

Web-Distribution of Labeling Work Group Discussion Paper Lifespan of Web-Distributed Labeling

ISSUES:

Assuming that EPA establishes a system whereby purchasers and users may obtain a legally valid copy of the labeling for a pesticide product from a website or toll-free telephone service,

1] should such labeling have an expiration date that definitively limits its “lifespan”?

2] if so, how long should the “lifespan” of such labeling last?

BACKGROUND:

A. The Current System

Because FIFRA’s misuse provision in §12(a)(2)(G) makes it unlawful to “use a pesticide in a manner inconsistent with its labeling,” the labeling¹ 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. Under historical and current industry and regulatory practice, nearly all pesticide products are distributed with all labeling accompanying the pesticide container.² 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. (FIFRA §12(a)(2)(A) makes it unlawful for a person to detach or alter the labeling approved for a registered pesticide.) 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 quantity of pesticide originally in that container.

Under this system has one very important advantage: a person who purchases a pesticide can confidently expect to be able to use the pesticide according to the labeling accompanying the product until the all of the pesticide has been used up, unless EPA takes regulatory action to prohibit use of the product. Although EPA has the legal authority under FIFRA §§ 6, 12(a)(2)(J), and 12(a)(2)(K) to issue cancellation and suspension orders prohibiting the use of pesticide stocks in the hands of end-users, it should be noted that the Agency has only imposed such prohibitions in very rare

¹ As defined in FIFRA §2(p)(2), “labeling” is “written, printed, or graphic matter—(A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide or device. . . .” Labeling typically includes extensive “directions for use” and contains provisions regarding the use of a pesticide that are designed to ensure that its use does not cause unreasonable adverse effects on the environment.

² Only a small number of pesticide container labels contain reference to materials – thereby making that material “labeling” – that do not accompany the pesticide product. For example, portable chlorine gas products labeled for use in “shooting” swimming pools refer to the application practices manual issued by the Chlorine Institute.

circumstances when EPA believed that the continued use of a pesticide posed an extraordinarily high risk to public health or the environment. As a consequence, users have come to expect EPA will not take action that would make their planned use of the pesticide unlawful.

While anecdotal reports indicate most people use up a pesticide reasonably soon after they purchase it (i.e., within 6 - 12 months after purchase), this is not always the case. Sometimes a person may buy a product and not need to use it because, for example, the expected need to control a pest problem did not arise, and the product is kept in inventory until it is next needed – for agricultural products, commonly the growing season in the following year. A small percentage of pesticides are kept for even longer periods; chemical collection days indicate that some containers may be years, even decades, old. As far as EPA is concerned, therefore, the labeling of pesticide products effectively has an indefinite and potentially long lifespan – the amount of time that the user has possession of the pesticide container which the labeling accompanies, which may vary significantly.

Because the current system creates no definitive lifespan for pesticide labeling, there are ongoing problems with enforcement and existing stocks of pesticides. The major problem is that users do not have the benefit of the most current directions about how to use a pesticide safely and effectively. Using the product according to old labeling may result in unnecessary risks to public health or the environment.

Finally, the existing regulatory system typically involves significant delay between an EPA decision to add new or revised labeling provisions to protect public health and the environment and the actual appearance of the labeling on products in the hands of pesticide users. Once EPA makes a regulatory decision and a registrant agrees (or is legally compelled) to revise existing product labeling, the registrant must develop a new version of the labeling and submit it to the Agency for approval. Then, the registrant must print new labeling and ensure that the new labeling is attached to newly produced products. Although EPA may specify a shorter time period, the Agency typically allows the registrant 12 to 18 months to implement the labeling requirements on product newly released for shipment.³ Quantities of a product bearing the revised labeling must then be distributed through wholesale and retail distribution networks before they finally reach the user.

C. The Proposed System

EPA is considering a system that would establish a new way of making all of the labeling of a pesticide product available to purchasers and users. Instead of obtaining the labeling along with the pesticide container at the time of product purchase, a purchaser or user would be required to 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. Because the new system of obtaining labeling would depart from

³ Under the requirements at 40 CFR 152.130(c), registrant-initiated changes have to be incorporated within 18 months.

the widely prevailing practice of associating labeling with a specific container (which physical association effectively establishes a lifespan for the validity of labeling), the new system raises questions about how EPA should design the system so that users obtain and follow a relatively current version of the labeling for a pesticide they use repeatedly.

