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Pest Management Regulatory Agency

Value Guidelines for New Plant Protection Products and Label Amendments

PMRA Guidance Document

Protecting human health and the environment

Protéger la santé humaine et l'environnement

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April 2016	Initial creation. This document replaced Regulatory Directive DIR2003-04, Efficacy Guidelines for Plant Protection Products and incorporated information presented in Regulatory Proposal PRO2010-07, Value Guidance – Benefit Information and Use History as well as stakeholder comments on Regulatory Proposal PRO2010-07. The information in this document reflects the value approach that the PMRA has implemented as described in DIR2013-03, Value Assessment of Pest Control Products.

Disclaimer

This document does not constitute part of the *Pest Control Products Act* or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

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1.0 Introduction

The purpose of this document is to outline the general principles of pesticide value assessment in Canada. It describes the types of information that could be provided to register new plant protection products and to support label amendments, and provides guidance on summarizing value information prior to submission to the Pest Management Regulatory Agency (PMRA).

The value of a pest control product, as defined by the *Pest Control Products Act*, 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 and rotational crops, health, safety and environmental benefits, and social and economic impact. The value assessment is an evaluation of these various components and provides the baseline for health and environmental risk assessments, and risk management decision making. In determining acceptable value, a weight of evidence approach is taken that considers all the factors that may contribute to a product's value.

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 both efficacy and benefits information. It can include information on various components, which includes experimental data generated from research trials, use history information from other jurisdictions, existing scientific literature, scientific rationales and benefit information. 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 the regulatory burden for applicants. It will also provide opportunities for alignment with Organisation for Economic Co-operation and Development (OECD) countries and increase efficiency of the value assessment process.

This value guidelines document is meant to serve as a general guideline and should be interpreted as such. As the specific details regarding the use of a pest control product can vary, there is a need for flexibility in interpretation and application of the guidance regarding the manner in which value requirements can be addressed. The guidelines in this document are primarily for applications to register pesticide products based on new or registered active ingredients and to amend the labels of currently registered pesticide products (for example, to add a new crop or pest).

This document consists of two parts: general principles and considerations for value assessments and preparation of the value information package. Under considerations for value assessments, guidance is provided regarding benefit and efficacy information that could be used to support an application to register a new use or to add new uses to registered labels. Benefit information is discussed with some examples to clarify the kind of information that may be provided to the PMRA. The section on efficacy includes guidance on conducting research trials, information on rate justification, extrapolation principles, and updated approaches to value assessments for certain types of applications. The second part provides information on the importance of pre-submission consultations and guidance for organizing the various elements of the value package.

Information provided in this document applies to all pesticide uses for plant protection products. Applicants should also consult published guidelines for specific uses, where appropriate, such as guidelines for non-conventional products (PMRA Guidance Document, *Registration of Non-Conventional Pest Control Products*). Guidance for

antimicrobial pesticides and structural pesticides will also be available on the Policies and Guidelines page on Canada.ca.

2.0 General principles and considerations of value assessments

Value assessments consider the benefits of the proposed use, determine whether the product is likely to provide acceptable efficacy when used according to label directions, and establish whether the proposed use is safe to the crop or to rotational crops. Value assessments establish the use pattern that serves as the basis for the risk assessment. They contribute to longer-term product sustainability by confirming that the application rate is appropriate and not excessive.

Value assessments are based on sound science and a weight of evidence approach is used in formulating conclusions. Applicants have flexibility in addressing information needed for the value assessment. Information could be provided in the form of use history, results of research trials, published information or scientific rationales. Various types of benefit information should be provided, as appropriate, to provide context about the proposed use. This can include agronomic, economic, social, health or environmental benefits. Templates for preparing the value dossier and use history information are available upon request through the Pest Management Information Service and may be used by applicants as a guide. This facilitates the compilation of the application package in a manner that contributes to efficiency of the review process.

2.1 Consideration of benefits

Insight into the actual or potential benefits associated with the availability of a new use or new product is an integral component of the value assessment. Information should be provided to show how and to what extent its registration would benefit Canadians. The PMRA will accept documents submitted to other regulatory bodies such as public interest findings or review documents containing benefit information from member countries of the OECD. A public interest finding is a document prepared by applicants for the United States Environmental Protection Agency (USEPA). It explains how the proposed registration is in the public interest by addressing certain established criteria such as lack of a registered alternative product or if there is a need for the new pesticide that is not being met by currently registered products.

The projected benefits should be described in relation to the pest problem and the use site or crop production system. Quantitative estimates (such as incremental benefits based on assumptions relating to increased yield quantity or quality or reduced production costs) are preferable, but qualitative information is also useful. A description of the various types of benefit information that may be relevant follows. These types of benefit information are provided as examples and may not be applicable to all situations.

2.1.1 Contribution to sustainability and compatibility with current management practices including integrated pest management

The contribution of the proposed use to agricultural sustainability is considered in the value assessment for pesticides. Any agronomic benefits that are expected to result from the registration of the proposed use may be included in the value dossier. A description of the product's fit within the production system in relation to registered alternatives may be provided, including information regarding the extent to which the current alternatives

address the pest management need. If the proposed use is the first potential solution to the pest problem and no alternatives are currently available, its role in pest management should be explained.

A description of how the proposed use can be integrated into the production system with regard to its contribution to integrated pest management may also be included. For example, information regarding pest management programs that could incorporate the proposed use or a summary of experience gained through operational trials in actual grower fields could be provided. Recommendations by extension personnel or information demonstrating the product's role and contribution to sustainability, such as the use of the product in an Integrated Pest Management (IPM) program, may be included. The effects on beneficial insects or other non-target organisms may be explained in relation to sustainability of the proposed use.

2.1.2 Contribution to resistance management

The contribution of the proposed use to resistance management may be explained. Applicants may provide a table of registered alternatives for the proposed use where products are classified into conventional or non-conventional pesticides. Information on registered alternatives is useful in the consideration of resistance management strategies.

The following information may be included, as relevant:

- resistance risk of the pesticide active ingredient, the pest and the proposed use pattern
- reports of known, or possible resistance in the target pest
- whether the product represents a new pesticide mode of action for the crop
- whether the product can be incorporated in a resistance management strategy as a tank mix partner or a rotational product

Resistance management label statements (DIR2013-04, *Pesticide Resistance Management Labelling Based on Target Site/Mode of Action*) should be included in the product label.

2.1.3 Contribution to risk reduction

The contribution of the proposed use to risk reduction, in consideration of other registered alternatives, may be included. For example, use of the product may reduce reliance on chemical alternatives or the proposed use may be considered a replacement for a product that is being phased out through re-evaluation.

2.1.4 Social and economic impact

Information on social or economic impacts associated with the proposed use may be considered. Information such as effects on the sustainability of the sector or trade implications (for example, competitiveness of Canadian growers) may be included, where available.

Information on indirect benefits that could result from the proposed use could also be included. An example is a use that could reduce overall fuel costs or reduce soil compaction. 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 could impact product cost. There are no specific limits or standards (for example, farm gate value or crop acreage) that apply to this type of

information. Applicants are encouraged to provide the type and amount of information that will best support the proposed use.

2.1.5 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 may be provided. This is not a summary of the information provided to support the human health or environmental risk assessment. Rather, it is a statement of the value of the pesticide. For example, the applicant could indicate that the proposed use seeks to control a poisonous plant, a plant disease with harmful effects on humans/livestock (such as ergot) or an invasive species. A product with a higher potential for crop safety (lower phytotoxicity) or a broader spectrum of activity on pests would also be beneficial. Indicating the potential for the product to replace, or reduce applications of, chemistries with restricted use patterns would be useful.

2.2 Efficacy

2.2.1 Proposed use pattern

The proposed use pattern describes how the pest control product is going to be used. Value information that is provided to support an application to register a product or amend the label of a registered product should be relevant to the proposed use pattern. The following elements should be addressed and should be consistent with the supporting value information being provided:

- crop(s)/site(s)
- pest claims with an indication of level of control (for example, control or suppression) for each pest
- product proposed for use (formulation and guarantee)
- application rate (g or kg active ingredient per hectare)
- adjuvant or any other spray solution additive (if any) and its rate
- application method (foliar spray, chemigation, broadcast application, in-furrow, etc.)
- number of applications per season and interval between applications
- application timing relative to crop growth stage
- application timing relative to pest growth stage
- pre-harvest interval
- spray volume applied (as appropriate)
- nozzle type and spray quality if relevant to the proposed use (such as a flat fan nozzle producing a medium spray)
- appropriate interval after which a rotational crop can be planted
- general use directions, such as conditions that warrant the use of the higher or lower application rate, or shorter or longer retreatment interval

2.2.2 Sources of information

Different types of information may be used to demonstrate efficacy, including use history information, published papers, scientific rationales and trial data. Further guidance for each of these information sources is provided in the following sections. The value information package may include one or a combination of these types of information.

