Regulatory Proposal PRO2010-07

Regulatory Proposal, Value Guidance – Benefit Information and Use History

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Preface

The objective of this Regulatory Proposal is to reduce the regulatory burden on stakeholders by providing a more flexible approach to fulfill the value requirements for registration of pest control products. This new approach aims to facilitate access to new and effective crop protection tools and technologies and supports the objectives of the federal Agricultural Regulatory Action Plan and the Growing Forward Agricultural Policy Framework.

Introduction

In accordance with paragraph 4.(2)(*d*) of the *Pest Control Products Act* (PCPA), only pest control products that are determined to be of acceptable value are approved for use in Canada. Value in respect of a pest control product is defined in subsection 2.(1) as:

> the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration and includes the product's:
> a) efficacy;
> b) effect on host organisms in connection with which it is intended to be used [e.g. crop tolerance]; and
> c) health, safety and environmental benefits and social and economic impact.

Approaches to value assessment
The Pest Management Regulatory Agency (PMRA) of Health Canada requires applicants to submit data and/or a scientific rationale (extrapolated from data) to identify the level of control, crop safety and other non-safety adverse effects[1] associated with the proposed registration. This data is assessed based on PMRA's understanding of the appropriate level of control and crop safety, other non-safety adverse effects and in context with other available information (e.g. resistance management, Integrated Pest Management (IPM), registered alternatives, user identified needs), in order to determine whether the proposed registration is of acceptable value.

This document describes how and when information other than the efficacy, crop safety and other non-safety adverse effects that PMRA normally expects applicants to provide, may be used to determine acceptable value for the purpose of the registration of a pest control product. This information may include evidence of a product's use history in another country as well as analysis of the potential benefits of a product.

Submitting use history information can provide evidence to determine that the proposed use of a product has acceptable value in situations where efficacy and crop safety data are insufficient, or on occasion unavailable. Furthermore, insight into the potential benefits of a product to users would be relevant in order to determine whether the product is of acceptable value, i.e. where data or use history information are not fully conclusive; or where there is uncertainty on the appropriate performance level against which data and other information should be assessed.

[1] Non-safety adverse effects encompass not only crop safety but also adverse effects related to industrial uses (e.g. corrosion, impact on industrial process, staining) and other non-crop use sites (e.g. domestic animal injury, corrosion and plugging of equipment).

Experimental data (efficacy and crop safety) are still an important part of the value assessment, however, for minor uses, accurate benefit and use history information may be sufficient to establish acceptable value without the need for supporting trial data. This new approach is expected to facilitate earlier registration of minor uses in Canada by leveraging the experience gained in other countries and increasing our understanding of the benefits associated with minor uses. For applications involving major uses which have a history of use in other countries, acceptable benefit and use history information could, depending on the level of detail provided, supplement, reduce or in certain cases replace the data that would otherwise be expected to be submitted.

Scope
Benefit analysis and use history can be used to support the registration of most pesticide uses except for those uses that relate directly to public health for example, swimming pool and spa products, disease vector control products and personal insect repellents. For these types of uses, trial data are required given the potential human health implications.

Description of Use History and Benefit Analysis

1) Use History

a) Relevant use pattern

Details on use history in another country should be provided by experts who are familiar with the product, its performance under commercial conditions, and the factors that can affect its performance. To be eligible for consideration, the product or use must have been fully registered in a country with a pesticide regulatory system broadly comparable to Canada (e.g. OECD countries) and used under commercial conditions such that product use and level of performance can be reliably documented.

The use that is documented should be comparable to the use proposed for registration in Canada in terms of product formulation, rate(s), number of application(s) and timing. When non-safety adverse effects are the only concern, use histories with higher rate(s) and number of application(s) are acceptable. The application should document the use history, whenever possible, under comparable use conditions for non-crop uses and for crop uses. Such information *may* include (on a crop or site specific basis): how often the product is recommended; estimates of percent crop or site treated for the specific area (level of user adoption); estimates of crop injury or product failure; and performance level.

b) Use history analysis

Technical experts knowledgeable about commercial production practices, such as extension personnel, university researchers or agricultural department officials should provide use history analysis or validate use history supplied by the registrants. It is the responsibility of applicants to solicit, coordinate, and submit any use history analysis to PMRA.

