

## **PPDC Web-Distributed Labeling Workgroup Discussion Paper Enforcement of Web-Distributed Labeling**

### **I. Introduction**

This paper discusses the enforceability of web-distributed labeling and potential impediments to effective compliance monitoring and enforcement of the labeling provisions of FIFRA. EPA is working to establish a system whereby purchasers and users may obtain a legally valid copy of the labeling for a pesticide product from a website, toll-free telephone service, or other delivery mechanism. Web-distributed labeling raises potential compliance monitoring and enforcement issues relevant to the pesticide's registrant, dealers (or other distributors), and users.

Pesticide labeling is a critical component of the regulatory framework for ensuring that a pesticide's use will not cause adverse effects on man or the environment. As part of the process of registering a pesticide product, EPA must ensure that the product's labeling is sufficient to allow a user to apply the product safely. Registrants are responsible for ensuring that the labeling on a pesticide product accurately reflects the labeling accepted by EPA in connection with the product's registration. Pesticide users are responsible for applying the product as required by the label. 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 person may not distribute or sell any pesticide that is not registered under FIFRA. All pesticides must be distributed bearing their EPA-approved pesticide labels. It is unlawful for any person to sell or distribute a registered pesticide with claims that differ from those approved by EPA or is misbranded. A pesticide is "misbranded" if, among other things, its labeling: bears any false or misleading statement; does not bear the establishment or product registration number; does not prominently display any required word, statement, or other information; does not contain directions for use that are adequate to protect health and the environment; does not contain a warning or caution statement adequate to protect health and the environment; or does not contain the use classification. Normally, registrants attach the most current approved version of product labeling to the containers that they release for shipment.<sup>1</sup>

Under current practice, most pesticide products are distributed with the requisite labeling accompanying the pesticide container at the point of sale, commonly as a leaflet or booklet.<sup>2</sup> Consequently, each time that a pesticide is used up and its container disposed of, the user must obtain a new container with new labeling that he cannot alter or deface. This means that the labeling accompanying the container is legally valid for as long as the user possesses the specific product container, and is only valid with respect to the quantity of pesticide originally within that container.

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<sup>1</sup> However, under certain circumstances EPA allows previously approved labeling, which is not the most current version, to be distributed or sold by the registrant for a period of 18 months after EPA's approval of a labeling revision. See 40 CFR §§ 152.130(c) and (d).

<sup>2</sup> A current exception to this rule is fumigants.

EPA is considering a system that would establish a new way of making the labeling of a pesticide product available to purchasers and users. Instead of obtaining the full product labeling along with the pesticide container at the time of product purchase, a purchaser would obtain a copy of the labeling either by downloading a file from a website or by calling a toll-free telephone service that would then mail or fax the labeling to the caller. While the responsibility of the pesticide purchaser/user to obtain and follow all label and labeling instructions will not change under the proposed system, how the user obtains the most current labeling will. The Agency's expectation is that the purchaser/user will have in their possession the most recent and pertinent labeling information approved by EPA including directions for use. Because the new system will depart from the current federal and state practice of associating labeling with a specific pesticide container (which physical association effectively creates the limited lifespan for the validity of labeling), the new system raises liability questions for pesticide registrants, dealers, and users. The proposed framework also raises enforcement issues for EPA and the states because collecting the labeling accompanying the product at the time of the violation is critical to successful compliance monitoring and enforcement.

Pesticide labeling is enforced by FIFRA § 12 which lists various unlawful activities. 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.

A registrant generally must obtain a State registration to sell or distribute a pesticide in that State.<sup>3</sup> States may also regulate the sale and use of any pesticide in the State but only if the regulation does not allow any sale or use prohibited by FIFRA. States have primary enforcement authority for pesticide use violations. EPA generally pursues violations of the FIFRA's labeling requirements. Compliance monitoring will be a joint federal-state effort to monitor labels in the marketplace and ensure that applicators are using current and appropriate labels when applying pesticides.

## **II. Enforcement of a Registrant's Responsibilities**

### **A. Overview**

Currently, registrants are ultimately held responsible for ensuring that the labeling accompanying a product when it is released into channels of trade is current and accurate. FIFRA §§ 2(q) and 12(a)(1)(F) and 40 CFR Part 156. 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

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<sup>3</sup> Certain pesticides are not registered with EPA even though registration is required at the state level (e.g., Section 25(b) pesticides or medical disinfectants regulated by the FDA).

labeling scenario, the registrant would still 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. There are a number of methods that have been proposed for distribution of labeling, including authorized web sites, 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 user of the product would be responsible for obtaining the most recent version of the labeling appropriate for the state in which the application will take place, and for following the labeling's directions for use. FIFRA § 12(a)(2)(G).

