

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PC Code: 000692
DP Barcodes: 335272, 335451, 335453
Date: May 23, 2007

MEMORANDUM

SUBJECT: Review of registrant submission entitled "Pyrasulfotole: An Assessment of Risk to Endangered Species Associated with Small Grains" (MRID 469743-01)

TO: Tracy White, Chemical Review Manager
Joanne Miller, Risk Manager
Registration Division (7505P)

FROM: Melissa A. Panger, Ph.D., Biologist
Marietta Echeverria, Environmental Scientist
Environmental Risk Branch IV

M. Panger 5-23-07
Marietta Echeverria 5/23/07

Megan Thyng, Environmental Protection Specialist
Environmental Information and Support Branch
Environmental Fate and Effects Division (7507P)

M. Thyng 5-23-07

APPROVED
BY: Elizabeth Behl, Branch Chief
Environmental Risk Branch IV
Environmental Fate and Effects Division (7507P)

E. Behl 5/23/07

The Registration Division (RD) in the Office of Pesticide Programs requested the Environmental Fate and Effects Division (EFED) to review a registrant submission entitled "Pyrasulfotole: An Assessment of Risk to Endangered Species Associated with Small Grains." EFED performed an evaluation of the following items: the initial selection of taxa of concern; the sources of information presented in the document; the process of elimination used to remove species from those requiring additional analysis; and the utility of the registrant's submission as it relates to EFED's Overview Document process. This final part of the review focuses on whether the submission document alone can adequately evaluate the potential of a federal action (*i.e.*, registration decision) to affect a Federally-listed threatened or endangered species (listed species). The submitted document was reviewed in relationship to the assessment process and information needs

US EPA ARCHIVE DOCUMENT

described in EPA's Overview Document. This review does not include an exhaustive list of comments, but instead highlights issues EFED considers to be major issues of concern.

After reviewing the registrant's endangered species assessment for pyrasulfotole, EFED concludes that this assessment does not include sufficient documentation to support the findings of "no effect" for most of the listed plant species initially identified as species of "potential concern" by the co-occurrence analysis at the county level of resolution.

I. The Selection of Taxa of Concern

The selection of taxa to be considered in Bayer's endangered species assessment was based on the findings from their screening level ecological risk assessment, "Ecological Risk Assessment for the Cereal Herbicide AE 0317309" (MRID: 468019-47). The only risk quotients (RQ = exposure/toxicity) that exceeded the Agency's levels of concern (LOCs) in Bayer's screening-level assessment were the RQs for terrestrial dicots. Therefore, they include terrestrial dicots and other terrestrial plant taxa that were not tested in their screening-level assessment. Therefore, Bayer's endangered species assessment addressed the following plant taxa: conifers, cycads, dicots, ferns (and their allies), and lichens.

A screening-level ecological risk assessment conducted by EFED, however, shows the possibility of direct effects to listed aquatic vascular plants and mammals (chronic exposure), in addition to terrestrial and semi-aquatic dicotyledonous plants. For indirect effects, all other taxa should also be considered since there is a potential for indirect effects to taxa that might rely on plants and/or mammals for some stage of their life-cycle. Therefore, based on its screening-level ecological risk assessment, EFED concludes that no Federally-listed taxa should be excluded from further analysis due to the potential for direct and/or indirect effects from the proposed uses of pyrasulfotole. As Bayer's endangered species risk assessment only considers terrestrial plants, it is considered incomplete at this time.

II. Sources of Information Presented in the Document

The submitted document relies principally on information available through the FIFRA Endangered Species Task Force Information Management System (FESTF IMS) to identify listed plant species co-occurrences for the following proposed pyrasulfotole use sites: wheat, barley, oats, and triticale. The IMS was used to provide listed plant species co-occurrences for use sites at a county level of geographic resolution. Consequently, the document does not provide the specific location of any listed plant species within an established action area that might be directly or indirectly affected by the proposed federal action of the registration of pyrasulfotole for use on cereal grains.

III. The Process of Elimination Used to Remove Species from Concern for Further Analysis

Bayer's species co-occurrence analysis did not include counties in CA, FL, NY, or the "New England" states since pyrasulfotole is not intended for registration in these states (according to Bayer's risk assessment). However, no state-level geographic restrictions exist on the current proposed label for pyrasulfotole. Since the federal action that EPA is required to assess, as it relates to the Endangered Species Act, is the action as described on product labels, these states should not be excluded from an endangered species assessment unless specific geographic restrictions are noted on the label. By excluding states from its assessment that are not currently excluded on the proposed pyrasulfotole label, Bayer's endangered species risk assessment is considered incomplete at this time.

The submission uses a hierarchal process for systematically reducing the scope and number of listed species from further analysis of potential impacts resulting from federal actions. The elimination process begins with an IMS run to identify county-level associations between locations of listed plants and the proposed use sites for pyrasulfotole, namely wheat, barley, oats, and triticale. These are termed co-occurrences and form the basis for all further evaluations.