Use history information provided by field technical experts should include:

- an explanation of the technical expertise and scope of experience with the use of the product, familiarity with the level of pest infestation that the product is intended to control and knowledge of the applicable production system(s) in which the product is used;

- a description of the relevant use pattern of the product, how the product is used under commercial conditions (formulation, rate(s), timing and number of application(s), changes in the use directions over time) and level of adoption of the product by the users in production practices;

- insight into the observed performance of the relevant use of the product on its own, relative to no control and/or relative to alternative methods of control, and how it meets commercial expectations, as well as the factors that may affect performance; and

- a discussion of the product's contribution to pest management, including any additional benefits to users, contribution to resistance management, and link to IPM.

The field technical experts contact information must also be provided in the event that clarification is required.

c) Additional use history information and rationales

Registrants should provide information on any incident or product failure reports, and any remedial actions/changes to use directions made in response to such reports. Market information (e.g. product adoption and sales) may also be provided. This information can be submitted separately to PMRA by the registrant if the applicant is a third party.

When the use pattern documented in the expert analysis is different from the use proposed in Canada, the applicant must provide a rationale to explain why it is applicable to support the proposed Canadian use.[2]

[2] Additional data may be required, depending on the extent of the difference.

2) Benefits analysis

Insight into the potential benefits associated with the availability of new use(s) or new product(s) allows increased flexibility in the regulatory decision. For example, knowing the level of control and crop safety needed by users under commercial conditions instead of relying exclusively on data which sometimes do not reflect the proposed use(s) can have a significant impact on the registered rate of application.

The type of "benefits" information and level of detail that applicants should provide will vary from situation to situation. However, the objective is to show why the proposed product is needed, and to emphasize how and to what extent its registration would benefit Canadian users.

Applicants should explain the pest control need that the proposed use(s) would address. This could relate to a combination of the following factors (this is not an exhaustive list; other considerations may also be relevant depending on the circumstances):

- uncontrolled or sub-optimal control of pests causing widespread or sporadic crop damage;
- limitations in existing methods of control such as narrower pest spectrum, duration of control, conditions of use (e.g. long re-entry intervals, large buffer zones), application methods (e.g. aerial vs. ground);
- economic benefit and performance level considerations from the users perspective;
- the need for additional pest control tools to support resistance management, IPM, and risk reduction strategies;
- acceptability of use in certain countries or sectors with specific requirements (e.g. organic production)
- the phase-out of a product(s) following re-evaluation, giving rise to the need for alternative tools of control;
- an emerging pest problem or one that is expected to arise in the short to mid-term (e.g. invasive alien species); and
- export trade impediments (e.g. domestic producers lack access to an important product either used by foreign competitors or required by another country as a condition of importation).

Projected benefits of the proposed use should be described in relation to the pest problem. Quantitative estimates (e.g. incremental benefit based on assumptions around increased yield/quality or reduced costs of production) are preferable, although qualitative information may be acceptable.

When to Submit Use History and Benefit Analysis

Consideration of use history and analysis of the potential user benefits for product registration forms part of the value assessment process. The submission of this new value information provides a method to replace some or all the efficacy and non-safety adverse data required for registration or to overcome data limitations. It can also provide a response to uncertainties with respect to a product's acceptable value that might otherwise necessitate the modification, withdrawal, or rejection of an application for registration. Where trial data submitted by applicants in support of a registration are sufficient for PMRA to make a determination of value for the purposes of registration, submission of benefit and use history information is not necessary.

Nevertheless, benefit information is always useful to help provide context with regard to the regulatory decision, even when a complete data package is submitted. Communication between applicants and PMRA through presubmission meetings and/or during the submission review process affords opportunities to discuss the availability or generation of value information to support registration.

Submission Process

Applicants should incorporate the use history and benefit information into the data code (DACO) 10.1 Value summary with subheadings. This document could be associated in the e-index builder with as many or as few DACO as apply. The document should contain an executive summary that highlights the overall value of the product (10.1), and as appropriate a discussion of efficacy (10.2), non-safety adverse effects (10.3), economics (10.4), sustainability (10.5) or other (10.6).

Supporting Documents:

Separate documents are being developed and will be made available separately on the Pesticides and Pest Management portion of Health Canada's website and through e-mail distribution to provide more details on how to generate the use history and benefit information package.