**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA–HQ–OPP–2010–0648; FRL–XXXX–X]**

**Web-Distributed Labeling of Pesticides**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY: EPA is considering an initiative to make portions of pesticide labeling for certain products available electronically. Web-distributed labeling would allow users to download streamlined labeling specific to the use and state in which the application will occur. More concise labeling should increase users' comprehension and compliance with pesticide labeling, thereby improving protection of human health and the environment from risks associated with improper pesticide use. Web distributed labeling would also allow new labeling to enter the marketplace and reach the user more quickly than the current paper based labeling thus implementing both new uses and risk mitigation in a more timely manner. This notice describes potential approaches for a web-distributed labeling system and seeks stakeholder feedback on a variety of issues.**

**DATES:** Comments must be received on or before [*insert date* **90** *days after date of publication in the* **Federal Register**].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2010-0648, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

*Instructions*: Direct your comments to docket ID number EPA–HQ–OPP–2010-

0648. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket*: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

**FOR FURTHER INFORMATION CONTACT: Michelle DeVaux**, **Field and External Affairs Division**, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: **703-308-5891**; fax number: **703-308-2962**; e-mail address: **devaux.michelle***@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you **use pesticide products occupationally, manufacture or distribute pesticides, regulate pesticide products, or provide pesticide labeling to users.** Potentially affected entities may include, but are not limited to:

- **Persons who manufacture, distribute, sell, apply, or regulate pesticide**

**products, including agricultural, commercial, and residential products (NAICS codes 325320, 325311, 424690, 424910, 926140).**

**• Establishments, such as farms, orchards, groves, greenhouses, and nurseries, primarily engaged in growing crops, plants, vines, or trees and their seeds (NAICS code 111).**

**• Establishments primarily engaged in providing pest control for crop or forestry production, or for exterminating and controlling birds, mosquitoes, rodents, termites, and other insects and pests (NAICS codes 115112, 115310, 561710)**

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

## II. Background

*A. What Action is the Agency Taking?*

### I. Introduction

Since 2007, the U.S. Environmental Protection Agency (EPA or the Agency) has been exploring the feasibility and advisability of an initiative that would allow registrants to make portions of some pesticide product labeling available via the internet. The goals of this initiative, called web-distributed labeling, are a) to provide streamlined labeling that contains only the most current labeling information pertinent to the state where a pesticide is to be used and for the particular intended use, and b) to move new labeling (with new uses and/or new risk mitigation) into the hands of the user in a more timely manner. This streamlined labeling will omit unrelated directions and thus should reduce the overall length of labeling by a significant amount. EPA expects shorter, more focused labeling should improve readability, and user comprehension and compliance. Web-distributed labeling would be proposed initially as a voluntary option for registrants and would not be appropriate for all pesticide products.

The web-distributed labeling initiative would create a system that would make the most current version of pesticide labeling available to purchasers and users via the internet and by other means. For certain types of pesticide products, portions of the labeling would no longer accompany the pesticide container. To obtain the additional labeling, a statement on the container label would direct a user to a specific website on the Internet. Once logged onto the website, the user would enter information identifying the product, the state where it would be applied, and the intended application site. The website would then provide the user with legally sufficient labeling appropriate for the proposed use, which the user could choose to download or print. Because it would contain only information relevant to the specified use, the labeling provided by the website would be "streamlined" compared to labeling currently on registered products, which often contain labeling information for dozens of uses. The website would only return state-specific labeling, not EPA's "master labeling." The web-distributed labeling system would also offer alternate delivery mechanisms for users who cannot or prefer not to access the Internet.

The Agency has had many useful discussions of its web-distributed labeling initiative with stakeholders in both formal and informal settings. Through these discussions, EPA has identified the critical elements of a web-distributed labeling

system for distributing information to pesticide users via the internet. These discussions have also raised a number of issues on which EPA seeks further comment.

This Notice is organized into five units, starting with this Introduction. Unit II provides background information on the history of the initiative and particularly the Agency's goals in pursuing this new technique for conveying enforceable labeling information to pesticide users. Unit III discusses the significant elements of web-distributed labeling and Unit IV identifies issues for further consideration. Finally, Unit V describes a proposed path forward for determining whether, when, and how to begin implementation of the web-distributed labeling initiative.

## II. Overview

This unit discusses the legal framework within which EPA and the states regulate the format and content of the labeling on pesticide products; the kinds of problems that exist with pesticide labeling; and how a web-distributed labeling system would address those problems.

### A. Legal Framework

#### 1. Federal Authority

A web-distributed labeling system would be implemented under EPA's existing authority and would follow essentially the same process as is currently used. EPA regulates pesticide products under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA establishes a pre-market review and approval system called "registration." With limited exceptions, no pesticide may be sold or distributed in the United States unless EPA has first issued a registration for the product. As part of the registration process, EPA reviews and approves the labeling of pesticide products. EPA may also review amendments to labeling proposed by the registrant, such as a change in use site or application rate. Labeling describes how a pesticide may be used safely and effectively. Traditionally, labeling has been limited to what is attached to or accompanies the product and is provided to users at the point of sale, commonly as a leaflet or booklet. The "misuse provision" in FIFRA § 12(a)(2)(G) prohibits the use of a pesticide "in a manner inconsistent with its approved labeling." In effect, the labeling is the law.

Because FIFRA requires users to follow the requirements and limitations in labeling, the labeling for a pesticide product becomes the primary mechanism by which EPA communicates enforceable requirements to pesticide users about how to use a product safely and effectively. FIFRA § 2(p) clearly allows for both a "label" and "labeling." The term "label" means "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." "Labeling" means

> all labels and all other written, printed, or graphic matter accompanying the pesticide or device at any time; or to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Agency, United States Department of Agriculture,

> Department of the Interior, and Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides. 7 U.S.C. § 2(p)(2).

Although not common currently, labeling sometimes uses a reference to other enforceable documents that do not physically accompany the container, as evidenced by the Worker Protection Standard and Bulletins Live (for threatened and endangered species and their habitats).

A registrant may distribute or sell a registered product with the composition, packaging, and labeling currently approved by the Agency. 40 CFR 152.130(a). Likewise, a registrant may distribute or sell a product under labeling bearing any subset of the approved directions for use, provided that in limiting the uses listed on the label, no changes would be necessary in precautionary statements, use classification, or packaging of the product. 40 CFR 152.130(b).

### 2. State Authority

EPA does not anticipate that a web-distributed labeling system would affect state authority with respect to pesticide regulation in any way. Section 24(a) of FIFRA provides that a state may regulate the sale or use of any federally registered pesticide or device in the state, but only if and to the extent the regulation does not permit any sale or use prohibited by FIFRA. Section 24(b) holds that such state shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under FIFRA. State lead agencies have the final authority to approve marketed product labeling submitted by registrants for sale and distribution in their states. Under state laws in every state, sale or distribution of a pesticide product may not occur within a state until the state registers the product.

Section 26 of FIFRA provides that a state shall have primary enforcement responsibility for pesticide use violations provided the state has adopted adequate pesticide use laws, has adopted and is implementing adequate procedures for the enforcement of such state laws and regulations, and will keep such reports showing compliance with the conditions listed above.

## B. What Problems is Web-Distributed Labeling Intended to Solve?

Many people have voiced criticisms about the labeling currently on many pesticide products. Among other problems, critics complain that labeling attempts to convey too much information and that the existing process for implementing labeling changes is too slow. Both types of problems can result in the use of pesticides in ways that, EPA has determined, cause risks to human health and the environment and that might be avoided by changing the way users obtain labeling. In particular, critics note that because the labeling of a single product may contain precautions and detailed use directions for multiple uses, the labeling is often quite long – sometimes exceeding 50 pages in length. As a consequence, pesticide users complain that it is difficult to find all of the relevant parts of the labeling, and some state regulatory officials suspect that overly lengthy labeling materials has diminished user compliance rates. Further, the Agency is concerned with how much time can elapse between EPA's approval of the addition of both new uses and new restrictions on

pesticide use and when products containing such statements actually reach users' hands. Many factors contribute to the delay including the need for approval by state regulatory officials following EPA approval and the long lead time involved with printing new labeling and getting the new versions on products in the marketplace. More timely implementation of approved labeling would reduce risk when new risk mitigation measures have been registered. These delays also mean that identical products bearing different versions of labeling are often available simultaneously in the marketplace. State officials and users have complained that different but legal versions of product labeling lead to confusion of users and challenges for enforcement.

