

**ENVIRONMENTAL PROTECTION AGENCY**

[OPP-00645; FRL-6496-2]

**Pesticide Tolerance Reassessment and Reregistration; Proposed Public Participation Process****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice.

**SUMMARY:** This notice announces EPA's proposal for a public participation process for pesticide tolerance reassessment and reregistration. This proposal is in response to a joint initiative between EPA and the Department of Agriculture (USDA) to increase transparency and stakeholder involvement in the development of pesticide risk assessments and risk management documents and decisions. EPA and USDA have been actively employing a pilot public participation process for tolerance reassessment and reregistration of organophosphate pesticides for over 1 year (since August 1998), which was developed in consultation with the Tolerance Reassessment Advisory Committee (TRAC). Consideration must now be given as to whether this public participation process or some modification of it should be adopted as the final process, and whether it should be used for tolerance reassessment and reregistration of all pesticides.

**DATES:** Comments, identified by docket control number OPP-00645, must be received by EPA on or before April 14, 2000.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit III. of the "SUPPLEMENTARY INFORMATION." To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-00645 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** Karen Angulo, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvannia Ave., NW., Washington, DC 20460; telephone number: (703) 308-8004; e-mail address: angulo.karen@epa.gov.

**SUPPLEMENTARY INFORMATION:****I. Does this Action Apply to Me?**

This action is directed to the public in general; however, a wide range of stakeholders will be interested in

submitting comments on the public participation process that EPA is proposing for tolerance reassessment and reregistration, including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the use of pesticides on food. As such, the Agency has not attempted to specifically describe all the entities potentially affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under "FOR FURTHER INFORMATION CONTACT."

**II. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?**

*A. Electronically.* You may obtain electronic copies of this document and other related documents from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

To access information about the pilot public participation process that is now being used for the organophosphate pesticides, you can also go directly to the Office of Pesticide Programs' (OPP) organophosphate pesticide web page at <http://www.epa.gov/pesticides/op/>.

*B. In Person.* The Agency has established an official record for this action under docket control number OPP-00645. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as CBI. This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

**III. How Can I Respond to this Action?*****A. How and to Whom Do I Submit Comments?***

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-00645 in the subject line on the first page of your response.

*1. By mail.* Submit comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvannia Ave., NW., Washington, DC 20460.

*2. In person or by courier.* Deliver comments to: Public Information and Records Integrity Branch, Information Resources and Services Division, Office of Pesticide Programs, Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

*3. Electronically.* Submit electronic comments by e-mail to: "opp-docket@epa.gov," or you can submit a computer disk as described in this unit. Do not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file, avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard computer disks in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by the docket control number OPP-00645. Electronic comments may also be filed online at many Federal Depository Libraries.

***B. How Should I Handle CBI Information that I Want to Submit to the Agency?***

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential

will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under "FOR FURTHER INFORMATION CONTACT."

*C. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve this notice.
7. Make sure to submit your comments by the deadline in this document.
8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

**IV. What Action is EPA Taking in this Notice?**

EPA is making available for public comment a proposal for a public participation process for pesticide tolerance reassessment and reregistration. This proposed public participation process was developed with USDA.

Public comment received as a result of this notice will be considered by EPA and USDA and a final public participation process will be developed and released to the public in a notice published in the **Federal Register**. Implementation of the final public participation process will begin according to a schedule established and published in the final notice.

This notice discusses 3 public participation processes: Pilot, modified, and final. The pilot public participation process refers to the process that EPA and USDA are now using for organophosphate pesticide tolerance reassessment and reregistration. The modified public participation process refers to the process that EPA and USDA proposed to the Tolerance Reassessment Advisory Committee (TRAC) during their October 20–21, 1999, meeting. The

final public participation process refers to the process that is being proposed in this notice. In addition, for the purposes of this notice the words "public" and "stakeholders" are used interchangeably.

