

US EPA ARCHIVE DOCUMENT

Web-Distribution of Labeling Workgroup Discussion Paper Website Functionality

Issue

The primary goal of web-distributed labeling is to make the most current version of state-approved marketed product labeling available to users electronically. In order to facilitate access to the breadth of information that will be available, what minimum functionality is necessary for the web-distributed labeling website to meet this goal? What enhanced capabilities should be considered?

Assumptions

- Other issues associated with web-distributed labeling (e.g., web-distributed labeling lifespan, scope of web-distributed labeling, and potential hosts for the website portal and databases) are beyond the scope of this discussion paper and will be addressed separately.
- Any option for web-distributed labeling website functionality should not result in unfunded mandates on states or requirements for states to change their existing infrastructure for reviewing and approving container labeling.
- The host(s) of the web-distributed labeling website will be able to meet the minimum standards necessary to provide the functionality recommended.
- The website(s) operator(s) will ensure near 24/7 access and provide prompt customer support.

Background

For certain products, EPA is currently exploring the concept of distributing pesticide labeling information over the internet as web-distributed labeling. The goal of this project is to have a website or websites that could provide users, the public, States, registrants and EPA with the ability to download and print labeling for a specific pesticide product.

For purposes of this discussion, there are two types of labeling: “master labeling” and “marketed product labeling.” When EPA reviews and approves an application, the resulting “master labeling” reflects all of the uses that EPA has allowed to be registered for the specific product. After master labeling is generated, EPA regulations allow the registrant to sell the pesticide with marketed product labeling that is consistent with the “master labeling.” In many cases registrants choose to sell products containing only a subset of the full range of EPA-approved uses; in fact, in a single state, registrants may have multiple versions of marketed product labeling for the same EPA-registered pesticide. Thus, the “marketed product labeling” frequently differs from the master labeling. For purposes of discussion, the term “marketed product labeling” refers to the following: the label physically attached to the container (“container label”), any paper labeling accompanying the product (“container labeling”), and in the future, any “web-distributed labeling” associated with that product.

States require registrants to submit and obtain state registration for any product to be legally sold and distributed in their state. States have different requirements for what registrants must submit – some states require the labeling for each variation of a single product (e.g. labeling for each container size, fragrance, etc. of Brand X insecticide), while others accept one version of labeling per product (e.g. one set of labeling for all Brand X insecticide products that differ only in

container size, fragrance, or other minor characteristics). Pesticide users are required to comply with marketed product labeling. To address the variations in state programs, web-distributed labeling will use a unique identifier for each state registration of a product to ensure that the user can obtain the labeling for the specific product to be used.

As the Agency moves closer to developing a pilot for web-distributed labeling, it must decide what website functionality would best serve all stakeholders. This paper discusses which functions are critical elements of the website, and which would be helpful and encouraged, but are not necessary. The minimum functionality of the website will affect which entity or entities could host the website portal(s) or database(s).

Critical Functionality

To achieve the goals of web-distributed labeling, the website must be able to do the following:

1. House current and accurate, as well as historical versions of web-distributed labeling

Housing the most current and accurate version of web-distributed labeling is critical to implementing this program. A major benefit of web-distributed labeling is that it will put the most current version of marketed product labeling into users' hands more quickly than under the existing processes and procedures. This will benefit the public and environment by getting risk mitigation measures and updated label requirements into the field sooner than under the current paper-based system, registrants by allowing them to amend labels to add or delete uses and have the changes realized almost immediately in the marketplace, and users by giving them access to new or amended use directions more quickly.

In order to achieve these benefits, the host of the website (or authorized administrator) must have the ability to post the revised labeling promptly after approval. Likewise, users should be able to access the labeling promptly after it is approved. When the most current version is downloaded and printed, it will require a time/date stamp for when it was printed as well as when the labeling expires. In addition, the printed labeling will bear the same unique identifier as the label on the container. (See Labeling Lifespan Issue Paper.)

Pesticide labels and labeling are often critical components of enforcement actions. Under the web-distributed labeling system, updates to marketed product labeling will likely occur more quickly than under the existing system. Often, enforcement actions are not immediate; therefore, it is necessary for State and Federal enforcement staff to have access to historical versions of pesticide labeling. For these reasons, the website must also host historical versions of web-distributed labeling.