**C. Web-Distributed Labeling as a Solution**

State regulators suggested that EPA consider web-distribution of pesticide labeling as a solution to some of the problems identified. In response, EPA initiated an internal workgroup to explore the concept of web-distributed labeling. The workgroup had extensive outreach to and conversations with stakeholders. EPA found that if accepted by users web-distributed labeling appeared feasible, and it could have benefits for many stakeholder groups.

For pesticide users, a new web-distributed labeling system would provide simplified labeling. Under the new system certain information on the label would be required to be attached to the container and the user would be required to obtain and follow a copy of state- and site-specific use directions and precautions for the product from an alternate source, either the Internet or a toll-free phone service that would mail or fax a copy of the labeling to the user. To obtain full use directions specific to the state and crop the product is intended to be applied, the container label would require a user to go to a website on the Internet, enter the EPA product registration number, the state where it would be applied, and the application site in order to download streamlined use directions and associated labeling. The user would be required to comply not only with restrictions appearing in the label securely-attached to the container and in labeling accompanying the container, but would also have to obtain and follow those in the web-distributed labeling available from a referenced Internet source or toll-free number.

The web-distributed labeling generated by the user's specification of a particular use and state would eliminate information that is not relevant and would dramatically simplify labeling. Most web-distributed labeling could then contain relatively brief, very specific use directions and precautions that would not be obscured by information applicable to use on other sites or with other legally sufficient application methods. Moreover, a web-distributed labeling system could make additional information available to users that they could find valuable, e.g., rate calculators or demonstration videos. The users ultimately would have in their possession all pertinent labeling information.

For pesticide regulators (i.e., EPA and the states) whose mission is to protect human health and the environment, web-distributed labeling could bring at least two primary benefits in terms of protecting human health and the environment. First, EPA thinks that users would more readily understand the streamlined labeling available through a web-distributed labeling system and therefore would be more

likely to comply with the requirements in the labeling. Second, by providing use-direction labeling electronically, rather than as a printed document that accompanies the pesticide container, registrants could significantly reduce the amount of time between when EPA approves a change to pesticide labeling and when the labeling reflecting the change actually reaches users in the field thus reducing risk in a more timely manner.

For registrants, web-distributed labeling could reduce printing costs and the time needed to implement new uses. When pesticide labeling changes under the current system, registrants have to arrange for printing of new labeling material to accompany each newly released container of pesticide. Many products require a large, multi-page booklet attached to the container. Under a web-distributed labeling system, the process for developing new printed labeling could be more orderly and less costly. Note: The cost of printing labeling (in a streamlined form) would be transferred to the user. Finally, for pesticide enforcement staff (states and EPA regions) web-distributed labeling could have several advantages over the current system. First, enforcers could find higher rates of user compliance with pesticide labeling and faster implementation of risk mitigation measures. Enforcers would also benefit from fewer versions of pesticide labeling in the marketplace because the portion of labeling that changes most often would not be attached to the container. In addition, web-distributed labeling that is state-specific would also make it easier for state enforcement personnel to verify that a user is complying with a state-approved version of the labeling.

EPA requests stakeholders to consider the following:

- How would web-distributed labeling benefit your organization? What problems with pesticide labeling could it address?
- How could audiences that do not traditionally use the label, such as farm workers, farm worker advocacy organizations and environmental interest groups, benefit from web-distributed labeling?
- What resource savings could be achieved in your organization if web-distributed labeling were implemented? What costs would be incurred?
- Please provide any general comments about the concept of web-distributed labeling and the potential benefits to stakeholder groups including pesticide users, registrants, regulators, farm worker advocacy groups, environmental interest organizations, and the public.

## III. Overview of Web-Distributed Labeling

### A. The Current System

In most cases, registration of a pesticide product begins with approval by EPA of a “master label,” which is EPA-approved labeling that contains the complete set of precautions and use directions for all approved uses of the product. This is followed by state approval of a “marketed label,” which is specific labeling associated with a product as it will be sold in a state; the “marketed label” must be the same as (or a legally sufficient subset of) the approved FIFRA master label.

#### 1. EPA’s Registration Process

EPA authorizes the use of pesticide product primarily under section 3 of FIFRA (federal registration). Under this provision, EPA is responsible for ensuring that approved pesticide products will not pose unreasonable adverse effects to human health or the environment. EPA defines risk standards, identifies data studies required to evaluate these risks, and specifies the requirements for product labeling.

Applicants for registration are responsible for developing the formulation of a product, providing data from required studies), and providing product labeling which details how a product is to be used. Much of the labeling content is prescribed based on the chemical and toxicological properties of the product, for example if a product is a severe skin irritant, it is labeled as toxicity category II (see 40 CFR 156 and various Pesticide Registration Notices). It is left to the applicant to propose the directions for use describing the application timing, method, and equipment, use rates, re-treatment intervals, maximum quantities per application and year, and other restrictions. These use directions are used to define the exposure parameters in a risk assessment. EPA's registration decisions are based on conducting a risk assessment of the pesticide developed using environmental fate, toxicology, and ecological effects data provided by an applicant as the applicant proposed the pesticide be used (i.e., as specified in the proposed product labeling.) Following EPA's risk assessment, a detailed review is conducted to ensure that the proposed labeling adheres to current EPA regulations and policies. Issues identified during the risk assessment can often be mitigated by adjusting the labeling on the product prior to approval.

When EPA has completed a review of the application for registration and finds that the product will not pose unreasonable adverse effects to human health or the environment, the product is registered and EPA approves a master label. The master label contains a complete set of precautions and use directions for all approved uses of a product, but is not generally the label that accompanies the pesticide container. The master label is used to develop marketed product labeling (discussed below).

More information on EPA's pesticide registration process is available at http://www.epa.gov/pesticides/regulating/registering/index.htm.

**2. State Registration**

All states have a state pesticide registration requirement under their respective state laws. Therefore, in addition to registering all pesticides with EPA under FIFRA for approval of a master label, pesticide companies must also receive approval from a state in order to distribute, sell, offer for sale, and in some cases use, the product in that state. The process to obtain a state registration can vary greatly among states, as can the level and type of review conducted by the state lead agency. While some states may simply record the existence of each marketed label, other states may do a detailed comparison of the "marketed label" to the EPA "master label," or conduct extensive risk assessments or other reviews.

In addition to varying greatly in how they register pesticide products and approve labeling, states vary greatly in how they manage labeling and other supporting documents. Because of available resources or statutory requirements, some states may manage pesticide labeling in their files in hard-copy format. Other states receive, review, and/or manage pesticide labels in electronic format, including

sophisticated online portals for registrants to submit online pesticide registration applications, electronic documents, and payments. Regardless of how they manage labeling as part of their state pesticide registration program, most state lead agencies agree that the labeling found on or accompanying the product in the channels of trade, despite the version, is the labeling that is enforceable in instances of misuse.

### 3. Pesticide Labeling Production Process

Despite the complexity and time involved in getting a pesticide product label registered with both EPA and states, registration is only one aspect of moving a product from initial concept to final use by applicator. Even focused simply on the labeling aspects, the overall production process encompasses product development, regulatory approval of the master label by EPA, development of the marketed label, regulatory approval of the marketed label by states, printing of state approved marketed labels, filling and labeling of product containers, distributing product to the point of sale, and providing post sale product stewardship to both applicators and enforcement staff.

## B. History of Development of Web-Distributed Labeling

State officials involved in pesticide regulation deserve credit for initiating EPA's consideration of a web-distributed labeling system. The State-FIFRA Issues Research and Evaluation Group, a group of representatives from State organizations responsible for state level regulation of pesticides, produced two issue papers on the electronic submission and distribution of pesticide labeling. EPA's Office of Pesticide Programs formed an e-label review workgroup, tasked with exploring ways of using technology to make the pesticide labeling submission, review, approval, and dissemination process more efficient. In the summer of 2007, the Association of American Pesticide Control Officials (AAPCO), the national association representing State lead agencies for pesticide regulation, presented the idea for web-distributed labeling to the director of the Office of Pesticide Programs.

After receiving the request to consider web-distributed labeling, EPA formed an internal workgroup with members from the Office of Pesticide Programs, Office of Enforcement and Compliance Assistance, Office of General Counsel, Regional Offices, and 2 state representatives. The workgroup discussed the mechanics of web-distributed labeling and how it would complement ongoing label improvement programs. The workgroup conducted extensive stakeholder outreach to individuals and associations to describe the concept of web-distributed labeling and to solicit stakeholder feedback. Using the stakeholders' input, the EPA internal workgroup developed discussion papers to describe some of the details around specific elements of web-distributed labeling.

