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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Pesticide Registration (PR) Notice 2003-2

NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: Expedited Review of Experimental Use Permits for New Uses of Conventional Methyl Bromide Alternatives, Organophosphate (OP) Alternatives, and/or Reduced-Risk Pesticides

This PR Notice advises applicants for registration or amended registration that the Environmental Protection Agency (EPA or "the Agency") has identified circumstances where it is likely that the Agency can give expedited review and approval to Experimental Use Permit (EUP) applications. In response to requests from interested parties, the Agency has considered what conditions would allow for more timely determinations of whether EUP applications meet the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, without significantly increasing the resource burden to the Agency. Through this analysis, EPA has identified circumstances where it believes it can immediately begin to offer expedited review and approval of EUPs without interrupting the priority system described in PR Notices 97-2, 97-3, and 98-7.

I. APPLICABILITY

This Notice provides guidance to all applicants for EUPs for new uses of pesticides with a previously registered use designated as a conventional methyl bromide alternative, organophosphate (OP) alternative, and/or reduced-risk pesticide typically handled by the Registration Division. Depending on the Agency's experience under this guidance, EPA may consider expanding it to include other types of pesticides and/or pesticide products typically handled by other OPP divisions.

II. BACKGROUND ON THE AGENCY'S EUP REVIEW PROCESS

Under Section 5 of FIFRA, EPA issues EUPs to allow interested parties the opportunity to gather information necessary to register a new pesticide or a new use of an existing pesticide under Section 3 of FIFRA. In order for any foods treated with the experimental pesticide to lawfully enter commerce, EPA must establish a tolerance (maximum residue level) or exemption from the requirement of a tolerance utilizing the procedures and standards of Section 408 of the FFDCA as amended by the FQPA.

Before issuing an EUP, EPA must make several statutory findings. Under FIFRA, EPA must determine that use of the experimental product, under the conditions proposed in the EUP application, will not result in "unreasonable adverse effects" to man or the environment. If the experimental use would result in pesticide residues in or on food, and the applicant seeks to allow that food to enter commerce, EPA must also determine, under FFDCA, that "there is a reasonable certainty of no harm" from aggregate exposure to the pesticide, including exposure resulting from use under the EUP.

Prior to passage of FQPA, EPA issued approximately 20 conventional EUPs and established corresponding tolerances each year. Since passage of FQPA, however, the Agency has issued significantly fewer EUPs each year. In addition, the Agency's review times for EUPs, particularly EUPs for evaluating new active ingredients, are approximately equal to the review times for registration of these same new active ingredients. As a result, many registrants have elected to pursue full registration of these new technologies rather than to evaluate the product under field conditions with an EUP.

In response to requests from several interested parties, the Agency considered what conditions would enable the Agency to make the applicable findings under FIFRA and FFDCA, and thereby approve more EUPs without requiring EPA to commit significant, additional resources to EUP review. EPA now believes that certain EUP applications can be reviewed and approved on an expedited basis, as described in this Notice.

III. CONVENTIONAL METHYL BROMIDE ALTERNATIVE, OP ALTERNATIVE, AND REDUCED-RISK PESTICIDE EUP APPLICATIONS FOR WHICH MINIMAL REVIEW RESOURCE EXPENDITURES ARE EXPECTED

As described in Section II above, the resources EPA must commit in order to evaluate an EUP application for a new food use of a pesticide for which EPA has not completed tolerance reassessment are virtually equivalent to those needed to review an application for registration of that pesticide for the same food use. The resources needed to review a registered chemical that has not been evaluated under FQPA are also nearly equivalent to those needed to evaluate new active ingredient applications. However, EPA recognizes that in certain instances, it may be possible to approve an EUP without drawing significant resources from the priority reviews described in PR Notices 97-2, 97-3, and 98-7. In particular, where EPA has already completed

an FQPA-compliant tolerance assessment or reassessment and the EUP application presents a use pattern very similar to one already reviewed, EPA's resource burden may be very slight. Under circumstances where the resources required to review an EUP application are very slight, EPA has the opportunity to attempt expedited approval of EUP applications for methyl bromide alternative, OP alternative, and reduced-risk pesticides.

Because the dietary risk assessment required under the FFDCA as amended by the FQPA is ordinarily the most burdensome part of EPA's review of an EUP application, EUP applications that require a new dietary risk assessment are not suitable for expedited review. However, where EPA has already completed an FQPA-compliant tolerance assessment or reassessment, much of the analysis necessary for review of an EUP application has been done. Exposure assessments are simplified where application methods and use rates are similar to those previously approved by the Agency for the same chemical on other crops/use patterns. EUPs involving significantly different application methods or use rates would require detailed review of the potential risks to farm workers and pesticide applicators, and therefore, would not be suitable for expedited review. Similarly, EUPs that allow for use over large areas would require detailed science reviews to determine whether they might significantly increase dietary (food and drinking water) and ecological exposures and would also not be suitable for an expedited review.

