

PPDC Subgroup on Web-Distributed Labeling Workplan & Schedule

The Workgroup on Web-Distributed Labeling will advise the US EPA through the Pesticide Program Dialogue Committee on a process to ensure the most current version of pesticide labeling is available to purchasers and users electronically. The Workgroup members will provide feedback on documents, provide input based on expert experience, and ultimately present their recommendations to the full Pesticide Program Dialogue Committee. While Workgroup consensus is welcome, it is not required – EPA is interested in receiving feedback from the PPDC Workgroup members.

Discussion Papers

To begin, the PPDC Workgroup received a briefing on the basic issues involved with web-distribution of pesticide labeling. This will be followed by a series of face-to-face and teleconference meetings to review discussion papers developed by an EPA workgroup and to discuss additional issues raised by the PPDC Workgroup. The discussion papers cover major aspects of web-distributed labeling that EPA believed warrant focused attention based on initial conversations between EPA and stakeholders. The papers are designed to lead the PPDC Workgroup through consideration of elements of the web-distribution of labeling process from development to implementation and assessment. With all discussion papers, the primary questions to the PPDC Workgroup are:

1. Are the issues framed clearly enough?
2. Are the advantages, disadvantages and all options covered?
3. Do you agree or disagree with the recommendation? Why?

Synopses of the eight discussion papers developed by the EPA workgroup follow.

Scope of Web-Distributed Labeling

EPA is working to establish a system whereby purchasers and users may obtain a legally valid copy of the labeling for a pesticide product from a website or toll-free telephone service. This paper explores the scope of this system and also the scope of a pilot project by considering which products should be included, whether the system should be mandatory or voluntary, and if additional selection criteria should be considered for the pilot project.

Content of Container Label vs. Web-Distributed Labeling

Some elements of pesticide labeling are required by statute or regulation to appear on the container-affixed label, and others are required to accompany the pesticide container. This paper outlines what labeling elements must or should appear on the container-affixed label or accompany the container, and what elements could benefit the user by being delivered using a streamlined, dynamic method under web-distributed labeling.

Functionality of Web-Distributed Labeling

The primary goal of web-distributed labeling is to make the most current version of state-approved marketed product labeling easily available to users electronically. To achieve this, the web-distributed labeling system must have certain features, like access to current labeling, historical versions of labeling for enforcement, and the ability to retrieve labeling approved for

use in a specific state. This paper covers what minimum functionality would be necessary and what enhanced capabilities should be considered for inclusion in the web-distributed labeling system.

Outreach, Education and Culture Change

An effective communication strategy that informs pesticide users about the transition to web-distributed labeling, how to obtain labeling, and their continued responsibility to comply with the labeling is necessary to ensure that web-distributed labeling provides at least the same, if not a greater, level of protection for public health and the environment as traditional paper-based labeling. This paper provides an overview of the types of communication messages, how they will be delivered and who should be involved in development and dissemination of the information.

Website Portal & Database Hosting

The primary goal of web-distributed labeling is to make the most current version of state-approved marketed product labeling available to users electronically. This system will require large amounts of labeling language to be available via the Internet. This paper builds on the website functionality paper by reviewing what entity or entities should host the state-approved marketed product labeling for web-distribution and whether this type of labeling should be accessed through a single or multiple portals & websites. This paper discusses options for the website portal (entry point) and databases, and potential hosts and the advantages and disadvantages associated with each.

Alternative Delivery Mechanism for Web-Distributed Labeling

EPA must ensure that all pesticide users have access to any pesticide labeling delivered through a web-based system. As such, alternate mechanisms of delivery must be developed to provide pesticide labeling to those users who do not have access to the web and/or the necessary technology to download and print pesticide labels. This paper outlines alternative delivery mechanisms (fax on demand, U.S. Postal Service) and the advantages and disadvantages associated with each.

Web-Distributed Labeling Lifespan

Web-distributed labeling would establish a new way of making the labeling of a pesticide product available to purchasers and users. Instead of obtaining the labeling along with the pesticide container at the time of product purchase, a purchaser or user would be allowed / required to obtain a copy of the labeling either by downloading a file from a website or by calling a toll-free telephone service that would then mail or fax the labeling to the caller. The new system of obtaining labeling would decrease the time between a protective regulatory decision related to pesticide labeling and implementation in the field, but it would depart from the widely prevailing practice of associating labeling with a specific container (which physical association effectively creates the limited lifespan for the validity of labeling). This paper addresses questions about how EPA should design the system so that users obtain and follow a relatively current version of the labeling for a pesticide they use repeatedly.

Program Assessment

A critical element of program implementation is measuring its impact. For web-distributed labeling, program assessment has both short- and long-term goals. In the short-term the Agency

wants to determine the capability and effectiveness of the pilot, how the pilot was received by users, and the user's preferences when given choices for delivery of the labeling. The data collected must be meaningful, meet the needs of various stakeholders, and inform the future direction of the web distributed labeling program. A longer term goal is to determine if web distributed labeling has had an effect on the Agency's ultimate goal of protection of human health and the environment by changing the way users interact with and follow product labeling. This paper covers potential areas of evaluation and assessment, and how they could be conducted.

Additional Areas for Consideration & Information

In addition to the areas covered by the discussion papers, EPA encourages consideration of other issues raised by Workgroup members as time and interest permit. At the initial meeting, the PPDC Workgroup offered several other areas related to web-distributed labeling for consideration: enforcement, liability, standardizing the content and/or format of pesticide labels and labeling, impacts on stakeholders, and how the recommendations will be realized in a pilot. PPDC Workgroup members have also suggested informative presentations that could enhance the Workgroup members' overall understanding of pesticide labeling and allow better informed feedback and discussion. These presentations include a pesticide labeling flow chart, EPA's e-submission initiative, and information from private pesticide labeling websites and a discussion with pesticide users on how they use and are affected by pesticide labeling. A tour of an agricultural retail facility may also be possible. The additional areas for discussion and potential presentations are briefly summarized below.

