



**U.S. Environmental Protection Agency
Office of Pesticide Programs**

**Pesticide Registration Notice 2014-1
Web-Distributed Labeling for Pesticide Products**

April 4, 2014

Web-Distributed Labeling for Pesticide Products Pesticide Registration Notice

Notice To: Manufacturers, Producers, Formulators, and Registrants of Pesticide Products

Attention: Persons Responsible for Initial and Continuing Federal Registration of Pesticide Products

Subject: Web-Distributed Labeling for Pesticide Products

This Notice presents the Agency's guidance on optional participation in web-distributed labeling for pesticide products. The Agency believes that voluntary adoption of these recommendations by pesticide registrants will help pesticide users to better understand and comply with pesticide labeling. In addition, the Agency believes that web-distributed labeling could allow addition of new uses, modification of existing labeling, and implementation of labeling-based risk mitigation measures more quickly. EPA undertakes initiatives such as this facilitate access to specific pesticide product labeling. This Notice is intended to improve existing labeling by allowing users to download the portions of the pesticide labeling specific to their intended state and site of use. Registrants who wish to adopt web-distributed labeling should follow the instructions in this Notice. No registrant is required to take any action in response to this notice.

EPA plans to reevaluate this Pesticide Registration Notice within 5 years of the final publication date to ensure that the web-distributed labeling system is keeping up with current technology.

I. Products Potentially Affected by This Notice

This Notice is targeted to pesticide products marketed primarily to applicators for use in the course of commercial activity, such as commercial applicators applying to agricultural, turf, and structural sites, and private applicators in the course of producing an agricultural commodity. If you have questions on applying this Notice to your product, please contact the EPA Product Manager or Regulatory Action Leader.

II. Scope of Policy

This PR Notice provides guidance to pesticide registrants and to EPA. Although EPA encourages registrants to adopt the following options for making labeling content available via the internet, this Notice is not binding on either EPA or pesticide registrants, and EPA may depart from this guidance in individual circumstances. Likewise, pesticide registrants who voluntarily choose to participate in this initiative may assert that the guidance is not appropriate for a specific pesticide or situation.

III. Background

Since 2007, the U.S. Environmental Protection Agency (EPA or the Agency) has been exploring the feasibility and advisability of allowing registrants to make legally enforceable pesticide product labeling available to users via the internet, an initiative referred to as "web-distributed labeling" (WDL). At the end of 2010, EPA initiated a "user acceptance pilot" that ran until April 2011. (75 FR 51058, August 18, 2010; EPA-HQ-OPP-2010-0632) The user acceptance pilot involved a simulation of a WDL website that users could visit and on which they could

provide feedback. The user acceptance pilot did not involve any changes to existing pesticide labeling on containers or legally valid electronic versions of pesticide labeling. EPA also published a *Federal Register* notice that outlined EPA's positions on issues related to WDL and also sought comment on a number of these issues. (75 FR 82011, December 29, 2010; EPA-HQ-OPP-2010-0648)

Based on its review of the comments and other feedback received from the *Federal Register* notice, the user acceptance pilot, and the draft of this Pesticide Registration Notice (; EPA-HQ-2012-0906), EPA is implementing a voluntary approach to WDL that would allow registrants to distribute pesticide products with labeling that refers the user to the website from which the user may download legally valid, enforceable labeling. The container would still be accompanied by a physical copy of the EPA-accepted labeling sufficient for the correct use of the product. However, a user could access the most current version of the state- and site-specific labeling from a website identified on the container label. Offering WDL while retaining the full labeling on or accompanying pesticide containers would allow users, registrants, and EPA to acquire a better understanding of the strengths and limitations of WDL and possibly serve as a transition to a system that relies more heavily on the internet and other technologies to provide users with legally enforceable labeling. For example, registrants could determine whether specific types of products would be better suited to WDL and users could evaluate the relative benefit of WDL versus the current pesticide product labeling.

As considered by EPA, WDL would make available via the internet site- and state-specific use directions for pesticide products as downloadable electronic files. To access this labeling, a user would visit the website identified on the pesticide label, enter information identifying the product, and select the intended state and use site. The website would return a streamlined version of the pesticide labeling containing the language applicable to all uses, such as hazard and first aid statements, and the relevant state/site specific directions for use (e.g., application to cranberries in Maine).

This PR Notice provides guidance about how EPA intends to implement WDL under this system.

