OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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Suggestions to Registrants on Providing Benefits Information for New Conventional Pesticide Registrations and New Outdoor Uses of Conventional Pesticides

Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides for federal regulation of pesticide distribution, sale, and use. All pesticides distributed or sold in the United States must be registered by EPA. Before EPA may register a pesticide under FIFRA, the applicant must show, among other things, that using the pesticide according to specifications "will not generally cause unreasonable adverse effects on the environment.'' FIFRA defines the term ''unreasonable adverse effects on the environment'' to mean: ''(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act.'' EPA's risk assessments describe the potential adverse effects on human health and the environment resulting from use of the pesticide, which allows EPA to consider the negative consequences of pesticide use such as the "economic, social, and environmental costs." If no risks are identified, a benefit assessment is not necessary. If risks are identified, EPA evaluates whether those risks are unreasonable.

To determine whether there are unreasonable risks under FIFRA, the Office of Pesticide Programs evaluates the benefits of the use of a pesticide. The benefits are weighed against the costs of using the pesticide which EPA delineates through risk assessments. EPA grounds its decision based on information provided from assessments of the benefits of the use of a pesticide and assessments of the risks of the use of a pesticide. In the Office of Pesticide Programs' risk management process, EPA integrates the results of risk assessments with other considerations, such as benefits, to reach decisions regarding the need for and practicability of implementing various risk mitigation measures.

This document describes EPA's approach to evaluating the benefits of the use of a conventional pesticide[1] for new registrations. This document also identifies key concepts involving benefit assessments in the Office of Pesticide Programs and the types of information that registrants can submit to facilitate the review of benefits. Registrants or their designee may submit a benefits document for new active ingredients or new uses that summarizes and describes the benefits of the use of the active ingredient.

[1]Conventional pesticides are all active ingredients other than biological pesticides and antimicrobial pesticides. Conventional active ingredients are generally produced synthetically, i.e., are synthetic chemicals that prevent, mitigate, destroy, or repel any pest; or that act as a plant growth regulator, desiccant, defoliant or nitrogen stabilizer.

EPA's approach of evaluating pesticide benefits is based on weight of evidence and may include, among other things, information from the registrant, extension services, published scientific papers, or comparative product performance trials. If applicants are uncertain about what aspects of a pesticide's use constitute a benefit that EPA is willing to consider, applicants are encouraged to contact their Product Manager in the Registration Division.

EPA has historically waived the requirement to submit product efficacy data with the application for registration unless the pesticide product bears claims against public health pests,[2] wood-destroying insects, or certain invasive species. Nevertheless, registrants must ensure through testing that a conventional pesticide product is efficacious when used in accordance with label directions and be prepared to submit such data upon request. As EPA has explained, EPA reserves the right to require, on a case-by-case basis, submission of efficacy data for any registered pesticide product or product proposed for registration. Registrants may also choose to submit comparative performance trials to support benefit claims. These data can be useful to demonstrate benefits for conventional products.

Purpose and Scope

FIFRA defines the term ''unreasonable adverse effects on the environment'' to mean: ''(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act.''

EPA's Office of Pesticide Programs conducts risk-benefit analysis to determine whether certain risks are unreasonable. Risks that fall under the purview of the Federal Food, Drug, and Cosmetic Act, such as dietary risks, may not be weighed against benefits. When risks are identified, EPA weighs the benefits of the use of a pesticide against the potential economic, social, and environmental costs of the use of a pesticide (as informed by sources such as risk assessments) and subsequently proposes a decision about the pesticide considering these factors. Generally, the Biological and Economic Analysis Division within the Office of Pesticide Programs is the division that reviews benefit submissions for conventional pesticides and completes benefit assessments as necessary to inform registration decisions.

The benefits of a new pesticide or new use may be measured in terms of improved control leading to reductions in yield loss or increases in crop quality, the extent to which it facilitates integrated pest management and/or resistance management, and the extent to which it decreases cost of production. Benefits may not necessarily be monetary but could also be measured in terms such as effort, flexibility, time, and management complexity. For non-agricultural situations, benefits would be measured in a similar way, although yields and crop quality would be replaced by other positive measures of outcome such as aesthetics, improvements for recreation, improved utility conveyance, and transportation safety. Benefits are typically measured against common alternative control strategies including non-chemical means, if applicable. EPA typically reviews how the use of the pesticide will benefit the user. However, benefits may also be social, such as improved recreation or aesthetics, or environmental, such as habitat restoration or invasive species control.

[2] https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0017

The benefits of pesticides depend on various agronomic or biological factors, chemical characteristics, and alternative control strategies, all of which influence how a pesticide user manages pests. The unit of analysis for a benefit assessment is typically an acre of a crop or similar unit that would normally be treated with pesticide. EPA's goal is to compare benefits of the use at a similar level to the assessment of risks. For example, risks to pesticide handlers treating a field or area, risks to workers entering a treated field or area, and risks to non-target organisms in and around a field or treated area.

Registrants may provide benefits information from a variety of sources including research trials, scientific publications, or historic use information from registrations in other countries. Given that specific details regarding the benefits of the use of a pesticide can vary substantially depending on the pesticide type, use site, and target pests, there is flexibility in how EPA evaluates the benefits using a weight-of-evidence approach. Details about the proposed product's application parameters or niche in the pest control market may also be used in the development of protective mitigation while minimizing potential impacts to product usability. Note that the Biological and Economic Analysis Division does not evaluate claims related to human health or ecological risks (e.g., "favorable risk profile") as a part of the benefit review process. However, other divisions within the Office of Pesticide Programs may review or evaluate comparative risks for a registration decision.

