Registration Review Update

Susan Lewis/Jay Ellenberger – OPP

PPDC Workgroup Members

PPDC Meeting

October 21, 2004

Agenda

- Quick review—What is Registration Review, Proposed Process, Rule?
  - Jay Ellenberger
- Feasibility Study – Susan Lewis
- Public Participation, Discussion
  - Eric Olsen, George Wichterman
- Data Needs, Discussion – Ray McAllister, Julie Spagnoli, Sue Crescenzi
- New Issues,Discussion

Rule-making Process

- ANPRM -- 2000
- PPDC recommendations – May 2004
  - Design of registration review process
  - Test the design
- Feasibility study -- September 2004
- Publish proposed rule -- 2005
- Final rule -- 2006

Design Requirements for Registration Review

- High efficiency -- 50 chemical cases (80 AIs) per year
- Sound science, transparent, open process, credible/value-added decisions
- Flexible process

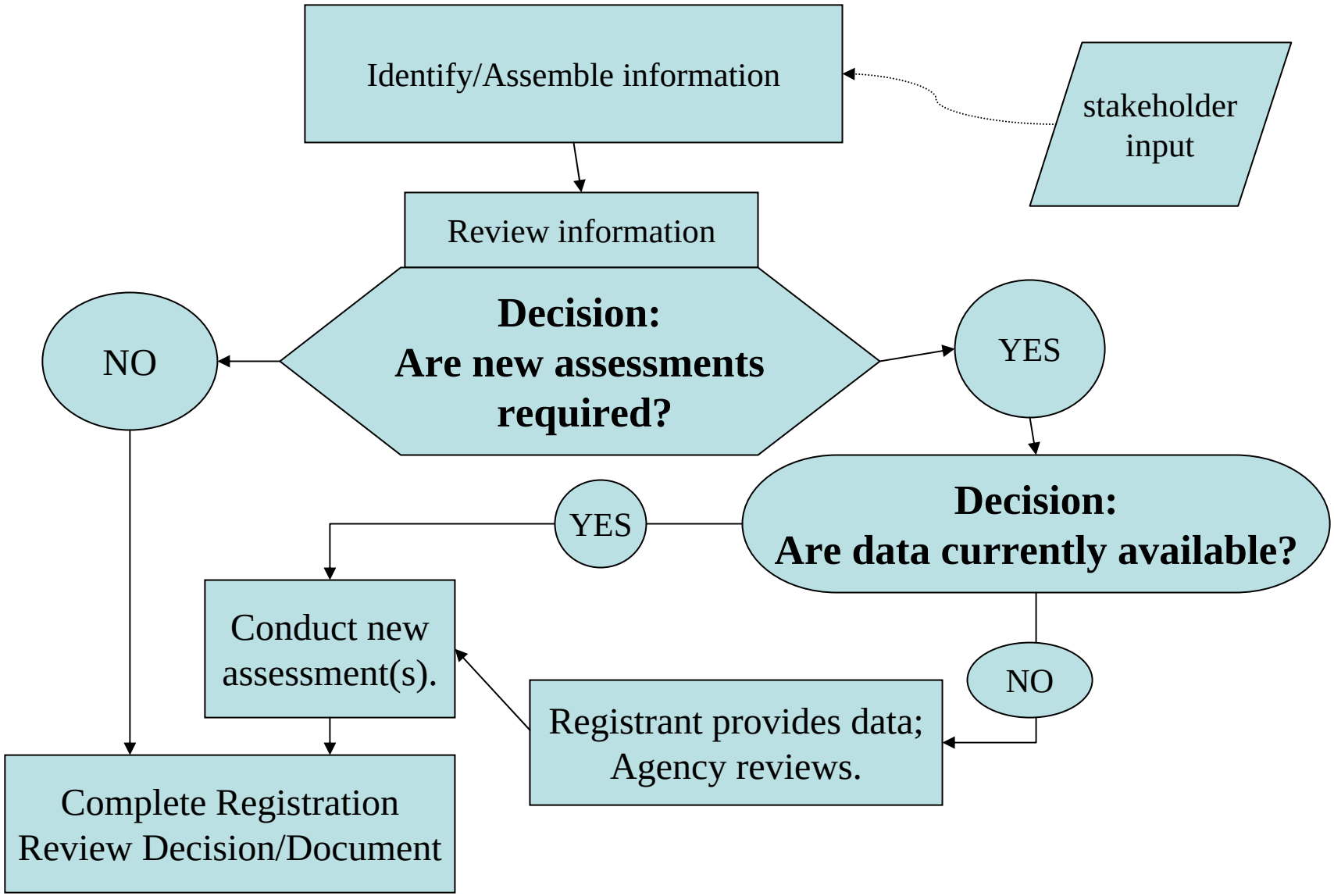
PPDC Recommendations

- Need reliable, predictable schedule
- Address new issues when they arise - outside of registration review
- Tailor review to depth/scope of issues
  - new data may be required
- Registration review should be a safety net

