Web-Distributed Labeling

Presentation for PPDC Workgroup
October 2, 2008

1

Web-Distributed Labeling: Overview of Presentation

- Overview
  - Background
  - What It Is Not
  - What It Is
- Mechanics
  - Changes to Container Labeling
  - Process to Obtain Labeling
  - Enforcement
- Benefits
  - Users
  - Industry
  - EPA
- Progression
  - Enhancements
  - Activities to Date
  - PPDC Role
  - Next Steps

2

Web-Distributed Labeling Background

- Substantial work done by States and other stakeholders on researching elements of electronic submission and distribution of labeling
  - 2005 and expanded 2007 SFIREG Issue Papers submitted by POM E-label Subcommittee
  - OPP E-label Review Work Group
- At Summer 2007 AAPCO meeting States presented the topic to OPP's new Office Director, Debbie Edwards

3

Web-Distributed Labeling: What It Is Not

- It is not referring to electronic submission or review of labels by the Agency (but that effort is underway)
- Would not require standardized labeling
- Would not diminish legal procedures that EPA must follow to change labeling
- Would not change process registrants use to amend product labeling
- Would not change users' duty to follow labeling requirements
- Would not return EPA master labeling

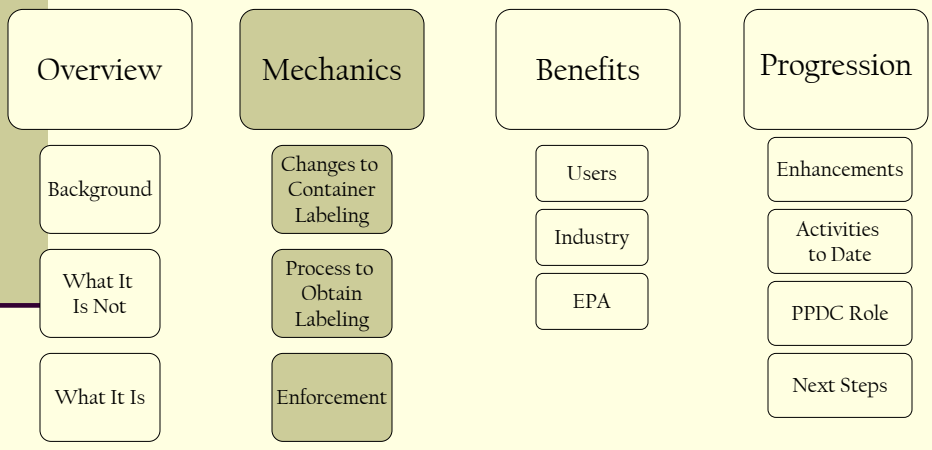
4

Web-Distributed Labeling: What It Is

- Web-distributed labeling is a system which would make current versions of the state-approved marketed pesticide labeling available to purchasers and users electronically.
- Web-distributed labeling will result in simplified container labels.
- Web-distributed labeling will allow for rapid updating of the labeling.

5

Web-Distributed Labeling: Overview of Presentation



6

Web-Distributed Labeling: Changes to Container Label

- A URL would be placed on the pesticide label, directing users to the website.
- Container label would still have all FIFRA mandated elements (product name, registration number, net contents, ingredient statement, etc.).
- Container label could have other key information, e.g., directions for use, warranty statements

7

Web-Distributed Labeling: Process to Obtain Labeling

- Distributors, purchasers or users would visit the web-distributed labeling website referenced on the container
- After entering the product registration number or other unique identifier, the approved marketed product labeling for the state in which the product would be used would appear in a printable format
- An alternative method of obtaining the web-distributed labeling, a toll-free phone number, would be available for those without access to the necessary technology

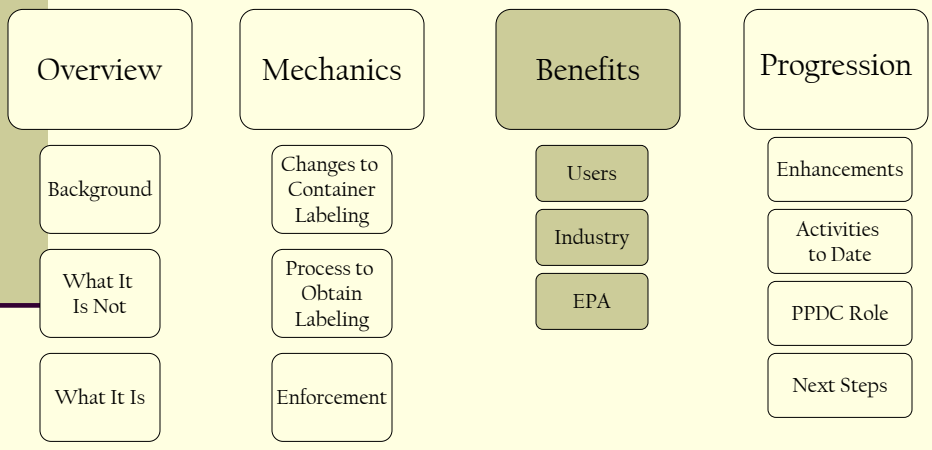
8

Web-Distributed Labeling: Enforcement

- The label would require users to have a valid copy of the labeling from the website at the time of application
- Labeling would be valid for a specified duration of time (e.g., six to eighteen months) from the date of download
- A user's failure to follow all label and labeling instructions or to have a valid copy of the labeling at the time of application would be considered a violation
- The most current and accurate version of labeling would be available through the website and a responsive alternate delivery mechanism
- System would allow States and EPA access to historical labeling to facilitate enforcement actions

