

August 20, 2002

Pesticide Registration (PR) Notice 2002-2

Notice to Manufacturers, Producers, Formulators and Registrants of Pesticides

Attention: Persons Responsible for Registration and Reregistration of Pesticide Products

Subject: Guidance for Submitting Requests for Threshold of Regulation (TOR) Decisions to the Office of Pesticide Programs

In the Federal Register of October 27, 1999 (64 FR 57881), the Environmental Protection Agency (EPA) announced the availability of a document entitled "Threshold of Regulation Policy - Deciding Whether a Pesticide with a Food Use Pattern Needs a Tolerance." The Threshold of Regulation (TOR) Policy describes criteria and procedures to be considered in determining whether a use of a pesticide in a location and manner that has the possibility of resulting in residues in food is below the threshold of regulation. As explained in the policy notice, a use may be below the threshold of regulation if: a) using a reliable and appropriately sensitive analytical method to measure residues in the commodity, no residues are detected in the commodity under the expected conditions of use; and (b) using reasonably protective criteria, the estimated potential risk of any theoretically possible residues in food is not of concern. The TOR Policy also describes data that might be used to support a finding that a use is below the threshold of regulation. As stated in the October 1999 notice, there is no fee for requests for TOR decisions.

This PR Notice provides guidance on how to submit a request for a TOR decision and explains how EPA will make TOR decisions in the course of a pesticide registration action, pesticide reregistration or tolerance reassessment. A registrant may submit a request for a TOR decision on a proposed pesticide use as part of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) section 3 registration process. A registrant or other person may request a TOR decision on an existing use during reregistration under FIFRA section 4 or tolerance reassessment under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA). A State may request a TOR decision for a use that the State is considering for registration under 24(c) or as part of a request for an emergency exemption under FIFRA section 18.

Standard Operating Procedures (SOPs) provide guidance to EPA staff for processing TOR requests. The Agency developed the SOP with input from the public. The SOP explains how to apply the criteria and procedures described in the October 1999 TOR Policy and how evaluation of a TOR request relates to other aspects of a registration decision, reregistration eligibility decision or tolerance reassessment.

I. Section 3 Registrations

Before EPA can register the use of a pesticide in a location and manner that has the possibility of resulting in residues in food, EPA must determine whether a tolerance is needed for residues in or on the food, and if so, whether a tolerance has been established. Ordinarily, EPA presumes that use of a pesticide in the vicinity of growing crops or food produces residues in the food for which a tolerance is required. Under the TOR Policy, EPA may decide that a tolerance is not needed in certain cases where a pesticide use in the vicinity of growing crops or food results in no detected residues in the food.

A registrant may send a letter to EPA asking the Agency to determine whether a proposed use of a pesticide qualifies as a TOR use for which no tolerance or exemption is required. The registrant should explain why he believes that the use is below the threshold of regulation and should attach data to support this position. As described in the TOR policy, data supporting a TOR request would usually be of the same type and quality that are ordinarily required to support a petition for a tolerance. The submission should meet the format requirements given in PR Notice 86-5. If the TOR request is directed to the Office of Pesticide Programs' Registration Division, the submitter should provide information on the priority of the action as described in PR Notices 98-7 and 97-2. The TOR request and supporting information should accompany the registrant's application for registration of the new use under FIFRA section 3.

The TOR request should be directed to the product manager or chemical review manager who will be processing the request. In accordance with PR Notice 2000-4, TOR requests should be addressed as follows for mail delivery to the Office of Pesticide Programs:

Document Processing Desk – TOR
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460.

For delivery by courier, use this address:

Document Processing Desk – TOR
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202-4501.

EPA will review the request for a TOR decision as described in the SOP for TOR determinations and notify the person making the request in writing of the results of the review, including, if possible, a determination whether the use meets the standard for pesticide registration in FIFRA section 3(c)(5).

- ◆ If EPA determines that a pesticide use is below the threshold of regulation and a tolerance is not required for the use, and also finds that the use does not pose an unacceptable risk under FIFRA 2(bb)(1), the Agency will announce in the Federal Register that it proposes to establish that the use is below the threshold of regulation and request comments on the proposal. After publication of the final TOR determination, EPA will register the use under FIFRA section 3.

TOR decisions will also appear in Title 40 of the Code of Federal Regulations (CFR). In the Federal Register of December 27, 2001 (66 FR 66769) EPA created a new subpart in 40 CFR 180 for Pesticide Chemicals Not Requiring a Tolerance or Exemption from Tolerance. Under this proposal, pesticide uses that are below the threshold of regulation would appear in 40 CFR Part 180.2010.