Based on these resource considerations, EPA believes that it is likely that it would be able to give expedited review and approval to applications having all of the following characteristics:

A. Active Ingredients Factors

1. The EUP application is not for a food use, or if the EUP application is for a food use, either (a) the application identifies a tolerance or exemption from the requirement of a tolerance for the same active ingredient issued or reassessed since October 1998, or (b) the application provides for destruction of all treated crops; and

2. The EUP application has use rates, application methods, and levels of exposure that are not significantly different from those already approved for an existing product containing the same active ingredient; and

3. The proposed food or non-food use does not involve any increase in residential, bystander or worker exposure.

B. Risk Factors

1. The application supports the conclusion that the proposed use would not result in aggregate or cumulative exposures exceeding the acute or chronic population adjusted dose; and

2. The application proposes use on less than 2,000 total acres for a major use;

less than 100 total acres for an aquatic or minor use; and

3. No more than 100 acres per watershed [For further clarification of the relevant watershed(s) for a specific EUP, consult the "Surf Your Watershed" web page at http://www.epa.gov/surf/. Click on "Locate your watershed"; scroll down the page to "locate by geographic unit". Click on the drop down box arrow that will provide the choice of using a zip code, a city, a town, a county, a watershed name, an eight digit hydrologic unit code or a stream name to best identify the watershed(s) relevant to the EUP. Additional information can be found on the EPA Office of Wetlands, Oceans, and Watershed's website at http://www.epa.gov/owow/watershed/]

C. Other Factors

1. The application demonstrates either (a) that the Levels of Concern (LOC) for endangered species are not exceeded or (b) that no counties containing endangered species will be included in the EUP program per the Endangered Species Act.

Although these factors clearly have substantial influence on the extent of the review an EUP application will require, they are not in themselves determinative. Each EUP application may present unique issues and thus require, on a case-by-case basis, an individual review and decision on whether the EUP might be approved without significant burden to the Agency. Because dietary risk assessment required under the FFDCA as amended by the FQPA is ordinarily the most burdensome part of EPA's review of an EUP, EUPs that require a dietary risk assessment probably could not be reviewed significantly more expeditiously than an application for full FIFRA section 3 registration. The active ingredient factors identified in Section III. A determine whether EPA must conduct a dietary risk assessment, thus, it is highly unlikely that EUP applications inconsistent with these factors could be expedited. The limitation to pesticide active ingredients for which a tolerance or tolerance exemption has been issued or reassessed after October 1998 assures that the active ingredient has been subject to a dietary review conforming to the FQPA. In the alternative, EPA is also likely to be able to give expedited review where the EUP application provides for destruction of all treated crops.

Application methods and use rates similar to those previously approved by the Agency for the same chemical on other crops/uses are likely to allow for expedited review in comparison to significantly different application methods or use rates which would require more detailed review of the potential risks. The residential/bystander exposure factor (A3) will enable the Agency to assess whether the EUP will require re-evaluation of its previous aggregate exposure determinations.

Similarly, EUPs that allow for use over large areas may result in a significant increase in dietary (food and drinking water) and ecological exposures which would require additional

science review resources. Accordingly, expedited review will ordinarily not be possible for EUP applications that propose use exceeding the acreage limits in Section III. B2 and B3. The factor in Section III. C1, regarding endangered species, is similar to that currently used for all EUPs.

IV. REQUESTING EXPEDITED EUP REVIEW

Applications for EUPs must meet all the requirements of FIFRA Section 5 and 40 CFR Part 172, and, where applicable, FFDCA section 408 and 40 CFR 180.31. Because the rationale for expedited review is the minimal burden on the Agency's review resources, EPA is unlikely to pursue expedited review of applications where, for example, the similarity to existing, approved application methods is obscure, or it is not clear that tolerances for all ingredients have been subject to a review conforming to the FQPA. Thus, applicants seeking expedited review are encouraged to explain why review of the EUP application would not require significant EPA resources.

Any data submitted with the EUP must comply with the data formatting requirements of 40 CFR 158.32-33. Applicants should review PR Notice 86-5 for guidance on formatting and PR Notice 2000-4; for guidance on submittal procedures. The Office of Pesticide Programs (OPP) uses distribution codes to facilitate the delivery of registration and other submissions within the program. When preparing your submission to mail or deliver to OPP, direct your submission to the Document Processing Desk and include the following distribution code: **EUP-EXPEDITE**.

The submission delivered via the U.S. Postal Service should be directed to OPP using the following address:

Document Processing Desk (**EUP-EXPEDITE**)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20460-0001

Submissions via personal or courier delivery should be directed to the Document Processing Desk between the hours of 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding Federal holidays. OPP's Document Processing Desk is located at the following address:

Office of Pesticides Programs
Document Processing Desk **(EUP-EXPEDITE**)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Finally, applicants should note that it is unlawful to falsify any portion of an application. FIFRA Section 12(a)(2)(M) and 18 U.S.C. Section 1001 make such actions unlawful and subject to civil or criminal penalties. An application that does not conform to the procedures outlined above may not receive expedited processing.

V. SCOPE OF THE POLICY

This PR Notice describes the requirements set forth in Agency regulations and FIFRA, and provides general guidance to EPA and to affected parties as well. While the requirements in FIFRA and Agency regulations are binding on EPA, applicants, and the public, as a guidance document, this is not binding on either EPA or any outside parties, and the EPA may depart from this guidance where circumstances warrant and without prior notice.

This PR Notice does not limit any person's ability to submit an EUP application for a chemical or new use that is not consistent with the factors described in Section III above. However, if an applicant chooses to do so, the company should include this request on the company's registration priority list. The Agency will determine on a case-by-case basis if other EUP submissions can be expedited.

VI. FOR FURTHER INFORMATION

For further information on this program, contact Rachel Holloman, Chief, Registration Support Branch, Registration Division at (703) 305-7193 or via e-mail at holloman.rachel@epa.gov.

Debra Edwards, Director
Registration Division
Date: September 15, 2003