2. Provide access to web-distributed labeling

- Access marketed product labeling approved in a specific state
Pesticide users are required to comply with marketed product labeling approved and/or registered in the state in which the product will be used. In order to improve label compliance with current and accurate versions of pesticide labeling, users must be able to conduct the initial search for labeling by state.

- Retrieve portions of the labeling segmented by use on a specific site (e.g. use on apples)

Currently, some labeling that accompanies a product is very long, dense and confusing. Users should be able visit the web-distributed labeling website for the state-approved labeling for a specific product and print only the relevant parts of the label for the intended use. For example, a grower using a pesticide on apples should be able to download the required portions of the label related to apples, not for all registered or labeled uses. By providing only the appropriate use directions for apples, the labeling is not cluttered with specific information for other crops. Reducing the amount of information presented to the user to that which is necessary (FIFRA mandated labeling elements, specific use instructions) creates simpler labeling and eliminates unnecessary paper use. Shorter, less confusing labeling could increase the likelihood that users will read the labeling completely and follow all instructions, rather than skimming a long document and potentially missing critical protection information.

- Provide access reliably

The website would need to operate in a manner that is accessible at any time and could handle as large a number of requests for information as could reasonably be expected. In all likelihood, EPA would need to specify some performance standard for the availability of the website.

3. Have a user-friendly interface and be easy to navigate

The website(s) will be utilized by a wide cross-section of pesticide users, regulators, and the general public. Some of the users may have little to no experience navigating the Internet. In order to encourage utilization of the web-distributed labeling system website, it is important that it be intuitive and easy for an inexperienced Internet user to navigate. For example lists and drop down menus should be utilized where possible. [Note: The specific characteristics which would make a website “easy to navigate” will depend to a significant extent on the functionalities the website is expected to have. There will also be alternate delivery methods via phone, fax or mail by which users can obtain web-distributed labeling.]

4. Enforce appropriate security and access rights

To apply pesticides in a safe, lawful manner, users will rely on the information accessed from the web-distributed labeling website(s). Therefore, it is critical that the application’s design will minimize the possibility of unauthorized users uploading, editing or otherwise tampering with web-distributed labeling information. For example, the system will maintain password-protected access and an audit history for users performing any activity other than accessing labeling (e.g. uploading web-distributed labeling).

Other Potential Functionalities

The functionalities described below could benefit stakeholders, but are not critical components of a web-distributed labeling system. These functionalities would expand on the critical functionalities outlined above by providing enhanced search capabilities, more refined label retrieval, and links to non-labeling resources. Although EPA will consider the inclusion of these elements as part of web-distributed labeling, we recognize that they are not necessary.

- Single URL to access web-distributed labeling; static web-distributed labeling sites

A single URL, e.g. www.webdistributedlabeling.com, would allow users to visit a single website to search for and download all labeling. All marketing and outreach materials could focus on a single message and website, rather than instructing users to find and visit the website listed on each container. Users could enter the product registration number or another unique identifier to access the labeling for the specific product.

Static web addresses for web-distributed labeling could be used for bookmarks and shortcuts. For example, www.webdistributedlabeling.com/ProductX_current.htm would always link to the current labeling for Product X. This static web address could function in several ways: allow the user to choose the state where the pesticide will be applied and enter the registration number or unique identifier, or link directly to the marketed product labeling. This would allow users to ensure that they are always linking to the current version of the labeling without having to search through the website.

- Highlight changes to the labeling

Users frequently purchase the same product year after year. Once they are familiar with the labeling requirements, they may not take the time to read the labeling carefully each time they use the product. In order to assist with compliance the system should be able to highlight changes (e.g. application rate, new uses, new restrictions) made within a certain time period. This period could be linked to the lifespan of web-distributed labeling or based on other factors.

- Access related materials, such as material safety data sheets (MSDS), training modules, manuals and reference materials.

Although not a critical component of pesticide labeling, ancillary materials that support the safe use of a pesticide are valuable tools. Registrants could use this feature to provide information to its customers that is not required to be part of labeling, but could be beneficial to users. Training organizations could use the platform to provide training material related to specific application techniques such as calibration of nozzles for aerial application. Users could benefit from the additional knowledge.

