US EPA ARCHIVE DOCUMENT

Pesticide Program Dialogue Committee (PPDC) Process Improvement Workgroup

June 15, 2006

Pesticide Registration Improvement Act (PRIA)

- Effective March 23, 2004
- Coalition
  - Industry and Trade Associations
  - Public Interest Groups
  - Environmental Groups
  - Consumer and Labor Groups
  - EPA

Pesticide Registration Improvement Act (PRIA)

- Maintenance Fees and Reregistration
- Enhanced Registration Service Fees
  - 90 categories of registration fees
  - Mandated timeframes for Agency decision making
  - Fee Waivers
    - Small Business
    - IR-4
    - Minor Uses
    - State/Federal Government
  - Set Asides
    - Worker Protection
    - Inert Ingredients

Benefits of the Statute

- Reduced timeframes and greater predictability in the timing of registration decisions
- More accountability for registration decisions
- Increased resources to assist EPA in meeting its FQPA and reregistration deadlines
- More stable, predictable, and augmented funding for the pesticide program

Statutory Provision

- "To the maximum extent practicable consistent with the degrees of risk presented by pesticides and the type of review appropriate to evaluate risks, the Administrator shall identify and evaluate reforms to the pesticide registration process under this Act with the goal of reducing decision review periods in effect on the effective date of the Pesticide Registration Improvement Act of 2003 for pesticide registration actions for covered pesticide registration applications (including reduced risk applications)."

PPDC PRIA Process Improvement Workgroup

- Formed summer, 2004
- Meetings
  - August, 2004
  - October, 2004
  - January, 2005
  - September, 2005
  - January, 2006
- Minutes of past meetings http://www.epa.gov/pesticides/ppdc/pria/index.html

Summary of June 14, 2006 PPDC PRIA Process Improvement Meeting

Ron Derbyshire
JohnsonDiversey

Topics

- OPP Labeling Committee
- Blue Book Focus Group report
- Product Chemistry Panel Discussion
  - EPA and Industry identification of problems and solutions

Labeling

- PPDC PRIA Process Improvement Workgroup identified labeling as a priority issue for the EPA

- In response, OPP formed a Labeling Committee in April, 2005

OPP Labeling Committee

- Representatives from 5 Divisions within OPP:
  - Registration Division
  - Antimicrobial Division
  - Special Review and Reregistration Division
  - Biopesticides and Pollution Prevention Division
  - Field and External Affairs Division
- And two other Offices
  - Office of Enforcement Compliance and Assurance
  - Office of General Counsel

Purpose

- To oversee labeling policy issues across pesticide registration and reregistration, resolve them and communicate their resolution both internally and externally

Charge

- Revise and keep current the Label Review Manual (LRM)
- Serve as a clearing house for broad cross cutting label issues
- Determine the Scope and Nature of cross cutting label policy needs
- Recommend solutions and measures for implementing solutions for senior management consideration
- Manage a web site devoted to labeling issues

Electronic Addresses

- E-mail box is available at:

  OPP_labeling_consistency@epa.gov

- Web page can be found at:

  http://www.epa.gov/pesticides/regulating/labels/label_review.htm

Questions and Answers

- Received 36 questions as of June 1
- Answered 16 of these
- Posted 14
- Two require clarification
- Response in progress on 16 questions.

Current Actions

- Updating the LRM
  - Team has reviewed the LRM for straightforward corrections and compliance with current policy- **currently <u>not</u> considering any changes in policy**
  - LRM Team is working to have LRM version on the Web page more user friendly
  - Revised LRM should come to Labeling Committee by end of June and be posted sometime after that.

