



May 10, 2013

Steven Bradbury  
Director, Office of Pesticide Programs  
U.S. Environmental Protection Agency (Mail Code 7501P)  
1200 Pennsylvania Ave NW  
Washington, DC 20460-0001

**RE: Pesticides; Draft Guidance for Pesticide Registrants on Web-Distributed Labeling for Pesticide Products. 78 FR 3418. January 16, 2013. Docket No. EPA-HQ-OPP-2012-0906**

Dear Dr. Bradbury:

CropLife America ("CLA") submits these comments on the subject draft Pesticide Regulation Notice ("PRN"). CLA is the national trade association representing the companies that develop, manufacture, formulate, and distribute crop protection chemicals and plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell, and distribute virtually all the crop protection and biotechnology products used by American farmers. CLA is dedicated to supporting responsible stewardship of our products to promote the health and well-being of people and the environment, and to promote responsible, science-driven legislation and regulation of pesticides.

### Overview

CLA commented on a previous version of EPA's proposed Web-Distributed Labeling ("WDL") system on December 29, 2010. Those comments raised significant issues with the proposal. We appreciate that EPA has addressed several of those comments in the current proposal. Specifically:

- 1) Registrant participation is optional;
- 2) Container will carry complete label;
- 3) Each registrant will control its own WDL website;
- 4) There will be no container label expiration date.

We recognize there are still diverse viewpoints among concerned stakeholders on the WDL concepts. Chief among ongoing concerns of CLA and its members about how WDL would be put in practice under the draft Pesticide Registration Notice ("PRN"), are the issues of liability. While some companies are ready to move forward with WDL, others feel that the effort and risks outweigh the benefits. Numerous remaining doubts about the value and practicality of WDL cannot adequately be confirmed or dispelled without a more thorough trial of the ideas. In these comments, we enumerate a number of the concerns and questions that have been raised. We also suggest a "live" pilot project to provide all parties concerned with hands-on evaluation of the

concepts, and to see how the concerns could and would be addressed, before the Agency is irreversibly committed to a particular path.

### **A “live” pilot project to test WDL**

We recommend that EPA conduct a “live” pilot project of the WDL concepts before finalizing guidance in a PRN. This would extend the experience gained in a previous pilot project to a more practical level and could reveal unanticipated difficulties and benefits. It would allow flexibility in adapting requirements while testing such a system, and adjusting what doesn’t work smoothly in actual practice. If a robust, successful pilot effort cannot be mounted, it is highly unlikely that a final PRN would lead to success. When the system proves of value to all involved, the final guidance can be based on actual experience and success.

Similar “live pilots” have been tried with the concepts of own-use import of products into Canada and NAFTA labels. In those circumstances the pilot projects were quite successful in demonstrating the limitations of the concepts, but did not require a great deal of effort on the part of registrants, regulatory authorities, or other stakeholders.

Suggested features of a “live” WDL pilot project:

- Committed representation would be needed from all key sectors that would influence or be influenced by WDL.
- Participants in the pilot should arrive at a consensus up front that representation is sufficient for a meaningful test of the concepts. For example, if key participants or sectors are absent, proof of concepts may not be achievable.
- Interested registrants would be recruited to propose products and submit the corresponding label amendments to adopt WDL. Registrants who are not interested could simply enjoy observer status.
- A handful of interested state lead agencies would be recruited to test the concepts. WDL would only be valid in those states during the pilot project.
- WDL in the pilot project would be legally valid for field use by growers and applicators.
- EPA and states should suspend enforcement of label violations related to WDL participation during a pilot project, working rather on a cooperative notification process, while the details are ironed out.
- A participating registrant could withdraw products from the WDL pilot project or revert a product back to standard labeling by a simple notification, removing the codes and web references from the container label.
- EPA might suggest some specific products from interested registrants for WDL (such as products subject to risk mitigation).
- Two years might be necessary for an adequate study:
  - to get the labels approved and a distribution network (websites) in place;
  - establish a reasonable number of labels for a representative study;
  - accept a limited number of applications;
  - establish EPA and state review processes for approving WDL;
  - commitment by EPA to review the applications promptly;
  - gain experience of label users;

- evaluate the implications of conditions of registration (under FIFRA §3(c)(7)), in light of current controversies.
- Alternative approaches for addressing some of the aims of WDL might be incorporated into the pilot project, such as expansion of supplemental labeling.
- Follow up with a workshop where pilot project participants, EPA, and state regulators share their experiences with all stakeholders.