In May, 2008, EPA requested formal feedback on web-distributed labeling from the Pesticide Program Dialogue Committee (PPDC), a federal advisory committee for the Office of Pesticide Programs. In response, a PPDC workgroup was formed to review and respond to the discussion papers developed by EPA. The PPDC workgroup includes representatives from user and grower groups; public interest groups; trade associations; industry; state, local, and tribal government; educational organizations; federal agencies; and others. From October 2008 through October

2009 the PPDC web-distributed labeling workgroup met to discuss and provide comment on papers. A full listing of the meetings and papers considered is available at: http://epa.gov/pesticides/ppdc/distr-labeling/index.html.

In October 2009, the PPDC workgroup discussed a pilot for web-distributed labeling that would allow users to test the functionality of one or several web-distributed labeling websites using mocked-up labeling. The pilot would be conducted without any actual labeling changes. Based on the feedback received from the PPDC workgroup, EPA decided to shift the focus of the pilot from developing websites capable of delivering web-distributed labeling to soliciting user feedback on the concept of web-distributed labeling. The pilot is discussed in further detail in Unit V of this Notice. EPA invited participation in it customer acceptance pilot through a Federal Register Notice published on August 18, 2010. See http://www.gpo.gov/fdsys/pkg/FR-2010-08-18/pdf/2010-20449.pdf.

## C. Web-Distributed Labeling Elements

### 1. Scope of Web-Distributed Labeling

A primary consideration before web-distributed labeling could be implemented is which products should be eligible to participate. EPA does not anticipate that all products would be eligible for web-distributed labeling initially.

EPA is not inclined to limit products' eligibility for web-distributed labeling based on how the product is registered or distributed. Web-distributed labeling would be available for otherwise eligible products whether they are sold by registrants directly or through another company as supplemental distributor products.

Both unrestricted (general use) and restricted use products (RUPs) may be appropriate for web-distributed labeling. General use products are accessible to all applicators and can be used in agricultural, residential, and industrial settings, among others. RUPs are available only to applicators that have been certified as competent by a state, tribal, or federal agency, and applications are generally conducted as part of the applicator's primary occupation rather than incidentally. Both types of products would benefit from streamlined labeling available through web-distributed labeling. In general, EPA believes that RUP applicators, because of their training, certification, and awareness of legal responsibility to comply with all labeling, are more likely to comply with the requirement to obtain web-distributed labeling. However, many professional applicators also use general use products and would also comply. Therefore, EPA would invite manufacturers of both general use products and RUPs to participate in web-distributed labeling.

EPA proposes to limit the scope of products eligible to use a web distributed labeling system to those that are used as part of a money-making or business operation, or as a public regulatory function. Residential, consumer use products would not be included in web distributed labeling and would continue to be distributed with the full labeling accompanying the product container. Registrants may choose to post the labeling for residential products to the websites, however, so that consumers may obtain some of the benefits of web distributed labeling, such as viewing text in a larger font size.

Further consideration of the potential scope of web-distributed labeling is available at http://epa.gov/pesticides/ppdc/distr-labeling/oct08/wdl-scope.pdf.

EPA requests feedback on the following:

- What should be the scope of products under consideration as eligible for web-distributed labeling?
- What criteria should be used to determine which types of pesticides should be eligible for web-distributed labeling?

**2. Voluntary vs. Mandatory Participation**

EPA thinks that participation in the web-distributed labeling system should initially be voluntary. As discussed above, EPA would invite both general and restricted use pesticide manufacturers to participate in the program. Once web-distributed labeling is established and has operated for a few years, the Agency would expect to evaluate its impact on pesticide safety and may consider implementing a mandatory system if appropriate.

EPA requests comments on the following:

- What are the benefits and drawbacks associated with voluntary and mandatory participation in web-distributed labeling?
- How would pesticide registrants, states, and users benefit from a voluntary web-distributed labeling system?
- How would a voluntary system negatively affect these groups?
- Why would stakeholders support mandatory participation in a web-distributed labeling system?
- What would be the drawbacks of a mandatory system?

**3. What's on a Pesticide Container and on the Web-Distributed Labeling Website?**

Implementation of web-distributed labeling would require decisions be made regarding which types of information would appear on the label securely- attached to the container, which would appear in labeling accompanying the container, and which would be web-distributed, or available through alternate delivery mechanisms. Currently, for virtually all products, all labeling is attached to the pesticide container or distributed at the point of sale with the product. The labeling includes all information required by FIFRA and EPA's regulations. Web-distributed labeling would be used for state-approved, marketed product labeling, not EPA's master labeling.

Under web-distributed labeling, EPA would partition the label and labeling elements according to whether they would be securely-attached to the container, accompanying the container, or in web-distributed labeling. The securely-attached or accompanying label and labeling would contain all safety and product identification information; state- or site-specific use direction information would be available through web-distributed labeling. Users accessing the labeling through an alternate delivery mechanism would receive a copy of the labeling containing all information in the securely attached, in the accompanying labeling, and available via the web-distributed labeling system. A full list of the components that would appear on the

label and those components that would be available through the web-distributed labeling system can be found at: http://epa.gov/pesticides/ppdc/distr-labeling/oct08/container-label.pdf.

i. Information Securely Attached to the Container

In accordance with FIFRA § 2(q) and 40 CFR Part 156, specific label elements must be on a label securely-attached to the container. The same requirements would apply to a web-distributed labeling system. Thus, the following elements must be found on the label securely-attached to the container: directions for use or a reference statement to directions for use found elsewhere in labeling; use classification (Restricted Use Product statement); violation of federal law statement; product registration number; signal word; Worker Protection Standard referral statements; storage and disposal requirements; product establishment number; brand/product/trademarked name; ingredient statement; net weight or contents; skull & crossbones/POISON and statement of practical treatment if highly toxic; name and address of producer or registrant; warning or caution statement adequate to protect health and the environment (by regulation, this requires physical and chemical hazard information, and human health and environmental precautionary statements); and (for labels of products for export only) "Not registered for Use in the United States of America.

Under web-distributed labeling, a "released for shipment date" would be required to appear on the container label. The released for shipment date should appear with the registration number on the product container label and its purpose is detailed in Section B.3.

In addition to the existing requirements outlined above, under web-distributed labeling EPA would require a container label to include a reference statement, likely under the heading "Directions for Use" where the violation of federal law statement appears, that reminds users they are bound by the directions on the container as well as those included in the web-distributed labeling. The language requiring users to obtain and comply with web-distributed labeling would be similar to:

*You must obtain additional labeling, which includes directions for use, from [insert the website address for the web-distributed labeling system] or by calling [insert the toll-free telephone number]. This additional labeling must be dated after the "released for shipment date" appearing [indicate location on container]. 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 the additional labeling obtained in one of the methods listed above.*

While not required to be attached to the container, users and the environment would benefit from additional information attached to or physically accompanying the container. For example, since pesticides in their containers move in the channels of trade, it is important to provide basic information regarding safe storage, handling, and disposal of the product, as well as what to do in case of accidents and spills, to anyone who may come in contact with the pesticide, such as distributors, applicators, handlers, medical providers, or first

responders.

ii. Web-Distributed Labeling Content

Web-distributed labeling would encompass all labeling information not required to be affixed to the container. In order to minimize costs of reprinting product labels, pesticide companies would not want to put information in the label or in the labeling physically accompanying the container that would be likely to change frequently. The web-distributed labeling would include components of the labeling that are specific to the type of application, such as engineering controls, environmental hazards, use directions and advisory statements. There has been discussion about the concerns for putting the target sites and pests on the label that is securely attached or accompanying the container. However, any change in site or pest would require manufacturers to print new labels and have them in the channels of trade prior to making any changes to the web-database. If these items changed frequently and they were securely attached or accompanying the container, the benefit of web-distributed labeling would be reduced greatly.

EPA requests comments on the following:

- Do you agree with the proposed content that would be included on the web-distributed portion of the labeling?
- Should other content be included on the container-affixed label?

**4. Lifespan of Web-Distributed Labeling**

This unit addresses how a system for web-distributed labeling would affect the length of time that pesticide labeling would be valid. EPA proposes to adopt an approach that would operate in essentially the same manner as the current, paper-based system.