Registrant Submission of Benefit Information: Format and Content

Both quantitative information and qualitative information can be provided to assist EPA in a weight-of-evidence determination regarding benefits. In many cases benefit submissions are formatted where applicants list specific benefit claims and then provide supporting information for the claims. Supporting information, such as scientific rationale, published references, or summarized study data should be included for all claims. EPA reviews submissions when considering the benefits of pesticide use. Benefit submissions should clearly identify all information sources to facilitate the review. EPA may cite the sources in the review of benefits and/or make information sources public.

Below is a list of information to assist applicants in the creation of benefit submissions.

1. Draft label(s) with use directions for all proposed use sites.
2. A use summary table including a list of the proposed use sites and expected use patterns for each site, including application timing or application method(s).
3. A summary of key target pest(s) in the context of each use site, including the type and magnitude of damage caused by the main target pest(s); the frequency of occurrence; timing of occurrence; and any geographical or regional differences that may exist.
4. A summary of registered pesticides or other standard methods currently available and used to control the target pest(s) for each use site. This should include biological or cultural controls, if applicable.
5. A comparison of the new pesticide to the current standard control methods for each use site and a discussion of the benefits of the pesticide for each use site. Example benefits include:
    - Reductions in management effort or production costs due to:

- increased flexibility in application timing or application method,
- fewer/simpler applications due to broader control spectrum or longer residual control,
- fewer potential regulatory restrictions such as personal protective equipment requirements, length of restricted entry interval, length of preharvest interval, or size of buffers.

- Improvements or additions to integrated pest management[3] (IPM) as compared to other active ingredients such as application timing, selectivity against targeted pests, or decreased impacts to beneficial organisms that provide natural control of pests within the crop(s).
- Improved resistance management such as a new mode of action[4] or effective control of pests with documented resistance to current control methods.
- Equivalent or better performance or improvements to pest or crop management compared to what is currently registered and available in the marketplace. Submissions can include comparative performance trials that measure the proposed active ingredient against the identified standard control methods. EPA recommends that these trials be conducted in accordance with the draft label rate on appropriate pests on the proposed use site and that the candidate active ingredient not be mixed or used in rotation with other active ingredients for the trial, if practical. Performance trials as compared to an untreated control are also helpful.

Factors that Complicate Review and/or Increase Uncertainty

In some cases, benefit submissions lack information or include information that increases uncertainty and complicates EPA's determination of benefits to the user. To provide clarity to the process, EPA provides some examples of less helpful information below.

1. Marketing information is submitted in lieu of data generated from research trials, existing scientific literature, or scientific rationale.
2. Benefits information is only included for a subset of use sites rather than all proposed use sites.
3. Performance data issues:
    a. Data are submitted from tests based on experimental conditions that are not congruent to the proposed label parameters. For example, the proposed label says 3 applications, but data show 5 applications or studies contain results on labeled target pests but the crop in the study is not on proposed label.

[3] Integrated Pest Management is a sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks (See 7 U.S.C. § 136r-1). IPM may consist of insect resistance management or integrated weed management.

[4] If the action is for a new active ingredient, the registrant should reach out to the appropriate Resistance Action Committee (RAC) to have a mode/site of action assigned (insecticides and nematicides go to the Insecticide-RAC; fungicides go to the Fungicide-RAC, and herbicides go to the Herbicide-RAC).

b. Data are submitted without stating the application parameters used.
c. Submitted data do not include a comparison versus market leaders/recommended products for the target pests and are therefore of limited utility in a comparative benefit assessment. Performance trials as compared to the untreated control are useful to submit along with comparative performance trials versus current standard control methods.
d. Data are submitted for a tank-mix or pre-mix or used in rotation with other active ingredients such that the "benefit" of the new pesticide cannot be separated from the other active ingredients.

4. A benefits claim is made but lacks supporting data or explanation. For examples, "this pesticide will aid in IPM." However, nothing is submitted to indicate how the new pesticide "aids IPM" in a way that is comparable or better than other pesticides for the same use site and pest combination.
5. A registrant prefers that materials in the application for reduced risk status are used in place of a benefit submission. The reduced risk materials may not include information on all use sites or provide EPA with enough information to make conclusions about a benefit claim.

Registrant Benefits Document Submission Process

A benefit submission gives the registrant an opportunity to describe potential benefits of the use of the pesticide. For a new active ingredient, first food use, and first residential use cases, EPA recommends submission of a benefits package at the time of application to inform the registration decision. For other registration actions, such as new use sites or new use patterns, submission of benefits documents may be appropriate on a case-by-case basis. Additionally, EPA will assign Master Record Identifiers (MRIDs) to the benefits information as well as supporting studies so they can be catalogued and tracked appropriately with the action. Although there can be overlap between an applicant's benefits claims and information provided for a reduced risk action, the Agency generally considers these to be distinguishable. Therefore, if the applicant is submitting the action as reduced risk, a separate submission of a benefits information document would be helpful to submit in addition to the reduced risk rationale.

Disclaimer

The contents of this document do not have the force and effect of law and are not meant to bind the public or EPA in any way. EPA may depart from this approach when circumstances warrant and without prior notice.