Additional Discussion Areas

Enforcement of Web-Distributed Labeling

What changes in labeling, if any, would be needed to ensure that EPA, States, and Tribes can effectively enforce restrictions and requirements appearing in web-distributed labeling? What constitutes "possession of the label", a paper copy or an electronic file on a hand-held device or laptop? What other enforcement challenges and issues will be faced by EPA, the States, and Tribes?

Liability Associated with Web-Distributed Labeling

How would the implementation of web-distributed labeling affect the potential liability of users, dealers, registrants and EPA? How will it be addressed?

Standardizing the Content and/or Format of Pesticide Labels and Labeling

Should the PPDC Workgroup recommend to EPA (through the full PPDC) that EPA promote standardization of the content and/or format of pesticide labeling – either for products using web-distributed labeling or for all pesticides? If so, how should EPA approach such a project?

Impacts of Web-Distributed Labeling on Stakeholders

Implementation of web-distributed labeling will affect stakeholders throughout the pesticide development, registration, sales, use and disposal cycle. What impact will the proposed system have on each stakeholder group?

PPDC Workgroup Recommendations' Impact on the Pilot

Once the PPDC Workgroup has reviewed the discussion papers and made recommendations, how will they be incorporated into the pilot? Will the PPDC Workgroup be involved in the pilot?

Informational Presentations

Pesticide Labeling Flow Chart

A non-EPA workgroup has been developing a comprehensive flow chart to diagram the steps in a pesticide's lifecycle from research and development to sale in the marketplace. This is a very involved process and understanding the process would help PPDC Workgroup members understand the potential impacts of web-distributed labeling and how the process could be changed.

EPA's E-Submission Initiative

Apart from web-distributed labeling, EPA is developing an "E-labeling" initiative which will include structured labeling content, a searchable master labeling database, and the ability for EPA to receive, review and approve master labeling electronically. The system for web-distributed labeling may be linked to state or EPA websites, but it is not a requirement. Nevertheless, the PPDC Workgroup might benefit from an understanding of this initiative and its potential relationship to a web-distributed labeling system.

Private Labeling Websites

Several private and non-profit organizations currently maintain websites that make labeling information available online. Presentations from these organizations on how their websites operate, what capabilities they have, and how they have been developed could be helpful in providing and understanding of existing systems that could be used as models for or adapted to work with web-distributed labeling.

Discussion with Pesticide Users

EPA staff had the opportunity to meet with a panel of pesticide users and dealers to have a discussion on web-distributed labeling. The perspective offered by the end users on how frequently they purchase products, how long they keep them, and what labeling information would be most useful to them was very informative. A similar exchange between the PPDC Workgroup and pesticide users could be beneficial as well.

Agricultural Retail Facility Tour

Retail facilities are the link between pesticide manufacturers and end-users, and PPDC Workgroup members might benefit from a better understanding of retail facilities and their function in the pesticide lifecycle. Retail facilities may play a critical role not only in distributing products, but in providing information to pesticide users about pesticide formulation.

Schedule for PPDC Workgroup on Web-Distributed Labeling

The PPDC Workgroup will use a combination of conference calls and face-to-face meetings to review and provide feedback on the discussion papers, to develop and present the additional issues raised, and to listen to presentations that may enhance the workgroup's understanding of pesticide labeling issues. The sequence of the discussion papers, additional issues and presentations is designed to improve the PPDC Workgroup's overall understanding of web-

distributed labeling and how it will impact the existing system, so members can engage in productive discussion and provide informed comments. Some of the additional issues raised cannot be addressed until recommendations on specific discussion papers have been made. For the most part, these additional issues will be developed and presented by PPDC Workgroup members. An agricultural facility tour and discussion with pesticide users may be included depending on availability and interest of the PPDC Workgroup and the respective groups. The following schedule is flexible and includes check-in points to allow additional issues to be raised and addressed by the PPDC Workgroup as time and interest warrant.

Tentative Workgroup Schedule

January 2009 - Conference Call

- Discuss *Functionality of Web-Distributed Labeling*, and *Outreach, Education and Culture Change*

February/March 2009 – Conference Call

- Presentations on the pesticide labeling flowchart and EPA's e-submission initiative

April 2009 – Face-to-face meeting in conjunction with full PPDC meeting

- Presentations from and discussions of existing websites for pesticide labeling information
- Discuss *Website Portal & Database Hosting* and *Alternate Delivery Mechanism for Web-Distributed Labeling*
- Workgroup status discussion – any new issues?

May 2009 – Conference Call

- Discuss *Web-Distributed Labeling Lifespan*
- Discuss enforcement of web-distributed labeling

June 2009 – Conference Call

- Discuss *Program Assessment*
- Discuss liability associated with web-distributed labeling

July/August 2009 – Conference Call or Face-to-face meeting

- Discuss impacts of web-distributed labeling on stakeholders
- Discuss whether or not to recommend standardizing the content and/or format of pesticide labels and labeling
- Workgroup status discussion – any new issues?

September/October 2009 – Face-to-face meeting

- Wrap-up PPDC Workgroup discussions, finalize recommendations
- Discuss web-distributed labeling pilot
- Next steps for EPA, PPDC Workgroup
- Prepare presentation to full PPDC