IV. Discussion of Issues and Recommendations

A. Terminology in this Notice

The list of terms below provides a description of the meaning of each term for the purposes of this Notice only. These definitions do not supersede or otherwise alter any definitions contained in FIFRA or EPA's pesticide regulations.

1. Master labeling – The complete set of EPA-accepted labeling information, including all approved uses and associated use information for a pesticide product registration, regardless of whether this complete set is actually distributed or sold with the product.
2. Quick Reference (QR) Code – A barcode that can be read by a smartphone or other hand-held technology device with a camera that directs the user to a specific website.

3. Released for shipment – A product becomes released for shipment when the producer has packaged and labeled it in the manner in which it will be distributed or sold, or has stored it in an area where finished products are ordinarily held for shipment. Products stored in an area where finished products are ordinarily held for shipment, but which are not intended to be released for shipment must be physically separated and marked as not yet released for shipment. Once a product becomes released for shipment, the product remains in the condition of being released for shipment unless subsequent activities, such as relabeling or repackaging, constitute production. (40 CFR 152.3)

4. Released for shipment date – For the purposes of this Notice only, the date printed on the container label or body of the container that corresponds to the date on which the product container was released for shipment as defined in this Notice and at 40 CFR 152.3. The released for shipment date should be prominent and the location should be described on the container label. The released for shipment date should be located in a place that is visible without opening the label, package, or booklet attached to the container.

5. Rendered output – The final version of WDL returned to a user for a product where the user has performed a search for labeling using the product’s unique identifier, a state and specific site.

6. Unique identifier – For the purposes of this Notice, a series of characters, e.g., an alphanumeric combination, used to distinguish the labeling for a specific version of the product from other products with the same registration number and different labeling as permitted under 40 CFR 152.130(b). The registrant would need to establish a new unique identifier if a change in the labeling would render the previously approved version of the labeling invalid, for example, in the event of a change to the precautionary statements, use classification, or packaging of the product. For example, if product A’s labeling version 1 advised users that the product was flammable, and the registrant reformulated product A to eliminate flammability, product A’s labeling version 2 would need a different unique identifier than product A’s labeling version 1. The unique identifier must be distinguished from the EPA registration number, establishment number, and distributor number, but may start with the EPA registration number. Registrants would develop the unique identifiers for each product to which WDL would apply. The unique identifier should be identified clearly as the unique identifier. The unique identifier should be located in a place that is visible without opening the label, package, or booklet attached to the container.

7. Web-distributed labeling – Legally valid labeling for a pesticide product that is accessed through the Internet and can be tailored to the product user’s intended state and site of application.

B. Description of Process for Adding WDL to a Product’s Labeling

Each registrant wishing to use WDL submits an application for amended registration containing new labeling statements as described in more detail below. See Section V. If EPA approves the application, the registrant would be responsible for creating, publishing, and maintaining the website containing the WDL. This responsibility would be in addition to all other regulatory requirements related to pesticide registration and labeling. WDL would not change EPA’s

policies about and requirements for submission and review of final printed labeling. Registrants could control the formatting of the rendered output of the labeling, so long as the rendered output conforms to the existing applicable requirements at 40 CFR Part 156 (e.g. 40 CFR 156.10(a)(2)).

Users would follow the URL on the pesticide container label to the appropriate website using a computer, smartphone, or other internet-enabled device. They would enter the unique identifier for the product, the state where the product will be used, and then select the use site from an established list of some or all uses approved on the master labeling for inclusion as part of the WDL (known as a “pick list”; see <http://www.epa.gov/pesticides/foodfeed/> for EPA’s recommended terminology for some commodities). The website would return a streamlined version of labeling that includes all general information from the labeling and only the use directions and restrictions related to the specific state and site of use. The user would verify that the date on the WDL rendered output was later than the container’s released for shipment date (i.e., WDL labeling would be legally valid only if it bears an approval date on or after the released for shipment date). The user could print the WDL, save it electronically, or view it. Printing the WDL would not constitute production by the user as defined at 40 CFR 167.3. See 75 FR 82011, 82022; December 29, 2010. The user would be responsible for complying with either the WDL or the container labeling. Also, the user would be responsible for complying with applicable requirements (e.g., state regulations) that require users to maintain a copy of the labeling used for application. The use of WDL would not impose any additional recordkeeping requirements on users.