**Potential Liabilities:**

CLA continues to have concerns about the potential of the proposed WDL system to create or increase exposure to liability for pesticide producers, distributors, and applicators, due to potential confusion the program may engender. A number of potential liability concerns relating to EPA's proposed WDL system encompasses two broad categories: (i) liability for violations of FIFRA and/or corresponding state pesticide laws ("enforcement liability"), and (ii) liability arising from state-law damages suits, primarily for product liability and/or misapplication of pesticides ("product / tort liability"). A WDL system structured or operated in a manner that increases the exposure of registrants, distributors, dealers/retailers, or applicators/users to labeling-related product/tort liability by increasing label-related confusion would undermine the system's appeal and utility. In CLA's view, a WDL system would not be feasible unless liability concerns associated with a WDL system were adequately addressed by EPA.

For these reasons, it is essential that EPA not only identify with greater precision the categories or types of products that would or would not be covered by the WDL system (regardless of whether it is voluntary), but also set forth the rationale for inclusion or exclusion. In addition to developing a better definition of the scope of the system, there should be a mechanism for registrants to obtain from EPA a prompt and definitive determination whether a particular end-use product or type of product is covered by the system, and if so, in which state(s).

We understand that the entire label would be posted on a WDL website, and there is no confusion about what must be included on the complete product container label. But there must be a clear and uniform set of definitions, rules, and procedures regarding what information must appear on the "rendered output" from the WDL system.

Furthermore, the WDL system would need to clearly delineate and allocate functional responsibilities among EPA, state lead agencies, registrants, distributors, dealers/retailers, and applicators/users. In allocating responsibilities, the WDL system must preserve registrants' free enterprise commercial prerogatives. These include, for example, business decisions regarding which particular end-use labels (i.e., products) to market, and when.

**Recommendation:**

In designing a WDL system, EPA, in consultation with industry and other stakeholders, should carefully explore the system's potential enforcement and product/tort liability implications, and should design the system in a way that minimizes the potential for user confusion and the concomitant product/tort liability exposure.

**Simplicity**

Many stakeholders feel that pesticide labeling is too complex and often difficult to understand, and that the existing process of implementing labeling changes is too slow. WDL has been portrayed as one means of addressing these concerns. But simplifying one part of the label process may complicate other parts. In particular, conversion of label text to structured label formatting most consistent with WDL will be time-consuming for registrants and for label review by federal and state authorities.

One rationale for WDL is to provide for the user an excerpt of the complete pesticide label, having the instructions pertinent to a particular crop/use site and the state where the product is to be used, omitting information that is not relevant for that particular use. However, determining what part of a label is or is not relevant, is not necessarily straightforward, and may be subject to differing interpretations by equally competent parties. In the process of further refining the proposed WDL program, prior to finalizing a PRN, it would be useful for EPA to develop a number of detailed examples illustrating what parts of a master label are and are not included in the “rendered output” for a given use site. Until such time as the label format is more standardized (via structured labeling), determining what part of the label is required for each crop/use site by state is extremely difficult.

**Resources**

A complex undertaking like WDL can become a significant burden on already strained federal and state agency resources. The theoretical concept of WDL is promising, but we believe that EPA, state agencies, and registrants alike will face multiple challenges in attempting its implementation. CLA previously outlined a number of resource, logistical, procedural, enforcement, and liability challenges (December 2010, March 2011). It is impossible to anticipate all of the challenges at this early concept stage, one or more of which could seriously delay or hinder the project.

Some commercial services currently offer access for users to excerpted, “streamlined” pesticide labels for individual use sites, comparable to the “rendered output” described in the draft PRN. While such excerpted labels do not qualify now as *enforceable* labels, they offer the same functionality for the user, who has the complete label on the pesticide container.