- ◆ If EPA's review shows that the use exceeds the threshold of regulation and that a tolerance or exemption is required, the registrant or other person may submit a tolerance petition and pay the requisite fees.
- ◆ If the use exceeds the threshold of regulation and the Agency determines that the use does not meet the requirements of section 408 of the FFDCA, EPA will advise the person making the request that it cannot register the use under FIFRA.
- ◆ If the use is below the threshold of regulation with respect to potential exposure and risk from any residue theoretically present in the food, but the Agency finds in its review of the pesticide registration application that the pesticide use poses an unacceptable risk under FIFRA section 2(bb)(1) -- such as unacceptable risks to workers or non-target organisms or from pesticide residues in drinking water -- EPA will neither establish the use as a TOR use nor register the use unless the risk can be reduced to acceptable levels.

II. Section 24(c) Registrations

Under section 24(c) of FIFRA, a State may provide for registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs if EPA has not previously denied, disapproved or canceled the use. A State may not issue a registration for a food or feed use unless EPA has established a tolerance or exemption under 408 for residues of the pesticide on food or feed.

A State may ask EPA to make a TOR determination for a use of a pesticide. The State should explain why it believes that the use is below the threshold of regulation and should attach

data to support this position. Data supporting a TOR request should be of the same type and quality that are ordinarily required to support a petition for a tolerance. To avoid conflict with the requirements of FIFRA section 24(c)(3), the State should not register the use until EPA has notified the State of its decision on the TOR decision request.

III. Section 18 Emergency Exemptions

Section 18 of FIFRA authorizes EPA to allow States or Federal agencies to use a pesticide for an unregistered use for a limited time (no longer than one year) if EPA determines that emergency conditions exist. When a State identifies a problem situation which currently registered pesticides will not alleviate, the State lead agency (usually the State department of agriculture) may apply to EPA for a Section 18 emergency exemption for a particular use. The FFDCA requires EPA to establish time-limited tolerances for pesticides used under an emergency exemption.

The State may ask EPA to determine whether the use is below the threshold of regulation or EPA may conduct such a review on its own initiative. If EPA finds that the emergency use is below the threshold of regulation, a time-limited tolerance would not be required. EPA would document this finding in the memorandum notifying the State of the outcome of its review of the request for an emergency exemption. However, because of the time-limited nature of the emergency exemption, EPA would grant the exemption but would not propose to establish the emergency use as a TOR use in Part 180 of the Code of Federal Regulations.

IV. Reregistration

Before EPA can determine whether a pesticide use is eligible for reregistration under section 4 of FIFRA, EPA must determine whether a tolerance is required for residues resulting from the use, and if so, whether an existing tolerance may remain in effect or be modified or if a new tolerance can be established under section 408 of the FFDCA. Ordinarily, EPA will presume that a pesticide applied to – or in the vicinity of – crops or food will result in residues and that a tolerance must be established. If a registrant or other person believes that such a use qualifies as a TOR use and that a tolerance is not required, he may ask the Agency to make a TOR decision during reregistration. The registrant or other person should send the request to the address given in Unit I of this notice. The TOR decision request should explain why the use qualifies as a TOR use and should be supported by the kind and quality of data generally required to support a tolerance. Such requests should be made as early as possible in the reregistration process.

EPA will review the request for a TOR decision as described in the SOP for TOR determinations. EPA will respond to this TOR request in its preliminary risk assessment or, if the TOR request is submitted late in the reregistration process, as part of its consideration of public comments on the preliminary risk assessment.

- ◆ If the review shows that the use is below the threshold of regulation and is eligible for reregistration under FIFRA section 4, the Agency will announce in the Federal

Register its proposal to establish the use as a TOR use and to revoke any existing tolerance for the use. After reviewing and responding to comments, EPA will issue a final determination of the TOR status of the use and any existing tolerance for the use. TOR decisions will also appear in Title 40 of the Code of Federal Regulations (CFR), as described above.

- ◆ If the use exceeds the threshold of regulation, EPA will continue to review the use and any associated tolerances or exemptions. It will follow established reregistration procedures for this review.

V. Non-Binding Statement

This PR Notice provides guidance to EPA and to pesticide registrants. This notice is not binding on either EPA or pesticide registrants, and EPA may depart from the guidance provided in individual circumstances. Likewise, pesticide registrants may assert that the guidance is not appropriate for a specific pesticide or situation.

VI. For Further Information

If you have questions about the Threshold of Regulation Policy, please contact Vivian Prunier, Policy and Regulatory Support Branch, Field and External Affairs Division (7506C), Office of Pesticide Programs, U.S. EPA, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington D.C., 20460, phone:703-308-9341, fax:703-304-5884, e-mail: prunier.vivian@epa.gov.

If you have questions about preparing a TOR submission for a specific use, contact the Product Manager who handles pesticide registration matters for the pesticide or the Chemical Review Manager who handles the reregistration case for the pesticide.

Signed: _____

Marcia E. Mulkey, Director
Office of Pesticide Programs, (7501C)