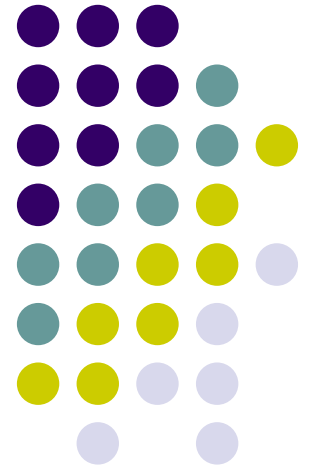


Overview of OPP Labeling Improvement Initiatives

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