

US EPA ARCHIVE DOCUMENT

## Public Participation in Risk Assessment

With the assistance of the Tolerance Reassessment Advisory Committee (TRAC), EPA is considering ways of increasing public participation in risk assessment and risk management processes. This increased public participation will aid in achieving the goals of increased transparency of regulatory processes and increased consultation with affected stakeholders.

### Risk Assessment

The TRAC initially considered three options for increasing public participation in the risk assessment process. TRAC Work Group 1 discussed issues associated with these options (see attached summary of the Work Group comments). During the Work Group meeting, Option 4 was suggested by a TRAC member as an intermediate position (see attached Staff Paper 13). At the July 14 meeting of the TRAC, EPA and USDA announced a plan to implement Option 4 as a pilot. This pilot provides an opportunity to identify issues associated with public release of risk assessments and determine how best to obtain public input in the risk assessment process. The pilot includes the following steps:

- The technical registrant(s) (i.e., owners of the data) are allowed to see the preliminary risk assessment for a 30-day period when the preliminary risk assessment is complete and may provide comments to correct errors and identify any confidential business information that should be excluded from public release.
- EPA reviews the comments provided as quickly as possible and may make corrections if necessary and appropriate or acknowledge that an error exists if it would be too time-consuming to make the correction before public release.
- EPA publishes a notice of availability of the preliminary risk assessment in the Federal Register, announcing a 60-day public comment period, and places the risk assessment in the public docket. (Option 4 showed a 90-day public comment period. Upon further consideration, EPA decided to test in the pilot whether a 60-day period would be sufficient, to help shorten the overall process.) The docket includes documentation of any comments from the registrant and EPA's action related to the comment.
- At the same time, the public portion of the risk assessment will be placed on the EPA World-Wide Web Homepage (i.e., any materials claimed as confidential business information or subject to FIFRA 10(g) affirmation regarding foreign and multinational company status will not be placed on the Web). A paper describing Internet posting procedures is attached.
- After the public comment period closes, EPA will consider all comments received, make any appropriate refinements to the risk assessment, and where appropriate, prepare a response to comments, generally within 60-90 days after the comment period closes.

- EPA will generally issue a final risk assessment some time after the comment period closes. This final risk assessment may be affected by comments received during the comment period, by additional data received by the Agency after preparation of the initial risk assessment, or by other changes in the information base or in scientific policy.
- The risk assessment then becomes part of the decision package for the chemical, which may be a Reregistration Eligibility Decision document.
- The final risk assessment and any response to comments will be placed in the docket and posted on the Internet.

#### Attachments

- Work Group #1 Comments on Options for Refining Risk Assessments
- Staff Paper 13–Refining Chemical Risk Assessments
- Distribution of Documents on the Internet