In order to include this functionality on the website, it would have to be differentiated from the elements of pesticide labeling with which the user is required to comply. Disclaimer language would need to be added to inform the website users that by linking to the ancillary materials, they are leaving the official pesticide labeling. Otherwise, changing, adding or deleting links or

pages for non-labeling materials could be considered labeling and would increase significantly the burden on EPA and States to review all materials, and on registrants to notify EPA and States of all changes.

Some of the product-specific external resources could include:

- a. Material Safety Data Sheet
 - b. Worker Protection Standard Training Materials
 - c. Endangered Species Protection Program Website
 - d. National Pesticide Information Center
 - e. Company contact information (see Error! Reference source not found.) (Note: we want to make it clear that questions on product information should be directed to companies whereas questions on use directions, etc. should be directed to states or EPA)
 - f. Incident reporting (state and Federal)
 - g. Poison control hotline
 - h. "How To" documents and videos (e.g., how to calibrate a sprayer, how to mitigate spray drift, how to apply aquatic pesticides)
 - i. Links to definitions and photographs of compliant PPE (e.g., label requirement to use a respirator with MSHA/NIOSH approval number prefix TC-21C links to a representative photograph)
 - j. Product-specific technical bulletins and FIFRA Sec 2(ee) recommendations on tank mixes, application timings, and adjuvants to enhance efficacy and/or reduce crop injury
 - k. Information on state clean sweep program locations and dates
 - l. Information on container recycling or disposal
 - m. Information on resistance management and IPM
 - n. Access to fillable forms (e.g., fumigation management plans)
 - o. Stewardship information
 - p. Rate calculator
 - i. Pounds active ingredient per acre (or other appropriate measure used by EPA for risk assessment purposes)
 - ii. Units of product per area as specified on product label
 - iii. Application estimator (i.e., how much of product X would be needed for a user-defined plot size applied at a user-defined application rate not to exceed the maximum labeled rate)
- Search and refine queries across all web-distributed labeling products to filter pesticide products by various criteria (e.g. application site, target pest, signal word, personal protection equipment required, pre-harvest interval)

The cross-cutting search function of any web-distributed labeling system could prove to be an important marketing tool to highlight the benefits of web-distributed labeling to users and other stakeholders. For example, users can use this search function to search all web-distributed labeling products to find those registered in a specific state for use on a specific crop. This search function could also be important to consultants, dealers, university research and extension staff, and advocacy groups.

Some of the features that could be part of such a search function include:

1. Product locator
 - a. Select product from list/dropdown menu
 - b. Search by manufacturer's name, product name, active ingredient(s), EPA Registration Number, state and use site, target pests, product type (Section 3, Section 18, Section 24c)
 2. States/counties that permit application
 3. Search by state/county, use site, pest; drop-down menus are populated based on previous drop-down menu selection
 4. Interactive state/county map
 5. Compare labels
 - a. Compare current/historical labels of the same product
 - b. Compare current labels of multiple products
 - c. Toggle "highlight changes" on/off
- Submit and access the most current and accurate version of master labeling

Currently, the public can access master labeling through the Pesticide Product Labeling System. As mentioned above, the master label contains all registered uses approved by EPA. This does not mean that States have approved each use for a product, or that registrants have marketed every use in every state. Apart from web-distributed labeling, EPA is developing an E-label 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. We anticipate that this database, which will encompass all products, will be more comprehensive than the web-distributed labeling database(s), because it will include all products rather than only those employing web-distributed labeling. It may be possible to use the structured EPA database to populate the web-distributed labeling database, either as the primary database or as one of several databases with product information.

Options

Pilot

The pilot for web-distributed labeling will likely include at most a few products in a few states. It may be limited to certain uses for the participating products. Since this exercise will be limited in scope, the associated website does not need to provide each functionality outlined above. At a minimum, the pilot website must:

- House current and accurate, as well as historical versions of web-distributed labeling
- Provide access web-distributed labeling
- Have a user-friendly interface and be easy to navigate
- Enforce appropriate security and access rights

Full Implementation

The functionality of the website for full implementation may evolve, and will depend on the outcomes of the pilot. At a minimum, the website must include the critical elements outlined

above. Offering a search function to users would broaden the audience that could potentially benefit from web-distributed labeling.

- Critical elements
- Ancillary materials
- Master labeling
- State-specific and cross-state searches