While the registrant would be responsible for providing the latest EPA approved label to the user, there may be instances where the Agency may also find the operator of the registrant's website 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 as well as that of the person employed. As with current practice, the Agency may charge the website's operator as the registrant's agent with violating FIFRA, as well as the registrant itself, depending on the circumstances of the violation. 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 § 3, documentation of their 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.

## **B. Potential Problems with Web Distributed Labeling**

### **1. Incomplete, Inaccurate or Differing Labeling Provided by the Website**

Discrepancies between the web-distributed labeling and the EPA-approved master labeling might include the following situations:

- The labeling on the website doesn't accurately reflect the current EPA-approved labeling<sup>4</sup>
- The user requests a subset of the labeling by use from the site but the query returns an incomplete document (although complete and accurate labeling is available on the website).
- Labeling is available for a user in a state which has not approved the use of that specific pesticide in that specific state.<sup>5</sup>

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<sup>4</sup> See the next section for a discussion of how to approach a discrepancy that arises from the failure of the website to reflect an approved revision.

<sup>5</sup> Note: this would not necessarily constitute a violation of FIFRA, but would constitute a violation of state law in most or all states.

Providing inaccurate or incomplete labeling from the website would violate FIFRA §§ 12(a)(1)(B) or FIFRA 12(a)(1)(E). Please note that both authorities would apply to any person who is selling or distributing pesticide products. In addition, the registrant and/or website operator would be liable under FIFRA § 12(a)(2)(A) if the labeling is altered in whole or partially. This provision does not require that the pesticide be sold or distributed as in the case of violations committed under FIFRA § 12(a)(1). If website labeling is noncompliant, EPA has enforcement authority under FIFRA §§ 14(a) or 14(b) to charge the registrant and/or website host with violating FIFRA.

## 2. Website Fails to Reflect Most Recent EPA Approved Master Labeling

If the website does not provide the most recent, updated labeling to users requesting downloads of such labeling, the registrant, website-operator, and user may find themselves in violation of FIFRA. 40 CFR Part 152 provides the procedures, requirements and criteria concerning the registration of pesticides under FIFRA § 3. 40 CFR § 152.130(c) currently allows the registrant of paper-based labeling 18 months to sell products under previously approved labeling before voluntary amendments to the labeling must appear on the product, unless otherwise directed by an order issued under FIFRA §§ 6 or 13. 40 CFR 152.130(d) allows the Agency to specify a date by which a product's label is required to be revised as a result of a Registration Standard, Label Improvement Program notice, or a notice concluding a special review process.

The part 152 rules discussed above were written in the context of a system in which paper-based labeling accompanied product containers; these rules do not make sense for a product that relies on web-distributed labeling. A registrant could easily post new versions of the product labeling on its website and much more quickly than registrants can produce new paper versions of the labeling to attach to the product containers they release for shipment. To the extent that a labeling revision contained new directions that would mitigate risks of using a product, EPA thinks it important for such revisions to reach the users as soon as possible.<sup>6</sup> To implement such a policy, the Agency would need to pursue one of two approaches. EPA could amend the rules in 40 CFR 152.130 to limit their applicability to paper-based labeling sent with product containers. Alternatively, EPA could impose a condition on any approval of amended labeling that the registrant would need to change the website to reflect the revision within a short specified period of time. If EPA establishes new time requirements for implementing amendments to web-distributed labeling, those requirements would govern how quickly after approval a revision to labeling must be reflected in the posting of material to a web site.

It is unlawful for any person to distribute or sell any registered pesticide if any claims made as part of the pesticide's sale or distribution differ from any claims made as part of the pesticide's registration. FIFRA § 12(a)(1)(B). Assuming that the Agency has established a time period for changing the website to reflect approved labeling amendments, EPA has several options if the website does not provide the most recently approved labeling. First, if the website

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<sup>6</sup> There could be less urgency for posting other types of labeling revisions, e.g., the addition of new uses. In order to give a registrant the ability to manage the marketing of a product, EPA could allow a registrant flexibility in when to post a revision that does not involve risk mitigation.

does not post labeling in a timely manner and timely posting is a condition of registration, EPA has (1) enforcement authority under FIFRA §§ 14(a) or 14(b) against the registrant and/or website host, and/or (2) cancel the conditional registration under FIFRA § 6(e). Second, the failure to timely update the labeling will result in a misbranding violation committed by the registrant. If the registrant has been granted only a certain period for using previously approved labeling, after that period runs anything other than currently approved labeling would be misbranding violations under FIFRA § 12(a)(1)(E).