Registrants may choose to further refine the web-distributed labeling returned to the user as long as the web-distributed labeling content includes all general information and the use directions and restrictions related to the specific state and site of use chosen by the user. For example, registrants may choose to offer the user the option to refine the web-distributed labeling by application method or to retrieve the labeling in both English and another language.

C. New Labeling Statements

The Agency recommends that a statement be added to the container label of each pesticide product using WDL and on the rendered output of the WDL. For WDL labeling to receive EPA approval, the statement should: (1) direct users to the relevant website, (2) note that the electronic version of the labeling is also legally valid, and (3) inform users in cases where the additional labeling conflicts with the container label, the user may choose which version of the labeling to follow. The statement should make clear that for areas of overlap or conflict, the user must use only one set of labeling instructions, either the attached container label or the downloaded labeling. The following statement should appear at the beginning of the directions for use immediately following any required text. Minor wording changes may be acceptable.

“You may obtain additional labeling from {insert website URL}. If using the additional labeling to apply the product, you must possess a copy of this additional labeling at the time of application. It is a violation of federal law to use this product in a manner inconsistent with its attached label or any additional labeling, including any web-distributed labeling. In instances where the additional web-distributed labeling conflicts with the container label, the user may

choose a single, valid version of the labeling to follow. However, for areas of overlap or conflict, the user must use only one set of labeling instructions, either the attached container label or the web-distributed labeling. Do not mix and match labeling directions.”

To facilitate linkage to labeling that changes over time, pesticide labeling for products using WDL should bear a released for shipment date and a unique identifier. These pieces of information would be used to match the product with the correct set of WDL. The released for shipment date and unique identifier, both clearly identified as such, should appear either on the pesticide container or on the labeling. The labeling should inform the user of the specific location on the container or labeling of the released for shipment date and unique identifier. This statement should follow the WDL statement listed above or an equivalent statement:

“The released for shipment date is in {specify format, e.g., Month DD YYYY, DDMMYYYY, or MMDDYYYY} format and can be found {location, e.g., on the neck of the container}. The unique identifier format is {format, e.g., 10 character alpha-numeric combination} and it can be found {location, e.g., on the neck of the container}.”

The first page of the rendered output of WDL should include a statement indicating the legal validity of the label and explaining how labeling must be followed when different versions are available to the user. For example, WDL could contain the following statement in a prominent location, for example, at the top of the page following any required text, such as the restricted use statement:

“This labeling is legally valid only for use in {state} and only with container of product {name of product & unique identifier} that bears a “released for shipment” date on or before {date of website access}. For pesticide applications following this labeling, you must possess a copy of this labeling at the time of application. If this labeling conflicts with labeling found on the pesticide product, use only one set of the labeling instructions in its entirety. Do not mix and match labeling directions.”

“Currently the user is responsible for complying with the requirements of product labeling obtained when the user took possession of the product’s container. The user must comply with all instructions and requirements in the labeling and must keep the labeling as long as the user has the container. Similarly, the user who relies upon WDL may meet this requirement by maintaining a printed or electronic copy of the labeling to meet federal and state recordkeeping requirements. In the situations described above where the WDL labeling conflicts with labeling on the pesticide container, the user must be able to identify which labeling was used and followed at the time of the pesticide’s application.”

Subsequent pages of the labeling should include an abbreviated legal statement that references the primary statement on legal validity of the labeling. For example the following statement could be located in the header of the document:

“This labeling is legally valid only for use in {state} and only with the container of {name of product & unique identifier} that bears a “released for shipment date” on or before {date of website access}. See page 1 of this document for additional legal requirements on the use of this labeling.”

The registrant also should ensure that the web-distributed labeling includes on each page the following statements as part of the footer:

“This web-distributed labeling was rendered by accessing {website} on {date}.”

“{Product name} Web-Distributed Labeling – Page {page number} of {total pages}.”

In addition to the information and statements listed above, the registrant may include a Quick Response code or a similar symbol capable of being scanned by handheld devices to connect to the internet and to return to the website listed on the container label or accompanying material. Per Section 2(p)(2) of FIFRA, the content the Quick Response code or other similar symbol references would be considered labeling and therefore subject to review by the Agency.

D. Website

1. WDL Content

After the user searches by unique identifier, state, and site, the website should provide the user with the general labeling content that applies across all use sites as well as the content specific to the use site(s) requested by the user. The labeling content provided to users should be subdivided by use site and state. Additional subdivisions, such as application method, may be acceptable on a case-by-case basis.

