Registration Review

PPDC: November 9, 2006

What's Next?
Registration Review

- FQPA added FIFRA 3(g) to require periodic review of each pesticide's registration
- Covers all pesticides
- Goal is 15-year review cycle
- Final rule effective October 10
- Oct. 11 FRN announced schedule for opening dockets – 4 years instead of 3

Final rule

- Flexible, transparent, open process
- Includes public participation
- Ensures continuity in protecting human health and the environment

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

- Older pesticides
- One-time review
- ca. 20 pesticides yr
- Process set by law
- Comprehensive reviews
- Start from scratch
- Major data gaps

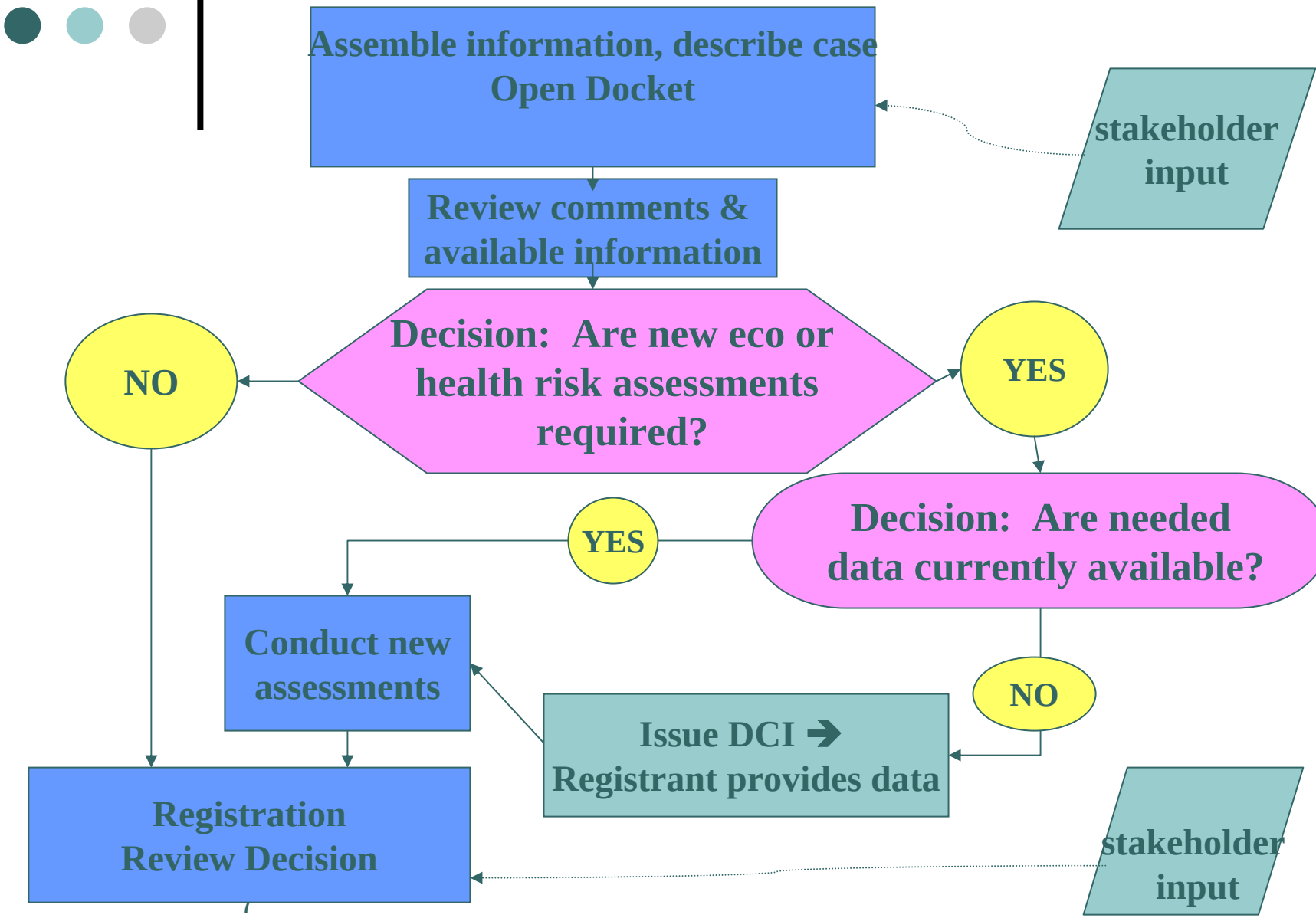
- All pesticides
- 15-year cycle
- 45+ pesticides yr.
- Process set by rule
- Updated reviews as needed
- Add to what we know
- Fewer data needs

