Staff Paper #33
9/3/98

Integration – Documents on Tolerance Reassessment and Reregistration

BACKGROUND.

The Agency is developing new processes for tolerance reassessment and reregistration of pesticides. FQPA presents new challenges for EPA, requiring that cumulative risk assessment methodologies must now be incorporated into the risk assessment process, and risk management decision-making on all pesticides that share a common mechanism of toxicity. Recognizing the potential for loss of some chemical/use combinations, EPA and USDA together are pursuing strategies for information and data gathering, and research into pest control alternatives (e.g., chemical and non-chemical). The goals of the new process and programs must include achieving tolerance reassessment under FQPA's new requirements and FIFRA reregistration in the most efficient way possible while ensuring the use of sound science in assessment and decision-making; implementation strategies that provide for reasonable transition for pesticide users and affected stakeholders; and transparency and public participation in all stages of the process.

This paper identifies the subject-specific documents developed by EPA and USDA that were presented to the Tolerance Reassessment Advisory Committee (TRAC) for their consideration. These documents present new ideas and describe proposed processes for conducting risk assessments, risk management decision-making, public participation, science policy issues, and implementation and transition, as well as summarizing thoughts and suggestions from the TRAC. This paper provides an overview of how these ideas and proposals fit and flow together. The reader is encouraged to read each accompanying document for more detail.

INTEGRATION OF DOCUMENTS.

1. **Science Policies for Tolerance Reassessment and Reregistration**. EPA has developed several documents relating to the Agency's risk assessment processes and the significant science policy issues that have been identified. The staff paper entitled "Plain English Risk Assessments" (Staff Paper # 25) describes in understandable language the Agency's risk assessment process (previous and anticipated new processes). This paper discusses how the Agency is integrating the new requirements of FQPA into the risk assessment process.

   In addition, the Agency developed descriptive papers on the 9 significant science policy issues related to tolerance reassessment and reregistration. A notebook on "Guidance on 9 Science Policy Issues," describes the Agency's interim approaches and policies for each, and discusses plans and timeframes for resolving them. For many of these 9 science issues, the Agency has already released to the public guidance documents on science issues (e.g., FQPA Safety Factor). The Agency has drafted a Federal Register Notice to be released soon that would announce a process for release of these science

policy papers for public notice and comment.

2. **Risk Assessment and Risk Management Process**. EPA is currently refining its processes for pesticide risk assessments, and making tolerance reassessment and reregistration decisions. The major goals of the process that EPA ultimately adopts must include achieving tolerance reassessment under FQPA's new requirements and FIFRA reregistration in the most efficient way possible while ensuring the use of sound science and transparency. Staff Paper #31, entitled "Risk Assessment and Risk Management Process," presents a process chart that displays how risk assessment and risk management activities can be conducted in parallel. The Agency will proceed with tolerance reassessment and reregistration for the organophosphates consistent with the consensus process that is presented in the paper.

3. **Public Participation in Risk Assessment and Risk Management.** EPA is considering how the public can most effectively participate in the Agency's risk assessment and risk management decision-making processes for pesticide tolerance reassessment and reregistration. The Agency has proposed pilot processes that increase transparency and opportunities for stakeholder consultation at key stages in the development of risk assessments and risk management decisions. Staff Papers #27 and #34 , entitled "Public Participation in Risk Assessment" and "Public Participation in the Risk Management Process," respectively, discuss the proposed pilots for public participation. These two papers fit together as a single process, flowing from risk assessment to risk management.

4. **Early Assessments**. The individual chemical risk assessments may identify early on chemical/use combinations that pose only negligible risk and/or are of such high public value that they should be retained (i.e., tolerances reassessed, and/or reregistered). Early assessment decisions could be made prior to the cumulative assessment and, therefore, before decisions are made on the bulk of the OP chemical-crop uses. Early assessment would allow the Agency to reduce, or narrow, the range of OP chemical-use combinations that would be subject to the final decision-making process. Staff Paper # 30, entitled "Early Assessment for OP Uses with Very Low Risk Contribution and/or High Public Value," outlines how such an approach might work. The Agency is preparing to define elements of an early assessment for public notice and comment.

5. **Decision-Making Criteria**. After conducting the risk assessments and taking action on early assessments (see paragraph #4 above), the Agency may conclude that the risks associated with registered uses of pesticides exceed the safety standard. In that case, EPA will need to reduce risks to meet the safety standard using a method that best selects those uses and/or tolerances that will remain and those that will not. Staff Paper #29, entitled "Decision-Making Criteria," discusses possible decision-making criteria that could be used in making tolerance reassessment and reregistration decisions. Decision-making criteria could be used in choosing among competing uses of an individual pesticide, and among competing uses of OPs after the cumulative assessment. Examples of the latter include using criteria to decide which uses would be retained among multiple chemicals that are

used on a single commodity or other use site. EPA expects to finalize the decision criteria, develop a process for applying them, and publish this information for public comment.

6. **Regulatory Tools for Implementation**. The Agency has a number of regulatory tools available for implementing the risk management decisions that will be developed. The attached paper entitled " Regulatory Mechanisms for Achieving Pesticide Risk Mitigation" (Staff Paper # 32) discusses regulatory mechanisms that the Agency will consider for the OP reregistration and tolerance reassessment. These mechanisms would only become relevant after the EPA completed its risk assessments for the individual OP pesticides or the cumulative risk assessment for the OP pesticides as a group, and determines that a "reasonable certainty of no harm" finding cannot be made, and applies its decision-making criteria to ensure risk is sufficiently reduced. The discussion in the staff paper provides the basis for stakeholder awareness of the regulatory tools that the Agency will consider for OP reregistration and tolerance reassessment.

7. **Transition**. Risk management conclusions must be implemented in a way that ensures a reasonable transition for agricultural and other pesticide users. USDA will work with EPA and other affected stakeholders to develop and implement approaches that allow users to move to new, or revised, pest management systems without significant disruption of domestic production. Paper28 # , entitled " USDA's Role in Risk Assessment, Risk Management, and Transition Strategies," describes how USDA plans to actively research short- and long-term pest management strategies, IPM, and alternative pest management controls, and develop "pipeline databases" and crop profiles for use in risk assessment and risk management. EPA and USDA will continue to work together to identify transition needs and develop transition strategies.

SUMMARY

EPA and USDA have developed these documents to provide transparency and public participation for the development of the new tolerance reassessment and reregistration processes. The thoughtful consideration by TRAC has helped the Agency identify the topics and issues that are important to stakeholders. TRAC has made valuable contributions to the drafting of these documents. Both EPA and USDA encourage stakeholders to participate in the notice and comment opportunities for the various science policies and risk management processes, and to contribute to the exploration of transition strategies.