### 3. Website is Nonfunctioning and Labeling is Not Available

In order for the web distributed labeling system to be viable, users must be able to consistently and reliably access the website 24 hours per day. Normal interruptions of service (e.g., routine maintenance) are to be expected, but when does a website become too unreliable to provide timely service? EPA should establish a website performance standard and make adequate website functionality a condition of registration for products with web-distributed labeling using FIFRA 3(c)(7)?<sup>7</sup> If a website is not available as prescribed by conditional registration, EPA has authority to (1) cancel the conditional registration under FIFRA 6(e); and/or (2) initiate an enforcement action under FIFRA §§ 14(a) or 14(b) against the registrant and/or website host.

A consequence of the website's unavailability may result in a user violating FIFRA § 12(a)(2)(G). For example, if a user must apply a pesticide immediately and cannot obtain the directions for use in a timely manner, a violation would occur even if the user applies the product based on his best recollection of the lawful application rate even if his recollection is correct. In such a situation, the user would be in violation of FIFRA 12(a)(2)(G) for misuse of a pesticide.

### **C. Compliance Monitoring for Registrants**

Registrants are responsible for ensuring that the content of web sites is accurate and current. The registrant is also responsible for ensuring that users can reliably access a web site and that there are other means of obtaining labeling if the user cannot access the web site. In order to perform timely and appropriate compliance monitoring, federal and state pesticide programs must have the infrastructure necessary to carry out its objectives, including hardware, software, staff, and cooperative agreements. It is absolutely necessary for successful compliance monitoring and enforcement that EPA timely disseminate to the states the most recent master label so that field inspectors can accurately compare the master label with the marketplace label. In addition, state pesticide laws must be evaluated to see if revisions are necessary to address web-distributed labeling violations. EPA and the states will monitor compliance with the content and availability of web distributed labeling. Web distributed labeling should streamline the process and with unique identifiers for labeling compliance monitoring will become easier for the states. Container labeling will be shorter and comparison with the label on file with the state can be done more easily and may not require a field inspection.

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<sup>7</sup> Setting a performance standard may require rulemaking. However, this option would make meeting the standard a requirement for users of web distributed labeling without having to utilize the condition of registration route.

### **III. Enforcement of Responsibilities of Dealers and Others who Sell or Distribute Pesticides**

Under current law dealers and other distributors of pesticides are also responsible for providing EPA approved labeling to their customers when they sell or distribute a registered pesticide. FIFRA §§ 12(a)(1)(B), 12(a)(1)(E), and 12(a)(2)(A). However, Congress intended to allow any person who violates FIFRA § 12(a)(1) 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).

As noted in the background section of this document, the proposed web-distributed labeling system would modify current labeling practices by severing directions for use from physical placement on the pesticide container. Users would be required to comply not only with the restrictions appearing on the label affixed to the container and in the labeling accompanying the container, but also with the additional labeling referenced on the pesticide container. As long as the dealer or other distributor provides the purchaser with all of the labeling required by the EPA-approved registration except for the web-distributed labeling itself, 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 they are now subject to. Further, a dealer will not be liable for inaccurate or outdated web-distributed labeling as described in Section II. except in the unusual situation where such person is affiliated with the website.

### **IV. Enforcement of Users’ Responsibilities**

#### **A. Overview**

For paper-based labeling, the user is responsible for complying with the requirements of product labeling obtained when the user took possession of the product’s container. The user must comply with all instructions and requirements in the labeling [FIFRA § 12(a)(2)(G)] and must keep the labeling as long as he has the container [FIFRA § 12(a)(2)(A)].

Under a new web-distributed labeling approach the attenuation of the labeling and the product container creates an issue about whether the downloaded labeling may be associated with different containers obtained over time. If the labeling is not uniquely associated with a container that the user empties and disposes of, the user could continue to use a “legacy” version of the labeling indefinitely with multiple containers. But versions of labeling for a pesticide approved by EPA are expected to change over time. Taken to its logical extreme, a version of labeling obtained under the new system could, in theory, be used with any product container unless there was a restriction that limited its applicability to specific containers or for a specific time period. Unless users must replace old labeling for a product with an updated version of the

labeling, any improved protections for public health and the environment would not be a condition of use at the time of application.

The Agency has developed two options for linking labeling to specific pesticide containers. The first option is labeling linked to a production date, which would allow the pesticide to be used according to any version of the labeling that existed after the date on which the product was produced. 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 “produced by [date].” Labeling that predated the production date on the newly obtained quantity of pesticide would no longer be valid. In effect, this approach gives web-distributed labeling an indeterminate lifespan equal to the amount of time a user takes to use up the pesticide material.

Under a second approach, referred to as the finite labeling lifespan, the pesticide could lawfully be used according to the downloaded labeling only for the stated lifespan of the labeling. Consequently, if a user thought he might still possess some quantity of the pesticide after the lifespan of his version of the labeling had expired, he would need to obtain a newer version of the labeling with a lifespan running until a later expiration date. Of course, the user would be required to comply with all directions and restrictions on the subsequent version of the labeling. So too would users who purchased a pesticide after EPA had implemented new risk mitigation measures through revisions to the version of a pesticide’s labeling posted on the website.