**V. Background**

*A. Food Quality Protection Act—Process Improvements for Tolerance Reassessment and Reregistration*

The Food Quality Protection Act (FQPA) of 1996 amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). These amendments fundamentally changed the way EPA regulates pesticides. The many new FQPA requirements included a new safety standard (i.e., reasonable certainty of no harm) that must be applied to all pesticides used on foods. EPA recognized that FQPA implementation would require changes to the Agency's existing risk assessment processes and its approach to communication with the public (stakeholders). The process improvements would be responsive to Vice President Gore's directive to increase transparency and opportunities for stakeholder consultation.

*B. Inception of TRAC*

TRAC was established in April 1998, as a subcommittee under the auspices of EPA's National Advisory Council for Environmental Policy and Technology (NACEPT). TRAC provided a forum for a diverse group of individuals representing a broad range of interests and backgrounds from across the country to consult with and make recommendations to the Administrator of EPA and the Secretary of USDA on an approach for pesticide tolerance reassessment and reregistration, including those for organophosphate pesticides, as required by FQPA. The Committee held seven public meetings: May 28–29; June 22–23; July 13–14; July 28–29; September 15–16, 1998; and April 27–28 and October 20–21, 1999. TRAC membership included approximately 45 members approved by the Deputy Administrator of EPA and the Deputy Secretary of USDA.

Members were selected based on their relevant experience and diversity of perspectives on organophosphate pesticide and food safety issues, including those from the following sectors: Environmental and public interest groups; pesticide industry and trade associations; user, grower and commodity organizations; pediatric and public health organizations; Federal agencies; Tribal, State, and local

governments; academia; and consumer groups. The Deputy Administrator of EPA and the Deputy Secretary of USDA served as TRAC Co-Chairs.

*C. Development of the Pilot Public Participation Process*

In the summer of 1998, EPA, USDA, and TRAC set out to design a process that would increase transparency of regulatory processes and consultation with affected stakeholders; expand public access to risk assessment and risk management processes; and find more effective ways for the public to participate at critical times in the Agency's development of organophosphate pesticide risk assessments and risk management decisions. At the July 14, 1998, meeting of the TRAC, EPA, and USDA announced that one of the public participation process options considered by TRAC would be implemented as a pilot. By piloting a public participation process, EPA, USDA, and TRAC could test whether the process achieved the goals of increasing transparency and stakeholder consultation. A pilot effort would provide an opportunity to identify issues associated with public release of risk assessments and management documents, and to evaluate how best to obtain public input into the risk assessment and risk management development processes.

*D. Need for a Final Public Participation Process*

EPA and USDA have been actively employing the pilot public participation process for tolerance reassessment and reregistration of organophosphate pesticides for over 1 year (since August 1998). Consideration must now be given as to whether this process or some modification of it should be adopted as the final process, and whether it should be used beyond the tolerance reassessment and reregistration for organophosphate pesticides and be applied to all pesticides.

In addition, EPA and USDA will soon begin to consider the stakeholder involvement that will be needed for the cumulative assessment stage. FQPA requires the assessment of cumulative effects of pesticides that share a common mechanism of toxicity. Once the individual pesticide risk assessments are complete and the Agency has a cumulative assessment methodology, EPA and USDA will encourage the public to participate in the cumulative assessment process.

## VI. The Pilot Public Participation Process

### *A. Description of the Pilot Public Participation Process*

The following provides a brief overview of the pilot public participation process:

*Phase 1—Registrant “Error Only” Review (30 days).* EPA sends its preliminary human health and ecological risk assessments to registrant(s) of the pesticide for a 30-day error correction review, and to USDA. They are asked to identify any computational or other errors that EPA has made in developing its preliminary assessment of the pesticide's risks.

*Phase 2—EPA Considers Registrants’ Error Comments (up to 30 days).* EPA summarizes and considers comments from registrants and USDA. EPA incorporates comments or makes changes in the preliminary risk assessments to correct any errors identified. By the end of this phase, EPA opens a public docket for the pesticide.

*Phase 3—Public Comment on Preliminary Risk Assessments (60 days).* EPA publishes a **Federal Register** (FR) Notice of Availability announcing its preliminary risk assessments, and opening a 60-day public review and comment period. Registrants, grower groups, other stakeholders, and the public are encouraged to submit data and other information to refine EPA's preliminary risk assessments. They also may begin submitting risk management proposals to address any risk concerns identified in the document. EPA may meet with registrants and other stakeholders to discuss risk related data, use information, and risk assessment/risk management alternatives.