**Authority of State Governments:**

As the Agency is well aware, FIFRA §24(b) provides that states may not impose labeling requirements in addition to or different from those required by FIFRA. To avoid the potential for confusion, we encourage EPA to provide specific guidance to state regulators and other stakeholders as to how the “state-specific labeling” discussed in the draft PRN will comport with this limitation on state labeling authority. If EPA intends by the use of the term “state-specific” to indicate regional or geographic restrictions or directions for use included on EPA-approved labeling, the Agency should consider using the term “regional” or “geographic”. Use of the term “state-specific” needlessly creates confusion over compliance with FIFRA §24(b). Alternately the PRN should clarify that no state can require a registrant to provide WDL as a condition for state registration, or require label text that can only be practically implemented through WDL.

Similarly, in the public discussion of WDL concepts to date, some state lead agencies have expressed firm opposition to implementation of WDL, based on conflicts with their own state laws and regulations, as well as for other reasons. We are also aware that some states strongly endorse the concept of WDL. It is not readily apparent that the revisions in this draft PRN would adequately address all of the states' concerns. By definition, a PRN is "... not binding on either EPA or pesticide registrants ...", and this draft PRN specifically states that "... EPA is proposing a voluntary approach to WDL ..." It is assumed that it would be voluntary for states, as well, to accept WDL.

How would EPA address a situation where some states choose not to accept or allow WDL use within their states? Such a situation could pose significant complications for registrants wishing to participate in WDL. One might assume that a user searching a label for a particular use site in a given state could find a response to the effect that "... WDL is not valid in the state of \_\_\_\_ at this time. The user must rely on the labeling obtained at the time of purchase of the product." Alternatively, the WDL web site might omit that state from possible selections. Such limitations, based on selective acceptance of WDL by states, could reduce the willingness of registrants to pursue WDL. Making newly approved product uses available via WDL to users could be uneven across markets, as would implementing important risk mitigations, if states are not uniformly willing to accept WDL.

**Faster Access:**

WDL has the potential to speed up the availability of new uses to end-users, as well as implementation of new risk mitigations. EPA needs to keep the following issues in mind:

1. Issuing Supplemental Labels is the current method to accelerate the availability of new uses, and works quite well. This avenue for introducing new uses should continue to be available without further complication for registrants who choose not to amend a product label for WDL. Would use of supplemental labels continue regardless of whether a product has been amended for WDL?
2. Using WDL to accelerate implementation of risk mitigation appears to change long-established labeling policies, which would have to be done by separate action, with appropriate opportunity for public notice and comment.
3. The Draft PRN states: "EPA anticipates that it would require registrants to provide updated labeling within a specific time frame if necessary to implement risk mitigation measures." Would such a specific time frame differ for a similar or identical product that does not have WDL? Such a difference could be a significant deterrent to adoption of WDL.
4. How much will be involved in extra review of WDL labels at the federal and state level? Will this negate the advantage of WDL? It is not uncommon for state reviewers to disagree with label statements after they have been approved by EPA, necessitating additional rounds of federal review and label amendment. While the draft PRN would permit fast-track amendment of labels to enable WDL, some states may choose to review the various possibilities of "rendered output." The work load could actually increase for federal and state regulators.

**IT Requirements**

Complex IT requirements and conditions of registration may discourage WDL participation and adoption by registrants. Any conditional reporting requirements regarding IT function should be spelled out in detail up front, made available on request, and agreed to by the applicant for a WDL label amendment. The burden that such requirements might entail would be a factor in the applicant's decision to pursue WDL. The extent of such requirements should not come as a surprise midway through the applicant's investment in technology and effort needed to implement WDL.

The draft PRN indicates: "EPA will consider website functionality when deciding whether to approve an amendment to add WDL." If the website functionality changes significantly, must the registrant submit additional label amendments to account for that? Additionally, EPA is recommending registrants maintain an "audit history for users performing any activity other than accessing labeling." We are unclear as to whether EPA has the authority to request this information in the future.

Making WDL available through tablet computers or smartphones would likely involve "apps" (other than Adobe Acrobat software) that would have to be downloaded, contrary to the statement that "Users should not be required to download software specific to the WDL site ..." Such apps could be made available free of charge.