9

Web-Distributed Labeling: Overview of Presentation



10

Web-Distributed Labeling: Anticipated Benefits

- Enhanced protection of human health and the environment by providing pesticide users with the most current, accurate information available.
  - Example: updated PPE requirements
  - Example: updated directions for use
- Anticipated benefits to all stakeholders
  - Users
  - Industry
  - NGOs
  - States
  - International
  - EPA

11

Web-Distributed Labeling: Anticipated Benefits for Industry

- Easy to modify labeling
  - Add newly registered use (no need for “supplemental labels”)
  - Make other labeling amendments
- Reduces printing costs
- No need to re-sticker or recall when changes must be made quickly but do not affect the container label
- Promotes a level playing field
  - All products could make a regulatory change at the same time

12

Web-Distributed Labeling: Anticipated Benefits for Users

- Labeling information is always current
- Labeling is electronically searchable
- Printable in large font
- Simplified container label
  - Health and safety information is more noticeable
  - Should increase comprehension
- More concise labeling directions
  - State, crop/site specific
    - Reduces time necessary to understand use directions
    - Simplifies labeling content
- Level playing field
  - Users would not have to worry about dealing with existing stocks of products having different mitigation measures or use directions (e.g., lower rates, longer pre-harvest intervals)

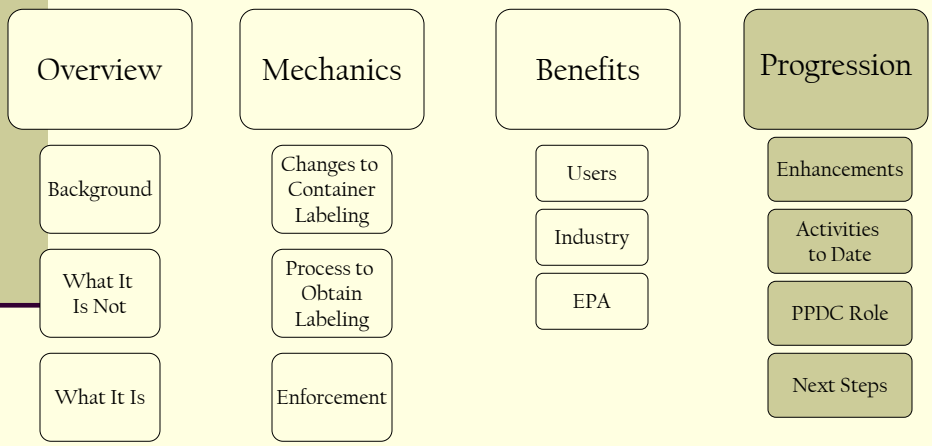
13

Web-Distributed Labeling: Benefits to EPA

- Measurable improvements in protection of human health and the environment
  - Communicate labeling changes quicker
    - Faster market entry of reduced-risk uses
    - Earlier implementation of risk mitigation measures
    - Greater ability to make revisions based on user feedback
  - Accuracy of final printed labeling
    - Labeling on the website will be the version that is EPA-approved, state-approved, and authorized by the registrant for release

14

Web-Distributed Labeling: Overview of Presentation



15

Web-Distributed Labeling: Enhancements to the Basic System

- Labeling links to Endangered Species bulletins, State requirements, site-based regulatory decisions, advisory information, NAFTA labels, MRLs
- User feedback on labeling issues
- Download WPS requirements for posting

16

Web-Distributed Labeling: Further Enhancements

With e-submission, additional enhancements become possible:

- Customize printed labeling
  - Highlight changes to labeling within a given timeframe
  - Labeling in different languages
- Searchable database
  - Search on many parameters, e.g., use sites or products with groundwater concerns

17

Web-Distributed Labeling: Activities to Date

- Engaged a number of stakeholders
  - Individual stakeholders & associations; PPDC
  - Continue to refine details of web-distributed labeling
- EPA workgroup developed discussion papers
- Formed PPDC workgroup for formal feedback to the Agency

18

Web-distributed Labeling: Role of the PPDC Workgroup

- Provide additional feedback on the concept
- Review and provide comments on the discussion papers
- Provide advice to EPA through recommendations to the full PPDC

19

Web-Distributed Labeling: PPDC Workgroup Discussion Areas

Topics under consideration

- What types of products would be covered?
- What content should be on the label and what should be on the labeling?
- How will stakeholders be educated about the change in distribution of labeling?
- How will users without internet access obtain the current labeling?
- Where should the website should be hosted and what content should be included?
- If web-distributed labeling should have a lifespan, and how long it should be?
- What metrics will be used to measure the effectiveness of the pilot?

20

Web-Distributed Labeling: PPDC Workgroup Process

- Series of meetings/conference calls to provide comments on discussion papers developed by EPA workgroup
  - 2 discussion papers per meeting/conference call
  - Monthly meetings
- Provide input based on experience
- Report back to full PPDC in Spring 2009

21

Web-Distributed Labeling: What are the next steps?

- Engage PPDC Workgroup
- Develop set of proposals based on feedback, including: elements of scope; necessary rulemaking; implementation issues (e.g., timing, transition)
- Put proposals out for broad-based public comment
- Develop, implement, and assess a pilot project

22