PPDC's "Tailored Approach"

- Assemble baseline information for each case
  - current registrations
  - bibliography of studies
  - last risk assessments
  - use patterns
  - incidents
- Invite public comment on baseline information
- Ask, "What's changed since last risk assessments?"
- Are new data or new risk assessment needed?
- Invite public comment on findings

Registration Review Flowchart



Feasibility Study

- Purpose: test the decision process and gather data on program costs.
- Randomly select 28 cases among potential candidates
  - 283 total cases in program for first 5 years of program
- Assemble “baseline” information
  - Current uses, bibliography of studies, last risk assessments, incidents

Sample Design of Feasibility Study

Category	Population (First 5 years)	Sample
Conventional Chemicals	165	12
Antimicrobial Pesticides	63	6
Biological Pesticides	55	10
All Pesticides	283	28

Feasibility Study (cont.)

- September 28, 2004 PPDC Workgroup meeting
  - Purpose and structure of feasibility study
  - Presented 3 case studies
  - Aggregate findings
  - Discussion of “What has changed” since 1984

Feasibility Study

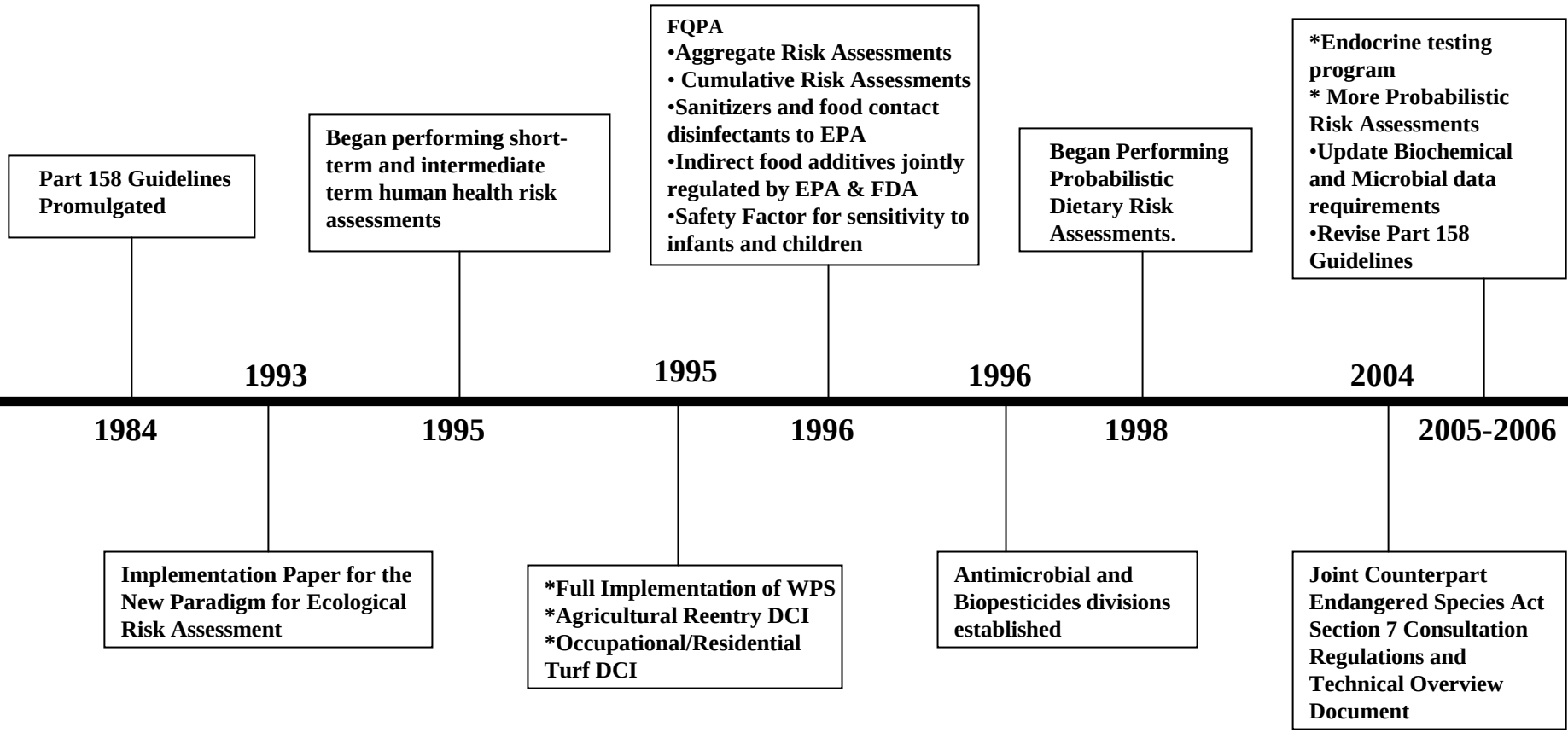
- Ask: What do we know, what do we need to know, and what is the value of the new information?

