

US EPA ARCHIVE DOCUMENT

Web-Distributed Labeling Workgroup Discussion Paper Potential Benefits & Challenges of Web-Distributed Labeling

Introduction

During a recent meeting of the PPDC Web Distributed Labeling (WDL) Workgroup, several group members questioned further investments of time and energy towards implementing WDL until potential benefits of the initiative are identified. The document identifies potential benefits of WDL to different stakeholder groups, along with challenges and unresolved issues. This paper explores many of the perceived benefits of WDL that are known today, although additional benefits may be realized as WDL develops.

It is also noted that WDL is initially proposed as a voluntary option for registrants, and WDL would not be appropriate for all pesticide products. Instead, it is likely that WDL would be used primarily for those products with labeling that is long or changes frequently and that are used by people primarily in the course of their business activities. The potential benefits described in this paper would be realized only for those registrants, users, and dealers of products that are labeled with WDL.

Some benefits will be realized by all involved stakeholders, although others are more stakeholder-specific. The following are just some of the key benefits of WDL that are discussed in this paper:

- Access to state-specific and site-specific streamlined, easy-to-read labeling
- Labeling available in larger fonts
- Improved labeling compliance
- Web linkages to product stewardship information
- Reduced labeling costs and redistribution expenses to registrants
- Faster access to newly-registered uses
- Faster implementation of risk mitigation measures
- Reduction in multiple versions of labeling in the marketplace

Benefits and Challenges for Specific Stakeholder Groups

The following sections outline potential benefits and challenges for:

- Pesticide Users
- Registrants
- Pesticide Dealers/Retailers
- Farm Workers and Worker Advocacy Groups
- State and Tribal Pesticide Regulators
- United States Environmental Protection Agency

Pesticide Users

a. Benefits

1. *Access to streamlined, easy-to-read labeling*
WDL would be used to deliver streamlined labeling for users, thereby replacing 50-page multi-crop labeling with site-specific labeling that is only a few pages. This could make it dramatically easier and faster to ascertain how to safely, effectively, and legally use products. It should also improve compliance with labeling restrictions.
2. *Access to larger fonts*
A common complaint among users is the small font size found on many container labels and attached labeling. WDL should make it possible for users to customize font size for printed labeling. Users with electronic versions of WDL can simply use software to enlarge the labeling image on a computer screen.
3. *Faster access to newly-registered uses*
Re-labeling of containers with hard-copy labeling is a time-consuming and expensive process. Because of this, there is often a significant lag time in re-labeling containers as newly-labeled containers gradually replace existing containers in the channels of trade. Users may therefore be unable to immediately access container labeling that contains newly-registered uses. They may also be unable to quickly access supplemental labeling with the newly-registered uses. With WDL, updated labeling could immediately be posted on the Internet upon EPA and state approval, making newly-registered uses immediately available. This should provide greater flexibility in dealing with existing stocks of materials since existing containers would not need to be re-labeled with the updated container labeling.
4. *Verified access to state-approved labeling*
Some users make applications in more than one state, and there is increasing use of Internet vendors to market pesticide products. As stated above, many states require users to comply not only with a product's container labeling, but more specifically with the labeling approved by that state. Under the current system of hard-copy labeling, there is no good means for users who buy products in a different state or from the Internet to verify whether the labeling in their possession matches the labeling version approved in the state where the product is being applied. WDL could make it much easier for users to verify that the labeling in their possession is approved for use in the state in which they intend to use the product.
5. *Improved standardization of labeling*
Although federal regulations require all pesticide labeling to have certain sections, there are generally no requirements for the order in which those sections are

found on labeling. Furthermore, related restrictions and precautions can be found throughout the labeling in different sections. This lack of standardization can make it difficult for users to find those portions of the labeling pertaining to their intended use site. A parallel project to WDL is the electronic submission of pesticide labeling for pesticide registrations. The electronic submission process and building websites for WDL may be facilitated through the use of structured product labeling and increased standardization of how labeling is formatted and arranged. Greater standardization could make it easier for users to read (and therefore, comply with) labeling restrictions, precautions, and directions.

6. *Better access to product stewardship information*

The container label on a WDL product would direct users to a website to access and download the labeling specific to the product. The website could also provide or link to useful information in addition to the labeling, such as product stewardship information on reducing drift, choosing nozzles, calculating use rates, state pesticide disposal programs, container recycling, and more.

