

US EPA ARCHIVE DOCUMENT

Purpose of Registration Review Initial Dockets

Pesticide Program Dialogue Committee
Registration Review Implementation Work Group
March 8, 2007

Registration Review Overview

- 1996 FQPA mandate; rule effective Oct '06
- Covers all pesticides, periodic review

New Decision Paradigm

- What has changed since the pesticide's last assessment?
- How significant is this change?
- Do we need new information?
- Is the regulatory position likely to change as a result of the new information?

Reregistration vs Registration Review

- Old pesticides
 - One-time review
 - ca. 20 pesticides/year
 - Process set by law
 - Comprehensive reviews
 - Start from scratch
 - Major data gaps
- All pesticides
 - 15-year cycle
 - 45+ pesticides/year
 - Process set by rule
 - Updated reviews as needed
 - Add to what we know
 - Fewer data needs

First steps of Registration Review

- Open docket, receive comment
 - Tell public what we know & anticipate doing in *Preliminary Work Plan*
- Review public comments & additional information received
- Determine if new risk assessments are required and if data call-in is needed, develop *Final Work Plan* for case

Registration Review Process, continued

Based on Final Work Plan:

- EPA issues DCI, if needed, gets data
- Completes preliminary & final assessments
- Develops proposed risk mitigation
- Publishes decision for comment
- Final decision
- Implement any mitigation

First Dockets

- OPP opened first dockets on Feb. 2nd
 - Clomazone, Hexythiazox, Lactofen
 - No docket needed for Sulfosate
 - *Discussion today does not constitute formal public comment on the open dockets*
 - *Any public comments on a particular Registration Review case must be done through the official docket*
- Initial experience tracking well with 2004 feasibility study
 - Human health assessment mostly OK
 - Endangered species compliance may require more data from registrant or open literature
- Initial dockets are serving as models for next set
- Seeking PPDC advice on usefulness of dockets

Docket Structure

- Docket contains key documents showing recent actions and background information on pesticide case, including
 - *Summary Document*
 - Use & usage information
 - Recent reregistration, new use & tolerance actions
 - Recent risk assessments
 - Tolerance/MRL comparisons
 - Summary of incidents

Summary Document

- *Summary Document* explains what information EPA has on the pesticide and the anticipated path forward
 - *Preliminary Work Plan: (1)* highlights anticipated risk assessment and data needs, *(2)* provides an anticipated timeline for completing the review, and *(3)* identifies especially useful information we're seeking
 - *Fact Sheet* provides background & current status
 - *Ecological risk assessment problem formulation* describes anticipated assessment & data needs in more detail
 - *Human health scoping* sections describes anticipated assessment & data needs in more detail
- Goal is to explain clearly what we know, our thought process for determining anticipated data and assessment needs, expected timeline to decision, & types of data or other information that would be helpful

Science considerations

Human Health:

- Dietary generally OK based on tolerance reassessment
- Consider residential uses
- Consider all worker MOEs vs. LOC
- Consider in house data & lit searches
- Consider all policy changes that might affect the assessment & safety finding.

Science considerations

Environmental

- Consider likely acute/chronic risks, or uncertainties based on available data, for taxa of concern
- When possible, describe potential direct or indirect effects on endangered species from screening level risk assessment
- Indicate expected scope of more refined risk assessment

PPDC Input on Docket

- OPP benefited from PPDC input in designing Registration Review
- OPP is also interested in getting advice on development of Registration Review dockets
 - Provide input on our docketed presentation of what we know & preliminary work plan
 - Have we emphasized the right issues?
- This PPDC meeting may be the first of several based on outcome of today's meeting.
 - Future WG meetings may focus on antimicrobial, biopesticide, additional conventionals

Conclusion

- Registration Review has started
- Goal is to make dockets as transparent as possible to facilitate comments
- Today's presentations will focus on our thinking for two dockets
- OPP looks forward to feedback on the format and content of the dockets