One premise of the new 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 could be considered to “accompany” a product, but it does not necessarily accompany just a single specific container as has been and currently continues to be the case. Rather the customary physical association of the labeling and a pesticide container is attenuated, and the downloaded labeling could legitimately “accompany” more than one container. (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 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 in theory could continue to use an old version of 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 were 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, any improved protections for public health and the environment would not become applicable.

DISCUSSION:

The new approach is expected to accelerate the time between an EPA decision to require new risk mitigation measures and the appearance of the new use directions or restrictions in labeling. Following an agreement with the registrant, the Agency could make the revisions in labeling posted on the website, and users would be able to obtain the labeling for products already in the channels of trade. In that way users would get the new labeling sooner than if they had to wait for the revised labeling to be printed and applied to the containers of newly produced pesticide that would then be distributed through wholesale and retail channels.

As indicated in the Background section above, however, the new approach of distributing labeling via the internet attenuates the physical connection between labeling and a single specific container. Such attenuation means that, in the absence of any restriction, the labeling potentially could be used indefinitely with multiple pesticide containers and that changes in labeling designed to improve protection for public health and the environment might never be fully implemented. Thus, EPA believes any new

approach to web-based distribution of labeling needs to make a link between specific containers and the web-distributed labeling in a way that avoids this problem.

A. Should There be a Definitive Lifespan for Web-Distributed Labeling?

The Agency sees at least two possible ways to address the issue of linking labeling to specific containers.

- First, EPA could require product containers to bear a statement that the specific container was “produced on [date]” and also require the user to obtain a version of the labeling approved on or after that date. This approach would essentially duplicate many characteristics of the existing system with its current advantages and disadvantages.
- Second, EPA could require that web-distributed labeling have a defined lifespan, after which the user would need to obtain a new, potentially updated version of the labeling. This approach would impose some costs on users, but it would have many advantages in terms of quicker, universal implementation of new risk mitigation measures.

Labeling linked to production date. The first approach would work as follows. Each pesticide container would bear a registration number and another “unique identifier” (possibly an alphabetical code) associated with a specific version of the container label for the product, as well as the date on which the product was “produced,” e. g., the date on which the pesticide mixture was put into the labeled container. The container label would also require the user to obtain a copy of the labeling for the product from either a website or a toll-free telephone service. Finally the container label would specify that the product could be used only in accordance with a version of the labeling obtained after the production date from one of these sources.

The consequence of this first approach would be that the pesticide could lawfully 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.

Finite labeling lifespan. The second approach would work as follows. The label on a pesticide container would bear a registration number and another “unique identifier” associated with a specific version of the container label for the product, as well as a requirement that the user obtain a copy of the labeling for the product from either a website or a toll-free telephone service. When the user obtained a copy of the labeling, the labeling would bear an expiration date, after which the labeling would no longer be valid. The lifespan would be of a fixed length – for example, 6, 9, or 12 months (or

longer) – and would be calculated from the date of the downloading / printing of the labeling. For example, if the labeling lifespan were 12 months, labeling downloaded from the website on March 12, 2009, would be valid through March 11, 2010. (Note: the expiration date would not affect the validity of the registration or the validity of any tolerances or tolerance exemptions.) Also, an expiration date for downloaded labeling would be independent of any statement about the time period for which the product could reliably be stored without any adverse changes in the composition of the formulation.

Under this second approach the pesticide could lawfully be used according to the downloaded labeling only for the 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 labeling available for the product could change between the user's downloads. For example, EPA might have approved additional uses, and if so, those uses would be reflected in the new labeling and the user could then lawfully apply the product on new sites. Similarly, EPA might have approved new labeling to mitigate potential risks. In either case, the user would be required to comply with all directions and restrictions on the subsequent version of the labeling.

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

To the extent that the web-distributed labeling system incorporates a limited lifespan on labeling, it would straightforwardly permit EPA to apply new requirements to products that had not been completely used up prior to the posting of the changes on the website. As noted above, if users possess some quantity of a pesticide for which their downloaded labeling had expired, they would need to obtain and follow all requirements contained in new, current versions of labeling for the products. Therefore, all of EPA's regulatory decisions would eventually take effect as the lifespan of older labeling expired. For example, if EPA had imposed new risk mitigation measures on all labeling downloaded after April 8, 2009, and downloaded labeling had a 12-month lifespan, by April 8, 2010, all users should be complying with the new risk mitigation measures.