*Phase 4—EPA Revises Risk Assessments (up to 90 days).* EPA summarizes and considers comments, data, and risk mitigation proposals received during the Phase 3 public comment period. EPA develops the revised risk assessments and sends them to USDA for review. EPA and USDA may host public meetings to share the revised risk assessments with interested stakeholders and discuss risk management ideas.

*Phase 5—EPA Solicits Risk Management Ideas (60 days).* EPA releases the revised risk assessments to the public for viewing in the public docket. EPA publishes an FR Notice of Availability opening a 60-day public consultation period during which risk management proposals are solicited. Registrants, grower groups, other stakeholders, and the public are encouraged to participate and submit their risk management proposals. EPA

and USDA may meet with registrants and other stakeholders to discuss risk management alternatives and strategies. Meeting minutes will be included in the public docket.

*Phase 6—EPA Develops Risk Management Strategies (up to 60 days).* EPA considers all risk management proposals received. With input from USDA, EPA develops risk management strategies that ultimately will contribute to the Agency's risk management decisions for this and other organophosphate pesticides.

### *B. Success of the Pilot Public Participation Process*

To date, the pilot public participation process has provided EPA and USDA with a great deal of information for use in refining the risk assessments and in developing risk management options. Stakeholder participation has risen substantially. In the fall of 1999, EPA and USDA took a qualitative look at the strengths and challenges of the pilot public participation process. The following provides a qualitative look at the comments EPA received from registrants and other stakeholders during the phases of the pilot public participation process, and how these comments affected the risk assessments and process schedules.

Registrants were given an opportunity in Phase 1 to identify computational errors as well as grammatical and spelling errors in the preliminary risk assessments. In this way, if the Agency agreed with the registrant's error identification, EPA could correct the errors in Phase 2 prior to the release of the preliminary risk assessments to the public docket (Phase 3). EPA would inform the public of the registrant's error comments and the corrective actions taken by the Agency. However, the large majority of comments received from registrants during their error-identification period were considered to be non-error comments. In the cases where errors were identified, only a few resulted in a substantial change to the preliminary risk assessments and a delay in the release of the assessments to the public. The majority of non-error comments received were general comments about the preliminary risk assessments and promises to submit new studies. New studies were submitted in a few instances.

Comments received during the public comment period on the preliminary risk assessments (Phase 3) substantially affected approximately one-third of the organophosphate preliminary risk assessments, typically because of the submission of information on the pesticide's use and usage, studies, or

other technical information. In several cases, registrants submitted new studies and studies to confirm or upgrade existing, submitted studies.

The Agency and USDA used Phase 4 to revise the preliminary risk assessments based on public comment. EPA released the revised risk assessments and related documents to the public in Phase 5 and initiated a public participation period for risk management. Risk management comments and ideas were usually received by EPA during meetings and conference calls rather than through written submissions. Minutes of meetings and conference calls were recorded and placed in the public docket.

### *C. A Proposal for a Final Public Participation Process was Made at the October 20–21, 1999, TRAC Meeting*

EPA and USDA proposed a modified public participation process to TRAC during their October 20–21, 1999, meeting. EPA and USDA approached TRAC with a proposal because the pilot public participation process had been tested for over 1 year and it was time to consider a final public participation process. The proposed modified public participation process was based on USDA's and EPA's experiences using the pilot public participation process. The proposed modified public participation process included several stakeholder participation enhancements. A special emphasis was placed on the public involvement activities that take place prior to Phase 1—before the start of the public participation process—to ensure that the most complete and accurate set of information was being used in the risk assessments. In addition, stakeholders would be much more informed of the schedule of pesticides that EPA and USDA would be working on in the next year, and would know when EPA and USDA needed information. Conference calls and public meetings (technical briefings that describe the revised risk assessments in general, and stakeholder meetings where the description of the risk assessments is focused on a particular pesticide user group's area of concern) would be used to initiate the public comment period on the risk assessments, engage the public in a discussion of the risk assessments, and begin the discussion of risk management.