**i. The Current System**

The current, paper-based system generally does not result in a fixed "lifespan" for pesticide labeling – the duration of time over which a user may lawfully use a pesticide according to its labeling. Users may use a pesticide consistent with the labeling that accompanied it when the pesticide was obtained for as long as they have the pesticide or unless EPA issues an order that affects such use. FIFRA §12(a)(2)(A) makes it unlawful for a person to detach or alter the labeling on a registered pesticide product. Consequently, each time that a pesticide is used up and the container is disposed of, the user must get a new container with new labeling that he cannot alter or deface. This means that the labeling accompanying a container is legally valid only for as long as the user possesses the specific product container and is only valid with respect to the quantity of pesticide in that container.

Currently, when EPA approves changes to a registrant's labeling, the registrant places the revised labeling on newly produced quantities of the pesticide within 18 months of the approval. These time periods allow application of the new labeling in the production process over an extended timeframe rather than requiring the registrant to collect, relabel, and redistributed the product with

an amended label. Users buying product containers bearing the revised labeling thus become subject to the new requirements.

In sum, pesticide users have come to expect that they will be able to use a pesticide according to the labeling accompanying the product container until the all of the pesticide has been used up. This expectation holds even if EPA requires changes to the labeling on quantities of the identical product when sold in the future.

**ii. The Proposed System**

One premise of a web-distributed labeling system is that labeling would not physically accompany the pesticide product at the time of sale. Instead, material would become "labeling" because the container label would refer to it and make it legally binding. Referenced labeling would be obtained separately from the product container. Once obtained, such labeling applies to all products that refer to it, not necessarily just a single specific container as is the case for the paper-based system. One result of this is if a user possesses multiple containers of the same pesticide product, it may not be necessary to require the user to obtain separate labeling for each discrete container of a pesticide he possesses.

The attenuation of the labeling and the product container creates a potential problem – old, out-of-date labeling could be associated with newly produced quantities of a pesticide by virtue of having the same registration number. Further, just as now happens under the current paper-based system, when EPA amends the labeling of a pesticide product to incorporate new protections for human health or the environment, those protections should apply prospectively to users who purchase products sold after the date of the amendment. But, because web-distributed labeling is not linked to particular containers, the new system must ensure that users do not continue to follow old labeling when using new products.

To address this situation, EPA proposes the following approach. EPA would require product containers to bear a statement that the specific container was "released for shipment on [date]" and also require the user to obtain a valid version of the labeling from the website on or after that date. The date on which a product was released for shipment is the date on which the registrant made a pesticide product available for sale or distribution to another person. (40 CFR 152.3) Finally, the container label would specify that the product could be used only in accordance with an approved version of the labeling obtained after the production date from the website listed on the labeling. In addition, labeling obtained would include a prominent statement of the date on which the labeling was generated, along with a statement that the user could use the labeling only if the product container indicated it had been released for shipment before the date in the labeling. Once a product is in the channels of trade and the container label changes, it would be treated the same way existing stocks are treated under the current system, and dealers could lawfully sell the product with labeling that had been superseded by a new version.

The consequence of this approach would be that a pesticide could lawfully be used according to any version of the labeling that a user obtained after the date on which the product was released for shipment. Once the pesticide in the container

was used up (or disposed of), if the user wanted an additional quantity of the pesticide, the user would need to obtain a new container of the pesticide labeled with a new "released for shipment on [date]." Labeling that predated the date on the newly obtained quantity of pesticide would no longer be valid. In effect, this approach would give web-distributed labeling an indeterminate lifespan equal to the amount of time a user takes to use up the pesticide material – the same lifespan as under the current system. (As with the paper-based system, EPA would retain the authority under FIFRA to cancel or suspend the registration of a pesticide using web-distributed labeling, and could further prohibit use of existing stocks, if deemed necessary.)

EPA requests comments on the following:

- What are the benefits and drawbacks associated with tying the lifespan of web-distributed labeling to a "released for shipment date?"
- What are the benefits and drawbacks of a requirement for web-distributed labeling to have a specific expiration date?
- If a specific expiration date is recommended, should it be a firm date or a set time period after the product is released for shipment? Why?

**5. Functionality and Hosting of Web-Distributed Labeling Website(s)**

This section presents EPA's thoughts on the web-distributed labeling website functionality and website hosting. The functionality section describes in a general sense what users would be able to do if the web-distributed labeling website were available. The hosting section presents several basic concepts the EPA has discussed for housing and maintaining the software and hardware that support the web-distributed labeling website. EPA has differentiated the major components of website functionality in two categories: critical components and desirable components. The critical components are those that EPA believes are necessary for implementing a useable web-distributed labeling website; without these critical components, the key benefits described earlier in this Notice may not be realized. The desirable components are those that EPA believes would add value to a web-distributed labeling website; however, these desirable components are not necessary for implementing a useable web-distributed labeling website. A full discussion of the proposed functionality is available at http://epa.gov/pesticides/ppdc/distr-labeling/jan09/functionality.pdf .

**i. Critical Components of the Website(s)**

The first three critical components relate particularly to users of pesticide products. Users must be able access web-distributed labeling. This would include searching the web-distributed labeling database by the registration number, the state in which the application is to be made, and the use site to which the application is to be made. By specifying these search criteria, the user would choose the labeling he/she wishes to view. Second, the website must allow all users to view both current and historic versions of product labeling for pesticides in the web-distributed labeling system. This would include the most recently approved version of the labeling, as well as all versions of web-distributed

labeling that had been previously approved and available for download so that users could access versions of the labeling that correspond to a container purchased at an earlier date and compare historic and current versions of labeling, and inspectors could access all versions of labeling that corresponds to a container. Finally, the website must have user-friendly interface and be easy to navigate. Some people that would use a potential web-distributed labeling website might 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.

There are also critical components related to the posting of labeling and security of the website. In order to house accurate current and historical versions of labeling, the web-distributed labeling website must allow participating registrants (or agents with appropriate access rights) to upload new versions of web-distributed labeling. This component will ensure that only authorized users are permitted to make timely updates to web-distributed labeling website content. In addition, the web-distributed labeling website must employ appropriate security measures to minimize the possibility of unauthorized persons uploading, editing or otherwise tampering with web-distributed labeling information. For example, the system could maintain password-protected access and an audit history for persons performing any activity other than accessing labeling. Appropriate functionality would allow the website to meet the needs of users by delivering streamlined labeling and to ensure the integrity of the labeling through necessary security measures.

**ii. Desirable Components of the Website(s)**

In contrast to the necessary functionality listed above, the following components are desirable in a web-distributed labeling system to facilitate a more positive user experience. The desirable components of a website are providing single URL (website address) to access the web-distributed labeling system, providing a static URL for each product, allowing users to select the format for the labeling, highlighting changes between current and historical versions of labeling, and providing links to training and other tools for applicators.

A single uniform resource locator (URL) (e.g. www.webdistributedlabeling.com) as opposed to multiple URLs (e.g., www.webdistributedlabeling.com, www.webdistributedlabeling22.com, etc. Note: These websites are fictional and will not provide legally enforceable pesticide product labeling. ) would allow users to visit a single website to search for and download all labeling. While the container label will identify the website for each product, having a single website address on all products participating in the web-distributed labeling system should make education and training of users easier and more effective.

Static web addresses for web-distributed labeling would always link to the current labeling for Product X, for example www.webdistributedlabeling.com/ProductX_current.htm. 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.

A feature that allows users to specify the format of the labeling, e.g., PDF, html, mobile version, would provide users with flexibility to download or view the labeling in the format most convenient and accessible to them.

A feature that highlights changes made in the most recent version of web-distributed labeling by comparing the most recent version with a historic version of web-distributed labeling would assist users in quickly determining what components of the labeling had changed.

Finally, the web-distributed labeling website could also be used to house or link to materials that may be helpful to pesticide applicators or other users, such as training materials, rate calculators, supplementary health and safety information, equipment calibration instructions, stewardship information, versions of labeling in different languages, and many other types of information.

EPA considered an optional feature of providing the EPA-approved master labeling, but decided that it would not be a good fit in the web-distributed labeling system. An electronic version of the master labeling can currently be found in the Pesticide Product Labeling System (PPLS). Since the intent of web-distributed labeling is to provide state-approved labeling to the user and master labeling is already available electronically, the Agency decided against adding this as a desirable component of a potential web-distributed labeling website.

**iii. Website Hosting Approaches**

Although the specifics of the technological architecture used to implement the WDL should be left up to those involved in the actual development, EPA considered some basic concepts of web site and database design, including who should host, or be responsible for hosting, the WDL website(s). This section discusses options for the website portal and databases, and potential hosts and the advantages and disadvantages associated with each. A discussion paper on web-distributed labeling website hosting is available at http://www.epa.gov/pesticides/regulating/registering/index.htm.