The WDL rendered output should also include the statements and content listed in Unit IV.C. or equivalent. The rendered format of the labeling must conform to existing applicable standards at 40 CFR Part 156.

Where practicable, all WDL website functionality and rendered output should be accessible by handicapped individuals.

2. Website References on Labeling

Registrants (or their content providers) may develop a website for WDL distinct from existing websites. The simplest WDL URL would direct the user to a website where he or she could input the unique identifier, state, and site of application. The website would return only the WDL requested by the user. Any links from this WDL website to other information could 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.

Should the registrant wish to add or retain a reference to the company’s website on the labeling, including by directing the user to the registrant’s primary website to download labeling, the registrant should be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. For example, if the container label directed the user to www.website.com

to download the WDL, all content on www.website.com would be considered labeling. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. Again, any links from the WDL portion of the website to other information could 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.

In addition, regardless of whether a website is referenced on the product's labeling, claims made on the website may not substantially differ from those claims approved through the registration process. FIFRA section 12(a)(1)(B). Therefore should the Agency find or if it is brought to EPA's attention that a website contains claims substantially differing from the EPA-approved registration, the website could be referred to the EPA's Office of Enforcement and Compliance Assurance.

3. Website Function

EPA will consider website functionality when deciding whether to approve an amendment to add WDL. In order to ensure that the WDL website, and thus pesticide labeling, is readily available to users, ideally, the website would have minimal down time and be accessible 24 hours a day, every day of the year, exclusive of website maintenance downtime. Registrants should schedule routine website maintenance at times when expected user traffic is minimal. The website would also have a reasonable minimum response time. The content provider should consider the potential number of people that may attempt to access the site at one time.

Registrants (or their content providers) should not limit users from accessing labeling content through the website by requiring users to log in or pay a fee, even where other non-WDL services do require users to log in or pay a fee. The website should not require advanced (i.e., more than current common computer capabilities or standard software) computer systems or software. The labeling content should be provided, at a minimum, in PDF format, although registrants may choose to make WDL available through other technology, such as "apps" for tablets or smart phones. Users should not be required to download software specific to the WDL site when accessing the WDL site from a traditional computer (i.e., not a smartphone or other hand-held internet-enabled device). The website should direct users who do not have the Adobe Acrobat Reader program installed on their computers to the website where users can download and install the program.

The website URL should be easy to read and easily identifiable, generally with no more than 25 characters. The URL should link directly to the WDL webpage where the user can search for the labeling content by unique identifier, state, and use site. When designing websites, registrants should be aware that many rural areas still lack broadband internet access.

4. Website Security

Registrants should ensure secure access to upload or change labeling on the WDL website. Registrants would be responsible for ensuring that the content of the WDL site, including labeling, is accurate and up to date. Registrants should ensure the labeling provided from the

WDL website (rendered output) cannot be altered by users. EPA recommends that registrants maintain an audit history for users performing any activity other than accessing labeling.

5. Website Usage Data

In order for the EPA to analyze the success, needs, and future direction of the WDL program, EPA may periodically discuss with registrants website usage information on the WDL websites. Website usage information that may be of interest includes:

- Number of website hits
- Average time user spends on the website
- Number of downloads/printed labels
- Other web content that is provided
 - Other content that is accessed by the users

Where feasible, EPA may also seek information on the registrant's WDL activities by state and use site.

E. Discontinuing Web-Distributed Labeling

A registrant may choose to discontinue making labeling available through the internet at any time. To discontinue participation in web-distributed labeling, the registrant would cease to make available labeling at the website designated on the pesticide container labeling. The website listed on the product container labeling would inform the user that no web-distributed labeling is available for the product and instruct the user to follow the label that is attached to the container.

V. What Registrants and Applicants Can Do

A. Adoption of Web-Distributed Labeling

To initiate the process of adding WDL to an existing product registration, the company would file an application for an amendment with EPA. Adding WDL to an existing product registration is not necessarily an action covered by the Pesticide Registration Improvement Act (PRIA). Submitting an amendment that only seeks to add WDL to labeling would be a non-PRIA Fast Track action. However, a registrant could include an application to amend labeling to include WDL as part of an action covered by PRIA, such as adding a new use site.

A registrant may also choose to add WDL to a proposed new product's labeling.