Public Comment in Registration Review

- 1st comment period on opening docket, EPA presents what it knows
- 2nd comment period generally on Preliminary Risk Assessment
- 3rd comment period on draft decision
- Other comment periods as needed

Registration Review Process

Announce schedule, then, for 1st year cases ➔



Transparency

- Same docket number will be used throughout Reg Review for each case – showing case development

- Website to provide pesticide status and docket information

Ramping up ➔ Registration Review

- Non-food REDs done in FY ’08
- RED follow up will require a significant investment through FY ’08
- Product reregistration continues
- **Goal is seamless transition to Reg Review**
- Start ramping up Reg Review program beginning in FY ’07

FY ’07 Goal: Open 25 dockets, including **15 Conventionals**

- Fenarimol
- Cyromazine
- Paclobutrazol
- Fenoxycarb
- Sulfosate
- Clomazone
- Hexythiazox
- Triflumizole
- Fenoxaprop
- Lactofen
- Sodium salt of fomesafen
- "Urea, sulfate (1:1)"
- Clofentezine
- Ethofenprox
- Pyridate

And 10 Antimicrobials & Biopesticides

Antimicrobials

- Benzene-methanaminium
- Busan 1024
- 2,4-Imidazolidinedione
- Zinc borate (3ZnO, 2B03, 3.5H2O; mw 434.66)

Biochemicals

- Linalool
- Chitin
- Farnesol & Nerolidol

- **Microbials**
- Trichoderma species
- Pseudomonas syringae
- Pseudomonas flourescens

First steps of Registration Review

- Open docket, receive comment
- 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
- Proceed with review (DCIs, RA, or proposed decision

First Dockets

- OPP working on several dockets now
- 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
- Goal ➔ open some dockets early in FY ’07
- Serve as model for others

Goals for Docket – we are learning by doing

- Explain clearly our current understanding & anticipated path forward
- Give thought process for dietary, residential, occupational, ecological
- Explain rationale for any data or assessment needs
- Pose questions for public comment

Steps in preparing docket

- Assemble & review background information
- Prepare summary describing what we know & don't know, & significance of any gaps
  - Consider endangered species effects
  - Emerging concerns – like endocrine disruption
- Include anticipated work plan – any data and/or assessment needs
- Describe thought process in reaching these preliminary conclusions
- Pose questions on which we want comment

Docket example: Current understanding & path forward

Human Health:

Anticipates no additional HH RA necessary

- Dietary risk < LOC (includes Drinking Water)
- No residential uses
- All worker MOEs < LOC
- Current understanding considers in house data & literature searches
- Considers all policy changes that might affect the risk assessment & safety finding.

Docket Example: Current understanding & path forward

Environmental

- Poses acute risk to terrestrial plants
- Incident reports describe harm to terrestrial plants
- Buffer zones were added to most product labels
- Anticipate buffer zone assessment may be necessary for different formulations, potentially using air models
- Potential chronic risk to mammals
- Poses acute risk to freshwater & estuarine/marine invertebrates

Current understanding & path forward

Environmental (continued)

- Predicted risk to non-target organisms
- Screening level RA indicates use may potentially directly or indirectly impact endangered species
- A more refined RA will be required that includes
  - acute risk to terrestrial plants
  - acute risk to freshwater & marine/estuarine invertebrates
  - chronic risk to small & medium-sized mammals, & freshwater & estuarine/marine invertebrates
  - indirect effects on all listed species.

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 work plan for a couple of early case studies
  - Provide input on our docketed presentation of what we know & preliminary work plan
  - Have we emphasized the right issues?
- Short term PPDC subgroup requested

Conclusion

- Registration Review is here
- Begin transition from Reregistration
- Make dockets as transparent as possible to maximize comments
- OPP looks forward to feedback on process

Information on EPA Website

- EPA Office of Pesticide Programs
  www.epa.gov/pesticides/
- Registration Review
  www.epa.gov/oppsrrd1/registration_review/
- Registration review schedule
  http://www.epa.gov/oppsrrd1/registration_review/schedule.htm