The proposed modified public participation process would have eliminated a public comment period on the preliminary risk assessments. This modification was a result of the recognition that the risk assessments

now under development contain many more refinements than previous preliminary risk assessments. In the past, the preliminary risk assessments that were released to the public did not usually have refinements, such as probabilistic dietary risk assessment tools or the data needed for the use of these tools. The Agency saw the benefit of releasing these unrefined, preliminary risk assessments to the public as a means of encouraging the submission of data that could be used for refinement purposes. The risk assessments being developed now typically contain these refinements, therefore, the Agency proposed that 2 comment periods on the refined risk assessments were not necessary. Even though the proposed modified public participation process would have eliminated a public comment period on the preliminary risk assessments, EPA and USDA would continue to encourage and organize stakeholder communications throughout the modified public participation process through a series of meetings and conference calls.

In addition, EPA and USDA asked TRAC members if the modified public participation process should be applied to pesticides other than the organophosphates, which currently are the only class of pesticides in the pilot public participation process.

#### D. Summary of TRAC's Feedback

During the October 20–21, 1999, TRAC meeting, TRAC members verbally responded to the proposed modified public participation process that EPA and USDA presented. Many TRAC members voiced strong support for increased and enhanced EPA and USDA activities in the months prior to formal start of the public participation process (i.e., Pre-Phase 1), including stakeholder meetings and conference calls, the release to the public at the beginning of the process of a general pesticide use and usage description and the schedule of pesticides entering the process, and discussions with pesticide registrants and stakeholders about the submission of data and the data submission schedule.

Several TRAC members voiced concern over their perceived reduction in public participation opportunities resulting from the elimination of one risk assessment comment period, and also objected to the proposed plan for having public comment on the risk assessments and risk management options occur during the same phase. Certain TRAC members voiced concern that the risk management options issued for public comment would be perceived

as the Agency's final risk management decision, giving stakeholders no real opportunity to weigh-in before the final decisions were made. Concern was also raised about issuing risk management decisions on any uses of a pesticide before the conclusion of the public participation process; however, the Agency has always reserved this authority if certain uses of a pesticide warranted action because of the risk levels identified in the risk assessments.

TRAC members expressed support for EPA issuing only highly refined risk assessments for public comment, and for longer public comment periods. Support was also expressed for technical briefings and stakeholder meetings at the time the risk assessments are released for public comment, and for an enhanced public role for USDA at that time, including the organization of stakeholder conference calls and meetings. In addition, TRAC members supported the application of the final public participation process to all other pesticides scheduled for tolerance reassessment and reregistration.

### VII. Proposal for the Final Tolerance Reassessment and Reregistration Process

#### A. EPA and USDA's Consideration of a New Public Participation Process

EPA and USDA have considered the comments received from TRAC during their October 20–21, 1999, meeting, and are releasing in this notice a proposal for a final public participation process. EPA and USDA reconsidered the process approach presented to TRAC, and have developed a new public participation process proposal. The new proposed public participation process melds together the pilot public participation process and the modified public participation process that was proposed to TRAC. The new proposed public participation process retains the 6 phases and much of the structure of the pilot public participation process currently used for the organophosphate pesticides, and it incorporates the considerable enhancements to public participation found in the modified public participation process that was presented to TRAC. These enhancements include increasing the communication with stakeholders prior to the initiation of the public participation process, the addition of conference calls with stakeholders throughout the process, the lengthening of a public participation phase, and the release of risk management proposals to the public at the beginning of Phase 5. In addition, the proposed public

participation process emphasizes increased communication among those Federal government agencies concerned with pesticides.

EPA is also proposing that this public participation process be applied to all pesticides scheduled for tolerance reassessment and reregistration. Interim planning for bringing non-organophosphate pesticides under a formal public participation process is discussed at the end of this notice.