The information to demonstrate efficacy should permit an assessment of the level, duration and consistency of control provided by the product. The amount of information used to support each pest or crop claim may vary by pesticide class, product chemistry, and whether or not there is a need to justify the proposed application rate or rate range.

The information should demonstrate the product's performance (that is, the resulting level of control or intended effect) at the proposed application rate, timing and method of application at expected pest pressures and under the range of conditions likely to occur in practical use in Canada. This includes a representative range of crops, climatic and soil conditions and agronomic practices.

Information generated outside of Canada may be used to address Canadian requirements provided that it can be shown how the information is relevant to the proposed use in Canada. Factors such as similarities in climate, soil conditions, production system, and pest pressure and susceptibility, may be discussed. Information from greenhouse settings outside of Canada may be used since the conditions can be assumed to be similar to the Canadian greenhouse production system.

Controlled environment tests (for example, growth chamber or laboratory tests) may be useful in preliminary screening of candidate pest control products, selection of one or more products or rates for field testing, and in providing supporting data. However, information related to controlled environments is not necessarily a realistic indicator of field performance and should be supplemented by information related to field use.

2.2.2.1 Use history information

Use history information consists of a record of the performance of a pest control product in another country for the use proposed in Canada. The information may be supplied by applicants to support efficacy or crop tolerance-related claims for the registration of a new product or new use (crop and/or pest).

Use history information may be particularly useful when (a) the proposed use is currently registered and adopted in an OECD country, (b) there is little or no efficacy and crop tolerance data available to support the use or (c) a scientific rationale is not appropriate to support the proposed use.

For applications involving unregistered active ingredients, or major new uses of registered active ingredients with a history of use in other countries, use history information could supplement, reduce or replace efficacy data. This is possible because a product's record of performance is included in the use history information that should be submitted by applicants.

The PMRA has developed a template to facilitate the preparation of use history information that is available to applicants upon request through the Pest Management Information Service. The template consists of three components: a comparison of the Canadian-proposed and foreign-registered use patterns, a record of the performance and experience associated with the use of the product in the foreign jurisdiction, and a validation of the use history information.

To compare the Canadian-proposed and foreign-registered use patterns, the applicant should do the following:

- provide the foreign label
- compare all use pattern parameters between the two labels and explain any differences
- if applicable, state any currently registered Canadian uses that may be useful for extrapolation purposes, specifically, if the product is already registered for a similar pest or for the same pest on a different crop

A description of the performance and experience associated with the pest control product registered in the foreign jurisdiction is needed to enable a determination to be made regarding the efficacy of the proposed use and its effects on the host crop. The applicant should do the following:

- describe the relevant use pattern of the product and the factors that may affect performance
- provide an insight into the level of control (control, suppression, etc.) provided by the product on its own and relative to no control and/or registered alternatives
- state whether the product meets commercial expectations
- describe the level of adoption of the product by the users

Details related to use history should be provided by experts who are familiar with the product, its performance under commercial conditions, and the factors that can affect its performance. When use history information is provided by an individual who does not have direct experience with the proposed use, the validation statement should be included.

2.2.2.2 Published papers

Published scientific papers may be used to address both efficacy and crop tolerance. Applicants should clearly indicate how the information in the paper relates to the proposed uses and include a copy of the article in the value information package.

2.2.2.3 Scientific rationales

Arguments based on established scientific principles and precedent registrations can be used to address both efficacy and crop tolerance. When a rationale is provided, the scientific basis on which it relies, as well as specific details related to precedent registrations should be clearly indicated. Any documentation cited in a scientific rationale should be submitted.

2.2.2.4 Efficacy Trials

Any efficacy trials should be conducted in accordance with established scientific principles. General guidance on conducting trials, and data analysis and interpretation can be found in the documents that follow, which are published by the European and Mediterranean Plant Protection Organization (EPPO). Note that trials to address Canadian applications do not need to be conducted in accordance with Good Experimental Practice (GEP). Furthermore, there are also differences in the type of information as well as the number of efficacy trials that could be provided to support an application.

- Efficacy evaluation of plant protection products: Phytotoxicity assessment. PP1/135(4) (EPPO, 2014).
- Efficacy evaluation of plant protection products: Design and analysis of efficacy evaluation trials. PP1/152(4) (EPPO, 2012).
- Efficacy evaluation of plant protection products: Conduct and reporting of efficacy evaluation trials, including good experimental practice. PP1/181(5) (EPPO, 2021).
- Efficacy evaluation of plant protection products: Effects on succeeding crops. PP1/207(2) (EPPO, 2007).
- Principles of acceptable efficacy. PP1/214(4) (EPPO, 2017).
- Efficacy evaluation of plant protection products: Introduction to the efficacy evaluation of plant protection products. PP1/223(2) (EPPO, 2012).

When efficacy or crop tolerance trial data are provided to support a pest or crop claim, assessments should be made on an individual pest or crop basis with each organism identified by its Latin binomial name and may involve qualitative and/or quantitative assessments. The degree of control (for efficacy assessments), or crop injury (for crop tolerance assessments) should be reported as a percentage relative to an untreated check. In cases where other rating systems are used, the report should clearly describe the rating system and define the conversion factor to percent control where appropriate.

An assessment of the initial pest pressure prior to application of treatments should be made. For use patterns with multiple applications, efficacy assessments should be made after the first application and each subsequent application. If a range in application rates is proposed then both the low and high end of the range of application rates should be evaluated. Guidance should be provided to indicate the conditions under which an application rate at the lower or higher end of the range should be applied by the user. When proposing a use that involves more than one active ingredient, information should be provided to demonstrate the contribution of each pesticide to pest management.

When several similar formulations are tested in the course of developing a new product, the specifications of each formulation should be provided. Side-by-side comparisons (bridging data) should be made when trials are conducted with multiple formulations of the proposed active ingredient to demonstrate similarity among the formulations and allow the performance data to be pooled across formulations.

Rainfastness statements are not required on pesticide product labels. However, adding these statements to a product label (in other words, the period of time following application when rainfall will not negatively affect efficacy of a foliar applied product) should be supported by information demonstrating that product efficacy is not reduced as a result of simulated rain during the proposed rainfast period. If trial data (under field or controlled environment conditions) are used to support a rainfastness claim, the trials should be specifically designed to determine the rainfast period. This is achieved by including a set of treatments where a simulated rainfall event is applied at varying times after product application, up to and including the proposed rainfast interval. The performance of these treatments is typically compared to that of a treatment in which no simulated rainfall event is made following product application.

2.2.3 Application rate justification

Application of products at a rate that is effective, without being excessive, contributes to achieving sustainable pest management practices. It helps delay pest resistance

development and reduces risks from pesticide use by minimizing exposure of humans and the environment. Applicants should demonstrate that the proposed application rate provides effective control of a target pest, in terms of level, duration and consistency across the range of conditions under which the product will be applied.

To justify the proposed application rate , it should be shown that the proposed application rate provides an acceptable level of control, in consideration of the full range of conditions that may impact performance (environmental conditions, soil conditions, pest pressures, etc.) and other relevant factors (such as resistance management), without being excessive. Application rate ranges may allow for higher application rates when warranted, for example, due to pest pressure or environmental conditions affecting efficacy or pest development.

Applicants should clearly explain why, based on the weight of evidence available, the proposed rate is appropriate. A number of factors could be considered in justifying the appropriateness of the proposed rate. This could include the observed level of control at the proposed application rate or at reduced application rates, pest pressure, resistance management considerations, and registered rates in other jurisdictions. Field trial data, use history information, published papers and scientific rationales could all contribute to justification of the proposed application rate. Given that required levels of control may vary according to the nature of the pest to be controlled and the variability in pest response to the proposed treatment, there is flexibility in terms of the type and amount of information used to confirm that the proposed application rate or rate range is appropriate.

For unregistered active ingredients, the proposed application rate should be justified for major pests on major crops. For registered active ingredients, the rate justification should be provided for the addition of major crops or major pests if extrapolation is not possible. This justification is not required for minor uses provided the proposed application rate is similar to that proposed for major uses. If the rates are different, then justification should be provided for the proposed minor use.