7. *Multiple delivery methods*

With WDL, pesticide users would be able to choose the delivery method and format of WDL that best meets their needs, including direct download in portable document format (PDF), HTML or PDF via email, mobile labeling delivery via text message, barcode scan delivery to a mobile device, FAX on demand, or an email/phone request for a hard copy to be mailed through the US postal system. This flexibility does not exist under the current system of hard-copy labeling.

b. Challenges & unresolved issues

1. *Lack of high-speed Internet access in all areas*

Many parts of the rural U.S. still lack high-speed Internet access, and many farmers continue to rely on dial-up modems for Internet access. In addition, not all pesticide users have Internet access of any kind. However, people are resourceful and rely a variety of means to get the information that they need. Also, delivery mechanisms other than direct Internet access will be offered for WDL.

2. *Need for culture change*

The transition from hard-copy container labeling to WDL will require a significant amount of education of the regulated community. Not all pesticide users may be comfortable with this change, especially if they are unaware of the concept until it is implemented. WDL would not be used for all products so outreach can be targeted to industry sectors. Implementation of a web-distributed labeling system would include sufficient time to transition from the traditional paper-based system, allowing regulators, extension personnel, and others to educate the public.

3. *Expiration dates and older products*

Under the current system of hard-copy labeling, users can continue to use a product according to the labeling found on the container for as long as they possess the product. The exceptions to this are the rare instances when EPA has issued a use cancellation date or when a product is no longer registered in a state and that state's laws prohibit the use of unregistered pesticides. This practice allows users to use a product many years after the product is purchased. With WDL, the labeling accessed at an Internet site would change over time as uses are added or removed. This could mean that labeling might not be valid indefinitely. One strategy is to establish an expiration date for WDL based on download date or production lots. However, the challenge is to establish expiration dates long enough to allow the large majority of users to continue using product until the product is completely used, but not so long that a user can continue using the downloaded labeling forever. If the expiration date is too short, some purchasers of pesticides may not be able to legally use the complete contents of a container for the site for which the product was intended at the time of purchase. This could create product disposal issues.

Registrants

- a. Benefits
 1. *Reduced labeling costs*

Labeling containers with hard-copy is extremely expensive. It is also expensive and resource-intensive for registrants to re-label containers in the channels of trade when new uses are registered or existing uses are cancelled. With WDL, registrants could "re-label" large numbers of products instantly by simply changing the document accessed at a defined Internet site.
 2. *More market sector-specific labeling*

The current paper-based labeling system makes it difficult for registrants distribute different versions of labeling for the same product in a similar region without causing confusion. WDL would include streamlined directions on the container label, but most of the site and state-specific instructions would be included on the downloaded labeling. Registrants could use WDL to target marketing and distribution to specific markets, use patterns, or user groups. Registrants could then be confident that users had ready access to the use instructions in a more readable format. For example, a product with broad use patterns (turf, industrial, agricultural, forestry) could be marketed differently based on the different uses through WDL.
 3. *Faster market access*

Because of the time involved with re-labeling containers with hard-copy labels, there is a usually a lag time between when uses are registered and when those re-labeled containers reach retailers and end users. This can delay user access to

newly-registered uses, even when registrants use supplemental labeling. WDL could result in almost instantaneous access of users to new labeling, as well as access of registrants to certain markets.

4. *Promotes level playing field*

Under the current system of hard-copy labeling, EPA may require labeling revisions for a category of products, for example products containing a specific active ingredient. Even though EPA may establish a single date for making such changes, the products from different registrants or for different formulations from the same registrant can reach the market at different times depending on market forces and differences in supply chains. With WDL, labeling revisions can be implemented simultaneously, promoting a level playing field for different companies marketing the same active ingredient.

5. *Faster removal of uses from marketplace*

Registrants frequently remove uses from pesticide labeling, either voluntarily through marketing decisions or through a regulatory mandate. Just as it allows for faster market access for new uses, WDL could facilitate faster removal of uses from the marketplace.

6. *Enhanced Inventory Management*

All states have a state pesticide registration program, making it illegal to distribute or sell (and, in some states, to use) a product that is not registered in the state. In some states, pesticides can also be deemed misbranded if they are distributed with labeling other than the labeling that has been registered by the state. Since the version of labeling approved in one state may differ from that registered in other states, registrants must manage their inventory to ensure that pesticides shipped into a state are appropriately labeled. With hard-copy labeling, this may necessitate the re-labeling of containers prior to shipping products across state lines, or a registrant may simply choose to not market products in certain states if inventory management is not feasible. With WDL, registrants could customize the labeling for a given state and site, thereby addressing state-specific differences in labeling without re-labeling containers.

b. Challenges & unresolved issues

1. *Tort liability questions*

There are many concerns about whether the institution of WDL will alter the tort liability of pesticide registrants. Would those who adopt the WDL approach be more vulnerable to tort litigation if users do not comply with requirements to obtain labeling? Conversely, would registrants who opt out of the WDL process be more vulnerable to tort litigation for failure to employ technology that could better inform customers how to use products safely and effectively?