The Agency anticipates that modifications to the public participation process will be appropriate for pesticides with limited use and usage, low risk concerns, small numbers of pesticide users, or other factors. EPA will inform the public of modifications to the public participation process that are warranted for a pesticide. For pesticides meeting these criteria, alterations to the public participation process will most typically include a tailoring of the stakeholder communication opportunities. For example, the public participation process could be modified for a pesticide with a small number of users by the substitution of a stakeholder meeting(s) for a technical briefing upon release of the risk assessments for public comment (Phase 3) (stakeholder meetings are opportunities for stakeholder groups to meet with EPA, USDA, and other appropriate Federal government agencies to discuss specific uses of the pesticide that are of significant concern to them, whereas technical briefings provide a general overview of the pesticide's risk assessments). In another example, a pesticide with limited use and usage, low risk concerns, and highly refined risk assessments may only need one public comment period on the risk assessments as long as ample public consultation opportunities are utilized. EPA will inform the public of pesticides that will have modified public participation processes.

EPA will continue to issue risk management decisions on certain uses of a pesticide at any time before or during the public participation process if such action is warranted by high risk levels identified in the risk assessments. While EPA may exercise this authority at anytime during this process, the Agency will ensure that stakeholders and other Federal government agencies will be informed and involved in the decisionmaking process through meetings and conference calls.

#### B. Proposed Public Participation Process

The proposed final public participation process contains many of the same elements of the Pilot Public

Participation Process and enhances public participation at important stages. It must be noted that the proposed final public participation process does not use the word "preliminary" to describe the risk assessments that are released to the public in the early phases of the public participation process. This is because the risk assessments now under development contain many more refinements than previous preliminary risk assessments.

**Pre-Phase 1—Public Engagement.** A significant focus of the process is to engage stakeholders as early as possible to ensure that 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 Federal government agencies (e.g., the Department of Health and Human Services (HHS), and the Food and Drug Agency (FDA)) will work cooperatively to organize meetings with interested stakeholders to discuss pesticide use and usage, and to encourage them to share their information with the agencies.

In addition, EPA will inform the public well in advance about pesticides that are scheduled for the public participation process. Registrants will be asked to identify any ongoing studies and analyses that are relevant to the risk assessments, and EPA will announce for each pesticide the due dates for the submission of data, information, and analyses. In this way, the public will be able to prepare for the initiation of the public participation process for pesticides that they may be interested in, including the preparation of data and information for consideration by the agencies.

**Phase 1—Risk Assessment Registrant Error-Only Review, Chemical Use and Usage Description, and Federal Government Agency Engagement (30 Days).** Phase 1 of the proposed public participation process is the same as the pilot public participation 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 Federal agency communication. EPA initiates the 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 assessments. EPA will not delay its work in assessing the potential risks associated with the use of the pesticide when a study submission date is beyond the timeframe for the public participation process.

In addition, EPA recognizes that the public would find useful for their planning purposes a description of the pesticide that has started the public participation process. The Agency will publish a FR Notice of Availability announcing the release of the pesticide's use and usage description to the public docket and internet website for 30-day public comment. The pesticide's use and usage description would characterize the use, usage, and types of data and information used in the risk assessments.

At the same time that the risk assessments are sent to registrants, EPA transmits the risk assessments and related documents (including the pesticide's overview that summarizes the risk assessments, the Qualitative Usage Analysis, and the pesticide's use and usage description) to USDA and other appropriate Federal government agencies for review and comment.

**Phase 2—Agency Considers Registrant Error Comments (Up to 30 Days).** 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, as appropriate. EPA will also address risk assessment comments received from other Federal government agencies. By the end of this phase, the risk assessments are prepared for public release. Discussions with other Federal government agencies on comments and issues will continue throughout the public participation process, as needed.

**Phase 3—Public Participation Period: Public Comment on Risk Assessments and Risk Characterization (60–90 Days).** Phase 3 provides the public with an opportunity to comment on the pesticide's risk assessments. The phase begins when EPA publishes a FR Notice of Availability of the risk assessments and related documents (e.g., overview, summary, table summarizing risk assessment information, registrant's error comments, and EPA's response to comments, etc.) for a 60 to 90-day public review and comment period. The summary documents will clearly characterize the risks associated with each use of the pesticide and include a use impact discussion that identifies

possible pesticide alternatives for significant uses, thereby allowing the public to discern the Agency's level of concern (if any) for each use at this stage in the development of the risk assessments. All of the documents will be made available in the public docket and EPA's internet website. The length of the public comment period will be set according to the complexity of the risk issues associated with the pesticide in order to give stakeholders adequate time for review and comment.