Current Label Issues Being Worked On

- Developed issue paper on “For Use Only By …” and reviewing stakeholder comments
- Mandatory versus Advisory label language
  - Internal training of regulatory divisions took place in February and April
  - Reviewers are putting the training into practice

Current Label Issues Being Worked On

- Warranty Statements
  - Updated Guidance to clarify it and provide examples
  - Plan to post on our web site, update LRM, and notify stakeholders- July
  - Will do internal training of personnel to obtain consistency in OPP reviews

Next Set of Issues to Be Considered

- Contains the same active ingredient statements
- Mosquito Misters
- Minimum Use Rates
- Maximum Limit on AI's per Crop per Acre

Status of the Blue Book

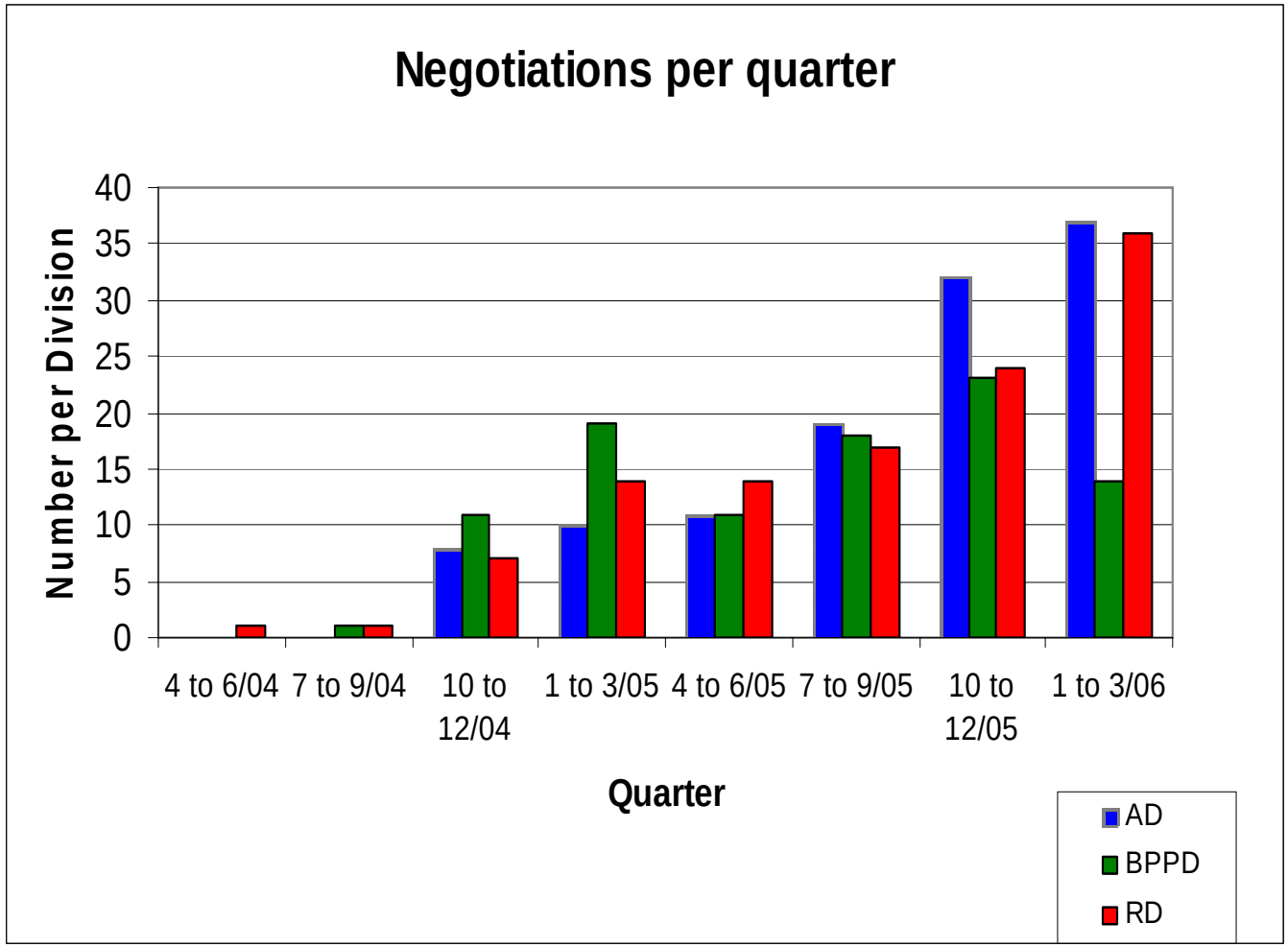
Background on the "Blue Book"

- Official Title: *General Information on Applying for Registration of Pesticides in the United States*
- Provides a basic "how-to" guide to pesticide registration and regulation.
- Current Version (Second Edition) issued in August 1992.
- Needs to be updated to reflect current-day regulations and procedures.