2. *Enforcement liability questions*
There are questions about how FIFRA enforcement might change under a WDL system, including who would be responsible if the WDL downloaded from a website is incorrect and whether a product is registered in a given state. This may concern some registrants because they are likely to be held responsible to ensure that all WDL labeling is correct. However, registrants also have this responsibility with hard-copy labeling, so the issue may be with information technology rather than regulation.
3. *Gaining acceptance by dealers and users*
Although the current system of hard-copy pesticide labeling is imperfect, most pesticide dealers and users understand it. With any significant change, there may be those that resist the change and voice their concerns. Discomfort with change and technology may push some customers and dealers toward products with hard-copy labeling, at least initially. Outreach and education targeted to both pesticide users and dealers may reduce the concerns expressed if WDL is implemented.
4. *Increased standardization of labeling format*
Implementation of WDL may lead to pressure for increased standardization of how labeling is formatted. Some registrants may view any increased uniformity as a limitation on their creativity.
5. *Customer Acceptance*
The transition from hard-copy container labeling to WDL will require a significant amount of education of the regulated community. Not all pesticide users may be comfortable with this change, especially if they are unaware of the concept until it is implemented. In order for registrants to realize the full benefits of WDL, they would need to ensure that their customers are aware of and willing to accept the transition.

Pesticide Dealers/Retailers

- a. Benefits
 1. *Greater customer understanding of product labeling*
How many times does a dealer get a question from customers on how to safely, effectively, and legally use a product that they have purchased or intend to purchase? With streamlined WDL, the use directions would be site-specific and may include application-specific instructions. This should increase customer understanding and reduce the number of questions to dealers on labeling interpretation.
 2. *Capitalizing on customer service*
People who apply pesticides as part of their business rarely go to a dealer and read the labeling in the dealer establishment. Therefore, they will continue to depend on dealers, agronomists, and other parties for expertise and assistance in making

product choices. WDL would allow for a direct connection between the dealer and the applicator that is purchasing the product. Some customers may also ask dealers to access and print WDL. This sales and communication opportunity could increase customer loyalty to dealers who offer these services.

b. Challenges & unresolved issues

1. *Increased demand for customer service*

There will almost certainly be requests from customers for dealers to access and download WDL for their purchases. While some retailers may view increased customer service as an opportunity to gain sales and customers, others could view it as a burden. Some retailers may also need to train their employees to better serve customers and deal with technology.

2. *IT investments & Lack of high-speed Internet access*

Some dealers may not have computers or high-speed Internet access. Many parts of the U.S. still lack high-speed Internet access, and dealers and farmers in those areas continue to rely on dial-up modems for Internet access. If they choose to download and print WDL as a service to their customers, those dealers will need to make technology upgrades and budget their services accordingly. Dealers may also build relationships with libraries, coffee houses, and other locations that already offer Wi-Fi and other technologies to access the Internet.

3. *Liability questions*

Some have raised questions as to whether dealers would have any responsibility to ensure that the purchaser of a product accesses the WDL, and whether dealers incur any liability if they access incorrect WDL on behalf of a customer. EPA's enforcement issue paper makes it clear that it is the ultimate responsibility of the pesticide user to obtain and comply with the correct version of the WDL. Such a regulatory position should adequately address the liability concerns voiced to date by dealers, although this issue continues to generate further discussion.

Farm Workers and Worker Advocacy Groups

a. Benefits

1. *Better risk mitigation*

As already discussed, two benefits of WDL would be the availability of a streamlined container label, and the ability of the WDL system to provide shorter, site-specific labeling. The first would allow employers and employees to find those sections of the container label that address worker safety, such as first aid, emergency contact information, personal protective equipment, and re-entry intervals. The shorter, site-specific labeling would also increase the likelihood

that pesticide users will read and comply with the labeling requirements, thereby improving risk mitigation.

