

US EPA ARCHIVE DOCUMENT



Session Topics

- Schedule for Reregistration and Tolerance Reassessment
- Public Participation Process
- Alternative/Non-Animal Testing

Schedule – Reregistration and Tolerance Reassessment



EPA recently released schedule for decisions in 2004 through 2008

- by August 3, 2006, will complete tolerance reassessments and REDs for food use pesticides
- by October 3, 2008, will complete REDs for non-food use pesticides

Schedule – Reregistration and Tolerance Reassessment

- Schedule provides anticipated decision date, by month, and contact information for the Chemical Review Manager. Will be updated annually.
- Posted on EPA's website at <http://www.epa.gov/pesticides/reregistration/candidates.htm>



Public Participation Process

- Public involvement: a vital component of EPA's pesticide decision making
- Strong EPA commitment to involve the public while meeting our deadlines
- Public Participation Process, published May 14, formalizes this commitment



Public Participation Process

- Based on experience with OP pilot
- Provides framework for public involvement in developing REDs, IREDs and TREDs
- EPA obtains robust input while meeting program goals



Features of Public Process

Focuses on communication with stakeholders beginning in new Pre-Phase 1

- EPA and stakeholders begin communicating early. SMART meeting in Pre-Phase 1 opens discussion about pesticide use.
- Updated use information vital to EPA in developing high quality risk assessments.
- Pesticide use information posted on website. Public comment welcomed.



Features of Public Process

- Includes conference calls, meetings with stakeholders throughout process
- Involves USDA and other Federal agencies (FDA, HHS, Commerce, Interior, Defense) as needed
- Provides opportunity for public comment on risk reduction options
- Key documents posted in Docket, EDOCKET, and on chemical pages on EPA's website



Flexibility

- EPA can tailor public process to each pesticide's uses and risks
- Targets public and private resources most effectively
- Avoids process where not needed
- Supports meeting program deadlines and goals



Tailored Approach

- 6 Phase, full process for pesticides with complex uses and issues; significant risk mitigation needed
- 4 Phase, modified process for pesticides with limited uses and risks; nominal risk mitigation needed
- Single-phase, low risk process for pesticides requiring little or no risk mitigation



Full 6-Phase Process

- Pre-Phase 1 -- Update use/usage information
 - Phase 1 -- Registrant "error only" review
 - Phase 2 -- EPA considers comments, completes risk assessments
 - Phase 3 -- Public comment on risk assessments
 - Phase 4 -- EPA considers comments, revises RAs, develops preliminary risk reduction options
 - Phase 5 -- Public comment on risk reduction
 - Phase 6 -- EPA considers comments, finalizes risk management, completes RED/IREN/TRED



4-Phase Process

- Pre-Phase 1 -- Update use/usage information
- Phase 1 -- Registrant "error only" review
- Phase 2 -- EPA considers comments, completes risk assessments, develops preliminary risk reduction options
- Phase 3 -- Public comment on risk assessments and risk reduction
- Phase 4 -- EPA considers comments, finalizes risk management, completes RED/IRED/TRED



Low Risk Process

- EPA's initial screening indicates pesticide poses low risk, requires little/no risk mitigation
- EPA goes straight to developing regulatory decision
- Issues RED/IRED/TRED, risk assessments, and related documents for comment

New Comment Period Schedule



- To assist stakeholders and the public in planning their involvement
- Shows public comment periods opening for pesticides during next 6 months
- EPA will update this schedule quarterly
- On EPA's website:

www.epa.gov/oppsrrd1/publicsched.htm



Participation is Key

Encourage your constituencies to use the new schedules and get involved early in the review of pesticides of interest.



Information on EPA Website

- EPA Office of Pesticide Programs

www.epa.gov/pesticides/

- Pesticide Reregistration

www.epa.gov/pesticides/reregistration/

- Schedule

www.epa.gov/pesticides/reregistration/candidates.htm

- REDs

www.epa.gov/pesticides/reregistration/status.htm



Alternative/Non-Animal Testing

- Current focus –
 - To develop a non-animal assessment approach for evaluating the skin and eye irritation potential and labeling requirements for antimicrobial cleaning product formulations.



Planning for a technical workshop

- EPA staff and management – OPP (AD, BPPD, RD, SRRD) and OSCP
- PPDC members:
 - Troy Seidle – People for the Ethical Treatment of Animals
 - Len Sauers – Proctor and Gamble
 - Pat Quinn – Accord Group



Planning for a technical workshop

Also Participating:

- Institute for In-Vitro Sciences
- S.C. Johnson
- ICCVAM - The Interagency Coordinating Committee on the Validation of Alternative Methods



Workplan

1. Data Collection and Preparation of Background Materials– IIVS and PPDC members – summer 2004
2. Presentation of Workshop Proposal to the PPDC at fall 2004 meeting
3. Agency holds open/public/technical workshop early in 2005



Workplan

4. Workshop summary and recommendations presented to the PPDC – spring 2005
5. Based on outcome of the workshop and PPDC advice, OPP will consider setting an interim policy for acceptance of non-animal tests to determine skin and eye irritation labeling for antibacterial cleaning products in defined product categories – spring 2005



Workplan

6. ICCVAM Technical Review of workshop recommendations and interim policy (if adopted) – summer 2005
7. SAP – guideline amendment – fall 2005
8. Full implementation – fall 2005