For herbicides, the application rate is based on weed susceptibility and may vary by weed, and among crops and management practices. Justification of the application rate does not need to be confirmed for all weeds. When susceptibility to the product does not vary by weed species, and grouping is therefore not possible, the justification for the proposed rate should be provided for representative weed species. In those cases where the weed susceptibilities differ, the weeds may be grouped on this basis and a rate structure proposed to account for any differential susceptibility among the groupings. When weeds are grouped based on their susceptibilities, justification of the proposed rate may need to be provided only for the less susceptible, or harder to control, group of weeds.

For insecticides and fungicides, the proposed application rate should be justified for an insect pest or plant pathogen, respectively, that causes significant damage or that is difficult to control on an economically important crop. When there are several pest claims being made, the appropriateness of the proposed application rate on a representative crop-pest combination should be explained. The choice of the crop-pest combination upon which the rate justification is based should take into account factors such as feeding damage, type of disease (for example, foliar versus soil-borne), or plant part attacked.

Applicants are encouraged to submit any additional information that includes other application rates as this may contribute to the weight of evidence, and may assist in

justifying the proposed application rate. For example, baseline susceptibility data, dose-response curves that have been developed in the early stages of the development of a new active ingredient, or data from trials conducted in Canada or other jurisdictions that include additional application rates may provide further support for the justification of the proposed rate.

Trial data demonstrating the efficacy of application rates lower than proposed are not needed in order to justify the proposed application rate. However, applicants are encouraged to continue to provide this information, when available, since it is an efficient means of justifying the proposed application rate. Additionally, if health or environmental risks associated with the proposed application rate are identified, the availability of efficacy information at lower application rates may provide potential risk mitigation opportunities.

2.2.4 Considerations by product type

2.2.4.1 Herbicides

Efficacy assessment

Efficacy information should describe product performance throughout the season following application (in field trials, evaluations would typically occur at 7–14, 21–35 and 42–56 days after treatment, with only one observation made per interval). If a claim for season-long control of an annual weed is proposed on the label, information related to the level of control late in the season near crop maturity is important. For perennial weeds, indications of the level of control in the year following application will be important in determining the appropriate label claim. When the herbicide is applied post-emergent to the weeds, the efficacy information should cover the range of weed growth stages proposed.

If only trial data are provided to demonstrate efficacy, the results from five trials are sufficient when rate justification is needed. Otherwise, data from three trials are adequate.

Level of control

Information should demonstrate that the level of control meets user expectations. The performance standard and user expectations may vary depending on the use pattern (for example, crop, intended purpose of the crop, value of the crop, competitive ability of the crop, or management/agronomic practices), the aggressive nature of the weed, the availability of alternatives and the level of control achieved with the alternatives. However, the level of control should, in all cases, be expected to provide a meaningful benefit to the user of the product.

The various performance claims for herbicides are defined in general terms in Table 1. Note that the values presented serve as a general guideline. The appropriate label claim is selected in consideration of the efficacy information, as well as market expectations, the performance of registered commercial standards, and any other relevant information.

Table 1 Summary of performance claims for herbicides

Label claim	Performance indicators
Control	A consistent level of weed management, as defined by commercial standards and expectations in the market. In general, weed control ratings would be at least 80%.
Suppression	A consistent level of weed management that is less than full control, as defined by commercial standards and expectations in the market. In general, weed control ratings would be at least 60%.
Partial suppression	A level of weed management that is less than suppression, as defined by the commercial standards and expectations in the market. This label claim will generally be considered only for non-conventional herbicides. In general, weed control ratings would range between 30% and 60%.
Top growth control	For perennial weeds where consistent reduction of top growth has been demonstrated in the year of treatment.

2.2.4.2 Fungicides

Efficacy assessment

Fungicide performance is defined as the product's ability to reduce disease on a plant or commodity, or reduce sources of succeeding infections (inoculum). Assessments could include the fungicide's ability to:

- reduce disease incidence or severity
- reduce spore counts
- prevent infection of or damage to seeds or seedlings by plant pathogens to increase the grade or quality of a commodity (for example, reduction in mycotoxins in grain)
- prevent yield loss that is directly related to infection by a plant pathogen

The performance of fungicides against plant diseases is assessed by reporting disease incidence (DI) or disease severity (DS). Disease incidence is the proportion of diseased plants within the total number of plants observed. Disease severity is the relative or absolute area of plant tissue affected by the disease. It is often referred to as the degree of infection of a plant or plant part. Disease severity may be assessed visually with or without the aid of disease diagrams, disease scales or ordinal rating scales. It may also be characterized by measuring disease progress over time.

The specific method of disease severity assessment is dependent on the disease being tested, and the symptoms exhibited by host plants. As much as possible, assessments of the plant part affected by the disease as well as other measurable effects should be provided such as crop yield, number of marketable plants, or proportion of marketable fruits.

When conducting field trials, multiple disease assessments should be made throughout the growing season, rather than a single evaluation at the end of the season. Disease assessments should be made on the following periods:

- on the day of or the day before the first fungicide application to determine baseline disease levels,
- the day of each subsequent application over the course of the trial, and
- 7–14 days after the final application (to assess duration of control after final application)

If fungicide treatments are aimed at controlling post-harvest diseases, information on fungicide performance should be made on the harvested fruit or vegetable under typical storage conditions. If research trials are conducted, applications of the product being tested should not be alternated with other products registered for the same claim since this will confound the results.

Fungicide performance in situations where there is low disease pressure does not provide adequate information regarding product efficacy under worst case scenarios. In cases where natural inoculum at field trial sites is unconfirmed, it is advisable to add artificial inoculum. Alternatively, controlled environment experiments may be used in which plants are inoculated with target pathogens. However, these are generally considered to be supplemental to field trials. The use of controlled environment studies alone may be considered in cases where the pest is not yet present in an area where the crop is grown, and where the study is being conducted or when conducting trials for invasive alien pests.

The assessment of fungicide efficacy should also consider when they act upon the plant pathogen. Preventative fungicides inhibit infection of the plant and are applied before the pathogen arrives or begins to develop, while curative fungicides affect the early development of fungal infections within plant tissues. Label claims relating to these fungicide properties should be supported by appropriate information.

When efficacy trials are being provided to support claims related to fungicide seed treatments, the guidelines in Table 2 should be followed. There are four main seedling diseases that can occur on the seed or seedling:

- seed rot (pre-emergent damping-off)
- post-emergence damping-off
- seedling blight
- root rot

They are part of a complex of diseases and can be caused by a single pathogen. These diseases have distinct characteristics, manifest at different seedling developmental stages, and occur under different growing conditions. A label claim involving one or more of these specific diseases requires supporting information relating to each disease stage.

The descriptions of the four seedling diseases and the data requirements to support these claims are presented below. The recommended timing of assessments is a guideline only, as emergence is influenced by seed variety, soil and environmental conditions, planting depth, and whether the trials are conducted in the field or greenhouse. If supporting value information consists of efficacy trials alone, a minimum of three trials should be provided with the appropriate assessments related to the proposed uses.

Table 2 Performance assessments for seed and seedling diseases

Disease	Performance assessment
Seed rot/Pre-emergent damping-off	Stand count within seven days of emergence.
Post-emergent damping-off	A minimum of two stand count assessments: at the seed rot stage and at 7–14 days following the first assessment.
Seedling blight	At least two stand counts: at 14–21 days after emergence and 7–14 days following the first assessment, plus an assessment of the appropriate plant disease symptoms.
Seedling root rot	Direct assessment of the hypocotyl or roots of seedlings.

Level of control

The threshold of acceptable disease reduction varies for each proposed use, and depends on many factors:

- the plant disease and crop
- the efficacy of registered alternatives and cultural control measures
- the impact on crop yield or quality
- the economic and disease thresholds for a pathogen
- user expectations for product performance

For both suppression and control claims, at a minimum, the product should perform consistently and reduce disease to a level significantly lower than observed in the control treatment under moderate to high disease pressures.

Guidance regarding what is considered to be control versus suppression for fungicide claims is presented in Table 3. Note that the values presented serve as a general guideline. The appropriate label claim is selected in consideration of the supporting data, as well as market expectations, the performance of registered commercial standards, and any other relevant information. Conventional fungicides that provide plant disease reduction consistently below 60% should be supported by additional information that explains its value relative to the observed lower efficacy.

