Registrant Information on the Use and Benefits of Antimicrobial Pesticides

This document presents background on the type of information that registrants may provide to assist the Antimicrobials Division (AD) in reviewing the benefits of a pesticide chemical, especially during the development of the Registration Review Proposed Interim Decision (PID). This guidance was adapted for antimicrobial registrants from a similar document published by the Biological and Economic Analysis Division in September 2018 to provide information on conventional pesticidal products at the time of registration.[1]

At the PID phase of Registration Review, EPA proposes any modifications to the way an antimicrobial pesticide is used if risks of concern are identified in the Draft Risk Assessment (DRA). The Agency may propose to cancel a specific use, multiple uses, or all uses of a pesticide active ingredient. As required by law, EPA considers the benefits of the use of an antimicrobial pesticide to the user and/or the general public when evaluating whether a pesticide meets the FIFRA standard for registration; however, part of EPA's assessment of whether a pesticide meets the FIFRA standard of registration involves determining whether any dietary risks from use of the pesticide are unsafe. For pesticides with uses that result in residues in or on food, EPA conducts an assessment of dietary risks, and in that assessment, EPA applies the safety standard found in section 408 of the FFDCA, which is a risk-only consideration that does not involve the consideration of benefits information. In practice, this means that benefits information may be relevant and considered only for evaluation of uses of a pesticide that are not likely to result in residues in or on food, and is not considered for evaluating the safety of uses that may result in residues (directly or indirectly) in or on food. While not all residues result in dietary risks of concern, if risks are triggered by residues, benefits would not be weighed in its safety finding.

Information indicating that use of an antimicrobial pesticide may or will lead to better outcomes (e.g., through the prevention of the spread of disease) and/or lower costs (e.g., through the production of higher quality products or maintaining the integrity of materials) will be considered by the Agency when assessing uses of a pesticide (or pesticide products) that will not result in residues in or on food. Information that explains how, why, and when consumers use the pesticide will help the Agency in assessing whether a pesticide meets the FIFRA standard for registration.

This information to registrants is not binding 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 information may be helpful to support AD's benefits evaluation?

For applicants/registrants who wish to submit information to support AD's benefits evaluation, EPA suggests that information from the list below, if applicable, would be helpful to highlight benefits to the pesticide undergoing Registration Review. EPA encourages the 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);
2. Application methods for each use site;
3. A summary of the issue(s) of concern, public health need(s), and/or target organism(s) being addressed in the context of the use site, including the type and magnitude of damage or harm

[1] "Suggestions for Applicants on Information Considered When Evaluating Benefits of New Conventional Active Ingredients/Significant New Use Site Requests." U.S. EPA (2018). Available at https://www.epa.gov/pesticide-registration/suggestions-applicants-information-considered-when-evaluating-benefits-new.

caused by the target organism(s) if use site is untreated; frequency and timing of required treatment; and any geographic or regional considerations that may exist;
4. Usage and/or production volume data by use site;
5. A summary of other biocides or non-biocide methods used to control or eliminate the target organism(s) or address the issue of concern;
6. A comparison of the chemical to its alternatives (biocidal and non-biocidal) listed by use site, including its advantages and disadvantages over the available alternatives to the end user or general public. If there are no registered alternative antimicrobial pesticides for a use site, this should be noted. Potential advantages that may lead to better outcomes, lower costs, or other benefits include, but are not limited to:
    a. Stronger efficacy against a target organism, which may include better performance under specific conditions and/or longer duration of control;
    b. Broader spectrum of activity;
    c. Widespread availability to end user;
    d. Easier handling;
7. The potential impacts to end users or the general public if the chemical is no longer available;
8. The potential risk mitigation measures that may improve safety or reduce exposure to human health or the environment; and
9. The international regulatory status of the chemical, which may include the effective date of regulation, allowed uses of the chemical, regulatory action(s) taken to reduce risk, and reasons for regulatory action(s).

In considering information that registrants submit, the Agency will review the submissions to determine whether the benefit 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.

How and when should registrants submit information to the EPA?

Applicants are encouraged to contact the Chemical Review Manager (CRM) for the chemical's registration review case with questions regarding registrant submitted benefits evaluations for antimicrobial pesticides. Although benefits information can be submitted at any time to the CRM, it is especially useful when submitted after the publication of the active ingredient's DRA and before the PID, as this is when the benefits statement is in development. To determine the correct CRM to contact, please visit the EPA Chemical Search Webpage, search by chemical or PC Code, and access the link to the registration review docket.[2] The link will lead to the public docket for the case on www.regulations.gov, which lists the current CRM. Alternatively, registrants can contact the registration review team leads that are listed in the Antimicrobials Divison contacts webpage.[3]

Information on benefits also can be submitted during the public comment periods prior to the PID for consideration in the development of the document. This is done via the public docket on www.regulations.gov, please see instructions in the preceding paragraph to determine the correct docket. Such comment periods occur after the publication of the Preliminary Work Plan as well as the DRA.[4]

[2] EPA Chemical Search webpage is available at: https://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1
[3] Antimicrobials Division contacts are available at: https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobials-division.
[4] To find information regarding the schedule for registration review, please visit https://www.epa.gov/pesticide-reevaluation/registration-review-schedules#antimicrobial