- Possible outcomes
  - No new assessment
  - New assessment, no new data
  - New assessment, new data

The Feasibility Study Did Not

- Consult with registrants or other stakeholders
- Prepare use/usage reports
- Search open literature
- Conduct new assessments
- Call in new data

Highlights of Changes since 1984



Case Study #1 - Conventional

- Herbicide registered in late 1980's with cereal crop uses – no new uses granted
- Recent tolerance reassessment action
- Last Environmental Fate & Effects review at time of initial registration – late 1980s

Conventional Case – Illustrative Results

- Human Health
  - Occupational risk requires updating
  - No new studies are required
  - Recent FQPA findings are adequate

- Environmental Fate & Effects
  - Ecological risk assessment is needed

Case Study #2 - Biochemical

- Pheromone registered in 1970's, Reregistered in 1990s
- Pheromone is always used in a trap at low rates and not applied directly to food or feed
- Illustrative Results
  - Last risk assessment is still valid
  - All data requirements are satisfied

Case Study - Antimicrobial

- Chemical registered mid 1980s, RED issued mid 1990s – pre FQPA

- Use Profile: Indirect food uses, FDA 409 clearances, multiple indoor uses such as cleaning products, HVAC, industrial uses and outdoor uses

Illustrative Results - AD

- New Human Health Risk Assessment is needed for Dietary, Residential, Occupational, Drinking Water and Aggregate.
- Ecological Risk Assessment is needed
- Ecological effects, environmental fate and worker/residential exposure data may be needed. Toxicity data base complete.

Case Study

- Additional information can be found on the EPA web

www.epa.gov/oppfod01/cb/ppdc/regisreview/sept04

Feasibility Study Aggregate Results

The ultimate outstanding data needs in a given case are expected to be significantly influenced by internal and external consultations. For practical reasons, this step was omitted in the pilot.

	Conventionals (12 cases)		Antimicrobials (6 cases)	Biopesticides (10 cases)
	Human Health	Environmental		
No New Assessment	83-92%	0-8%	17%	76%
New Assessment, No New Data	8-17%	25-33%	0%	6%
New Assessment, New Data	0%	58-75%	83%	18%

General Findings

- Process is feasible
- Highlighted importance of consultation
- Information technology/management needs
- Identified regulatory issues
- Identified process design issues

Public Participation in Pesticide Registration Review

Erik Olson, NRDC

George Wichterman, LCMCD

Philosophy of Public Participation

- “EPA will provide, in all its programs, for the fullest possible public participation in decision-making.
- “Requires…that EPA employees remain open and accessible to those representing all points of view
- “EPA employees [are] responsible for decisions take affirmative steps in an open manner to seek out the views of those who will be affected by the decisions.”

Philosophy of Public Participation (continued)

- "EPA will not accord privileged status to any special interest group, nor will it accept any recommendation without careful critical examination." –EPA Administrator's Fishbowl Memo

Philosophy (continued)

- Registration Review should reflect this approach, as embodied in OPP special review rules—
  - "To assure openness and responsiveness, no person or party outside of government will be afforded special or preferential access to…decisionmakers or [EPA]…process.

Philosophy (continued)

– “At the same time…EPA personnel are free to meet and otherwise communicate with persons or parties outside of government…to obtain information, exchange views, explore factual and substantive positions, or discuss regulatory options concerning…decisions.”—40 CFR §154.27(a)

Importance of Public Participation in Registration Review

- Provides EPA an opportunity for early identification of stakeholder issues
- Provides stakeholders a chance to learn of EPA plans, give early input
- Important to avoid misunderstandings and “surprises” for EPA and stakeholders

Key Points for Public Participation

- Public notice of schedules
- Public notice at initiation of review
- Public notice & DCIs or information requests well in advance of review (~2+ yrs?) *[No consensus; issue to be discussed]*
- Obviously, need for tiered studies or newly-identified study needs may be identified later

Key Points for Public Participation (continued)

- Opportunity for public to participate in “SMART Meetings”
- Importance of early notification of registrants, users, workers, environmental groups, public health representatives, e.g. National Center for Environmental Health (CDC) and other Federal agencies (e.g. USDA and U. S. Fish and Wildlife Service) who have need for data on pesticides to be reviewed.

