

US EPA ARCHIVE DOCUMENT

# PPDC PRIA Process Improvement Workgroup Status and Accomplishments

Elizabeth Leovey, OPP/EPA

Greg Watson, Syngenta

representing stakeholders in  
PPDC PRIA Process  
Improvement

# PRIA - Statutory Provision

## Process Improvements

- Both PRIA-1 and PRIA-2
- “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

- Stakeholder Subcommittee of PPDC formed
  - PPDC PRIA Process Improvement Workgroup
- Members – Industry, Trade Associations, Agency and Public Interest Groups
- Nine meetings - <http://www.epa.gov/pesticides/ppdc/>
  - August 2004
  - October 2004
  - January 25, 2005
  - September 14, 2005
  - January 31, 2006
  - June 14, 2006
  - November 2, 2006
  - April 10, 2007
  - September 27, 2007

# EPA - Process Improvements Applications

- In processing (front end)
  - Modified systems to accommodate fee payments and waivers and PRIA due dates
  - Process for Payments - Credit card/wire transfer payment of fee – Nov. 06, introduction of ‘pay.gov’
  - Established fee waiver process
- Developed information management systems to track financial data and due dates
  - E-mail notifications to applicants of payment invoices and receipt of payments
  - Monitor payments and follow-up on unpaid invoices
  - Status/Progress reports

# EPA - Process Improvements Applications

- Registering Divisions internal process improvements
  - Early discussions with applicant emphasized
  - Analyzed work processes and established timelines for milestones - an ongoing activity.
  - RD - ‘Scoping’ meeting and establishing a review team in science divisions
  - Increased joint reviews, use of other data, and “bundled applications”
- Data review and developing risk assessment process streamlined and tools developed
  - HED – streamlined peer review committee process and document development
  - EFED – one time data input, integrated models and refinements using Geospatial tools

# EPA - Process Improvements Applications

- Process for PRIA timeline extensions and PRIA Determination to Not Grant
- Analyze reasons for extending due dates – ongoing
  - Product Chemistry submissions need to improve
  - Less experienced applicants tend to have more problems with the application process
  - Additional application guidance needed – “Blue Book” close to completion needs to be revised for PRIA 2

# EPA - Process Improvements Applications

- Reduced application in-processing timeframe
- Reduced average decision time for fee waivers
- Increasing number of “decisions” completed
  - FY 04        208
  - FY05        1098
  - FY06        1347
  - FY07        1591
- Increased Reporting
  - Stakeholder meetings
  - Annual audit by Office of Inspector General
  - Annual Report due on internet March 1



# EPA - Process Improvements

## Labeling

- OPP's Labeling Committee and Labeling Consistency Website
  - Labeling issues a priority for Stakeholders
  - OPP wide Labeling Committee formed
  - Assure consistency across OPP on labeling practices
  - Update 'Label Review Manual'
  - Web site to address public's questions
  - Staff training
  - Resolve label language issues

# EPA - Process Improvements Information Management

- Electronic Application/Submission and Document Management –priority
  - Registration files (i.e. registration jackets) scanned
  - Transition OPPIN to PRISM
  - Long term goals:
    - » Web based application and submission with registrants applying on-line and the system will identify any inconsistent and incorrect information
    - » Milestone reports - Communication with applicant when application reaches an important stage

# PPDC PRIA Process Improvement Workgroup - Meetings

- Stakeholders / OPP identified priorities for efficiency improvements and opportunities to increase efficiency
- Agency reports status of implementation, efforts to reduce time to completion and status of projects of interest to stakeholders
- Productive and cooperative dialogue
  - pathway to introduce topics for discussion / resolution
  - allows for longer term projects like publication on EPA website a listing of EPA approved inerts

# EPA - Process Improvements

## Stakeholder View

- Food use RED timelines met, non-Food RED completion on track
- Additional funds made available for worker protection
- EPA OPP has met PRIA decision timelines for the overwhelmingly majority of decisions
- Predictability of decision timelines important for registrants / end user community
  - especially for new uses – important for expansion of minor crop & other new uses
- OPP RD new AI decision timeline for AI's submitted after PRIA ~16 months
- Multi-year AI plan possible for resource planning, publication of new AI / New Use work plan on EPA OPP web site

# EPA - Process Improvements Stakeholder View

- E-submission Improvements
  - Using e-methods to review amended labeling
  - E-submission of study reports / applications
  - AD - Electronic Amendment Submission template
- Culture change within OPP driven by division wide visibility of registering division work plan and established decision dates
- Submission diagnostics – use database & analysis to see where improvements were needed (product chemistry & others)

# PRIA 2 Challenges

- No start up time – developing/modifying as applications are being processed
- New fee categories, fees and payment process – IT systems modified
- Payment due at application
  - Web site to help applicants identify the fee category and fee
  - OPP developing guidance to make final determination on PRIA category shortly after receipt
- Content Screen – redesign to complete EPA screen and provide opportunity applicant response in 21 days
- Communication – changes in fee payment process and guidance on new categories web site being modified as applications are received

# PRIA 2 Challenges

- Complete “Blue Book”
- Address Product Chemistry issues in submission quality & review process
- Continue analysis of extensions and identify issues with the additional types of applications covered by PRIA 2 and work with stakeholders in improving these applications.
- Develop a web based application system as experience is gained developing interactive web sites.