Regulatory Directive DIR2013-03

Value Assessment of Pest Control Products

(publié aussi en français)

10 September 2013

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. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1197-7396 (print)
1498-5926 (online)

Catalogue number: H113-3/2013-03E (print version)
H113-3/2013-03E-PDF (PDF version)

Preface

This document describes the Pest Management Regulatory Agency's (PMRA) approach to the value assessment of pesticides. It outlines the considerations and key concepts of value assessments and describes information needed to support an application for proposed pesticide uses from a value perspective.

Previously, the PMRA relied primarily on efficacy information to establish the value of proposed uses of pesticides. The current approach is based on the weight of evidence from information on various components, which includes efficacy and benefits of the proposed use. In addition, the type of information that can be provided can come from a variety of sources.

The PMRA's approach to value assessment was developed in consultation with stakeholders and in consideration of approaches by other regulatory agencies. The consideration of the definition of value as stated in the *Pest Control Products Act* provides flexibility in fulfilling information requirements, which will help reduce regulatory burden for applicants. It will also provide opportunities for alignment with member countries of the Organization for Economic Cooperation and Development (OECD) and an increase in predictability and efficiency of value assessments.

This document replaces and addresses comments received by the PMRA regarding Regulatory Proposal 2010-07, *Value Guidance – Benefit Information and Use History*.

1.0 Introduction

In accordance with the *Pest Control Products Act*, only pest control products that are determined to be of acceptable value are approved for use in Canada. The value of a pest control product, as defined by the Act (Paragraph 2(1)), refers to the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration. This includes the product's efficacy, effect on host organisms, health, safety and environmental benefits, and social and economic impact.

The value assessment is an integral part of the evaluation conducted on all pesticides before they are registered in Canada. In determining acceptable value, a weight of evidence approach is taken that considers all the factors that may contribute to a product's value.

This document explains the PMRA's approach to the value assessment of pesticides. As the specific details regarding the use of a pest control product can vary, there is flexibility in interpretation and application of the approach with regards to the manner in which value requirements can be addressed. The type of information that can be provided for the value assessment can include one or a combination of the following: experimental data generated from research trials, use history information from other jurisdictions, rationales based on accepted scientific principles, existing scientific literature, and benefits information. However, trial data are required for uses that relate to control of pests having a direct effect on human health, such as swimming pool and spa products and disease vector control products.

2.0 Value Assessment: Approach and Considerations

2.1 Efficacy

Pesticide products should have a level of efficacy that significantly contributes to pest management in order to be registered in Canada. Different types of information may be used to address product efficacy. These include use history information, published papers, scientific rationales**,** and/or trial data. The information provided to support efficacy should permit an assessment of the level, duration and consistency of control provided by the product. It should demonstrate the product's efficacy (i.e., the resulting level of control or intended effect) under the proposed conditions of use in Canada.

When use history information is provided, it should include a comparison of the Canadian-proposed and foreign-registered use patterns, an indication of the performance and experience associated with the use of the product in the foreign jurisdiction, and a validation of the use history information, where appropriate. Published scientific papers may also be used to address efficacy provided that it is clearly related to the proposed use. Arguments based on established scientific principles and precedent registrations may be used to address efficacy. When a rationale is provided, applicants should indicate its scientific basis and/or any specific details related to precedent registrations that apply. When trial data are used as supporting information, a summary table in a spreadsheet format should be provided and the findings discussed in relation to the proposed label claims in the value summary document. Information on field trials generated outside of Canada may be submitted provided that it can be shown to be relevant to

Canadian conditions. Information from greenhouse trials conducted outside of Canada is acceptable and does not require additional information regarding trial conditions unless there are differences with respect to crop production practices.

Consistent with the goal of sustainable pest management, applicants should demonstrate that the proposed application rate provides an acceptable level of control under representative conditions without being excessive.

2.2 Effects on Host Organisms

The effects of the pesticide on host organisms or use sites should be explained in the value summary report. Information in the form of use history, published studies, scientific rationales or research trials may be provided. For field trials, observations on host crop tolerance may be made within efficacy trials unless phytotoxic reactions occur that necessitate further study. Applicants should describe the basis on which they have determined that an adequate margin of crop safety exists for each host and rotational crop. If the potential for crop injury exists then warning statements to this effect should be included on the product label.