In addition to any other required elements of the application, applications that incorporate WDL should include the master labeling and examples (preferably at least two) of the labeling in the rendered output (state- and site-specific labeling). Registrants could submit WDL to EPA as electronic files, such as a link to a non-public test website or a PDF file. EPA would also accept printed copies of the WDL for review.

As part of the approval process, EPA may review the website including rendered content through a link to a draft of the website not available to the public (if available), URL, and/or printed samples of the rendered labeling content. All content submitted to EPA for review should be clearly marked as draft and not valid for legal use. EPA may ensure the URL is easy to read and

that it directs the user directly to the WDL webpage. EPA may also review the website on a case-by-case basis to evaluate ease of use. EPA would also review the labeling in the rendered output to determine, on a case-by-case basis, if it correctly reflects the approved master labeling. Note: Only the master labeling would be stamped "accepted"; the sample rendered WDL labeling would not be stamped. As a condition of approval of the amendment, EPA may require the registrant to amend the website to provide updated labeling within a specific timeframe after the revised labeling receives all necessary approvals from EPA and a state. EPA anticipates that it would require registrants to provide updated labeling within a specific time frame if necessary to implement risk mitigation measures. For other changes, such as adding a new use, EPA would likely leave the labeling amendment schedule to the discretion of the registrant, provided the labeling and website are updated within 18 months of approval by EPA as is the standard timeframe for updating labeling when new labeling is approved. See 40 CFR 152.130(c).

B. Discontinuing Participation in Web-Distributed Labeling

To initiate the process of removing WDL from an existing product registration, the company would file an application for an amendment with EPA. Removing WDL from an existing product registration is not necessarily an action covered by PRIA. Submitting an amendment that only seeks to remove WDL from labeling would be a non-PRIA Fast Track action. However, a registrant could include an application to amend labeling to remove WDL as part of an action covered by PRIA.

C. Supplemental Distributors

The label of a distributor product must be the same as the label of the parent product, except as provided in 40 CFR 152.132(d). If the primary registrant for the product uses WDL, the supplemental distributor of that product can choose whether to participate in WDL for the supplementally distributed product under the terms of the agreement between the primary registrant and supplemental distributor. However, if the primary registrant does not use WDL for a product, the supplemental distributor of that product may not use WDL for that product.

VI. Effective Dates

This Notice will be effective immediately.

VII. Addresses to Use

Registrants should send amendments to one of the following addresses:

U.S. Postal Service Deliveries

The following official mailing address should be used for all correspondence or data submissions sent to OPP by U.S. mail:

Document Processing Desk (AMEND) (Distribution Code as identified in PR Notice 2006-1)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Ariel Rios Building 1200 Pennsylvania Ave., NW
Washington, D.C. 20460-0001

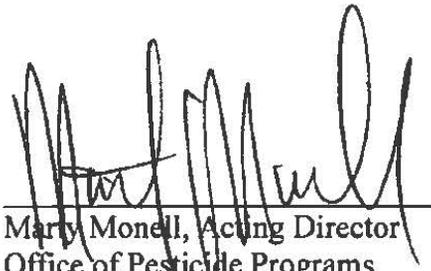
Personal/Courier Service Deliveries

The following address should be used for all correspondence or data submissions that are hand-carried or sent by courier service Monday through Friday, from 8:00 AM to 4:30 PM, excluding Federal holidays:

Document Processing Desk (Distribution Code as identified in PR Notice 2011-X) (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

VIII. For Further Information

If you wish to obtain further information on this notice, please contact Michelle Arling, arling.michelle@epa.gov, 703-308-5891. For questions about a specific product or active ingredient, please contact the product manager.



Marty Monell, Acting Director
Office of Pesticide Programs
U.S. Environmental Protection Agency

Dated: 25 MARCH 2014

Attachments

Attachments to PR Notice 2014-1

These attachments present how master labeling for a hypothetical product could be revised to include web-distributed labeling, a properly rendered example of web-distributed labeling, and several examples of improperly rendered web-distributed labeling.

The attachments are as follows:

- Bugtox Master Labeling (proper web-distributed labeling statements)
- Bugtox Web-Distributed Labeling for Pome (proper web-distributed labeling)
- Bugtox Web-Distributed Labeling for Pome (incorrect web-distributed labeling – missing directions for use)
- Bugtox Web-Distributed Labeling for Pome (incorrect web-distributed labeling – missing precautionary statement)
- Bugtox Web-Distributed Labeling for Pome (incorrect web-distributed labeling – only contains directions for use)