There are two critical components in the architecture of the web-distributed labeling system: 1) the portal, i.e., the initial website visited by users or the public to begin their search for web-distributed labeling, and 2) the database(s) holding the files necessary to generate web-distributed labeling. EPA believes that a single website portal connected to multiple databases maintained by pesticide companies would be the most appropriate option for a web-distributed labeling system.

A single website would provide users with one access point for all information related to web-distributed labeling. The website would contain software necessary to allow users to specify search criteria (i.e., registration number, state, and use site) and for the website to identify and interact with separate databases containing the information necessary to generate appropriate web-distributed labeling. This alternative would operate in a manner similar to a service such as the online bookseller, Amazon. All users visit the Amazon.com website to search for their products, and the Amazon website, in turn, searches multiple databases (of its warehouses and partner dealers) to provide the requested information back

to the user. For the WDL system, a single pesticide labeling portal would be linked to databases maintained by registrant and/or third parties. Multiple databases would allow multiple entities to share the responsibility for maintaining and updating databases. Such a system would require the use of consistent standards for data-formatting and searching to be effective.

One alternative is that all WDL information would be maintained in a single database. This approach would assure a standard delivery format for labeling, and the single access point would be easier for users to remember. A single database would assist federal and state enforcement personnel in reviewing the labeling. However, a single portal and database could require a single entity to process and maintain a large amount of information.

A second alternative is multiple website portals with multiple databases, which would require the user to visit a specific site for each product. It would be similar to the multiple options available to purchase a car online. A user can visit each dealer's website but cannot search all databases at once for information on a car; each database much be searched separately for different car models. This approach would allow each entity to maintain data in its own format, but would impose additional burden on users to visit a different website for each product they intend to use. Extra burden could lead to non-compliance. It would also be more burdensome for enforcement personnel who would have to search each website / database individually.

**iv. Potential Website Portal and Database Hosts**

Whether the approach chosen is a single website and database, a single website linked to multiple databases, or multiple websites with multiple databases, the options for hosts of the web-distributed labeling website portal(s) and database(s) are the same. EPA, registrants, and third-party vendors could operate the website(s) and database(s). While there are positives and negatives associated with each, if the preferred single portal, multiple databases approach is chosen, then the most likely hosts of the website would be EPA or a third-party vendor and the hosts of the databases would be registrants and third-party vendors.

Regardless of which entity hosts the website, registrants would be responsible for posting the marketed product labeling approved by the state. Registrants would have the flexibility to post each product's labeling as it approved by the state. States would be able to continue to use their current process for reviewing and approving pesticide labeling, whether it is done electronically or on paper. States would not be responsible for posting labeling but would have full access to the system in order to verify that the labeling posted is accurate and matches the state-approved version.

EPA

As the Federal authority for pesticide registration and regulation, EPA is involved in the registration of almost all pesticides. It maintains historical records of all master labels submitted and approved, and it is developing a structured database for all master labeling content (E-label program). If EPA were to host the website for web-distributed labeling, EPA would likely operate a single portal

website and would likely rely on other entities (e.g., registrants or states) to provide the electronic files on state-approved marketed product labeling that would be accessed by and through the website.

Potential disadvantages to EPA's serving as the host are that EPA may be unable or less likely than a third-party vendor to link to other commercial websites, limiting the potential benefit of web-distributed labeling to provide links to training and tools to users. Also, with EPA as host, determining who is liable for errors with the labeling could be more difficult.

Although EPA does maintain master labeling for all pesticide products, users rely on the state-approved marketed product labeling to make applications. EPA is not involved in the state approval process for marketed product labeling and does not require states or registrants to submit the approved marketed product labeling to the Agency. Making EPA the host of the web-distributed labeling website would increase burden on registrants to submit the final state approved labeling to EPA for posting.

Registrants

Registrants are ultimately responsible for obtaining approval for and distributing pesticide labeling. Registrants submit their applications for registration to EPA and, after receiving approval, use the master label to get state approval for marketed product labeling and updates. Because registrants track the labeling at each step of the approval process, they are in best position to ensure that the labeling provided to the web-distributed website(s) is the latest approved version. In addition, most registrants already have and maintain websites for their products and could use them as the basis for a web-distributed labeling.

Third-Party Vendor

Third-party vendors could include for-profit and not-for-profit organizations. Some already provide a service to registrants and states facilitating electronic submission of labeling, or to the public by harvesting available pesticide registration data and making it available online. Some third-party vendors charge a subscription fee.

Third parties could offer comprehensive services to create electronic files for labeling and submitting them for approval by the state, or could rely on other entities (e.g., registrants or states) to provide the electronic files on state-approved marketed product labeling that would be accessed by and through the website(s).

A registrant or third-party would likely be able to quickly adopt new technology with fewer constraints than apply to the federal government and might be able, therefore, to revise the website to improve the user experience. However, adding another actor to the pesticide labeling process introduces the potential for additional errors. Overall, third-parties are more flexible and attuned to the needs of their customers, whether they are users, registrants, or government.

States

EPA initially considered suggesting states as a potential host for a web-distributed labeling system. State lead agencies provide the final approval for a

product's labeling before it is released into the channels of trade. However, because states have independent processes for reviewing and approving labeling and may not have the capacity to build a website for labeling, EPA decided not to consider states as a potential host for a web-distributed labeling website.

EPA seeks comments on the following:

- Do the critical components of the web-distributed labeling website provide sufficient functionality for users and other stakeholders? Should any optional components be considered critical components?
- Are there other non-critical features of the website that EPA has not considered? Please describe their purpose and utility.
- Which website hosting approach does your organization support? Why?
- Are any proposed website hosting approaches not possible or practical? Why?
- Which potential website host is preferable? Why?
- Are there other potential benefits or drawbacks associated with having any of the entities listed above host the web-distributed labeling website?

**6. Alternative Delivery Mechanism for Labeling**

Alternate mechanisms of delivery must be developed to provide pesticide labeling to those users who do not have access to the web and/or the necessary technology to download and print WDL labeling. Alternatives for those without adequate access to the Internet include the alternative delivery mechanisms of faxing and U.S. Mail, alternate electronic mechanisms such as mobile technology, and accessing labeling from alternate locations that may have Internet access, such as the place of purchase, libraries, schools, and county extension offices.

The primary alternate delivery mechanisms the Agency expects to be used are fax on demand and U.S. Mail. Both the faxing and mailing options could be developed in conjunction with a toll-free hotline through which pesticide users could request the necessary labeling. The user would call the toll-free number, provide the state(s) and site(s) of intended use, and request the streamlined labeling via mail or fax. Users would also have the option to request the full product labeling. It is expected that the toll-free hotline number would need the following characteristics or functions to ensure faxing and sending labels via mail are viable alternatives: nearly 24-hour access; no charge to callers; multilingual capability; non-automation; ability to fax and send via mail; and ability to quickly respond to user requests.

Once the user requests the labeling through the hotline, it needs to be delivered to the user. Faxing the labeling is an option for users who have access to a fax machine. This mechanism seems most feasible for users that apply pesticides in the course of their work, such as commercial pesticide applicators, because this group is more likely to own fax machines. A mechanism accessible by all pesticide users is the U.S. mail. Standard delivery through U.S. Mail should not have any extra costs to the user but expedited delivery could be offered for an additional charge. First class mail takes about 1 to 3 days to get to the recipient, which is in addition to any processing time needed to select, print, and prepare the labeling to be mailed. This processing time needs to be minimized in order to keep this mechanism feasible.

Mobile technology is another possible alternative delivery mechanism because cell phones and other mobile devices may be more accessible for users that do not have access to computers and/or the Internet. However, mobile technology may be limited due to limited network coverage, the size of files that can be downloaded, and slower access speeds. Another issue with mobile technology is that some states may require the users to have a paper copy of the label and it isn't clear if labeling can be printed from these devices. For users in states that do not require the user to have a paper copy of the labeling, delivery of labeling to a smart phone is a feasible alternative to accessing and printing the labeling at a traditional computer.

Some places, such as the place of purchase, libraries, schools, and university extension service offices, may serve as alternate locations to access the Internet and/or fax machines, and thus access web distributed labeling. Access may be limited in some of these locations (e.g., libraries may have slow Internet connection speeds and limited availability of computers and printing, schools may not be accessible to non-students). While EPA recognizes that these locations could be a potential place for users to access web-distributed labeling, the Agency will not rely on the place of purchase, libraries, schools, or university extension services as the primary alternate delivery mechanism for web-distributed labeling.