2.3 Health, Safety and Environmental Benefits

Information concerning the actual or potential benefits associated with the proposed pesticide use may be considered during the value assessment. Information provided in this regard should demonstrate how and to what extent the proposed registration would benefit Canadian users and other direct stakeholders (e.g., consumers or applicators) from a health /safety and/or environment perspective. For example, a product may be needed to control a poisonous plant, a pest that impacts public health (e.g., mosquitos or ticks), an invasive species (e.g., zebra mussels), or a plant disease with harmful effects on humans/livestock (e.g., ergot). Actual or potential contribution to risk reduction of the proposed pesticide use could also be explained, e.g. a product that is considered a replacement for a pesticide that is being phased out following re-evaluation.

Information on the compatibility of the proposed use with an integrated pest management strategy may also be considered during the value assessment, for example, spot application of products with narrow pest spectrum or limited or no negative impacts on biological control agents or beneficial insects. Consistent with the PMRA’s goal of sustainable pest management, an explanation of how the proposed use contributes to resistance management in consideration of other registered alternatives should be provided, when applicable.

2.4 Social and Economic Impact

Information on social or economic impacts associated with the proposed use can also contribute to the value assessment of pesticides. This includes effects on the sustainability of the sector or trade implications (e.g., impact on competitiveness of Canadian growers), crop value (farm-gate, market value), acreage devoted to crop, influence of the pest on crop quality and marketability, additional costs associated with the pest presence (e.g., drying costs for grain), and/or indirect effects of the pest on the crop (e.g., alternate host for a crop disease). Applicants should indicate how the proposed use relates to identified pest issues that are important to Canadian users. It is also useful to indicate how the registration of the product would enhance Canadian competitiveness.

The projected economic benefits should be described in relation to the pest problem and the system in which the pesticide is to be used. Quantitative estimates are preferable, but qualitative information is also useful. Additional information such as an attribute that contributes to a product's value could be included. For example, if a product is stable for longer periods without the need for refrigeration, this attribute affects product cost.

2.5 Weight of Evidence Approach to Value Assessment

Applicants should consider how best to support the value of proposed pesticide uses considering that a combination of various types of information may be submitted. If the product is registered in a foreign jurisdiction and the use patterns are similar in the foreign registered use pattern and the proposed use pattern in Canada, supporting information for efficacy could predominantly consist of use history information. In cases where the active ingredient is new and the product is not registered elsewhere, efficacy trials may be the main source of value information. Scientific rationales to extend support for other uses based on information on certain uses or published information may also be provided.

In all cases, it would be useful to provide the PMRA with information on the benefits and the social and economic impact of the proposed use. This is particularly important when the scientific information to support the proposed use is limited. The PMRA's overall conclusion for the value assessment of pesticides is based on a weight of evidence approach in consideration of all value information provided to support the application.

3.0 Value Assessment Approach for Minor Uses of Pesticides under the Joint Health Canada/Agriculture and Agri-Food Canada (HC/AAFC) Minor Use Pesticide Program

The joint HC/AAFC Minor Use Pesticide Program is aimed at adding minor uses to the label of registered pest control products. A minor use is defined as a necessary use of a pest control product for which the anticipated volume of sales is not sufficient to persuade a manufacturer to register and sell the product in Canada (for further details, please refer to DIR2001-01, *User Requested Minor Use Label Expansion*). In order for a minor use of a pesticide to be registered, as with all uses of pest control products, it must be shown to have acceptable value.

Within this program, if a minor use is prioritized by growers at the Annual Canadian Minor Use Priority Setting Workshop as a project for which Agriculture and Agri-Food Canada's Pest Management Center will generate supporting information (i.e. an 'A priority'), and is submitted for registration under the joint HC/AAFC Minor Use Program, then the PMRA will not require value information to support the minor use registration. The priority setting exercise itself establishes the primary pest management needs for minor crops and satisfies the need to demonstrate acceptable value. A label review will be conducted to determine the extent to which the proposed use pattern is consistent with the registered use pattern and that any differences between them are justified.

4.0 Structure of the Value Information Package

The value information package consists of a value summary report (Appendix I) and associated documents such as use history information, or individual trial reports, if applicable. The value summary report provides a description of the overall value associated with the proposed use. It is an executive summary of the entire value information package. Key elements related to efficacy, host and rotational crop tolerance, health, safety and environmental benefits and social and economic impact should be integrated and discussed as they apply. The PMRA will also accept applicant generated supporting value information submitted to other regulatory agencies (e.g., public interest finding documents submitted to the United States Environmental Protection Agency and biological dossiers submitted to OECD).

