

# Registration Review Report from PPDC Workgroup

Presentation to PPDC

May 25, 2004

# Mandate for Registration Review

- FIFRA 3(g) provides for periodic review of pesticides registrations
  - Establish a procedure via regulation
  - FIFRA 3(c(5) finding
  - Goal of every 15 years

# Background

- Advanced Notice of Proposed Rule-Making (April 2000)
- PPDC Registration Review workgroup formed June 2003
  - Provide advice and recommendations on design and development of procedural regulations
  - 23 members

# Three Key Issues for Oct. 2003 PPDC meeting

- How will pesticides be scheduled for registration review?
- Should there be different levels of reviews?
- How should the public participate?

# PPDC Recommendations

## Scheduling

- Predictable schedule based on 15 years from date of registration, reregistration or other major risk assessment
- Criteria for departure from scheduling should be established
- Publish comprehensive schedule with regular updates

# Recommendations -Different Levels of Reviews

- Streamlined review of relatively “simple” pesticides e.g., low toxicity
  - Also stable regulatory history and science
- Pesticides with major complex issues require a more robust assessment

# Recommendations – Public Participation

- Publish FR to initiate chemical specific review
- Seek stakeholder input on use profiles, risk assessments, risk/benefit analysis and risk mitigation measures

# Public Participation Cont.

- Stakeholder process should be tailored to the level of review
- Use of a comprehensive e-docket to provide a continuum of information
  - History, status, public comments, previous regulatory decisions

# Recent Activity of PPDC workgroup

- Since Jan. 2004 held four meetings
- Discussions on three key issues
  - What actions initiate a pesticide's registration review?
  - Early submission of test data and other information
  - What is a registration review decision?

# 1. Initiation of a Registration Review

## **Considerations:**

- Schedules – both long-term and annual
- Background information on each active ingredient (AI)
- Basis of the review

# Initiation of a Registration Review

## Recommendations:

### ➤ Master Schedule

- Includes all AIs subject to Registration Review and target year for review (determined by date of initial AI registration or RED completion date)
- Public comment period
- Periodic (perhaps annual) update

# Initiation of a Registration Review

## **Recommendations:**

- **Annual Schedule**
  - Specific AIs scheduled for coming year
  - FR Notice and OPP's website
  - Public comment period

# Initiation of a Registration Review

## **Recommendations:**

- Background for each AI in E-docket
  - Registrants
  - Registered products
  - Use sites
  - Tolerances
  - Bibliography of data at EPA
  - Outstanding DCIs

# Initiation of a Registration Review

## **Recommendations:**

- Background for each AI (cont.)
  - Most recent risk assessment in each major category
  - Known Agency concerns
  - Review activities in progress
  - Summary of adverse effects data
  - Significant a.i. label issues if appropriate (e.g., restricted use classification)

# Initiation of a Registration Review

## **Recommendations:**

### ➤ Basis of the Registration Review

- Data and information in hand at initiation of the review would be considered
- Data requirements/policies in effect at initiation would guide the review

# Submissions to Support Registration Review

## **Considerations:**

- Public process open to all possessing valid, pertinent information
- Information needed as early as possible in the process
- Reduce need for rework

# Submissions to Support Registration Review

## **Potential Information Submitters:**

- Registrants
- Stakeholders – growers, commodity groups, public interest organizations, other members of the public
- Government Agencies – USDA, IR4, CDC, etc.
- Universities/Extension

# Submissions to Support Registration Review

## **Recommendations:**

- Publish schedule for review
- Articulate guidelines and data needs
- Describe data submission requirements
- Explain how data will be used
- Issue DCIs when necessary

# Submissions to Support Registration Review

## **Recommendations:**

- Provide a framework for communicating information needs
- Create and use a listserve of interested stakeholders for each active ingredient in Registration Review

# The Registration Review Decision

## Considerations:

- Procedures to address AIs as well as individual products
- Possible review conclusions
- Communication of decisions

# The Registration Review Decision

## **Procedural Options:**

- Registration review decision will address both AI as well as individual products
  - Two-step procedure similar to current reregistration process
    - Initial decision specific to AI
    - Later decisions for individual products
  - Registration review is concluded based on individual products with no AI-specific decision step

# The Registration Review Decision

## **Recommendations:**

- Decision on AI and its uses should be followed by review of individual products.
- Product labels must comply with decisions made for AI or particular uses, and with all current label policies.
- Products with multiple AIs may be reviewed and require updating more than once in 15-year period.

# The Registration Review Decision

## Recommendations:

- Possible review conclusions
  - "Easy Off-Ramp" – No changes needed beyond possible generic label changes.
  - Mitigation Required
    - Labels must be amended to reflect mitigation measures.
    - Generic label changes may also be needed.

# The Registration Review Decision

## **Recommendations:**

- Possible review conclusions (cont.)
  - Data Needed to Update/Supplement Database
    - Sufficient support for continued registration
    - Final or interim decision depending on possible data impact
    - Product label changes based on decision

# The Registration Review Decision

## **Recommendations:**

- Possible review conclusions (cont.)
  - Data Required for New Risk Assessments
    - Data call-in issued
    - Review deferred
  - Active ingredient voluntarily canceled – final decision pursuant to FIFRA §6(f)
  - FIFRA §6 cancellation/suspension initiated



# The Registration Review Decision

## **Recommendations:**

### ➤ Communication of Decision

- Letters to registrants
- DCIs, when necessary
- Public communication effort
- Agreements between registrants/EPA could set conditions
- Failure to amend labels could lead to cancellation

# Summary Schedule for Rule

**Goal: Program to be in place August 2006**

➤ **Final Rule – Mid-2006**

➤ **Proposed Rule – February 2005**

➤ **OPP/EPA reviews – Summer 2004**

➤ **Economic Analysis – Early Summer 2004**

# What Are the Next Steps?

- **Develop the list of all pesticides for the schedule of registration review**
- **Develop a credible economic analysis to implement the rule**
- **Test whether the proposed process for conducting registration review is suitable**

# Next Steps—Pilot the Process

- **OPP will conduct a pilot of the process -- June**
- **Include mix of pesticide types, sufficient number**
- **Conduct cursory review of each pesticide**
  - Current risk assessments
  - Uses and restrictions
  - Whether there are unreviewed studies or other significant information
- **Compare against current requirements, risk assessment methods, policies**
  - What's changed, how significant is it, what needs to be done?

# Pilot the Process (con't)

## ➤ **Record the findings**

- Pesticides with no additional needs
- New risk assessments needed, e.g. Endangered Species
- New studies needed
- Other needs for OPP and/or registrants

## ➤ **Pilot should provide valuable information:**

- For estimating costs for economic analysis
- Feasibility of process
- Determine appropriate level of label review
- Process adjustments
- Resource implications

# Conclusions

- **PPDC Work group's advice has been beneficial to OPP in process formulation**
- **Pilot will provide useful information for rule and process development**
- **Draft rule is scheduled for publication early 2005**
  
- **Discussion**