EPA believes that all of these mechanisms should be explored. At a minimum, faxing and mailing should be implemented as the primary alternate delivery mechanisms for web-distributed labeling, and outreach should be done to ensure that alternate locations are an option for at least some users.

EPA requests stakeholder input on the proposed alternate delivery mechanisms. Please respond to the following:

- Who should administer the alternate delivery mechanisms (maintaining the toll-free hotline, mailing and faxing the labels)?
- Who should pay for administering the toll-free hotline and mailing the web-distributed labeling?
- Are there other feasible alternate delivery mechanisms for web-distributed labeling? Please describe them and how they could be implemented.

### 7. Outreach and Culture Change

Web-distributed labeling would be a potentially major change for pesticide users. Although many may be familiar with using the Internet, they have not relied on it for pesticide labeling. Users would have to adapt to a new way of obtaining product labeling but regardless of the distribution system employed, their responsibility to obtain and follow all label and labeling instructions would not change. To avoid the increased risk to public health and the environment created if users do not obtain and follow the labeling as required, it would be essential to develop and implement a comprehensive communication plan about web-distributed labeling to educate users and those who conduct training or make pesticide use recommendations.

Outreach regarding the new labeling access method and the required culture changes will need to be multifaceted with different communication messages, timing, and collaborations depending on the stakeholders and target outreach audience. Although it may be necessary to tailor the information to specific audiences, locations

and products for the pilot, the underlying issues are the same. A more complete discussion of outreach and communication is available at: http://epa.gov/pesticides/ppdc/distr-labeling/jan09/ed-culture.pdf.

Two facets of a successful outreach campaign are a clear, consistent message delivered repeatedly to the user and involving all relevant stakeholders in the outreach effort. The three messages would be: 1) web-distributed labeling will replace paper-based labeling on only some products (but not all products) and only in some marketplaces (not home and garden or antimicrobials); 2) users still must follow federal and state requirements, including, where applicable, possession of the labeling at the time of application, and comply with all labeling use restrictions and instructions (whether attached, accompanying, or web-distributed labeling); and 3) there are different ways to obtain web-based labeling: Internet download and the alternate delivery mechanisms, such as fax or mail.

A number of pathways exist that provide information to stakeholders: EPA, registrants, cooperative extension service, state regulatory and enforcement agencies, trade associations, user groups, pesticide dealers and crop advisors, and farm worker advocacy groups. With an understanding of the benefits of a web-distributed labeling system, they would be better equipped to pass the information to the end user. Before implementing any web-distributed labeling program, EPA would work with the stakeholder groups identified above as well as any other interested parties to develop a comprehensive plan for outreach.

EPA plans to work with representatives from the groups listed above in developing a strategy to conduct collaborative outreach in order to ensure that culture change regarding web-distributed labeling occurs in the most effective manner possible. EPA would also work through existing committees, networks, and workgroups, including the Pesticide Program Dialogue Committee, the NAFTA label workgroup, the State-FIFRA Issues Research and Evaluation Group (SFIREG), The Pesticide Stewardship Alliance (TPSA), and the Association of American Pesticide Control Officials (AAPCO). The American Association of Pesticide Safety Educators (AAPSE) will be a critical partner because of its experience in developing educational material and its knowledge of how to conduct effective outreach into the pesticide user community. The message will be delivered most effectively if responsibility for doing so is shared, because each individual organization has its own expertise, experience and reach into the user community.

Education of users would begin well before implementing a web-distributed labeling system. Those delivering the web-distributed labeling message to users should have an understanding of it and their role as educators and information sources at least 6 months before the pilot begins. EPA recognizes the timing of training will dictate the most effective times to conduct outreach and would plan the initiation of the outreach and education component of web-distributed labeling with this timeframe in mind.

EPA requests comment on the proposed approach to stakeholder outreach and education.

- Are there audiences or partners that have not been identified?
- Are there alternate ways to deliver the message more efficiently or effectively?

## 8. Enforcement

Under the current system, a user is required to comply with the pesticide product labeling. The requirement for applicators to comply with labeling will not change under web-distributed labeling; as under the existing paper-based system, an applicator's failure to follow the use directions or other labeling language would be a violation of FIFRA § 12(a)(2)(G).

Pesticide labeling is enforced under FIFRA § 12 which lists various unlawful activities. FIFRA § 12(a)(1)(A) declares it unlawful to sell or distribute a pesticide not registered under FIFRA § 3. FIFRA § 12(a)(1)(B) declares it unlawful for any person to distribute or sell a product whose claims differ from those made in connection with its registration. FIFRA § 12(a)(1)(E) declares it unlawful for any person to distribute or sell a misbranded product as defined in § 2(q). FIFRA § 12(a)(2)(A) declares it unlawful for any person to detach, alter, deface, or destroy, in whole or in part, any labeling required under the Act. FIFRA § 12(a)(2)(G) declares it unlawful for any person to use any registered pesticide in a manner inconsistent with its labeling. FIFRA § 12(a)(2)(H) declares it unlawful for any person to use any pesticide which is under an experimental use permit contrary to the provisions of such permit. FIFRA §§ 13 and 14 describe the actions the Agency may take in response to violations of the Act.

Web-distributed labeling would mean a change in the way labeling is delivered, but not in the way it is enforced. Enforcement of FIFRA and EPA's regulations is necessary to ensure that pesticides continue to be used according to labeling requirements. This section explores how implementation of a WDL system would affect the legal responsibilities of users and registrants, users, and distributors to comply with FIFRA. Further discussion is available at: http://epa.gov/pesticides/ppdc/distr-labeling/june09/enforcement-paper.pdf .

### i. Registrants

States have primary enforcement authority for pesticide use violations. EPA generally pursues violations of the FIFRA's labeling requirements. Compliance monitoring would be a joint federal-state effort to monitor labels in the marketplace and ensure that applicators are using and following current and appropriate labels when applying pesticides. This approach would not be altered by a web-distributed labeling system.

Registrants are ultimately responsible for ensuring that the label affixed to or accompanying a product when it is released into channels of trade is current and accurate. Although the registrant may enter into contracts with other parties acting as the registrant's agent to produce or label products, the registrant is still ultimately responsible for the labeling of the product. Under a web-distributed labeling scenario, the registrant would be responsible for ensuring that current and accurate labeling is available for users to obtain. By listing a website address on the label, the registrant would take responsibility for the content of the website concerning that product. There are a number of alternative methods that have been proposed for distribution of labeling, including fax-on–demand services or toll-free telephone lines to request a copy of the label. Regardless of how the user

obtains the label, the registrant would be responsible for the labeling content delivered to the user.

The registrant would be responsible for providing a legally valid label to the user. There may be instances where a registrant contracts with a third party to provide labeling to users under a web-distributed labeling system. Transferring this duty from the registrant to the third party website host does not absolve the registrant of its ultimate responsibility. The Agency may also find the registrant liable for violations of FIFRA regarding the website's operations and content. FIFRA § 14(b)(4) provides that the act, omission, or failure of any officer, agent, or other person (e.g., a website host) acting for or employed by any person regulated by FIFRA (e.g., a registrant) shall be deemed to be the act, omission, or failure of such person (a registrant) as well as that of the person employed (the host). The Agency is considering whether registrants seeking to use web-distributed labeling for their products should be required to submit, as part of the pesticide's registration under FIFRA, documentation of their contractual arrangements with website operators. Such a requirement would serve many purposes including the following: (1) it will encourage registrants to enter into contractual agreements with reputable website operators; and (2) it will expedite federal and state compliance monitoring efforts.

**ii. Users**

Pesticide users are responsible for applying the product in accordance with the restrictions and directions in pesticide product labeling. The provisions of a product's labeling are generally enforceable, and violations of a product's labeling are punishable by civil or criminal penalties under FIFRA § 14. A user's responsibility to follow labeling instructions, and the consequences of not doing so, would not change under web-distributed labeling.

Under web-distributed labeling, the container's label will require the user to possess the labeling referenced on the pesticide container (i.e., directions for use) prior to mixing, loading, or applying the pesticide. Failure to possess the directions for use as required by the container's label will constitute misuse of the pesticide product and violate FIFRA § 12(a)(2)(G). There is an issue with respect to what actions by a user would constitute having an appropriate copy of the labeling in his possession. EPA would regard having either a paper copy of the downloaded labeling or an electronic file as meeting the requirement to have a copy of the labeling but state requirements may be different. Further, if the user had multiple containers of the same product, he would need to have only one copy (paper or electronic) of the labeling for that product. State laws may differ and may require hard copies.