Of course, a user who failed to use up all of the pesticide during the lifespan of the labeling would take a chance that the pesticide could no longer be used in the manner allowed when the user acquired the product. For example, a user might buy a pesticide that he intended, under web-distributed labeling, to use on his green beans in 2009. If the

pest problem that would have necessitated using the pesticide did not occur in 2009, and the labeling had a 12-month lifespan, the user would then need to download a new version of the labeling to cover use in 2010. There would be some possibility that the new version of the labeling might no longer allow the green bean use. Such a change would, however, be unlikely since the Agency does not ordinarily limit the use of a pesticide except as a consequence of the periodic EPA reexamination of existing pesticides through the registration review process. (In registration review, EPA plans to reexamine all registered pesticides at least every 15 years. Thus, apart from the unexpected appearance of new data, changes to restrict the use of a pesticide will not occur as frequently as other kinds of changes.) The potential for future labeling changes that might affect the intended use of a pesticide would, nonetheless, create an additional incentive for users to use up their inventory of pesticide products within the lifespan of the labeling valid when they purchased their product. Many stakeholders have argued that if EPA adopts an approach that creates a limited lifespan for downloaded labeling, the lifespan should be quite lengthy in order to avoid creating unusable inventories of the product that would require expensive disposal.

There are at least four ways to mitigate this disadvantage of a finite labeling lifespan: 1] advance notice to users; 2] the development of “user-to-user sales markets;” 3] repurchase by the registrant; and 4] length of the lifespan. Each is explained below.

To the extent EPA knows that it will be making a change in product labeling that will significantly limit an approved use, the Agency could minimize the potential for users to be left with unusable inventories by indicating on downloaded labeling the dates when uses will be canceled or other significant risk mitigation measures will be implemented. Here is how this could work under the web-distributed labeling system. Assume that in 2009 EPA and the registrant agreed that use A would be “phased out” by the end of 2011, i.e., in 2012 and afterwards, the product could not be sold with labeling permitting use A. Once that agreement had been reached, all downloaded labeling could contain a statement that use A was prohibited, effective January 1, 2012. This statement would appear on all downloaded labeling for years before it took effect, and all users would have ample advance notice. Note that even though labeling downloaded in the fall of 2011 would be valid for other uses after the phaseout date, under the downloaded labeling the product to be used for use A only until January 1, 2012.

Another way to address the problem of unusable inventory is through the development of user-to-user sales markets. In this kind of secondary sales market, a user, who no longer could apply a product for the use intended at the time of purchase, would offer the product to buyers who might want to use the product for one of its lawful remaining uses. EPA would encourage such secondary sales, because they would cost less and be environmentally preferable to disposal of the product. The Agency understands, however, that some states impose regulatory requirements that may constrain the operation of such markets. EPA intends to work with states to explore how to allow safe, efficient operation of secondary sales markets.

Registrants could help to address this problem by repurchasing unusable products from its customers. While there is not likely to be a legal requirement on registrants to do so, a company that offers this option will build significant good will among its customers. Further, since the product would likely not need relabeling, it is likely to impose relatively smaller burdens on the registrant.

Finally, as suggested by many stakeholders, the problem of unusable inventories could be lessened by extending the time period for using up the product. But, of course, extending the lifespan of the labeling would tend to reduce the advantages of having a limited lifespan for downloaded labeling. The next section discusses this issue in more depth.

Comparison of options. Each of these two approaches has advantages and disadvantages:

	Pros	Cons
Labeling linked to production date	<ul style="list-style-type: none"> • Similar to historical system. • Users may always use a pesticide according to the labeling approved at the time of manufacture. 	<ul style="list-style-type: none"> • Delays comprehensive implementation of new risk mitigation measures. • Does not change users' incentives to act unlawfully by refilling containers with out-of-date labeling.
Labeling with a finite, limited lifespan linked to the "download date"	<ul style="list-style-type: none"> • Would ensure comprehensive, timelier implementation of new risk mitigation measures. • Would create an additional incentive for users not to acquire and hold large inventories for long periods of time. 	<ul style="list-style-type: none"> • Represents a change to historical system. • Users would need to acquire a new version of the labeling if they did not use up all of the pesticide within the labeling lifespan, a modest additional burden. • Users would face some chance that new versions of labeling would change the way in which a product could be used, making it "unusable." • Any unusable product would need to be disposed of properly, increasing the costs to users and / or registrants.