Table 3 Summary of performance claims for fungicide products within field trials

Label claim	Performance indicators
Control	A consistent level of disease management, as defined by commercial standards and expectations in the market. In general, disease control ratings would be between 80% and 100%.

Label claim	Performance indicators
Suppression	A consistent level of disease management that is less than full control, as defined by commercial standards and expectations in the market. In general, disease control ratings would be between 60% and 80%. Suppression is defined as consistent disease reduction to a level that is not optimal but is still of commercial benefit.
Partial suppression	A level of disease management that is less than suppression, as defined by the commercial standards and expectations in the market. This label claim will generally only be considered for non-conventional fungicides. In general, disease control ratings would be less than 60%.

2.2.4.3 Insecticides

Efficacy assessment

For agricultural and forestry uses, value information should originate from areas that represent the major geographical regions where the product is intended to be used. They should also take into account possible differences in product performance under various pest population pressures. Artificially infested plots may be used in field trials where insufficient numbers of pests occur naturally. Regional variations in climate, insect resistance, soils, application methods, and/or cultural practices may also need to be considered to demonstrate efficacy under conditions of intended use.

The use of a pest control product could have hazardous effects to non-target species such as beneficial arthropods (such as predators or parasites) and microorganisms. While these side effects may not have been considered in designing efficacy trials, such data should be recorded, assessed and reported where observed.

With respect to insecticide seed treatments, the application rates included in efficacy trials should reflect the rate expression on the proposed label. For example, application rates are often expressed as mg product/kernel, g product/100 kg seed, or g product/ha. Supporting value information should be in the same units, or appropriate conversions provided.

Level of control

The following description broadly reflects performance indicators for various label claims. If other claims are considered appropriate to the crop/pest situation, they may be proposed.

To support a performance claim for "control" of an arthropod pest, the efficacy data should demonstrate that the product, when applied in accordance with the label directions, consistently reduces pest numbers or pest damage to a commercially acceptable level.

Generally, there is no single standard definable as commercially acceptable control for reduction in numbers of pests or damage that is applicable to all pest management scenarios. The pest management objective or the specific level of reduction in pest

numbers or damage that is required to support a "control" claim depends on factors such as:

- type of damage caused by the pest
- economic threshold levels for the particular pest
- tolerance for damage to the crop
- performance of other available commercial standard treatments

For example, for pests that cause direct damage to the marketable portion of the crop (such as codling moth on apples), a high level of pest reduction would be required to support a "control" claim to ensure that the damage caused will be reduced to a level that will allow the crop to be considered marketable. For pests where the crop can withstand considerable levels of damage without a negative impact on marketable yield, lower levels in reduction of pest numbers or damage can be considered to support a "control" claim.

When performance data show that a product, when used as directed, does not reduce pest populations or damage to a level typically required to achieve commercially acceptable control, a lesser label claim for "suppression" may be acceptable. That is provided that the applicant can show that the demonstrated level of performance has value in a pest management program. In such cases, the product might not be as efficacious as an available commercial standard treatment but other performance characteristics of the product might contribute to its value as a pest management tool. A "suppression" claim implies a consistent level of reduction in the pest population. This claim could be considered in the following situations:

- The product has a new or different mode of action which, when incorporated into a pest management strategy using products with other modes of action, could contribute to management of pesticide resistance.
- The product has little or no negative impact on pest predators or parasites and, therefore, could be incorporated into an IPM program.

Depending on the product's performance, label claims other than control or suppression may be considered (for example, reduces damage).

2.2.5 Adjuvants

Products with labelling that recommends the addition of a separately packaged adjuvant to the spray tank should be supported with information indicating the benefits and/or detrimental effects, if any, associated with the addition of the adjuvant.

Information to support the use of adjuvants with pest control products can be in the form of use history, scientific rationales, published information, or trial data. The adjuvant rate should be included on the pesticide product label if it is not stated on the adjuvant label itself. If a range of adjuvant rates is proposed, the performance of the minimum and maximum rates should addressed, including an indication of how to select the appropriate rate.

The performance of the tank mix of the pest control product and the adjuvant should be discussed, relative to the pest control product alone and the pest control product tank mixed with a registered adjuvant, if available.

The value of the addition of the adjuvant may be assessed in terms of increased level, duration or consistency of control, or increased spectrum of activity with respect to the range of pests controlled, or the growth stages at which they are controlled. Information related to host crop tolerance should be provided to assess the potential for increased injury to the crop associated with the addition of the adjuvant.

Two major categories of adjuvant products are commonly tank mixed with pesticides: non-ionic surfactants and crop oil concentrates. Regulatory experience indicates that adjuvant products within each of these two categories do not normally differ significantly in their ability to affect the performance of the pesticide with which they are used. Although differences in pest control and crop injury may be observed when interchanging one adjuvant product for another within the same category, these differences are considered to be acceptable.

Accordingly, the registrant of a pesticide product has the option to identify specific non-ionic surfactant products or crop oil concentrate products to be used in conjunction with the pesticide product, or to propose a generic reference to non-ionic surfactants or crop oil concentrates. If a generic reference is proposed, information would need to be submitted only for one representative product for each category.

2.2.6 Water volumes

Information to support water volumes may be addressed within information relating to product performance. For end-use products containing a new active ingredient, value information should be provided to support the minimum water volume for ground application. If only research trials are being submitted, three efficacy trials that include side-by-side treatments consisting of the proposed high and minimum water volumes should be included.

Minimum water volumes for aerial application of pesticides are generally less than those for ground application. All supporting information for the aerial application claim may be generated from ground application trials, or based on use history information, if available. To support an aerial application claim with field trials using ground equipment it is recommended that three trials be conducted that include the lower range of water volumes proposed for aerial application.

A range of water volumes may be evaluated within the ground application trials to permit side-by-side comparisons among water volumes for a particular pest control product, to confirm performance of the product when applied in spray volumes typical of aerial application. It is recommended that the most sensitive crop, or the major crop proposed for aerial application be assessed for crop safety. Extrapolation of an aerial application from one crop to another may be done by way of a rationale addressing factors that may impact efficacy and crop safety (such as crop architecture). Trials to support aerial application to forests and fruit or ornamental trees should be conducted using aerial application equipment.

For end-use products containing registered active ingredients, use history information, data from confirmatory field trials using ultra low volume applications, or a rationale, should be provided for all label expansions to add aerial application where only ground application is currently registered. A rationale can be based on a similar precedent product that is presently registered for use in the same or similar crop(s), or that is registered for aerial application at the same dilution volume and known to be effective. In the case of fungicides, the products being compared should have the same plant uptake characteristic (specifically, protectant, partially systemic or fully systemic).

2.2.7 Change in application method

Extending existing label claims to include a new application method (such as bridging from drench application to soil incorporation) is possible, providing value information is provided to demonstrate equivalency of the two methods, and there are no other changes to the use pattern. Use history information, published papers or scientific rationales may be provided. When research trials are being provided, they should demonstrate that product efficacy and crop tolerance are equivalent for the proposed and registered application methods. The application methods should be compared among representative crops and pest control claims. Since side-by-side plots may not always be feasible, trials that evaluate the application methods separately may be conducted.

2.3 Host and rotational crop tolerance

2.3.1 Host crop tolerance

Host crop tolerance information should be provided when the proposed use involves an application to a crop that is not yet registered on the pesticide active ingredient or a new application timing (specifically, pre-emergence to post-emergence application), particularly for herbicides. For fungicides and insecticides, crop tolerance information is generally not needed, but should be commented on in cases where it is known.

Use history information, research trial results, scientific rationales or published information may be used to demonstrate an adequate margin of safety for the host crop (taking into account different crop varieties) or rotational crop.

Crop tolerance information should describe the crop response throughout the season following application. For perennial crops, information describing the crop response in the year after application should also be provided. The level of crop tolerance to both the proposed application rate (1×), and twice the proposed rate (2×) should be described. When a herbicide is applied post-emergent to the crop, the crop tolerance information should address the range of crop growth stages proposed.

Crop tolerance information may be quantitative or qualitative and may be described in terms of visual injury, crop density, crop height, crop yield and yield quality. If injury is observed, a description of it should be provided (for example, chlorosis or necrosis), with care taken to distinguish injury symptoms that are attributable to the pesticide treatment from those caused by other factors. Particular attention should be given to providing an explanation for crop injury greater than 10%, which may necessitate a warning statement on the label. If only trial data are provided to demonstrate host crop tolerance, data from three to five trials are generally sufficient.

