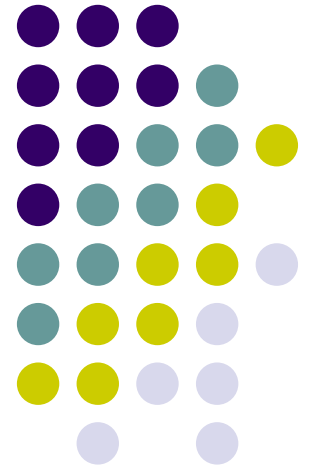


US EPA ARCHIVE DOCUMENT

# Overview of OPP Labeling Improvement Initiatives

PPDC Presentation  
May 2008





# Overview of Presentation

- Historical Background
- Summary of OPP Approach to Improve Labeling
  - Electronic Submission Initiative
  - Label Content Initiative
  - Web-based Distribution Initiative
- Potential Synergies Across Initiatives
- Stakeholder Involvement
- Timelines



# Historical Background

Current labeling problems exist because of an antiquated, conflicted system:

- Multiple goals for labeling
- Paper based system
- Product-by-product reviews
- Changing standards of acceptability
- Major resources needed to process changes affecting large numbers of products
- Long implementation time



# Existing Problems

- Labels too long: some with attached directions 80-100 pgs.
- Unenforceable, ambiguous, and/or internally inconsistent labeling language
- Different labeling on similar products
- Hard to change existing labeling
- Slow communication of labeling changes to users (18 months for new label to reach marketplace)
- Confusing / unclear / labeling

# Overall Labeling Approach



OPP initiatives to improve labeling fall into three categories:

- Electronic submission & review
- Improving content systematically
- Electronic dissemination of labeling

# Overview of Electronic Submission & Review



- Part of larger e-submission effort
- Harmonized with OECD
- Electronic files will expedite review process

# Electronic Submission



- XML (or similar) format will specify and capture all labeling “elements” in “fields” and “subfields”
- Two stage approach
  - Identify and categorize labeling elements
  - Create “Labeling Builder” software



# Review of Electronic Submissions



- E-submission would replace cumbersome “by-hand” process
- Provide better information to Label Use Information System (LUIS)
  - Automated: quicker, cheaper, and error free
- Product action reviews
  - Quicker routing
  - Automatic comparisons with prior versions
  - Simpler, more efficient capture of decisions

# Overview of Initiatives to Improve Labeling Content



Feedback from Stakeholders (e.g., PPDC SDWG, SFIREG/AAPCO, advocacy groups, pesticide companies) triggered exercises to characterize the extent and nature of the problems and to match solutions to the problems

- Procedural Changes
- Substantive Changes

# Procedural Changes to Improve Labeling Content



Label Accountability Workgroup (LAW)  
recommendations

- OD's "Labeling Principles" memorandum
- Training
- Update and expand Label Review Manual
- Divisional Quality Assurance Frameworks
- Priority Setting mechanisms
- Greater Stakeholder engagement

# Substantive Changes to Improve Labeling Content



Numerous content-focused initiatives including:

- Spray drift (PRN)
- Fumigants (RED)
- Mosquito adulticides (PRN)
- Sunscreen / Insect repellent combinations (FRN)
- Anthrax (Guideline and PRN)
- Cause marketing (PRN)
- EHS statements on consumer products (PRN)
- Global Harmonization System (GHS)

# Overview of Web-Based Distribution of Labeling



- Web-based distribution of electronic labeling is a system which would make the most current version of pesticide labeling available to purchasers and users electronically on an EPA-maintained Web site
  - Simplify label on container
  - Allow for rapid updating of the labeling

# Web-Distributed Labeling: Changes to Container Label



- A URL would be placed on the pesticide label, directing users to the Web site
- May replace the Directions for Use on the physical container
- Container label would still have all FIFRA mandated elements, e.g., product name, registration number, net contents, ingredient statement, etc.
- Container label could have other key information

# Web-Distributed Labeling: Process to Obtain Labeling



- Distributors, purchasers or users would visit EPA's Pesticide Labeling website
- After entering the product registration number, the product labeling would appear in a printable format
- Dealers could distribute printed labeling
- An alternative method of obtaining the web-based labeling, a toll-free phone number, would be available for those without access to the necessary technology

# Web-Distributed Labeling: Enforcement



- Users would need to have a copy of the labeling from the website at the time of application
- Labeling would be good for a specified duration of time (e.g., 6-18 months) from the date of “printing”
- Archival system would allow verification of the version of the labeling posted on any date



# Coordination Across Initiatives



- E-Submission & Content
  - “Label Builder” offers Label Review Manual (LRM) as first choice
  - Flag for reviewers when elements  $\neq$  LRM
  - Identify all products with an element  $\neq$  LRM (level playing field)
- E-Submission & Web Distribution
  - Customize labeling by use and site
  - Labeling in different languages
- Content & Web Distribution
  - Implement labeling changes for all products more quickly & concurrently (level playing field)
  - Searchable databases
  - User feedback

# Examples of Stakeholder Involvement



- Electronic submission & review
  - OECD involvement
  - PPDC PRIA Process Improvements WG
- Improving content systematically
  - SFIREG meetings on LAW
  - SFIREG process to review labeling issues
  - Public comment on PRNs, REDs
- Web distribution of labeling
  - 10/07, 5/08 PPDC presentations
  - Stakeholder discussions
  - Future Federal Register notice



# Timelines

- Electronic submission & review
  - Already underway in simple form (PDF files); more elaborate (XML/“structured”label) 2009 +
- Improving content systematically
  - Efforts beginning this spring – training, QA, response
- Web distribution of labeling
  - Possible small scale pilot in 2009
  - FR Notice in 2009, early 2010
  - Expanded pilot in 2010, 2011