2. *Better communication with non-English-speaking workers*

Use of technology would make it possible to better communicate to non-English-speaking workers or those persons with low levels of literacy. While the container labeling will direct users to Internet sites with enforceable labeling, the WDL system could also incorporate links to Internet sites with product stewardship information. These websites could use streaming video, pictures, and other methods to better convey how to safely use and handle pesticides. If resources have been translated, they could also be made available in languages other than English.

b. Challenges & unresolved issues

1. *Lack of high-speed Internet access*

High-speed Internet access, or any Internet access for that matter, is not accessible for some farm workers, especially migrant workers. Therefore, some workers may not be able to directly access WDL because full container labeling would not be available. However, safety-related information would be on the label affixed to the container.

2. *Limited scope of the WDL system*

Participation in the WDL system would be voluntary and advocacy groups may have interest in products that are not part of the WDL system. Although the WDL system might not meet all of the needs of advocacy groups, that instituting a WDL system would not decrease the amount of information available.

State & Tribal Pesticide Regulators

a. Benefits

1. *Better user compliance & risk mitigation*

A fundamental tenet of pesticide regulation is the belief that a pesticide will not cause unreasonable adverse effects to human health or the environment as long as it is used according to the labeling. However, pesticide labeling can be long and difficult to read, and anecdotal information suggests that some pesticide users do not fully read the labeling for that reason. WDL could be used to deliver streamlined labeling for users, thereby replacing 50-page multi-crop labeling with site-specific labeling that is only a few pages. This should increase the number of pesticide users reading, and therefore complying with, the pesticide labeling.

2. *Faster implementation of new labeling requirements*

Many times, new labeling restrictions are implemented to better mitigate risk or to add newly-registered uses. However, it can sometimes take months or years for re-labeled pesticide products to reach the channels of trade and the hands of users.

WDL could be used to get revised labeling in the channels of trade sooner. This is especially beneficial for market entry of reduced-risk uses and products.

3. *Reduction in multiple versions of labeling in the marketplace*

With the current system of hard-copy labeling, there is often a significant lag time in re-labeling containers as newly-labeled containers gradually replace existing containers in the channels of trade. During this interim period, there are multiple versions of product labeling in the channels of trade. The multiplicity of versions of product labeling also occurs as a consequence of the practice using supplemental labeling to allow for the legal use of newly registered uses. This proliferation of labeling can create confusion among pesticide users. It can also cause regulatory challenges because it is difficult to verify what version of a product's labeling a user had in their possession during use. For participating products, the WDL system would largely eliminate multiple versions of labeling in the channels of trade and the use of supplemental labeling.
4. *Easier verification of compliance with state-registered labeling*

All states have a state pesticide registration program, making it illegal to distribute or sell (and, in some states, to use) a product that is not registered in the state. This involves a state reviewing labeling. However, this labeling can vary greatly among states, either because some state-specific language may appear only in the relevant state or because of other voluntary differences in labeling by registrants based on market forces. In many states, a product can be deemed to be misbranded under state law if it bears labeling other than what has been registered by the state. Under the current system of hard-copy labeling, it is difficult or impossible for state regulators to verify whether the applicator is using labeling that matches approved by the state. By using technology available to compare different versions of similar electronic files, WDL should make this verification much easier.
5. *Increased standardization of labeling format*

Although federal regulations require all pesticide labeling to have certain sections, there are generally few requirements for the location or order in which those sections appear in labeling. Furthermore, related restrictions and precautions can be found throughout a product's labeling in different sections. This lack of standardization can make review difficult. A parallel project to WDL is the electronic submission of pesticide labeling for pesticide registrations. The electronic submission process and web-produced WDL may be facilitated through the use of structured product labeling and increased standardization of labeling format.

b. Challenges & unresolved issues

1. *Lack of Internet access for State inspectors*
Some agencies do not have Internet access for field inspectors. In order for WDL to be of most utility to regulators, State inspectors should be able to access the website in the field to compare the state-registered version of labeling with the version in the possession of the applicator.
2. *Defining appropriate labeling formats “in possession”*
With hard-copy labeling, regulators can usually verify labeling compliance during use inspections by simply referring to the labeling accompanying a product container (if the container is available). However, with WDL, the labeling would not be physically attached to the container. Because of this, most regulators agree that there should be a requirement for the user of a product with WDL to have a copy of the labeling in their possession during use. While some states may allow the labeling in the possession of the user to be in an electronic format, other states may want the labeling to be in hard-copy format. This may cause confusion among users, especially those that make applications in more than one state.
3. *Conflicts with state-specific laws or regulations*
Some states may have statutory or regulatory requirements that address the distribution of pesticide labeling, including the allowed formats for labeling being distributed. Distribution of web-based labeling may conflict with the laws and regulations in some states. If EPA establishes a WDL system, the effect of FIFRA sec. 24(b) – which prohibits states from “impos[ing] or continu[ing] in effect any requirements for labeling . . . different from those required under [FIFRA]” – on any such provisions would need to be evaluated.