2.3.2 Rotational crop tolerance

Information may be required to demonstrate the effect of a herbicide application on subsequent crops grown depending on the proposed use and the characteristics of the herbicide. Label directions should clearly indicate the time interval after which specific crops can be grown safely in succession, under various soil and weather conditions as appropriate.

Rotational cropping information should be representative of climatic (for example, temperature and rainfall) and soil variation across the intended area of use of the product. Information related to soil characteristics should be provided and includes soil

zone, type and texture (such as percent sand, silt and clay), organic matter content, and soil pH. The amount of information required to support rotational cropping directions may vary depending on the environmental fate characteristics of the herbicide and the range of climatic and soil conditions across the intended area of use.

Rotational crop tolerance information should be presented in consideration of the interval between the herbicide application and planting of the rotational crop. The guidance provided above on host crop tolerance to herbicides also applies to herbicide rotational crop tolerance. If only trial data are provided to demonstrate rotational crop tolerance, data from three to five trials are generally sufficient, depending on the specific herbicide and factors that influence its behaviour in the environment.

2.4 Value information for efficacy extrapolation and label amendments

Certain applications for label expansions may be supported by less information compared to when a pesticide is first registered. This is applicable to proposed label changes that may be directly comparable to existing label uses that are supported by sufficient information (for example, adding another crop to an established pest claim already made on several other crops).

Performance considerations, such as efficacy and crop tolerance, as well as benefits of the amended product may need to be addressed.

In all cases, the approach used to support the value assessment should be clearly stated in the value summary. Rationales to reduce the need for additional information can be based on a variety of factors, including:

- pest biology and interaction with the crop
- mode of action of the active ingredient
- use pattern of the product
- similarity of use directions
- similarity of formulations
- availability of use history and benefits information as described in this document

2.4.1 Efficacy extrapolation

2.4.1.1 General extrapolation principles by product type

Herbicides

The required level of control can vary among weed species and among crops for the same weed species. The level of control that can be achieved by a particular herbicide for a given weed can vary among crops depending on a variety of factors. These factors include competitiveness of the crop, timing of weed control, time of planting, and time or method of harvesting. If enough is known about the required level of weed control, the competitiveness of the crops, and the factors affecting the level of control in both crops, it may be possible to make a well-argued case for extrapolating efficacy claims, for the same weed, from one crop to another (crop grouping). Similarly, if enough is known about the biology of a group of weeds, including response to herbicides, it may be possible to make a well-argued case for extrapolating efficacy claims, within the same crop, from one weed to another (pest grouping).

Crop grouping

Efficacy extrapolation between crops is dependent on application timing and crop competitiveness (Appendix A).

For herbicides applied prior to weed emergence, extrapolation between crops may be possible, regardless of crop competitiveness.

For herbicides applied after weed emergence, extrapolation between crops is dependent on crop competitiveness. Extrapolations from a crop to one that is equally or more competitive may be possible.

Pest grouping

Efficacy extrapolation between weeds is dependent on similarity in weed biology and response to specific herbicides (Appendix B).

If efficacy has been established on a perennial weed, then it may be possible to extrapolate efficacy to a closely related (in other words, same genus) annual weed.

If efficacy has been established for a group of closely related weeds (in other words, same genus), extrapolation to an additional closely related weed may be possible provided that the level of control is similar among the closely related weeds for which information exists. That is, provided that it can be shown that the additional weed and the group of closely related weeds for which information exists are all controlled to the same extent by herbicides of the same mode of action and herbicide class.

Fungicides

Fungicide crop grouping claims should be supported by scientific information that explains the basis for extrapolation. The final acceptance of a fungicide crop group claim or use pattern extrapolation may be impacted by factors such as resistance management recommendations or availability of registered alternatives.

Crop grouping

The following criteria form the basis for extrapolating fungicide uses within a crop grouping or between crop groups: Similarity of plant pathogens causing the disease in other crops, similarity in pathogen biology with respect to site of infection and disease timing relative to the growing season, and similarity of crops with respect to seasonal growth and development, physical shape, target site of infection, and canopy size.

The following additional guidelines apply.

i) Plant host susceptibility

All proposed/extrapolated crops should be susceptible to the same disease, which should be caused by the same pathogen (genus, species and in some cases, sub-species). A claim for a disease that is caused by different pathogens (such as downy or powdery mildew) on various crops is not appropriate since many of these plant pathogens are host-specific.

ii) Pest biology

The disease should manifest itself in the same way, including timing of appearance (in other words, early versus late season), and on the same anatomical part of the plant (leaves, blossoms, stems, roots, etc.) for each crop.

iii) Crop biology

The crops should have similar biology with respect to seasonal growth and development, physical shape, target site of infection and canopy size. If crop biology is not considered to be similar, then it may be necessary to establish the appropriate rate for larger or smaller crops, appropriate coverage (dilution/carrier volumes) for the two crops. It may also be necessary to verify that the application technology is appropriate to ensure the fungicide reaches the target site of infection (application method may be different for different crops).

Pest grouping

When adequate information on three species of plant pathogens from one genus is provided, a claim for the entire genus may be supported. It is important to note that significant variability exists in plant pathogen/crop/product interactions and this will impact the scope of pest extrapolation that could be considered.

Insecticides

Crop grouping is the use of data from one crop to support claims for whole crop groups (such as pome fruit). Pest grouping is the use of data for arthropods of a few species to support efficacy claims for a whole species complex (for example, leafrollers or aphids). Both can be considered in lieu of providing data for each crop/pest combination if supported by an adequate scientific rationale.

Crop grouping

The described method of crop grouping for insecticide efficacy is confined to conventional chemical insecticides applied by foliar application. For other types of insecticides and application methods, acceptable scientific rationales will be reviewed on a case-by-case basis. Crop grouping for insecticide efficacy is loosely based on existing residue crop groups; although in some cases the crops that are suitable for efficacy extrapolation differ from those in the residue crop groups.

For most conventional insecticides, extrapolation from one crop to another can generally be made within a crop group (such as pome fruits) for foliar application provided that the following conditions are met:

- Pest distribution and locations of feeding damage (for example, leaves, fruits or stems) are similar.
- Dosage based on spray volume/plant structure/foliar volume is similar.
- Application timing (for example, early or late season) is similar such that the performance of an insecticide would unlikely be affected by abiotic factors, such as temperature, and/or biotic factors, such as differential susceptibility among insect life stages or generations.
- There is no evidence that significant regional population differences in susceptibility exist for a specific pest involved in the extrapolation.

Extrapolation between crop groups (for example, between pome fruits and stone fruits) may also be possible if dose equivalency can be demonstrated based on well-established spray practices (for example, similar spray volumes) for the different crops. Rationales addressing the four points listed above may be necessary to explain an extrapolation between crop groups.

Pest grouping

Extrapolation between pests may be acceptable for a specific insecticide or for a similar formulation when considering an equivalent application rate of the same active ingredient under similar conditions (for example, same application methods and timing, or similar growth stage of the pest). Extrapolation is limited by potential variability in pest/crop/product interactions; however, the scope for extrapolation may be extended as the supporting database and experience with a particular product increases. The broader the range of established uses of a given product, the greater will be the scope for extrapolation to additional uses of that product.

The following are key factors to consider during extrapolation for plant pests:

Pest: taxonomic relationship, biology, life cycle, behaviour, plant part(s) attacked, method of feeding (such as chewing/sucking/boring), and damage caused should be considered. There may be important differences even among closely related species. For example, a given pest species may behave differently on different crops, or different generations of a pest may cause different types of damage. On the other hand, similarities in feeding behaviour of insects may make extrapolation across a range of pest groups possible. Consideration of pest biology and the pest/crop/product interaction is required as part of the scientific rationale supporting extrapolation.

Crop and growing conditions: botanical family, morphology, growth pattern, cropping system and growing conditions (for example, field or greenhouse) should be considered.

Pest control product: factors to consider are rate, timing, frequency and method of application, mode of action and formulation.

2.4.1.2 Extrapolation involving uses on ornamental plants

Broad ornamental groups may be requested in the registration of pesticides for ornamental uses. This approach is intended to reduce regulatory burden when adding ornamental uses to pesticide labels by taking into consideration the significant diversity in ornamental plant characteristics. This flexible approach will contribute to timely access to new and effective crop protection options. Applications to add ornamental uses to fungicides, nematicides, insecticides, acaricides and herbicides fall under the scope of this approach. Plant growth regulators are not included because responses of ornamental plant species to these substances vary significantly, resulting in many discrete application rates for different groups based on plant morphology and physiology.