Key Points for Public Participation (continued)

- Should assure opportunity for comment on major EPA decision documents (such as proposed decision on review) before decisions are made

Meaningful Participation in Decisionmaking

- We recognize that ultimate regulatory decisions are EPA's alone
- We recognize that registrants may make their own decisions based upon business reasons to withdraw support for chemicals
- However, it is important that not only the public, but also any Federal Agency required under law for the purpose of consultation and data support be brought in before an EPA decision is determined.

Meaningful Participation in Decisionmaking

- Accordingly, Registration Review needs to incorporate and require participation from, the Department of Health and Human Services (National Center for Environmental Health (CDC)

Meaningful Participation in Decisionmaking (continued)

- FIFRA, Section 4(n) provides that during reregistration:
- CONSULTATION-In case of a pesticide registered for use in public health programs for vector control or for other uses the Administrator determines to be human health protection uses, the Administrator shall, upon timely request by the registrant or any other interested person, or on the Administrator's own initiative may, consult with the Secretary prior to taking final action to suspend registration under section 4, 6(e), or 6(f).

Meaningful Participation in Decisionmaking (continued)

- CONSULTATION (Continuned)

  In consultation with the Secretary, the Administrator shall prescribe the form and content of requests under this section.
- BENEFITS…Administrator, after consulting with the Secretary, shall make a determination whether the potential benefits of continued use of the pesticide for public health or health protection purposes are of such significance as to warrant a commitment by the Secretary to conduct or to arrange for the conduct of the studies required by the Administrator to support continued registration….

Procedures for Registration Review

- Comprehensive public e-Docket should be established as soon as EPA begins work on chemical (track pesticide dockets required in 40 CFR 154.15)
- Docket should also include information on DCIs and what studies outstanding
- No party should get a special opportunity to participate or comment not available to others

Assurances of meaningful public participation

- Special procedural protections should be in place to assure fair access of all parties to information and EPA thinking and decision making during registration review (based on 40 CFR §154.27)
- EPA should notify all stakeholders and provide opportunity to comment on proposed EPA decisions “on review such as a technical briefing similar to the kind held in the past by the Agency on the organophosphates.”

Registration Review as a “Safety Net” & Public Participation

- Registration review is not the only process for EPA action
- Registration review is only a “safety net,” and EPA should be free to act quickly under other authorities if necessary
- Detailed procedural requirements should not slow or impede EPA action if expedited action is needed to protect human health or the environment

Registration Review: Timing and Data Requirements

Pesticide Program Dialogue Committee

October 21, 2004

Types of Data Requirements

- New Guideline requirement
- Data not requested previously, but now required of similar products/uses
- Data needs triggered by a particular concern, but not previously requested
- Data requested but not supplied

New Guideline requirement

- If a new Guideline Study is applicable to support registration of all actives meeting particular criteria, DCI should be issued for those actives.
- Registration Review should not be used as mechanism for implementation of broad new data requirements.
- If such data are necessary to conduct a new risk assessment, then they must be submitted before Registration Review can be completed

Data not previously requested

- If Registration Review determines a new assessment is necessary and particular data are necessary to conduct such assessment, issue DCI for the data.
- Assessment can only be completed after submission of the data.
- If the data are only confirmatory, that is, not necessary for a new risk assessment, issue DCI at completion of Registration Review.

Data need triggered by a particular concern

- Registration Review could reveal a new concern that would trigger need for data to assess a particular risk (for example, adverse effects reports).
- When data needs are determined, DCI should be issued.
- Risk assessment will be completed after data are submitted and reviewed.

Data Previously Requested

- If a waiver request is pending, decision from EPA needed as part of initiation of Registration Review.
- If Generic Data Exemption was claimed by formulators, but the use is not supported by the basic registrant, EPA must inform those formulators, who must decide if they will support the use and supply the data.
- Data generation may be in process under a DCI, but not yet submitted.
- If these data are necessary to complete a new assessment, Registration Review is completed after data are submitted.

PPDC Workgroup, New Issues

- How to document Registration Review Decisions?
- To what extent should end-use products be reviewed?
- How should inert ingredients be considered in Registration Review?