**Electronic Label Structure**

Structured product labeling (SPL) has been discussed in the context of WDL, but we do not know the status of EPA's interest in pursuing this concept. Does the Agency see SPL as an essential component of WDL, something nice to have, or immaterial to the program? Do we need to have labels structured for efficient review before WDL is implemented?

**Miscellaneous comments and questions**

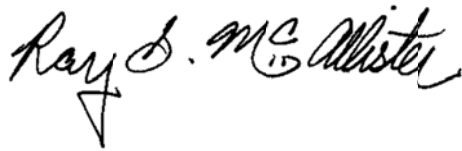
1. Could WDL be used with a product container manufactured and released for shipment before the label was amended to accommodate WDL (and thus, the label would lack RFS date and unique identifier)? If not, a "live" pilot project could take much longer.
2. Can a user download multiple WDL labels after purchase of the product and choose which one to use for a given application? Can he download different WDL for different uses at different times and choose which one to use? Can he use the container label for one crop use and WDL for a different crop use on the same label?
3. Can a user specify two or more use sites to be downloaded as WDL in a single label/document?
4. If a user farms in two or three states near a state border, must he download a separate WDL document for each state? Can the WDL output state that it is valid for use in multiple (specified) states?

5. Can a user request automatic email notification of when a label of interest is amended or updated?
6. How would a registrant demonstrate available web site time of 99.9%? Does this number correspond to some accepted industry standard? What would be the penalty of not achieving it? The user always has the container label, if he cannot obtain the WDL on short notice.
7. Website as labeling: a URL for a web site can have a great deal of specificity, to identify a specific page within a larger web site. A distinct domain name (e.g., [www.productname.com](http://www.productname.com)) can link seamlessly to a specific page within a larger website. EPA must carefully specify what becomes labeling subject to agency review when a URL is printed on a product label. This PRN statement must also be reconciled with other potentially conflicting policies regarding use of web sites on labels.
8. The draft PRN indicates that the registrant (or its content provider) should "... clearly indicate through a disclaimer statement that the user is exiting the portion of the website considered labeling and going to a website that is not part of the product's labeling." It goes on to state that if a registrant directs the user to the registrant's primary website to download labeling, the "... registrant should be aware that (all content on) the website becomes labeling under FIFRA and is subject to review by the Agency." It is unclear, therefore, whether the disclaimer statement serves any purpose.
9. EPA may find that the review and approval of WDL amendments may not be as simple as envisioned, and may not fit neatly into the fast-track amendment process. We understand that budget constraints are reducing the priority that can be given to non-PRIA actions, and fast-track amendments may suffer.
10. Would a WDL user be able to browse the entire label (master label? container label?) on the WDL web site, or would he only have access to the uses labeled for the state he specifies?
11. Because the proposed WDL program assigns weighty responsibilities to registrants and others, several important terms should be added to the definitions section to help establish the limits and parameters of those responsibilities. The definitions should be compatible with relevant legislation, regulation, and policy. Among terms to be added are the following (not necessarily a complete list):
  - a. User (of WDL);
  - b. Web, web distributed, web distribution, website;
  - c. Rendered output, rendered label;
  - d. Quick Reference code;
  - e. PDF format; (multiple software versions are available and in use, with differing capabilities).

12. Who would be responsible for maintaining an archive of label versions for a given product that are or have been available through WDL? How would state and federal regulators have access to such an archive? Would a product user have or need access to such an archive?
13. PRN Section III.5: Does an amendment potentially resulting in “conditions of registration” qualify for fast-track processing?
14. The draft PRN suggests that it “is targeted towards pesticide products marketed primarily to applicators for use in the course of commercial activity.” However, previous Agency policy has prohibited registrants from designating products “for commercial use only.” That policy and the guidance for WDL would have to be reconciled.

If you have any questions regarding these comments, please feel free to contact me [[rncallister@croplifeamerica.org](mailto:rncallister@croplifeamerica.org); 202-872-3874].

Sincerely,

A handwritten signature in black ink that reads "Ray S. McAllister". The signature is written in a cursive style with a large, stylized 'R' and 'M'.

Ray S. McAllister, Ph.D.  
Senior Director, Regulatory Policy

Cc: William Jordan  
Michelle Arling