Why Update Blue Book?

- Critical reference used to develop registration applications
- Some Applications are incomplete resulting in
  - Increases in number of PRIA negotiated or extended due dates.
  - Additional resources devoted to incomplete applications that could have been used to reach decisions earlier on complete applications.

Trends in PRIA Negotiated Due Dates



Focus Group

- Updated draft reviewed by a group of potential users – the Blue Book Focus Group.
- Focus Group met on April 20, 2006.
- Revisions and improvements were suggested.
- Focus group also suggested other means to improve applications.

Focus Group Members

- Industry Representatives
  - Russ Schneider, Monsanto
  - Ron Derbyshire, JohnsonDiversey
  - Ted Head, NuFarm America
  - Maria Herrero, Valent Biosciences
  - David Jones, Nice-Pak
  - Jim Kunstman, PBI Gordon
  - Patrick McCain, Syngenta
  - Barbara Christianson, Acta Group
  - Bob Stewart/Heather Bjornson, Technology Sciences Group
  - Karen Warkentien, Lewis & Harrison LLC
- EPA Representatives
  - Elizabeth Leovey, OPP/IO
  - Michael Hardy, AD
  - Beth Edwards, RD
  - Linda Arrington, RD
  - Mike Mendelsohn, BPPD

Summary of Focus Group Meeting

- The Blue Book is one of the most helpful EPA publications for registrants.
  - Geared for smaller companies but useful to all registrants, large and small.
  - A condensed “Cliffs Notes” version of the regulations.
  - Provides basic information with links to statutes, regulations, and guidance documents.
  - Need to resist the urge to include too much information (becomes too voluminous and unwieldy).

Major Recommendations of Focus Group

- Make more step-oriented (*e.g.*, decision tree or similar) and follow how applications are developed.
- Consider all aspects of registration such as enforcement and post-registration activities.
- Standardize application guidance
- Provide more examples and on the web version, links to all referenced materials, forms and examples.

Improving Registration Applications

- Develop an interactive web based system for generating a registration application.
- Conduct workshops on data formatting, application forms, and similar topics.
- Compile a list of common problems/pitfalls.
- Publish Agency checklists.
- Conduct a rejection rate analysis to identify problem areas.
- Produce a tutorial CD.
- Develop and publish standard evaluation procedures for applications.

Next Steps

- Agency staff are reviewing focus group comments and revising draft.
- Revised draft will be circulated to OGC and OPP staff for comment.
- Final draft will undergo Agency document approval process.
- Final hardcopy version expected by end of CY2006.

Product Chemistry Panel Discussion

Panel

- Industry
  - Ron Derbyshire, JohnsonDiversey
  - Amy Roberts, BPIA
  - Greg Watson, Syngenta
  - Ted Head, NuFarm
- EPA/OPP
  - Kathy Monk, RD
  - Pauling Wagner, RD
  - Debbie McCall, RD
  - Karen Hicks, AD
  - Kent Carlson, BPPD

Follow-up Items

- Inerts
  - Comprehensive list of inerts and tolerances
- SOP on Storage Stability
  - To be developed by cross OPP team
- Product Chemistry
  - Guidance on GLP requirements
- CSF Calculator on the web
- Panel will continue to discuss issues and identify solutions
    - OPP Product Chemistry Workgroup members are from all registering divisions

Next Issue for Workgroup

- E-Labels
  - Electronic review and submission of labels
  - Accuracy and consistency in label review
  - Initial stage to electronic submissions