The container's label will also require the user to follow the web-distributed labeling. Failure to follow the use directions or other requirements contained in the web-distributed labeling violates FIFRA § 12(a)(2)(G). FIFRA is a strict liability statute. Thus, if the user obtains an incorrect version of the labeling and applies the pesticide consistent with the incorrect directions, it may be a violation of FIFRA § 12(a)(2)(G) because the application was not made consistent with the approved labeling . The user may be able to argue as an affirmative defense the correctness and accuracy of the downloaded labeling or that they followed the

correct process to retrieve the correct labeling but nonetheless received the incorrect labeling.

A user could not use the unavailability of a website as a reason for not obtaining a copy of the web-distributed labeling because the container label will provide at least one alternative method of obtaining a copy of the labeling. EPA would expect the user to employ the alternative method in case the website was not available before mixing, loading or applying the pesticide.

**iii. Pesticide Dealers & Other Distributors**

Currently, dealers and other distributors of pesticides are also responsible for ensuring that the registered pesticides they sell or distribute have their complete labeling. If the labeling is incomplete the pesticide may be misbranded, and it is a violation of FIFRA § 12(a)(1)(E) to sell or distribute a misbranded pesticide. However, Congress intended to allow any person who violates FIFRA § 12(a)(1)(E) to shift his or her liability to the registrant from whom the person purchased or received the pesticide if that person holds a "guaranty" in writing from the registrant. FIFRA § 12(b)(1). A guaranty is a written agreement between the dealer or distributor and the registrant or other person who sells the pesticide to the dealer or distributor, and notes that the pesticide was lawfully registered at the time of the sale and that it complies with all requirements of FIFRA. The guaranty transfers liability for any violations associated with labeling or misbranding from the dealer or distributor to the registrant or other person who provided the pesticide. The FIFRA guaranty provision would not be affected by web-distributed labeling.

Dealers and distributors may elect under the current system to provide parts of EPA-approved labeling for a product to their customers when they sell or distribute a registered pesticide. Such accompanying material must travel with the pesticide product from a registered establishment where the product was produced. 40 CFR 167.3 defines "produce," in part, as "to package, repackage, label, relabel or otherwise change the container of the any pesticide or device." Further, 40 CFR 167.20 requires establishments where pesticidal products are produced to be registered with EPA. Since the container would bear an affixed label when dealers and distributors receive it, they would not be relabeling the product; therefore, they would not be considered producers and not required to register as establishments.

Under web-distributed labeling, there would be no requirement for dealers and distributors to register as establishments that "produce" pesticidal products because the web-distributed labeling is tied to the product by reference, and thus part of the labeling. As long as the dealer or other distributor provides the purchaser with all of the labeling required to accompany the pesticide container, the dealer or other distributor of the pesticide would not be in violation of FIFRA. Dealers may, as a service to their customers, provide the means for a user to obtain labeling through an Internet connection whereby the customer can download the labeling for the product he just purchased. Offering this service does not make the dealer liable for the failure of the user to obtain the proper labeling, nor does providing the means for obtaining labeling make the dealer's facility a production facility and subject to establishment registration. In sum,

dealers would need to meet the same state and federal requirements for selling pesticides to which they are now subject.

Under current law dealers and other distributors of pesticides may elect to provide parts of the EPA-approved labeling for a product to their customers when they sell or distribute a registered pesticide. Such accompanying material must travel with the pesticide product from a registered establishment where the product was produced.

EPA seeks comments from stakeholders on the potential enforcement of web-distributed labeling, specifically on:

- Would states be able to enforce web-distributed labeling under their current laws and regulations?
- Are there potential areas of enforcement that the Agency has not considered?
- Do users, states, registrants, or other stakeholders think that enforcement would be significantly different under web-distributed labeling? If so, please provide an explanation of how.

## IV. Issues

### A. User Access

It is necessary to ensure that all users can access web-distributed labeling in order to assure that they have the information needed to use pesticides safely and effectively. EPA would not implement web-distributed labeling if users were unable to access labeling and as a result did not comply with labeling directions during application.

While broadband penetration is expanding across the United States, especially in rural communities, not all users have internet access or the ability to download and print large files. A 2009 survey conducted by the United States Department of Agriculture found that 59 percent of farms in the United States had internet access. Internet access varies by geographic location and farm size. [See http://usda.mannlib.cornell.edu/usda/current/FarmComp/FarmComp-08-14-2009.pdf.] To ensure that all pesticide users are able to access the labeling, EPA will make labeling available either electronically or through an alternate delivery mechanism. However, EPA expects that as broadband penetration increases, users' reliance on the alternate delivery mechanism for web-distributed labeling would decrease.

EPA will continue to monitor internet and computer access in rural communities. To ensure that no system is implemented that would compromise access to and thus compliance with labeling, EPA plans to conduct several pilots related to web-distributed labeling (see Unit V.). The pilots will evaluate users' potential to access the internet to download web-distributed labeling and the feasibility of alternate delivery mechanisms.

EPA requests comments on the following:

- Are there other ways to reach pesticide users that do not have internet access other than those considered by EPA?
- What types of outreach should EPA and other stakeholders do to ensure that all pesticide users understand and could use web-distributed labeling, regardless of

internet access?

**B. User Acceptance / Outreach**

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 disposal, as well as other important information. Both FIFRA and pesticide labeling regulations assume that users follow the use directions on the label and labeling for registered products; users that do not comply with labeling are subject to penalties for non-compliance. To protect human health and the environment from the risks associated with pesticide misuse or misapplication, it is of the utmost importance that pesticide users follow labeling instructions.

Implementation of web-distributed labeling would have to ensure that risks to the public and the environment are not increased by users' failure to download and follow the pesticide labeling. EPA would not move forward with web-distributed labeling if EPA were to conclude that the system is unlikely to enhance users' understanding and following of pesticide labeling. To gauge user acceptance and to ensure that the web-distributed system is designed to be as user-friendly and functional as possible, the Agency is developing a pilot as described in Unit V.

EPA requests comments on the following:

- Is there data on professional pesticide users' reading and understanding of the label under the current paper-based system?
- In addition to doing a pilot to gauge user acceptance of the concept of web-distributed labeling and potentially doing a field-level pilot, what else could EPA do to measure users' acceptance of the concept and likelihood of downloading the labeling from a website?

**C. State Acceptance**

As discussed in Unit II.A.2., state registration of pesticide products varies widely. Since users are required to comply with the marketed labeling registered by states, it is essential that states are actively involved in the development of a web-distributed labeling system. To move forward with web-distributed labeling, EPA will need the support of all states. EPA has been working with both state lead agencies for pesticide regulation and cooperative extension services to get feedback from these stakeholders. The primary concerns of states are ensuring the enforceability of web-distributed labeling and not being required to significantly alter their registration systems.

A web-distributed labeling system would not require every state to adopt the same registration system. States could continue to use their existing registration systems, receiving the marketed labeling either electronically or as a hard copy from registrants. EPA anticipates that registrants would be responsible for entering the approved marketed labeling into the database(s) for the web-distributed labeling system, meaning no increased burden for review and approval of products in a state.

EPA also recognizes that coordination with states and registrants would be necessary to implement web-distributed labeling. If a company chooses to participate in web-distributed labeling, both the state and the registrant would need to understand

the process and the format of the approved labeling. States would need to notify registrants how the approval process would work to ensure that the labeling posted to and retrieved from the web-distributed labeling system would be valid.

The Agency will continue to work with states through the Association of American Pesticide Control Officials (AAPCO) and the State-FIFRA Issues Research and Evaluation Group (SFIREG) to ensure their concerns are addressed in the development and implementation of web-distributed labeling.

EPA seeks comments on the following:

- What are specific areas in which web-distributed labeling could affect state programs?
- What would be the impact of web-distributed labeling on state programs?
- How could EPA satisfactorily address concerns about the effect of web-distributed labeling on state programs?