Because of the difficulty in determining the potential risk of phytotoxicity to such a diverse range of species and varieties covered by the ornamental claim groups, appropriate cautionary statements should be included on the label. These statements should direct users to test product applications on a small number of plants before full scale treatments are made.

The classification of broad ornamental groups presented below are appropriate for applications to add pest genera or species that affect a wide range of host plants. Applicants may propose a use on a broad group (for example, Group 1: Ornamentals, Grown Outdoors) or a subgroup (for example, Group 1A: Soil grown perennials, shrubs, trees, and flowers or foliage for cutting).

The two proposed main groups and four subgroups are as follows:

Group 1 Ornamentals, grown outdoors

- 1-A Soil grown perennials, shrubs, trees and flowers or foliage for cutting.
- 1-B Container grown annuals, perennials, shrubs and trees.

Group 2 Ornamentals, grown in greenhouses or in protected environments

- 2-A Container grown flowering and foliage annuals and perennials, shrubs and trees.
- 2-B Container or in-ground or soil grown annuals, perennials and shrubs for cut flowers.

For fungicides and insecticides, recommended foliar application rates for ornamental plants should be expressed as a concentration to be applied up to a specified point (for example, to runoff or to glisten) to ensure adequate spray coverage of plants of various sizes and structure. In cases where rates are more appropriately expressed on a per area basis, the label should include recommendations to ensure that the adequate amount of product is applied.

Drench applications can be expressed as concentrations of product to be applied to growing media in varying container sizes until a specified point (for example, until thoroughly soaked). In contrast, the amount of product applied over a given area is typically used for herbicides. The expression of rates on the basis of per unit of area may also be used in special circumstances such as when the pesticide is applied to large plants using an air blast sprayer.

Applications to add ornamental uses to pesticide labels should be supported by value information. If efficacy trials are being provided, the guidelines that follow should be used. Information requirements for product performance may be reduced or replaced by other forms of value information (in other words, use history, published information or scientific rationales). Benefit information should also be provided relating to the value of the proposed use. Please refer to Section 2.1 Consideration of Benefits, and Section 2.2.2.1 Use History Information for more details.

Value information approach for ornamental uses

The efficacy of pesticides for ornamental uses may be supported by use history information, research trials, scientific rationales or published information. Please refer to Section 2.2.2 for additional details.

It is also useful to include any appropriate benefit information (Section 2.1) since these contribute to the weight of evidence that will be considered in the value assessment.

If research trials are being conducted to support pesticide uses on broad ornamental groups, the guidelines indicated in the following section apply.

Herbicides

If the use pattern proposed for ornamentals is similar to a registered use pattern for other crops, claims against weeds already appearing on the product label can generally be extrapolated to ornamentals without additional information. Efficacy information should be provided for currently labelled weeds if the proposed use pattern for use on ornamentals differs from the registered use pattern (for example, different application rate, timing or method). Efficacy information should also be provided to support the

addition of a new weed to the label. If trial data are being used to support new claims, then typically three trials per weed are sufficient.

If only trial data are being used to support new ornamental claims, then typically three trials on representative ornamental species are sufficient. Rationales to extrapolate from one ornamental species for which crop tolerance information is available to other similar species for which specific information is not available will be considered.

Proposed label wording may include a general reference to any or all of the four ornamental species groupings described earlier in this document. In addition, individual ornamental species that are known to be either tolerant or sensitive to the herbicide in question should be identified and indicated as such on the label.

As indicated above, if the proposed use pattern for ornamentals is similar to that already on the label for other crops, efficacy claims for those weeds currently appearing on the product label can generally be extrapolated to other ornamental groups without any further information.

In the case of a new application method or timing for labelled weeds where only trials are being provided, product efficacy should be assessed in three trials with the new proposed method or timing on a subset of representative labelled weeds.

Fungicides

If only trials are being provided, a total of six trials per plant pathogen species are typically required to support a claim for either a main group (for example, Group 1) or a subgroup (for example, Group 2B). Within these six trials, at least three different crop genera that reflect the diversity of hosts susceptible to the pathogen should be tested. Susceptible crops with different size and structure and selected from different ornamental plant categories (such as Canadian Nursery and Landscape Association standards) should be tested.

Additionally, a genus of plant pathogens could be supported if three different species of a particular genus are tested within these six trials and shown to be comparably sensitive to the proposed product. Shared common names of diseases such as powdery mildew and downy mildew are not a valid rationale for grouping disease claims. This approach is not applicable to multiple diseases sharing a common name caused by different genera and/or species of plant pathogens, and pathogens with a narrow host range.

Information regarding phytotoxic effects on the host plants as a result of fungicide, nematicide, insecticide or acaricide applications should be provided. This information can be obtained either from dedicated crop tolerance trials, through observations made in the efficacy trials, or in conjunction with use history and benefits information. It is important to explain the cause of any observed phytotoxic reactions and to state whether the effects were permanent or temporary. The impact of the phytotoxic reaction on product acceptability/marketability must be addressed, especially in the context of ornamental crops such as cut flowers.

If a disease claim is initially supported with trial data generated under greenhouse conditions and is subsequently requested for outdoor ornamentals, or vice versa, a reduced set of three field trials would be sufficient to extend the entire claim to the other ornamental group.

If an application method different than the one used in the initial six trials is proposed, a set of three additional trials employing the new proposed method of application should be provided. The justification for reducing trial data requirements is the same as described above for extension of claims from greenhouse to outdoor uses.

Insecticides and acaricides

For foliar applications, a total of six trials per pest species are normally sufficient to support a claim for a main group (for example, Group 1 or Group 2). Within these trials, the pest should be tested on plant species representative of the diversity of hosts that are damaged by the pest and in consideration of plant characteristics such as leaf attributes that could impact pesticide coverage. The following types of ornamentals should be represented (if applicable): herbaceous ornamentals, deciduous woody ornamentals, and evergreen woody ornamentals.

For soil applications, a minimum of three trials are generally sufficient to support a claim for a main group (for example, Group 1 or Group 2). If the pesticide's translocation property is expected to impact product performance, the pest should be tested on plant species representative of the diversity of affected hosts. The following types of ornamentals should be represented (if applicable): herbaceous ornamentals and woody ornamentals.

For soil application of a pesticide targeting a foliar pest, six efficacy trials are normally sufficient for a given pest species on a main group of ornamentals (Group 1 or Group 2), if only trial data is being used as supporting information. Within these trials, the pest should be tested on plant species representative of the diversity of hosts that are damaged by the pest. The following types of ornamentals should be represented (if applicable): herbaceous ornamentals, shrubs and trees. If hosts include deciduous and coniferous plants, then representatives of both of these types of plants should be included because of the possible impact of above-ground plant structure on pesticide translocation and its performance.

If a pest claim supported with trial data generated under greenhouse conditions is requested for the same pest on outdoor ornamentals, a rationale and/or a bridging trial to demonstrate that performance is not adversely affected by use in the field when used according to use directions should be provided.

If a pest claim supported with trial data generated on outdoor ornamentals is requested for the same pest under greenhouse conditions, a rationale and/or at least one bridging trial to demonstrate that performance is not adversely affected by use in the greenhouse when used according to use directions should be provided.

For most pests, a rationale is sufficient as environmental conditions are generally less severe in the greenhouse compared to the field. A bridging trial may be needed if indoor conditions could affect pesticide performance. For example, pest pressure for whiteflies under greenhouse conditions in Canada may be higher than in the field and could require different use directions.

Extrapolation between foliar and soil application is generally not possible using only rationales because of various factors (for example, differences in target pests, rate expression and time of application). Efficacy data and/or use history and benefits information should be provided to support each type of application.

Extrapolation between pest/crop combinations may be possible with scientific rationales. Refer to Section 2.4.1.1 General Extrapolation Principles by Product Type for additional guidance.

Guidelines regarding potential phytotoxic responses to insecticide applications are similar to considerations for fungicides and nematicides. Please refer to the Section 2.4.1.2. Extrapolation Involving Uses on Ornamental Plants for additional details.