Supporting guidance documents will be made available separately to stakeholders to assist in the preparation of the value information package. These documents are not intended to be prescriptive, but rather will be an additional resource to provide more specific guidance related to the preparation of efficacy information drawing on established international protocols such as OECD and European and Mediterranean Plant Protection Organization guidelines.

In addition to the guidance documents, templates to assist in the preparation of the value information package will also be made available regarding summarizing efficacy data and use-history information. Additional templates may be developed in the future. Furthermore, a pre-submission consultation can be requested in which the PMRA will provide advice regarding the compilation and organization of the value information package.

Appendix I Template for the Value Assessment of Pesticides

This template outlines the information considered in an application to register a pesticide or to add a proposed use to a currently registered product. It is intended to assist applicants in the preparation of the Value Summary upon which the value assessment is based. This template should be used in conjunction with relevant guidance documents, summary tables for efficacy or crop tolerance trials, and use history information templates, as appropriate.

Value Summary

1.0 Introduction

1.1 Product Description

Provide a description of the formulated product and the active ingredient.

1.2 Use Pattern

1.2.1 Registered Use Pattern

For products that are already registered in Canada, provide a summary description of the use pattern currently registered on the Canadian label. Include information that is relevant to any new uses that are being proposed below.

1.2.2 Proposed Use Pattern / Amendments to Registered Use Pattern

Provide a description of the proposed use pattern (for unregistered products) or proposed amendments to the registered use pattern (for registered products), e.g., crop(s), site(s), pest(s), application rate, etc.

1.3 Description of the Pest Problem

Provide a description of the pest(s) proposed to be added to the label, including common and Latin binomial name(s), the nature and severity of the damage to the crop(s) associated with the pest(s).

2.0 Efficacy

This portion of the value summary presents all information related to efficacy. This may include experimental results from research trials, published scientific literature, scientific rationales, and use history information.

2.1 General Factors Affecting Efficacy

Describe any general factors that may influence product efficacy.

2.2 Supporting information from earlier formulations of the product or similar products

If efficacy information is available for product formulations tested during earlier stages of development, or similar products, rationales and bridging data should be presented in this section to demonstrate equivalence between the products.

2.3 Requirement for Adjuvants

If an adjuvant is proposed to be used with the product, demonstrate why the adjuvant is required, or under what circumstances it is required.

2.4 Support for Proposed Claims

Each claim should be identified (i.e., each application timing, method of application, pest, tank mix, etc.), and the approach and information used to support each of these claims, with respect to efficacy, should be clearly indicated.

3.0 Effects on Host Organisms

This portion of the value package presents all information related to non-safety adverse effects (e.g., phytotoxicity to the host or rotational crop, damage to the site of application, etc.).

3.1 General Factors Influencing Effects on Host Organisms

Describe any general factors that may influence effects on host organisms.

3.2 Supporting information from earlier formulations of the product or similar products

If information is available for product formulations tested during earlier stages of development, or similar products, rationales and bridging data should be presented in this section to demonstrate equivalence between the products.

3.3 Support for Proposed Claims

3.3.1 Host Crop Claims

Each claim should be identified (i.e., each application timing, method of application, pest, tank mix, etc.), and the approach and information used to support each of these claims should be clearly indicated.

3.3.2 Rotational Crop Claims

Each claim should be identified (i.e., each rotational crop and its proposed replanting interval relative to application), and the approach and information used to support each of these claims should be clearly indicated.

4.0 Consideration of Benefits

4.1 Alternatives

An overview of products registered in Canada for the same uses currently being proposed. If the current alternatives do not address grower/user needs, an explanation should be provided.

4.2 Compatibility with Current Management Practices Including IPM

A description of how the proposed use can be integrated into the production system, including its contribution to integrated pest management.

4.3 Resistance Management

A description of how the proposed use contributes to resistance management, in consideration of other registered alternatives.

4.4 Contribution to Risk Reduction

A description of how the proposed use contributes to risk reduction, in consideration of other registered alternatives, should be provided.

4.5 Social and Economic Impacts

A description of any social or economic impacts associated with the proposed use such as effects on the sustainability of the sector or trade implications. Information explaining why the product is needed as well as how and to what extent product registration would benefit Canadian users should be provided.

4.6 Health, Safety and Environmental Benefits

A summary of any potential health, safety or environmental benefits that could result from the proposed use of the pesticide should be provided. It is not a summary of the information provided to support the human health or environmental risk assessment.

5.0 Summary and Conclusions

An integrated summary of all information provided to support the value of the proposed use(s).

6.0 References

A list of reference materials or documents cited in the value summary report.