B. How Long Should the "Lifespan" of Downloaded Labeling Last?

If EPA imposes a limited lifespan on the validity of downloaded labeling, such an approach has the potential to accelerate the pace with which users should begin

complying with changes in the directions and restrictions on pesticide labeling. Obviously, the shorter the lifespan of downloaded labeling is, the more rapidly the new risk mitigation measures will apply to all users. This important benefit, however, must be weighed against the possibility that a new labeling restriction will represent so significant a change that the user will no longer be able to apply the pesticide as originally planned. For example, if EPA cancelled the registration of a pesticide for a specific use, once the labeling changed and the lifespan of old labeling (the labeling which allowed the cancelled use) expired, users who had bought the pesticide intending to apply the product for that use would be left with a product of little or no value to them. Although this type of cancellation is rare, the impacts can be serious. In the past, EPA has negotiated with the registrant to accept return of unused product, but the Agency cannot necessarily compel such a solution, which would put increased burden on the end user following the cancellation. The Agency also recognizes that while changes in use directions or other restrictions may not effectuate complete cancellation of a use, for some users such changes may operationally have a comparable effect. For example, a new labeling requirement to employ highly specialized application equipment may result in a “de facto cancellation” for some users because they cannot afford the added cost of buying or renting such equipment. Extending the lifespan of downloaded labeling, however, would reduce such potential impacts by allowing users additional time to use up the pesticide they have purchased.

Most people think the lifespan of downloaded pesticide labeling should be only as long as users would typically need to use up purchased pesticide products. Longer lifespans would potentially delay the implementation of important risk mitigation measures. Conversely, shorter lifespans would potentially impose some burden on users to obtain new versions of labeling and occasionally could lead to some quantities of purchased pesticides becoming unusable due to changes in labeling.

The Agency believes there is considerable variation across kinds of pesticides and among users of the same type of pesticide product in terms of the timing of when a user purchases a product in relation to when the user intends to use the product, as well as in terms of how much and how long a user keeps inventory. The timing of use of an agricultural pesticide depends on the production cycle of the crop to which the pesticide is applied and the timing of the occurrence of pest problems. In general, before the start of the growing season an agricultural pesticide user will typically purchase the pesticide(s) he expects to apply during the season. Representatives of various agricultural groups have indicated that a grower would expect almost always to use up the purchased pesticide during the crop’s growing season. Excess pesticide carried over to the following growing season would represent an unproductive capital expense. Other kinds of pesticide products do not have the same cyclical use patterns. Other pesticide uses – for example, in the wood preservative treatment, for slime control in paper production, or in greenhouses – may occur more or less constantly throughout the year. In such cases, EPA thinks users would typically try to maintain enough inventory to address both scheduled and unexpected pest-control needs. But, like agricultural users, these users try to limit the quantity of pesticide products in their inventories to minimize cost. Thus, they will generally try to carry only as much as they need to address short-

term needs until such time as they could obtain any needed resupply. Nonetheless, representatives of some non-agricultural pesticide users have indicated that occasionally individual users will keep a pesticide in inventory to deal with infrequently occurring pest problems and will only need to purchase a new quantity of the pesticide every several years.

In sum, EPA thinks that most users of most pesticides obtained for use in a business context will, for financial reasons, try to minimize the size of their inventories and how long they hold a product. They will attempt to buy only as much pesticide as they think they will need to use before they could reasonably obtain a new supply to meet their anticipated pest-control needs. Accordingly, EPA would expect that a pesticide user in a business context would rarely hold significant quantities of pesticide products for longer than a year, and usually for much shorter periods.

Balanced against the impacts on the user are the benefits resulting from implementation of the labeling requirements. The Agency directs changes in labeling in order to mitigate risks to public health or the environment. The sooner users implement such changes, the quicker the unreasonable risks are redressed. EPA has previously considered how to weigh such impacts in its Endangered Species Protection Program (ESPP). In this program EPA will vary localized restrictions on the use of a pesticide in order to avoid potential adverse effects on threatened and endangered species. The Agency will communicate these localized restrictions to users through ESPP County Bulletins, available from an EPA website. Pesticide products will require users to obtain and comply with all requirements in the bulletin(s) for the counties in which the products will be used. After weighing the urgency of implementing new protections for endangered species and the users' need to rely on being able to apply a product to address his future pest control needs, EPA decided that ESPP bulletins will be valid only for a 6 month period following download. (It should be noted that users could be confused if web-distributed labeling has a different lifespan from ESPP County Bulletins.)

RECOMMENDATION:

EPA supports the position that web-distributed labeling should have a time-limited lifespan calculated from the date on which it is downloaded or requested by toll-free telephone system. The Agency does not yet have a recommendation regarding the specific lifespan for web-distributed labeling. While it should be long enough to allow most users to use up the quantities they purchase, it probably should not last significantly longer than a single use season. Finally, EPA would also support taking steps to diminish the potential for creating unusable inventories, especially providing advance notification of EPA phase-out decisions, i.e., decisions that specified uses of a pesticide would no longer be allowed after a certain date.