US Environmental Protection Agency

a. Benefits

1. *Improved protection of public health and the environment*
Product labeling is the primary mechanism used by EPA to communicate critical information to the pesticide user. The labeling contains use directions, health and safety information, and instructions for proper storage and disposal. Improved comprehension of and compliance with labeling and faster realization of risk mitigation measures in the field, expected benefits of web distributed labeling, would improve protection of human health and the environment.
2. *Improved labeling comprehension & compliance*
A fundamental tenet of pesticide regulation is the belief that a pesticide will not cause unreasonable adverse effects to human health or the environment as long as it is used according to the labeling. However, pesticide products’ labeling can be long and difficult to read, and anecdotal information suggests that many pesticide users do not fully read the labeling for that reason. WDL can be used to deliver streamlined labeling for users, thereby replacing 50-page labeling with labeling

that is only a few pages. The shorter web-distributed labeling would be targeted to the state and target site of the application, providing only the relevant required elements of labeling. Streamlined, simplified labeling should result in a greater likelihood of pesticide users reading and understanding, and therefore complying with, the pesticide labeling.

3. *Faster implementation of new labeling requirements*

The web-distributed labeling system has the potential to dramatically accelerate the speed with which new labeling requirements to protect public health and the environment could take effect. Rather than waiting for paper labeling to work its way through the printing and distribution processes, the new requirements could appear in labeling downloaded from the website within a week or even a day or two after EPA approval. Users who purchased products after the changes were posted on the website would find the new requirements in the labeling they downloaded. Thus, like the current system the new requirements would apply prospectively, to products purchased after the date of EPA's decision. Unlike the current system, it would implement changes much sooner after EPA concluded they were needed. Faster implementation of risk mitigation measures and registration of reduced-risk products could improve the overall safety of public health and the environment.

b. Challenges & unresolved issues

1. *Need for culture change*

The transition from hard-copy container labeling to WDL would require a significant amount of education of stakeholders throughout the regulated community. Not all people will be comfortable with this change, especially if they are unaware of the concept until it is implemented. Stakeholder outreach is critical to the refinement of web-distributed labeling; feedback and support from registrants, users, dealers, educators, state regulators, and environmental groups, and others is necessary to ensure that the concept can be successful. Once stakeholders are comfortable with the concept, broad outreach to all potentially affected parties will occur. Implementation of a web-distributed labeling system will include sufficient time to transition from the traditional paper-based system, allowing regulators, extension personnel, and others to educate the public.

2. *Ensuring a level playing field*

Web-distributed labeling has the potential to benefit registrants who elect to participate in such a system. Although some registrants may elect not to participate in web-distributed labeling, others may not have the capability. EPA must be sensitive to the concerns of those who cannot participate during the development of the web-distributed labeling system and should ensure that the web-distributed labeling system is available to all potential stakeholders.

3. *Conflicts with state-specific laws or regulations*

Some states may have statutory or regulatory requirements that address the distribution of pesticide labeling, including the allowed formats for labeling being distributed. Distribution of web-based labeling may conflict with the laws and regulations in some states. If EPA establishes a WDL system, the effect of FIFRA sec. 24(b) – which prohibits states from “impos[ing] or continu[ing] in effect any requirements for labeling . . . different from those required under [FIFRA]” – on any such provisions would need to be evaluated.

4. *Definition of ‘production’ and registration of establishments*
EPA regulations for the registration of establishments require that an operator must register his establishment if he engages in “production” of a pesticide. “Production” is described to include re-labeling a pesticide. EPA needs to clarify that the action of downloading WDL does not constitute “production” of a pesticide.
5. *EPA Internet Access*
Generally, the private sector adopts developing technology faster than EPA. Implementing WDL would require significant technological advances, including building a database for state-registered labeling, hosting a website/portal, and including security controls to maintain the integrity of labeling. If EPA is required to build and maintain the WDL system, adoption could take longer.

Summary

Although significant questions still remain, the potential benefits and challenges of WDL for regulators, pesticide users, registrants, and other stakeholders must be considered. Other benefits and challenges will likely be identified as the development of a WDL system moves forward.