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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

8/24/98

PESTICIDE REGISTRATION (PR) NOTICE 98-7

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

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: Changes to Registration Priority System Involving Organophosphate (OP) Alternatives and Reduced Risk Candidates

This notice amends EPA's current policy for the prioritization and expedited review of applications for new active ingredients (AIs) which can be used as alternatives to organophosphates (OPs), and new use registration applications for alternative, conventional pesticides regulated by the Registration Division (RD). This notice also changes how reduced-risk candidates will be treated in the priority system. Submissions to the Biopesticides and Pollution Prevention Division (BPPD) and the Antimicrobial Division (AD) are not covered by this notice.

The Office of Pesticide Programs (OPP) Reduced-Risk Committee has screened five AIs that are potentially significant alternatives for OPs. These five AIs have all passed the reduced-risk screen and have been placed into expedited review. Since it may become important to have as many OP alternatives in the market as possible, OPP will use the reduced-risk screening mechanism to identify significant OP alternatives. If the Reduced-Risk Committee determines that a pending registration action does not qualify for reduce-risk status, but is a potentially significant OP alternative, then it could recommend that action for expedited review even if it does not qualify for reduced-risk status.

In PR Notice 97-2 (April 18, 1997), RD indicated that registration actions would be prioritized in the following order:

- (1) methyl bromide alternatives
- (2) reduced-risk candidates
- (3) USDA-EPA identified potentially vulnerable crops
- (4) minor use priorities

- (5) non-minor use priorities
- (6) addressing trade irritants


This PR notice amends that priority scheme in the following manner:

- (1) methyl bromide alternatives
- (2) OP alternatives that pass the reduced-risk screen
- (3) Other reduced-risk candidates
- (4) OP alternatives that are submitted to the reduced-risk committee, judged to be significant OP alternatives, denied reduced-risk status, but recommended by the Reduced-Risk Committee for expedited review
- (5) USDA-EPA identified potentially vulnerable crops
- (6) minor use priorities
- (7) non-minor use priorities
- (8) addressing trade irritants

The Agency determines whether a candidate is a potentially significant OP alternative by using a weight of the evidence approach that includes, but is not limited to, consideration of the following factors: (a) whether the affected OPs collectively have a significant market share for the specified use pattern (e.g., crop/pest combination); (b) currently registered alternatives, if any exist, have constraints which have prevented their widespread adoption as alternatives to the affected OPs (e.g., inferior efficacy, pest resistance, etc.); and (c) the proposed reduced-risk alternative appears to overcome many of the constraints of the alternatives.

Any submission that passes the reduced-risk screen will become an Agency priority beginning with company priorities #11-#15. In addition, the registrant may substitute another submission in its place as long as such submission conforms with the criteria in PR Notice 97-2 which defines a priority. Also, any submission that is determined to be a significant OP alternative, which is not granted reduced-risk status, but is recommended by the Reduced-Risk Committee for expedited review, would become an Agency priority as well. An Agency priority does not count against a company's limit of five priorities.

The Agency is also seeking input from grower groups, who would work in conjunction with registrants, to identify potential OP alternatives for their crops, including but not limited to, registration actions already submitted to the Agency, but not currently included on a registrant's priority list. Submissions must conform with the requirements and procedures specified in PR Notice 97-3 (September 4, 1997) for reduced-risk petitions. For further information, contact Peter Caulkins, Associate Director, Registration Division at (703) 305-6550.


James Jones, Director
Registration Division
Office of Pesticide Programs