

Suggestions for Applicants on Information Considered When Evaluating Benefits of New Conventional Active Ingredients/Significant New Use Site Requests

Pursuant to FIFRA sections 2(bb) and 3(c)(5), the Office of Pesticide Programs (OPP) considers the “economic, social, and environmental costs and benefits of the use of any pesticide” when registering new pesticides. While EPA considers a number of factors in evaluating benefits, pesticide registrants have requested that EPA provide clarity on the type of information that OPP’s Biological and Economic Analysis Division (BEAD) considers when evaluating the benefits of a new chemical and/or a new use. In order to assist applicants/registrants of conventional pesticides, EPA is providing some suggestions on the types of information applicants could provide that would help BEAD review the benefits that accrue to potential users of the pesticide as part of the registration process.

In developing new products, registrants identify the performance qualities and pest control claims. This information is similar to the benefits information listed below. When provided to EPA, such data and related information, as well as other factors, helps facilitate EPA’s evaluation and can be an important aspect in EPA’s consideration of risks and benefits when making registration decisions under FIFRA.

This information to registrants is not binding on, and does not create any rights or obligations on the part of, either EPA or any outside parties. EPA may depart from this approach when circumstances warrant and without prior notice.

What types of information may be helpful to support BEAD’s benefits evaluation?

From EPA’s standpoint, a new pesticide for any use site is like any other new technology in agriculture. It benefits the grower if it improves yields, quality, and/or decreases cost of production. Cost is not necessarily only monetary, but could be measured in terms of effort, flexibility, time, management complexity, etc. For non-agricultural situations, benefits would be similar although yields and quality may be replaced by other positive measures of outcome (e.g., aesthetics, improvements for recreation, etc.).

For applicants/registrants who wish to submit information to support BEAD’s benefits evaluation, EPA suggests information from the list below, if applicable, would be helpful to highlight benefits that accrue to users of a new pesticide or new use(s) of a pesticide. EPA encourages submission of concise benefits documents. Supporting information, such as published references or summarized study data, should be included for all claims.

1. A list of the use site(s) (e.g., specify crop sites, crop groups, non-agriculture use sites);
2. Expected use patterns for each site, including application timing or application method(s);
3. A summary of target pest(s) in the context of the 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 geographic or regional differences that may exist;
4. A summary of registered pesticides or other methods used to control the pest;

5. A comparison of the new pesticide to the current standard control methods and a discussion of how the new pesticide will benefit growers. Potential advantages that can lead to greater user (*i.e.* grower or producer) flexibility, better outcomes or lower costs include, but are not limited to:
 - a new mode/mechanism of action for that site to facilitate resistance management;
 - facilitating integrated pest management (IPM), including specificity against targeted pests;
 - providing equivalent or better efficacy or performance or improving pest or crop management compared to what is currently registered and available in the marketplace;
 - characteristics that reduce impact on non-target organisms and the environment.

In considering any information that registrants submit, the Agency will review the submissions to determine whether the benefits claims have been adequately supported and the evidence provided can be verified by EPA. All information sources (e.g., academic, extension, or research) should be clearly identified to facilitate the review and may be cited in EPA reviews and made publicly available. For clarifications, explanations, and further discussions, including any uncertainties regarding what aspects of a pesticide constitute a benefit that EPA is willing to consider as part of registration, applicants are encouraged to meet with their Product Manager in the Registration Division.