Web distributed labeling will maintain the user’s responsibility for obtaining and following the labeling requirements. However, the user must take a more active role in obtaining the product labeling. The pesticide product’s container will bear most of the labeling with the exception of the directions for use. The product label will require the user to obtain the directions for use prior to applying the product. Because the product label references the web site and requires the user to obtain further labeling, downloading the label itself will not trigger the production establishment requirements of FIFRA § 7.

## **B. Potential Problems**

### **1. Misuse of the Pesticide**

The container’s label will require the user to obtain the labeling referenced on the pesticide container (i.e., directions for use) prior to his/her mixing, loading, or applying the pesticide. *Failure to obtain* the directions for use as required by the container’s label will constitute misuse and violate FIFRA § 12(a)(2)(G). There is an issue with respect to what actions by a user would constitute having a 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. 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 the product.

A user could not use the unavailability of a website as a reason for not obtaining a copy of the web-distributed labeling. The container label will provide at least one alternative method of

obtaining a copy of the labeling, and EPA would expect the user to employ the alternative method in case the website were not available.

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). If the user obtains an incorrect version of the labeling and applies the pesticide consistent with that labeling's directions, it is nonetheless a violation of FIFRA § 12(a)(2)(g) because FIFRA is a strict liability statute.<sup>8</sup> The user's liability exists regardless of whether the labeling archived on and downloaded from the website was correct.

## 2. Recordkeeping Issues

FIFRA allows EPA to require commercial applicators to create and maintain records when using restricted use pesticides and prohibits EPA from requiring private applicators to maintain records or file reports. However, the states may require recordkeeping by all applicators, and many states presently require recordkeeping that exceeds federal recordkeeping requirements. Since states have primary use enforcement authority, recordkeeping for web-distributed labeling involved with misuse violations becomes largely a state issue. Thus, it may be appropriate for states to determine what constitutes appropriate recordkeeping unless a minimum standard is not implemented by the states.

## C. Compliance Monitoring for Users

States have primary use enforcement authority and would monitor users to ensure that they possess and follow current labeling when applying a product.

## V. Violations

Under both the current and proposed FIFRA Enforcement Response Policy (ERP), each "independent violation" of FIFRA is subject to an enforcement action. A violation is independent if it results from an act (or failure to act) which is not the result of any other charge for which a civil penalty is to be assessed, or if the elements of proof for the violations are different. Consistent with the above criteria, the Agency considers violations that occur from each shipment of a product (by product registration number, not individual containers), or each sale of a product, or each individual application of a product to be independent violations.<sup>9</sup> Each of these independent violations of FIFRA is subject to civil and criminal penalties FIFRA § 14.

Under the FIFRA ERP, for example, when EPA can document that a registrant has distributed a misbranded product (one single EPA product registration number) in four separate shipments, EPA will charge that registrant with four counts of selling or distributing a

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<sup>8</sup> The user will be able to argue as an affirmative defense the correctness and accuracy of the downloaded labeling.

<sup>9</sup> Independent violations which can be documented as both per sale and per shipment are to be calculated only as either per sale or per shipment, whichever is more appropriate based on the supporting documentation, and whichever approach yields the highest civil penalty. For example, if Person A has a violation involving one sale and two shipments, and Person B has a violation involving two sales and one shipment, both persons would be charged for two violations of FIFRA (Person A is charged for two shipments and Person B is charged for two sales).

misbranded product. Similarly, when the EPA can document that a registrant has shipped four separate misbranded products (four separate EPA product registration numbers) in a single shipment, EPA will charge the registrant four counts of selling or distributing a misbranded product. An example of a dependent violation is multiple misbranding on a single product label. EPA may assess a count of misbranding each time that a misbranded product is sold or distributed. For example, a registrant who sells or distributes four distinct shipments of a misbranded pesticide product generally may be assessed a civil penalty for four violations (each time that a misbranded pesticide is sold or distributed). However, if a single product label is misbranded in one way or ten ways, as defined by FIFRA § 2(q), it is still misbranding on a single product label and is considered a single violation of FIFRA § 12(a)(1)(E).

Enforcement actions for web-distributed labeling violations should follow the current system. Thus, violations shall be determined on the following basis:

1. Each time inaccurate, incomplete, or nontimely labeling is downloaded by a user, the registrant and/or website host commits, depending on the facts, a single, independent violation of FIFRA §§ 12(a)(1)(B) and/or 12(a)(2)(E).
2. Each time a user attempts to download a web-distributed label from the website but the website is unavailable, the registrant and/or website host commits a single, independent violation of FIFRA § 12(a)(1)(B).
3. Each time a user applies the pesticide without possessing the appropriate labeling is a single, independent violation of FIFRA § 12(a)(2)(G).