2.4.2 Minor formulation changes

Certain minor changes in formulation do not typically require value information. These may include:

- change in the registered source of active ingredient
- change in substances added to preserve the formulation in the container (for example, preservatives and anti-freeze) or to improve safety to non-targets
- substitution of one formulant for another of similar property or characteristic
- changes in substances used to identify the formulation (such as dyes)
- in general, changes of less than 10% in the amount of any individual component of the formulation including active ingredients, surfactants, wetting agents and adjuvants, resulting, in general, in changes of less than 10% to the overall or absolute formulation
- formulation changes to herbicides applied pre-emergence, except for granular or slow-release products
- fumigants, vaporized or fogged products, where the new formulation is shown to release the gaseous active ingredient at a similar rate and level as the registered formulation

2.4.3 Bridging information

Bridging information may be provided in cases where a proposed new use is directly compared to either a use that is already included in the registration of another pest control product, or another proposed use that is supported by sufficient information. This approach is appropriate when adequate information has been provided as a basis for a comparison, and is more likely to be acceptable if performance has been well established on a range of crops or pest control claims. Equivalence of formulations need only be shown on a number of representative pest species, which can then be used to support the inclusion of other pest species on the label.

Similarly, equivalence need only be demonstrated on a number of representative host crops and rotational crops to support the inclusion of the other host and rotational crops on the label. Equivalence is best demonstrated by providing information on the most challenging label claims (specifically, the most susceptible or most sensitive crops or the most difficult to control pest species).

Examples of situations where the bridging approach may be applicable include:

- resolved isomers of active ingredients
- new formulation/guarantee (same application rate of active ingredient)
- co-formulation of two or more registered active ingredients
- change in adjuvant
- change in carrier
- change in water volume

2.4.4 Minor uses

In order for a minor use to be registered in Canada, information needs to be provided to demonstrate that it has acceptable value. There are three approaches to the value assessment of minor uses in Canada.

(A) If a minor use is prioritized as an "A" priority by growers at the Canadian Minor Use Priority Setting Workshop as a project for which Agriculture and Agri-Food Canada's Pest Management Centre will generate supporting information and is submitted under the joint Health Canada – Agriculture and Agri-Food Canada minor use program, the PMRA will not require value information to add to the label of a registered product. 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 ensure that the proposed use pattern is consistent with the registered use pattern.

(B) For products that have not been identified as "A" priorities at the Canadian Minor Use Priority Setting Workshop, there is a streamlined approach that can be followed provided they meet all the criteria as outlined below. In cases where a minor use is registered in a foreign jurisdiction, but not in Canada, applicants of user requested minor use label expansions (URMULE) may provide a document indicating that:

- The minor use is identified as a priority to growers as demonstrated in one or more of the following examples:
  - the use is a provincial priority submitted for consideration at the Annual Canadian Minor Use Pesticide Priority Setting Workshop
  - the use has been identified as part of a transition strategy
  - the use has been the subject of a previously granted emergency registration
- The minor use is currently registered in a foreign jurisdiction that has a pesticide regulatory system broadly comparable to that in Canada. A copy of the foreign label should be submitted.
- The product characteristics and use pattern of the foreign-registered product is very similar to the Canadian-registered product.
- The value assessment for these streamline minor uses consists of a review of the document explaining how it meets the criteria for the streamlined approach and the proposed label.

(C) For minor uses that do not meet the conditions in either (A) or (B) above, applicants should submit a value information package. They are subject to a value assessment that includes a consideration of the various components of value, and may be supported by any of the following: use history and benefits information, published scientific literature, and data generated from small-scale

trials and scientific rationales. A weight of evidence approach will be used in the consideration of all information provided to support the proposed use.

If only results from efficacy trials are being submitted, information requirements will depend on the nature of the minor use: addition of a new crop, new pest or new use pattern. For insecticides, acaricides and fungicides, when only trial data are submitted, at least one valid trial is generally sufficient to demonstrate efficacy for a new use that is similar to one already registered. If the minor use differs significantly from the registered uses then up to three efficacy trials should be provided.

For herbicides, when only trial data are submitted, three trials are generally sufficient to demonstrate efficacy for a new weed or crop safety for a new crop, for uses that are similar to those registered.

2.4.5 Tank mixes

A tank mix of pest control products may be defined as the simultaneous application of two or more pest control products from the same set of spray nozzles, with each product being referred to as a tank mix partner. Tank mixes may include tank mix partners of the same type (for example, herbicide + herbicide) or different types (for example, herbicide + fungicide) of products. The use of tank mixes is of particular value when it results in a broadening of the spectrum of pests controlled, contributes to resistance management or integrated pest management, or results in a cost- or time-savings to the user.

Use of pesticide tank mixes may result in additive, synergistic (increased) or antagonistic (reduced) pesticidal activity on the host crop or pest. Product labelling that recommends the use of tank mixes may require supporting information related to physical compatibility and value.

Value information is only required to support the addition of a tank mix to the product label if the tank mix introduces a change to the use directions that is not currently included on the product label (a reduced application rate, a new pest, etc.). The type of information required will vary with the nature of the tank mix (for example, efficacy information should be provided if an application rate is reduced). In these cases, it would be useful to highlight the benefits associated with the tank mix.

If the proposed tank mix application rates of one or more tank mix partners are less than those registered on each tank mix partner label when applied alone (for example, 1 x Product A + 0.8 x Product B), and the registrant of product with the reduced application rate is different from the applicant, then a letter of support from that registrant is required.

3.0 Preparation of the value information package

3.1 Pre-submission consultation

When seeking a new or amended registration of a pest control product, information may be required to demonstrate value, depending on the nature of the proposed uses. Applicants are encouraged to discuss with the PMRA the proposed uses of their product and the potential requirements and manner by which they can be addressed prior to submitting an application for registration. The pre-submission consultation enables applicants to obtain guidance for preparing a complete and concise value package that addresses all of the proposed label claims, and contributes to an efficient review process.

3.2 Value information package (Part 10 Data Codes)

The Part 10 Value package should contain at a minimum, one text document (the Value Summary) and, when experimental data are being included, one spreadsheet (Microsoft Excel). A copy of the individual trial reports should also be included under the DACO on Efficacy Trials, as appropriate. Applicants are encouraged to summarize the information associated with the various data codes (DACOs) in the Value Summary. The template for the Value Summary was published in PMRA Guidance Document, *Value Assessment of Pest Control Products*, available on Canada.ca. A copy of the template is available from PMRA upon request.

Note that the DACOs that need to be addressed will vary with the nature of the proposed use and that some types of information, such as a benefits analysis or use history information, may apply to several DACOs. For example, use history may provide information that relates to efficacy and non-safety adverse effects. When published literature and scientific rationales are provided, they should be submitted under the relevant DACO number. For example, information relating to efficacy of the pesticide should be provided under DACO 10.2.3.

Guidance on summarizing efficacy data

The following paragraphs provide additional guidance on how to summarize efficacy data when it is being provided. Templates are available upon request through the Pest Management Information Service.

When efficacy trials are used to support an application, individual trial reports should be compiled under the appropriate DACOs. The discussion of the trial reports should be incorporated into the value summary document. Applicants are encouraged to use a table of contents or some other method of indexing or providing direct links to the individual trial reports. Individual trial reports may be submitted as one combined electronic document.