**D. Registrant Liability**

In the PPDC Workgroup on web-distributed labeling, a number of stakeholders voiced a concern that implementing a system of web-based distribution of pesticide labeling could change the potential tort liability of registrants. "Tort liability" refers broadly to the body of law for establishing rights and remedies in non-criminal lawsuits to provide relief for persons who have suffered injury because of the wrongful acts of others. This area of the law addresses a wide variety of "civil wrongs" (referred to as "torts"), not arising out of contractual obligations. Although the legal principles governing tort liability are quite extensive and sometimes complex, the basic framework is fairly simple. If one person has been harmed by the behavior of another, the injured party may bring a lawsuit against the person who allegedly caused the injury in order to recover damages. If a judge or jury finds that the defendant's behavior caused the damage and that the behavior was "negligent," i.e., did not meet the relevant standard of care, the defendant normally could be found liable for damages caused. Negligence can occur in many different situations and can involve many different types of behavior. Whether a particular person's behavior constitutes "negligence" typically is determined on a case-by-case basis. When dealing with the sale of products, negligence claims can involve making a defective product (one that does not work as claimed), or failing to provide adequate instructions or warnings so that the user can use the product without injury.

The Agency asked participants in the PPDC Workgroup to explore the impact on registrants' potential tort liability of a web-based system of distributing labeling. In response several work group members collaborated on the preparation of an issue paper, "Liability Concerns Associated with Web-Distributed Labeling," which is available at: http://www.epa.gov/pesticides/ppdc/distr-labeling/sept09/liabilityissues.pdf In addition to tort liability, the PPDC issue paper discusses a number of other topics. One was registrants', dealers', and users' liability for violations of FIFRA and associated state regulatory requirements. Unit III.C.8. deals with enforcement of FIFRA requirements, and addresses the aspects of the paper dealing with liability for regulatory violations.

The PPDC paper also identified unsettled legal issues concerning the scope of

state authority to regulate pesticides, in particular whether a state has the authority to refuse to approve or register a product, therefore effectively prohibiting its sale, if the State did not consider the EPA-approved pesticide labeling adequate. Whatever the merits of the competing views of the legal issue might be, EPA believes that a decision to allow a registrant to use a web-distributed labeling system would not affect the scope of states' authority to regulate pesticides within their borders. States would have no greater or less authority to refuse to approve a pesticide using web-distributed labeling than they have to refuse to register pesticides under the current system. (EPA takes no position in this notice on the extent of State authority to refuse to register a pesticide and what reasons, if any, would be legally sufficient.)

Finally, with respect to tort liability, the PPDC paper raised several questions but did not suggest possible answers. The PPDC paper did not contain sufficient explanation for EPA to understand the basis for concern that a voluntary, web-distributed labeling approach might increase the risk of successful tort liability lawsuits against registrants, much less what steps EPA or others might take to minimize any such risk. Consequently, EPA asked the authors to revise and expand the paper using examples to illustrate how a web-distributed labeling, approved by EPA, could affect registrants' potential tort liability. EPA has not received a new version of the issue paper.

Because the legal authority, registration processes, and requirements for users to follow all pesticide labeling are the same under web-distributed labeling as they are under the current system, EPA does not believe that web-distributed labeling will introduce additional tort liability to pesticide manufacturers or distributors.

EPA requests comments on the following:

- Would a decision to adopt a system of web-based distribution of pesticide labeling affect the potential tort liability of registrants? As part of the comment, please describe the legal theory for potential negligence and how web-distributed labeling affects the likelihood of successful tort claims against a registrant, especially as compared with the current paper-based system of distributing labeling.
- What steps might EPA take to evaluate whether the extent of compliance with pesticide labeling increases, decreases, or does not change when comparing pesticide users who buy products using web-distributed labeling vs. users of products following the current system?
- To what extent could a system of web-distributed labeling affect the authority of a state to regulate pesticides?

## V. Next Steps

This section presents EPA's thoughts on the next steps for exploring the concept of web-distributed labeling. In addition to continuing its outreach efforts with stakeholders and considering feedback on this Federal Register Notice, EPA intends to conduct a User Acceptance Pilot. Based on the feedback gathered during the User Acceptance Pilot and from this notice, a Virtual Pilot and Limited Field Pilot may be developed.

**A. Customer Acceptance Pilot**

The User Acceptance Pilot would simulate the web-distributed labeling experience using a real website, which would be capable of providing web-distributed labeling for a limited number of pesticide products. The labeling downloaded from this website would not be valid for purposes of authorizing a user to apply the products involved. The users would go through the following steps:

1. Log onto an Internet-accessible website.
2. Enter a product registration number or other product identifier for one of several pre-determined products.
3. Select the relevant state/county in which the mock pesticide application would take place.
4. Select the relevant use pattern(s) for the mock pesticide application to filter the labeling according to use pattern(s).
5. View and download from the website the labeling appropriate for the identified product, use pattern, and state provided.

In addition, the pilot websites would:

1. Place a prominent statement on each page of the downloaded labeling making it clear that the labeling downloaded from the website(s) was not legally valid for purposes of making a pesticide application.
2. Offer users a mechanism for providing feedback on the web-distributed labeling experience.

The purpose of the User Acceptance Pilot is to research the extent to which users would accept a system requiring them to obtain labeling via the Internet. The specific goal of the pilot is to determine whether the benefits of web-distributed labeling would be sufficiently appealing to users that they would be willing to visit a website to obtain labeling for a pesticide product. The pilot would demonstrate how users could access labeling information using the website and would not involve the actual distribution to users of actual pesticide product labeling that would rely on the web-distributed labeling approach.

The results of this research are important for EPA in deciding whether and how to move ahead with further efforts to develop such a system. Consequently, the Agency not only expects participants in the Pilot to offer users a mechanism for providing feedback on the web-distributed labeling experience, but also encourages participants to summarize and submit to EPA the feedback obtained through the pilot. EPA hopes to receive information on users' opinions about paper labels, the web-distributed labeling website experience, web-distributed labeling overall, and other potential features of web-distributed labeling.

More information on the User Acceptance Pilot is available at http://www.gpo.gov/fdsys/pkg/FR-2010-08-18/pdf/2010-20449.pdf.

**B. Review of Public Comments on Federal Register Notice**

EPA is using this notice to solicit comments and suggestions from stakeholders and the public on the concept of web-distributed labeling. EPA will review comments as they are submitted and will present the information received to interested parties. EPA plans to incorporate feedback received through this notice into the development of the planned pilots and in refining the concept of web-distributed labeling.

EPA intends to continue communicating with WDL stakeholders to provide updates and gather feedback as it moves closer to implementing WDL. In addition to addressing comments received in response to this and other WDL Federal Register Notices, EPA will continue to provide updates on the EPA website, meet with and encourage the submission of information from stakeholders, and gather and respond to informal comments received on the User Acceptance Pilot and Virtual Pilot described above.

### C. Virtual Pilot

The Virtual Pilot would demonstrate the actual functionality of web-distributed labeling through the creation of an actual website and supporting database(s). The goals of the pilot would be to assess whether the website works properly for registrants, EPA, states, and users. The objectives, scope, assumptions, and program assessment are discussed in a paper at http://epa.gov/pesticides/ppdc/distr-labeling/sept09/wdl-virtualpilot.pdf. This pilot could be conducted in conjunction with the Limited Field Pilot discussed in Section D below.

### D. Limited Field Pilot

The Limited Field Pilot would implement web-distributed labeling on a trial basis, in a limited geographical area and with a small number of products. The Limited Field Pilot would be informed by the findings of the Customer Acceptance Pilot and comments on this Federal Register Notice. Users in areas participating in the Limited Field Pilot would only be able to obtain the full labeling for a participating product using web-distributed labeling. Containers would bear a limited set of the labeling (see Unit III.C.3 above). Since the Limited Field Pilot depends heavily on the feedback received from stakeholders, the concept will not be developed substantially until the other pilots have been completed.

## VI. Conclusion

After extensive stakeholder feedback and refinement of the concept, EPA believes that web-distributed labeling would be beneficial to users, registrants, states, other stakeholders and the Agency. Stakeholders would benefit from faster implementation of risk mitigation and new uses, faster access to new uses, reduced printing costs, and streamlined labeling. Since labeling is the critical component that allows EPA to communicate use and safety instructions to users, an initiative to make the labeling streamlined, and easier to read and understand could lead to increased compliance and therefore improved protection of human health and the environment. EPA recognizes that issues exist with implementation of a web-distributed labeling system. However,

given the potential benefits, EPA plans to move forward to pilot some of these concepts and to address outstanding questions. The Agency will continue to engage all stakeholders in the consideration of this ambitious system.

**List of Subjects**

Environmental protection, **electronic pesticide labeling, pesticide distribution, pesticide labeling, pesticide production, pesticide regulation, pesticide user, state pesticide regulation**.

Dated: _____

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[FR Doc. ??–?????? Filed ??–??–??; 8:45 am]
**BILLING CODE 6560–50–S**