership of the data.

Data from a USEPA RED that meet the above criteria will be given 12 years of compensable protection from the date the re-evaluation of the active ingredient started.

Appendix I

Stakeholder Comments Received During the Consultation Period
The PMRA received comments from several stakeholders, including industry associations, data providers, generic companies, grower groups and consultants. Most comments were on the following topics:

- negotiation / arbitration / timing of registration;
- minor use provisions for the extension of the exclusive period;
- protection of data used by the USEPA in the development of a RED; and
- equivalency.

The following is a summary of the comments received and the PMRA's position on the issues raised by stakeholders.

Negotiation / Arbitration / Timing of Registration
Stakeholders had divergent perspectives on this issue. Some found the proposed timelines to be short but manageable, while others believed it was impossible to meet based on the experience in the United States.

Some stakeholders strongly supported the proposed directive to register only after submission of a letter of access from the registrants. Others requested to have the same system as the USEPA where registration of a substantially similar product is granted on the basis of a letter indicating an Offer to Pay.

An alternative option was suggested to maintain a time-limited negotiation period without prior registration, but that registration be granted at the start of binding arbitration. A targeted overall registration timeline of one year was proposed.

The PMRA opted for this proposed alternative with some modifications, i.e. extending the initially proposed negotiation period from 90 to 120 days, granting a 1-year time limited registration at the beginning of binding arbitration and presentation of a letter of access within 1 year.

The Agency's rationale is as follows. It was seen as desirable to increase the chances for a negotiated settlement prior to registration to reduce the risk of legal challenges. Therefore, the Agency decided to increase the time allotted to negotiation to 120 days. The proposed 90-day timeline for binding arbitration was generally recognized as very difficult to meet, especially in the absence of experience on arbitration of pesticide data ownership in Canada. Therefore, the Agency decided not to attach a specific timeframe to the binding arbitration process, as long as a letter granting access to the protected data would be forthcoming within one year of the generic pesticide registration.

Limiting the registration of a generic pesticide to an initial one-year period in cases of binding arbitration will avoid seeing a "rogue" registrant who failed his commitment capture a significant part of the market for an extended period while the registrant's legal challenge proceed.

Minor Use Provisions for the Extension of the Exclusive Period
Some stakeholders supported the proposal that the extension of the exclusive protection period should be limited to those instances where minor uses are exclusively supported through data generated by registrants. Other stakeholders requested that all minor uses be eligible as they believe that the registrants are already providing significant support to the current government and user group program. These stakeholders questioned whether they would still have an incentive to lend support to the current program should minor uses with mixed financing not be eligible for obtaining an extension of the exclusive protection period.

Some also suggested that a system for the extension to the exclusive period of non-agricultural products should be put in place.

The PMRA will further analyze the comments on this issue and will revise the policy once the eligibility criteria have been established. Products that are registered in the mean time will remain eligible for an extension once the final provisions are in place.

Protection of Data Used by the USEPA in the Development of a RED
Some stakeholders suggested that studies identified in the USEPA RED should not be protected as the RED itself, a publically available document, and the underlying data might never have been submitted in Canada. However, the Agency is fully relying on the USEPA RED for re-evaluation decisions under Program 1. Thus, Program 1 is indirectly relying on the studies underlying the USEPA RED in its re-evaluation decisions. The PMRA will therefore maintain its original proposal and will protect data identified in the USEPA RED. It should be noted that the protection will begin from the date at which the re-evaluation was initiated rather than from the date of the study in order to make it consistent with the approach taken for other data.

Equivalency
Many commented that the criteria for establishing equivalency be published. The PMRA intends to publish the criteria the Agency applies to establish equivalency for technical grade active ingredients. The criteria of equivalency for end-use products and manufacturing concentrates are more difficult to define as there is a possibility of innumerable similar formulation. The Agency is currently working on developing guidelines for determining equivalency of formulation and will consult stakeholders once significant progress has been made.