BACKGROUND on REGISTRATION REVIEW PROGRAM - PESTICIDE PROGRAM DIALOGUE COMMITTEE

May 11-12, 2005

ISSUE: The Food Quality Protection Act of 1996 (FQPA) requires EPA to implement by regulation a new program to review all pesticides every 15 years. The purpose of Registration Review is to ensure each pesticide continues to meet current scientific and regulatory requirements. This challenges OPP to continuously improve its processes, science, and information management while maintaining a collaborative, open program for decision-making.

STATUS: The proposed rule is undergoing review with issuance planned this summer. The proposed rule will describe EPA's proposed approach to the registration review program. The proposed regulation is intended to ensure continued review of pesticides using procedures that provide for public participation and transparency in an efficient manner.

BACKGROUND

- FQPA amendment to FIFRA Section 3(g) requires this program, effectively replacing the tolerance reassessment and reregistration programs.

- OPP will complete its tolerance reassessment program in August 2006 for all food-use pesticides and reregistration in 2008 for pesticides registered before November 1984. Reregistration work on product reregistration and post-RED follow up/implementation will continue.

- The goal of reviewing each pesticide every 15 years will require decisions on almost 50 cases (about 80 active ingredients) per year.

- OPP has actively engaged the Pesticide Program Dialogue Committee (PPDC) and its Registration Review workgroup for advice on developing the new review program. The Registration Review workgroup was formed in June 2003. A summary of the PPDC's recommendations is provided in an appendix.

- EPA conducted a feasibility study in 2004 to test certain aspects of the registration review decision process that the PPDC recommended. EPA randomly selected 30 pesticides from among the likely candidates for review in the first five years of the program, assembled data that it would consider in registration review, and then simulated the review and decision process described in the proposed procedures. EPA is using this feasibility study to learn how the proposed registration review decision process might work and to identify aspects of the proposed process that need further development. The

results were presented to the PPDC last October. EPA is continuing to consult with the PPDC on registration review issues.

- The proposed registration review program will not compromise current protections for human health and the environment. EPA will continue to have the responsibility to address urgent human and environmental risks from pesticide exposures quickly pursuant to FIFRA requirements.

TIMING

- Publish proposed rule this summer with 90-day comment period
- Hold public meetings during comment period
- Consider posting draft review schedule on the Agency's web site
- Continue developing internal implementation process
- Publish final rule in mid-2006

APPENDIX

SUMMARY OF ISSUES WHERE PPDC HAS MADE RECOMMENDATIONS

The PPDC Registration Review workgroup has presented the following recommendations to the full PPDC, all of which have been endorsed:

How should pesticides be scheduled for registration review? There will be about 1,200 active ingredients and more than 20,000 products subject to registration review and new pesticides will be added in the future. The PPDC recommended that the administrative procedures for scheduling registration review should not be subjective, resource intensive or time-consuming. There should be a predictable schedule generally based chronologically on the date of registration, reregistration or other major risk assessment. Specific criteria for departure from scheduling should be established by regulation.

Should there be different levels of review? The PPDC recommended that the degree of assessment not be a "one-size-fits-all" process. The workgroup took into consideration that (a) not all chemicals pose the same risks, (b) the scope of the program mandates efficient use of resources, and (c) changes in data requirements, database, adverse effects data, science policies, and use and usage profiles could affect the scope or depth of a pesticide's registration review. Specifically, the process should focus on identifying what has changed since the last review and determining whether existing risk assessments could be used as the basis of a risk-benefit analysis. The PPDC recommended that the registration review process allow for a streamlined review for pesticides judged to be low risk and for pesticides with a stable regulatory history and science. Pesticides with major complex issues should receive a more comprehensive assessment.

How can meaningful public participation be accomplished? The PPDC took into consideration that a pesticide's registration review would benefit from early participation by all

stakeholders. It noted that stakeholders need a predictable schedule to prepare and participate in registration review and an understandable process where opportunities and expectations for public participation are clear. The PPDC recommended that the Agency seek stakeholder input regarding use profiles, risk assessments, benefit assessments, risk/benefit analyses, and risk mitigation measures and that stakeholder participation should be commensurate with the level of review. The PPDC recommended that the Agency use modern electronic technology to facilitate stakeholder access to information and asked the Agency to establish and maintain an electronic docket for each pesticide that would include comprehensive information about the pesticide, including history, status, public comments and all previous regulatory decisions.

How does registration review relate to other pesticide program activities? Because registration review doesn't supercede or replace EPA's other authorities under FIFRA, the PPDC recommended that EPA manage risk issues as they arise rather than relying exclusively on registration review for resolving these issues. To the extent possible, registration review should be a safety net to help assure that no risk-related issues have been overlooked.

How should EPA initiate a pesticide's registration review? The PPDC found that there is no need for a registrant to submit an application for registration review because payment of annual maintenance fees attests to a registrant's willingness to support a pesticide through the registration review process. The PPDC advised the Agency to publish a Federal Register notice to initiate a pesticide's registration review. The notice would announce the public availability of the documents that the Agency intends to review in its assessment of the pesticide. During the comment period, registrants and other persons could submit additional information for the Agency to consider during registration review.

How should EPA encourage early submission of test data and other information to support a pesticide's registration review? Before the Agency begins its assessment, registrants and other stakeholders should be allowed to comment on the information that the Agency had placed in the registration review docket for the pesticide. At this point, stakeholders could submit data and other information that would be pertinent to the review. However, the PPDC noted that registrants need a clear understanding of the Agency's requirements, guidelines, and issues of concern to assess what additional information would be useful. The Agency should explain how the data will be used. When necessary, the Agency should issue DCI notices under FIFRA sec. 3(c)(2)(B).

What is a registration review decision? The PPDC identified potential outcomes of a registration review, including conclusion of registration review with no changes in current registration needed; risk mitigation or other action required; confirmatory data requested; a possible need to review the decision once ongoing generic data call-in or other action is completed; active ingredient voluntarily cancelled; or a section 6 product cancellation or suspension action. There will also be the possibility that registration review cannot be concluded until additional data are submitted.