Most co-occurrences were excluded based on the following:

- "Species does not occur in the specified county"
- "Species is delisted"
- "Species habitat and use site conditions in the specified county preclude exposure"
- "Soil supporting this species is not suitable for use site"
- "State public management practices protect this species in the specified county"
- "Federal (non-EPA-OPP) management practices protect this species in the specified county"

For the proximity, habitat, and soil exclusions, none were based on any information regarding the actual locations of the habitat, its proximity to the proposed pyrasulfotole use site, or the extent to which effects may extend beyond the use site. Furthermore, there was no quantification of the term "near" that is used to describe the relationship of crop to habitat. Based on the information provided, it is impossible to determine if habitat requirements alone are suitable justification to conclude that no exposure to the pesticide or indirect effects associated with the pesticide can occur. In some cases, the arguments may have merit for a given species in a given location. However, additional analysis of the supporting documentation, knowledge of the actual locations of the use site, and considerations of the off-site transport of the pesticide need to be considered in the evaluation of each habitat exclusion statement. This would be the case for all proposed exclusions that are based on the above determination categories listed above, except for the "species is delisted" category.

IV. Utility of the Submission in the Context of the Overview Process and the Alternative Consultation Agreement

The submission states that the document *Pyrasulfotole: An Assessment of Risk to Endangered Species Associated with Small Grains* “follows, to the extent practicable, the guidance provided in the Joint Counterpart Regulations and EPA’s Overview Document (USEPA, 2004) on ecological risk assessment.” In order to determine how the submission follows these processes, it is important to understand that the majority of ecological risk assessment approaches, which support assessment of federal action effects on listed species, are described in Chapters 5 and 6 of the Overview Document. The procedures contained in these chapters of the Overview Document closely compare with the Services’ conceptual framework for conducting effects assessments on listed species. Though the order of each component may differ between USEPA’s ecological risk assessment and the Services’ conceptual framework for assessing effects on listed species, both processes minimally contain the following elements:

- I. A federal action description
- II. A description of the types of effects associated with the action
- III. Establishment of an action area in a spatial and temporal context
- IV. Determination of the proximity of listed resources in relation to the action area and whether effects associated with the action are applicable to the listed resource
- V. A determination of the likelihood that effects on the resource will be adverse for any listed resources within the action area for which the types of effects associated with action are applicable to the resource

In the process outlined within the Overview Document much of the analysis of the effects on listed resources is predicated on the establishment of an action area that considers both the direct and indirect effects of the federal action. It should be noted that this action area is not limited to the footprint of the action (*i.e.*, the immediate area of pesticide application). Instead, the action area must also consider the total area in which effects of the action can be anticipated. The effects of a federal action involving pesticide registration would not only consider the immediate pesticide action area but also the off-site extent to which pesticide exposures, or the indirect effects associated with the pesticide, would exceed the established thresholds for concern.

Species outside of the action area are considered to be not affected by the federal action (*i.e.*, the analysis results in a no-effect determination). Those species within the action area may be affected (a may effect determination) or may not be affected (a no effect determination) by the action, depending on further consideration of the nature of the action’s effects on the environment and how they relate to a listed species. If listed species may be affected by the federal action, there must be further consideration of the nature of the effects, their intensity, frequency, geographical scope, and the number and characteristics of potentially affected individuals of a given listed species, to determine if the effects on individuals are likely to be adverse.

In the submitted document, although the initial identification of co-occurrences between listed species and proposed pyrasulfotole use sites is made at the county level, the assessment fails to consider the degree to which direct and indirect effects may extend from the use site (*i.e.* the boundaries of the action area). This step is critical for determining whether species locations are external to the action area or not. The document repeatedly uses the terms “exposure,” “near,” and “proximity” to describe the rationale for excluding certain listed species from further consideration. However, the document does not quantify how those terms relate to an action area. This precludes an evaluation of the technical merits of any statement regarding whether a given listed species is within or external to the action area. The net result of this failure to consider the full extent of the action area is that the submitted document provides insufficient documentation to support findings of “no effect” for most of the listed species initially identified as of potential concern by the co-occurrence process at the county level of resolution. In this regard, the submitted document only follows the Overview Document at its most initial levels of screening.

IV. Conclusions

The submitted document provides some very important information for beginning an evaluation of the impacts of federal actions involving the proposed registration of pyrasulfotole use on wheat, barley, oats, and triticale. It is a catalogue of information resources that could be called upon to possibly establish, in quantitative terms, the nature of overlap between listed species and the full extent of the geographical area potentially affected by the federal action.

However, a number of important limitations are evident in the process of elimination employed in the analysis:

- The taxa of concern as identified by the screening-level ecological risk assessment conducted by Bayer do not agree with the taxa of concern identified by EFED’s screening-level ecological risk assessment. In addition to the taxa identified by the Bayer assessment, EFED also identified mammals and aquatic vascular plants as ‘taxa of concern’ for potential direct effects, and all other taxa for potential indirect effects. Therefore, Bayer’s submitted endangered species assessment for pyrasulfotole is considered incomplete at this time.
- The submission does not provide the specific location of any listed plant species within an established action area that might be directly or indirectly affected by the proposed federal action involving the registration of pyrasulfotole for use on cereal grains.
- Bayer excluded states from their analysis that are not currently excluded on the proposed pyrasulfotole label. Therefore, Bayer’s endangered species risk assessment is considered incomplete at this time.
- For the proximity, habitat, and soil species co-occurrence exclusions, none were based on information regarding the actual locations of the habitat, its proximity to the proposed pyrasulfotole use site, or the extent to which effects may extend beyond the use site.

- In the submitted document, the assessment fails to consider the degree to which direct and indirect effects may extend from the use site (*i.e.* the boundaries of the action area), and therefore it is not compliant with the Agency's Overview Document.