In addition, an effort will be initiated among Federal government agencies to engage stakeholders in a dialogue on the risk assessments and risk characterization, and will continue through Phase 5 of the public participation process.

**Phase 4—EPA Revises Risk Assessments and Develops Risk Management Proposal (up to 90 days).** EPA considers stakeholders comments received during Phase 3's public comment period, and develops the revised risk assessments and a risk management proposal. An inter-Federal government agency senior management briefing will be held to discuss the revised risk assessments and risk management proposal.

USDA may organize conference calls with stakeholders to review and discuss the revised risk assessments and risk management proposal. Minutes from all meetings and conference calls will be included in the public docket. EPA and USDA will work to summarize and address the comments and ideas received during the stakeholder conference calls. In addition, an effort will be initiated among Federal government agencies to engage stakeholders in a dialogue on the risk assessments and risk characterization, and this effort will continue through Phase 5 of the public participation process.

A technical briefing and/or stakeholder meeting(s) (as appropriate for pesticides with limited use and usage, low risk concerns, small numbers of stakeholders, or other factors) will be held at the end of Phase 4 in order to share with the public the revised risk assessments and the range of possible risk management options.

**Phase 5—EPA Solicits Comments on Risk Management Proposal (60 days).** EPA publishes a FR Notice of Availability announcing the release to the public of the revised risk assessments and the Agency's response to public comments. This FR notice will also release EPA's risk management proposal, a use impact discussion that identifies possible pesticide alternatives for significant uses, and a transition

strategy, and open a 60-day comment period during which the public is encouraged to comment on the risk management proposal.

The effort among Federal government agencies to engage stakeholders in a dialogue on the risk management proposal will continue throughout Phase 5.

**Phase 6—Develop Final Risk Management (up to 60 Days).** In Phase 6, EPA summarizes, reviews, and considers the comments, data, and risk management ideas and proposals received during the Phase 5 public comment period, and during stakeholder dialogue and the meetings that have occurred during Phases 3–5. With input from USDA and other Federal government agencies, EPA develops the risk management documents. EPA releases to the public the risk assessments, the response to public comments, and the risk management decisions for the pesticide.

### **VIII. Interim Public Participation Process**

EPA and USDA are now considering how to accomplish the movement from the public participation process that was tested as a pilot (i.e., the pilot

public participation process now used exclusively for organophosphate pesticides) to the public participation process that will be adopted for future pesticide tolerance reassessment and reregistration. The majority of organophosphate pesticides have made significant progress through the pilot public participation's phases, and many are nearing completion, therefore, the pilot public participation process will continue to be applied to those organophosphates. The public participation process that will be finalized after the notice and comment period described in this FR notice will be fully applied to pesticide tolerance reassessment and reregistration by 2001. An interim policy must be developed for the non-organophosphate pesticides scheduled for tolerance reassessment and reregistration development work in 2000.

The interim policy must take into account that the risk assessments are substantially complete for many of the non-organophosphate pesticides scheduled for 2000. An example of the public participation process that EPA is considering as an interim policy for pesticides that already have significant risk assessment work underway would

involve: A registrant error correction period; a period for the Agency to respond to the registrant's error comments; the release of the refined risk assessments and risk characterizations to the public via the docket and internet without a formal public comment period; a significant effort on stakeholder consultations, such as meetings and conference calls; and the issuance of the risk management document to the public after the consideration of issues and discussions with stakeholders.

EPA and USDA are in the process of identifying the development status of each pesticide scheduled for tolerance reassessment and reregistration. EPA will inform stakeholders of the interim plan for each pesticide once a final public participation process is selected.

### **List of Subjects**

Environmental protection, Chemicals, Pesticides and pests.

Dated: March 9, 2000.

**Marcia E. Mulkey,**

*Director, Office of Pesticide Programs.*

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