



PPDC – PRIA Process Improvement Workgroup

October 21, 2005



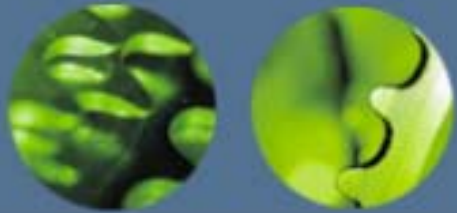
Statutory Provision

- **“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).”**



OPP Process Improvements Labeling

- **Labeling a shared issue identified in EPA, Fee Coalition Problem Statements**
- **Agreed to be initial priority for the Process Improvement FACA**
- **Led to establishment of OPP Labeling Committee**



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 (OGC)



Purpose

- **To oversee cross cutting labeling policy issues, resolve them and communicate resolution both internally an 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**



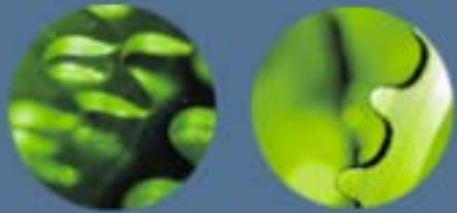
Items that will be handled by Labeling Committee

- Labeling issues covering all product labels
- Labeling issues covering a type of pesticide such as an antimicrobial, microbial, biochemical, fungicide, insecticide, herbicide, etc.
- Labeling issues covering a broad use site such as aquatic uses, indoor uses, greenhouse uses, etc.
- Labeling issues covering a specific crop such as soybeans, cotton, carrots, etc.
- Labeling issues covering a class of pesticides such as sulfonylureas, organophosphates, pyrethroids, etc.



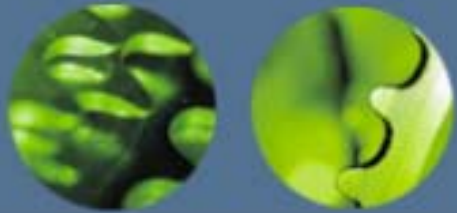
Items that will Not be handled by Labeling Committee

- **Issues limited to a specific product that would not have broader implications**
- **Issues dealing with an enforcement case**
- **Issues involving ongoing litigation**
- **Status questions dealing with pending FIFRA registration application actions**
- **Labeling issues dealing with unregistered pesticides, e.g. Section 18s, EUPs**



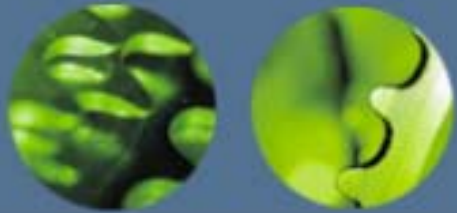
Current Actions

- **Development of internal procedures**
 - Draft Final Form - expect it to change over time
- **Establishment of an Email box and Web Page**
 - Email box will be available
 - OPPlabelingconsistency@epa.gov
 - Web Page under development
 - Questions accepted once web page is established
- **Appoint a Subgroup to keep the LRM current**
 - Appointed and is made up of representatives of same OPP divisions
 - Subgroup is Drafting an SOP



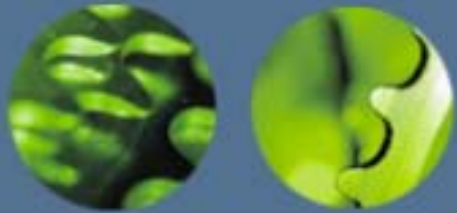
Current Label Issues Being Worked On

- **Mandatory versus Advisory label language**
 - PR Notice 2000-5
 - Planning internal training
 - Industry has requested the development of ‘For Commercial Applicators Only’, ‘Not for Residential Use’, or ‘For Professional Use Only’ language that is not ‘restricted use’ that is acceptable to the states & other stakeholders
- **Warranty Statements**
 - Updating Guidance
 - Planning internal training
 - External notification



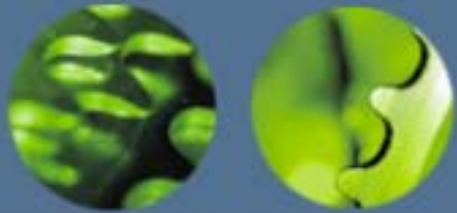
Next Steps – Labeling Committee

- **Labeling Committee will present progress on Warranty Statements, Mandatory vs. Advisory, and “For Sale by ...” during the next PPDC workgroup meeting in January and for public discussion.**
- **Committee review Industry’s suggestions to improve Label Review Manual and labeling in general**



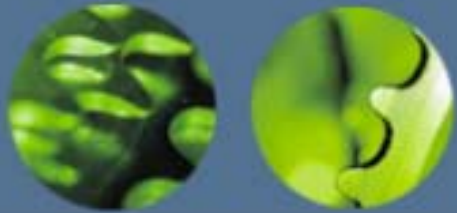
Application Guidance

- **A priority for EPA is to receive complete applications**
- **AD / Industry are developing application examples**
- **BPPD's web site provides answers to registrant questions and guidance on CSFs**



Application Guidance

- The **Blue Book** is the “General Information on Applying for Registration of Pesticides in the United States” will be revised by January 2006 for review by a focus group of applicants.
- The Focus group will also propose additional mechanisms to improve applications and meet in February.



Next Workgroup Meeting - Topics

- **Next PRIA Process Improvement Meeting – planned for January 2006**
- **Industry and EPA will present next issue to be given a priority**
- **OPP's Information Technology and Information Management plan for improvements over the next three years**
- **Labeling Committee report**
- **Application Guidance – EPA analysis of application deficiencies / problems**

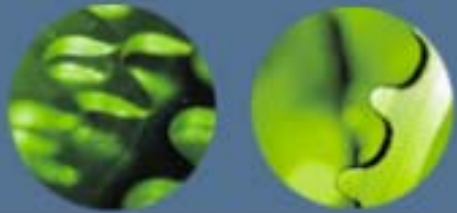


Background slides



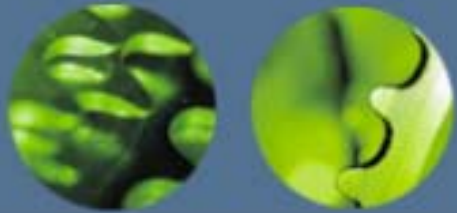
OPP Process Improvements Labeling – Industry Comments

Industry Fee Coalition



Suggested Priorities - Industry Fee Coalition

- 1) Establishment of the mail box / web site –
underway
 - Suggested mining the SLITS database for a) past resolutions, b) areas that need further clarification
- 2) Label Review Manual (LRM) Subteam –
underway
- 3) Chapter 7 – Precautionary Labeling
 - Suggested that the complete First Aid PR Notice 2001-1 be incorporated into the LRM.



Priorities Continued

- 4) 'Mandatory vs. Advisory' & 'For sale to / Use by'
 - underway
 - Need clarity on items covered by 'Mandatory vs. Advisory' category
 - **Requested the development of 'For Commercial Applicators Only', 'Not for Residential Use', or 'For Professional Use Only' language that is not 'restricted use' that is acceptable to the states & other stakeholders**
- 5) Warranty Statements – underway
 - Important for OCG to take the lead on this topic



Next Steps

- Agreed that formation of OPP Labeling Committee is a positive step forward
- Agreed to look at other 'problem statements' to select next issue to be given a priority