

Washington, DC Report

The following describes what I believe to be a process which is important to minor crop producers. During the last Tolerance Reassessment Advisory Committee (TRAC) meeting (October 20, 1999), EPA presented a discussion about how the “Pilot Public Participation Process” used for the organophosphates might evolve into the standard process within EPA for the future. The following information is taken from the EPA web page and from notes taken at the TRAC meeting. It is my understanding that this proposal will appear in the Federal Register toward the end of the month and public comment is encouraged.

Public Participation Process: Next Steps

Lois Rossi discussed a proposal to turn the Pilot process, which embodies stakeholder participation, USDA interaction, and transparency of process, into a permanent process. A suggestion for such a Public Participation Process is presented below:

Phase	Duration(days)	What Happens
Pre-Phase 1	30	<p>Public Engagement: A significant focus of the process is to engage stakeholders as early as practicable to ensure that the risk assessments reflect actual use and usage, available data, current labeling, and other information on use practices that stakeholders can provide. In the months prior to the formal initiation of the public participation process (which starts with release of the risk assessments to the registrants for error correction), USDA, EPA, and other government agencies (e.g., DHHS and FDA) will work cooperatively to organize SMART Meetings (use/usage discussions) with interested stakeholders and encourage them to share their information with the agencies.</p>
1	30	<p>Risk Assessment Registrant Error-Only Review, Chemical Profile, and Interagency Engagement: Phase 1 of the modified public participation process is the same as the pilot process in that the risk assessments are sent to the pesticide’s registrant(s) for error correction, but an increased effort at disseminating information to the public has been added as well as enhanced inter-agency communication. EPA initiates the formal public participation process by transmitting its human health and ecological risk assessments to registrant(s) of the pesticide for a 30-day error correction review. They are asked to identify and correct any computational or other errors that EPA has made in developing its assessment of the pesticide’s risks. Registrants will be asked again about due dates for the submission of data and information to EPA, and for an indication of how the study or analysis may change the risk assessment.</p>

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Phase	Duration(days)	What Happens
2	Up to 45	<p>Agency Considers Registrant Error Comments: In Phase 2, EPA summarizes and considers the errors that have been identified by the registrant(s) and makes changes in the risk assessments to correct any errors that are identified, as appropriate. Approximately 2 weeks before the close of Phase 2, EPA will send to USDA a revised risk assessment and Overview. USDA and EPA will organize conference calls with stakeholders to review and discuss the Overview. EPA and USDA will work to address the comments and ideas received during the stakeholder conference calls. EPA will also address risk assessment comments received from FDA and DHHS. By the end of this phase, the risk assessments are prepared for public release. Discussions with the other government agencies on comments and issues will continue throughout Phases 2, 3, and 4 as needed.</p>
3	90	<p>Public Participation Period: Technical Briefing, Public Comment on Risk Assessments and Risk Management Options: Phase 3 provides the public with opportunities for comment on the pesticide's risk assessment and risk management options, and with a Technical Briefing and/or Stakeholder meeting(s). The Phase begins with EPA publishing in the Federal Register a Notice of Availability of the risk assessments and related documents (e.g., Overview, Summary, registrant's error comments, agency's response to comments, Q&A, etc.), and risk management options for a 90-day public review and comment period. All of the documents will be made available in OPP's public docket and internet website.</p> <p>A public Technical Briefing or Stakeholder Meeting (as appropriate for pesticides with limited use and usage, low risk concerns, number of stakeholders, or other factors) will be held at the beginning of Phase 3 in order to share with the public the revised risk assessments and the range of possible risk management options. In addition, an inter-agency effort will be initiated to engage stakeholders in a dialogue on the risk assessments and risk management options. This dialogue is expected to continue into the fourth phase of the public participation process.</p>

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Phase	Duration(days)	What Happens
4	30-90	Develop Final Risk Assessments and Management: In the fourth Phase, EPA reviews and considers the comments, data, and risk management ideas and proposals received during the Phase 3 public comment period and during stakeholder dialogue and meetings. Dialogue with stakeholders will continue through Phase 4. EPA develops the revised risk assessments and, with input from USDA, FDA, and DHHS, EPA develops the risk management documents. An inter-agency senior management briefing will be held to discuss the revised risk assessments and risk management. EPA releases to the public the revised risk assessments and issues the risk management decisions (interim RED/Tolerance reassessment) for the pesticide.

If this new process is implemented, minor crop growers, and others, will be benefitted. The process has been tried recently for pest management tactics which did not include organophosphates. It was very clear to me, that having broad based discussions clarified many issues and brought out new information that was useful both to the Agency and registrants. Important minor uses can be described and considered during this process..

Article by Willis Wheeler

NEXT NEWSLETTER

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Revised March 1998