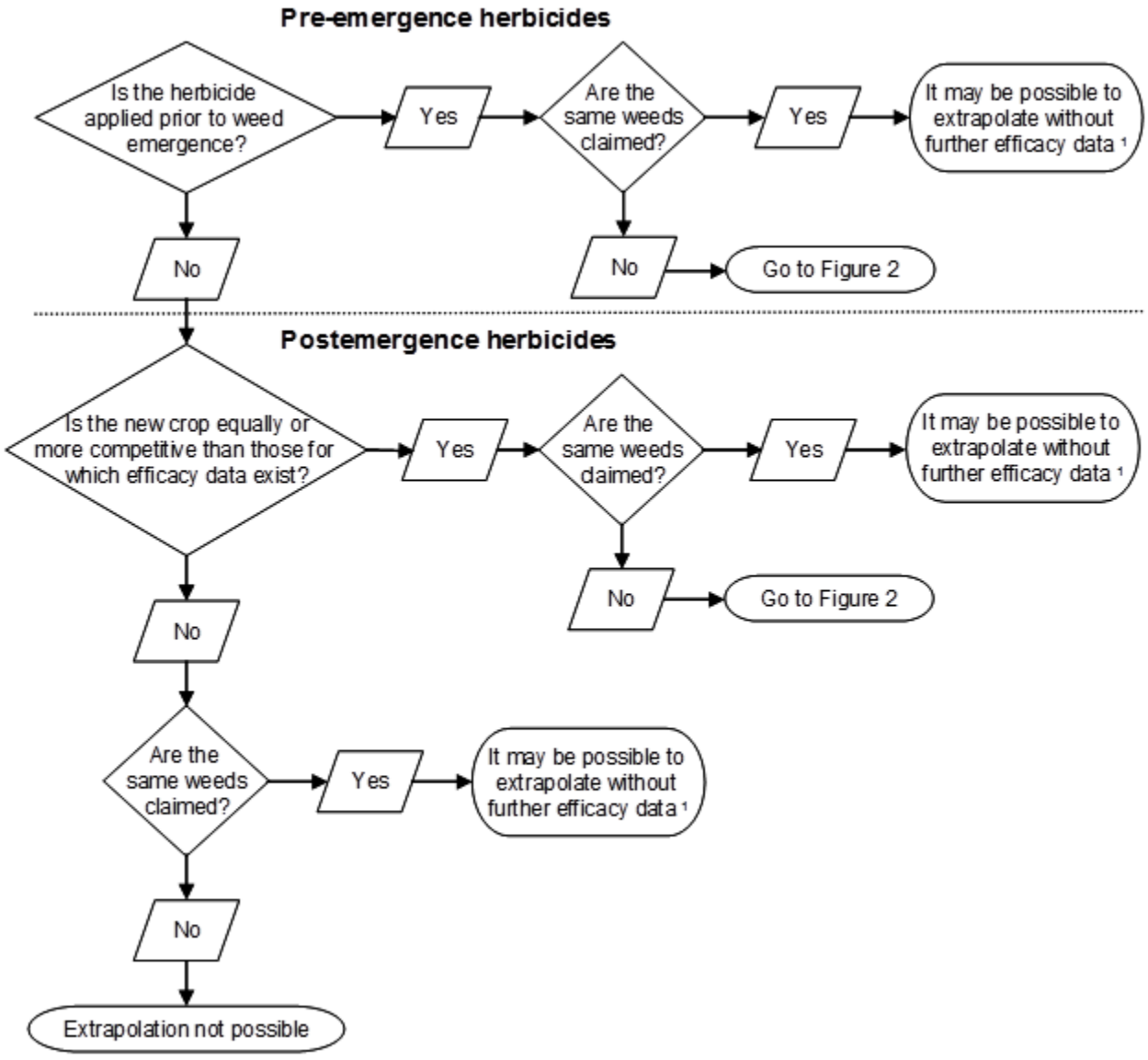
For herbicides, the complete data set should be summarized in a master spreadsheet in a format that allows sorting by the reviewer, if required. Comments on any trial can also be included, which are useful in providing explanations for outliers or unusual results. The master spreadsheet is used to generate frequency distribution tables for each specific claim (weed and host crop for each assessment period, and for each parameter assessed, such as percent control). The pivot table function in Microsoft Excel may be used to create the frequency distribution tables. Different conditions of use require separate frequency distribution tables. The frequency distribution tables may also be inserted into the Value Summary.

For fungicides, data from all submitted laboratory, field or operational studies should be summarized and presented in a spreadsheet. Each trial should be summarized separately, but grouped together in the same tab by pathogen claim. Additional tabs can be used for each pathogen. The following information, at a minimum, should be provided: trial reference number, trial location, date of trial, author, applications dates, description of treatments, product rates applied (in metric units), equivalent rates in grams of active ingredient per volume or area, carrier volume, assessment dates, and response variables (% DI, DS, yield, etc.) for each assessment date. Comments on phytotoxicity or other notable events may be added in a comments column at the end of the table.

For insecticides, the following information, at a minimum, should be provided: trial reference number, trial location, date of trial, author, application date(s), description of

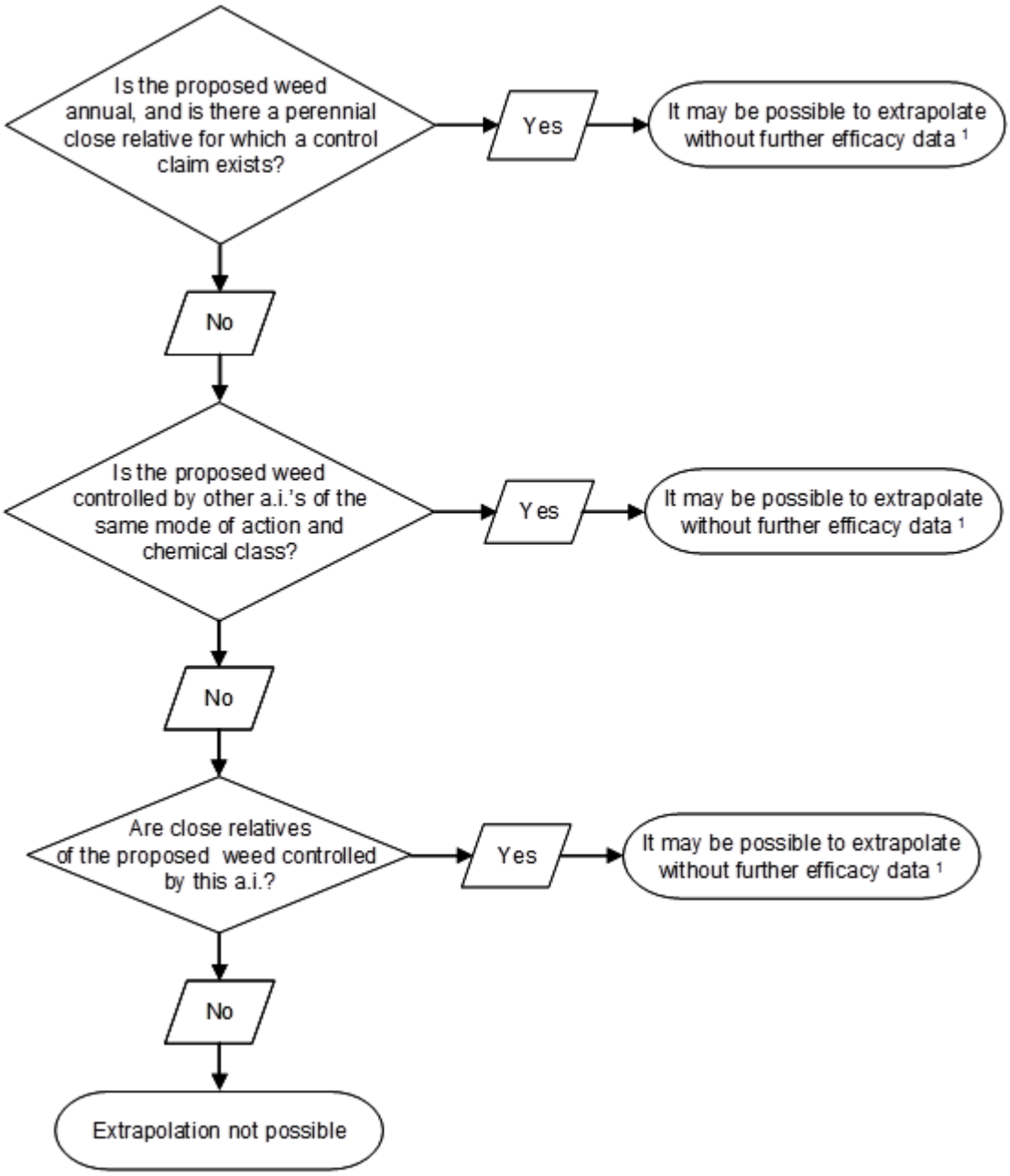
treatments, product rates applied (in metric units), equivalent rates in grams of active ingredient per volume or area (or other unit as appropriate), carrier volume, assessment dates, and ratings for each assessment date. Comments on phytotoxicity or other notable events, and a brief explanation of statistical methods used may be added in a comments column at the end of the table.

Appendix A Efficacy Extrapolation Between Crops for Herbicides (Crop Grouping) – Figure 1



[1] *On the assumption that the proposed use pattern for the new crop is the same as that registered on other crops with respect to application timing and application rate, and involves the same or an agronomically similar formulation.*

Appendix B Efficacy Extrapolation Between Weeds (Pest Grouping) – Figure 2



[1] *On the assumption that the proposed use pattern for the new crop is the same as that registered on other crops with respect to application timing and application rate, and involves the same or an agronomically similar formulation.*

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