Web-Distribution of Labeling Work Group Discussion Paper:
Scope of Web-Distributed Labeling

ISSUES:

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 or toll-free telephone service. This paper explores the scope of this system and also the scope of a pilot project. The following issues are discussed:

1] Which products should be included?

2] Should the system be mandatory or voluntary?

3] Are there additional criteria that need to be considered for the pilot project?

BACKGROUND:

Legal Framework

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.

Products

Under the current system, pesticide users receive the labeling with the product. The labeling may be physically attached to the container or it may be in accompanying literature. The proposed system would require users to obtain some of the labeling, such as the directions for use, from a website or by calling a toll-free telephone number. The Agency believes that users of certain products may be better equipped to obtain the labeling from these sources. For users of other products, it may too burdensome to require them to obtain the labeling, and therefore unreasonable adverse effects may occur if the labeling isn't obtained and followed. Therefore, the discussion describes which products are appropriate to include in a web-based distribution system.

Mandatory vs. Voluntary

The current system requires all labeling to be attached to the product container or to accompany the pesticide or device. With web-based distribution of labeling, the labeling may not physically accompany the product. The system could be mandatory, requiring all registrants of the products approved for the system to use web-distributed labeling, or it could be voluntary, allowing registrants to decide whether or not to use the system. This discussion describes the implications of a mandatory versus a voluntary system.

Pilot Project

It is expected that the pilot project will follow the scope of the proposed system. However, additional restrictions or requirements may be needed to properly evaluate web-distribution of labeling. In addition, since the pilot will occur early in the education process that will require a significant culture change in the regulated community, it is possible that additional restrictions may be needed, or a limited scope required, in order for an effective, safe and non-disruptive test of the new system.

DISCUSSION:

A. Which products should be included?

Registration as defined in the statute.

Under Section 3 of FIFRA, pesticide products must be registered by the Agency before they may be distributed or sold. Specific types of products defined in the statute are described below.

General Use products and *unclassified products* may be sold to and used by anyone, with some limited exceptions (e.g., termiticide products have labeling that restricts use to only those applicators licensed by the state). General use products, when used according to the label, are generally considered not to cause unreasonable adverse effects on the environment. The concern with web distribution of labeling is that adverse effects may occur if users do not obtain and follow the labeling. Since general use products include products used in a variety of settings, including agricultural, residential, and industrial, some users may be more likely to obtain the labeling than others. This will be described in the section Marketing Sectors. In general, the Agency believes that general use products and unclassified products are appropriate for web-distributed labeling.

Restricted Use Products (RUPs) may only be sold to and used by a certified applicator or under the direct supervision of a certified applicator. This is due to the concern that these pesticides may cause unreasonable adverse effects on the environment unless applicators have training that, in effect, supplements label precautions. Since RUPs are considered more risky than general use products, there may be some reluctance to allow these products to be sold without the full labeling attached or accompanying the product. However, certified applicators receive training and/or must pass an exam in order to be certified. These applicators are more likely to receive appropriate training and may be more likely to obtain the labeling from the website or through the toll-free telephone number. The Agency believes that web-distribution of labeling should be feasible for restricted use products, particularly if applicators can receive training on using web-distributed labeling during the certification training.

Section 5 of FIFRA allows applicants to obtain Experimental Use Permits (EUPs) for pesticides that have not been registered in order to obtain data needed for a Section 3 registration. One

concern is that the pesticide is not registered so the risks may not be known. In addition, the EUP registrations already have limited lifespans and there are only a small number of users. Since the applicant, researchers, or other users involved with research will receive the appropriate labeling, there is little benefit to including these products.

Section 18 allows federal or state agencies to obtain emergency exemptions for the use of pesticides not registered under Section 3. These pesticides may or may not be registered for use on other sites. Emergency exemptions may be granted to control a public health pest, to treat a quarantine pest, or, if certain documentation criteria are met, to prevent economic loss due to a pest. 40 CFR § 166.7(a) is flexible in the way users are notified about the emergency exemption. The State or Federal Agency may distribute in a variety of ways, and some may already use the internet. In addition, labeling does not appear to be required, as the regulations allow the State or Federal Agency to distribute copies of the approval letter or other information. However, it is possible that some states require labeling to be distributed. Web-distributed labeling would benefit users of the pesticides provided through an emergency exemption because they may be able to obtain the labeling, when required, more quickly and readily. Users of these pesticides may be state or federal agencies (in the case of public health or quarantine pests) or may be agricultural growers who have an economic interest in controlling the pest. It is expected that users of products granted through emergency exemption will be able to obtain the labeling through the website or through the toll-free number. If the toll-free number is used, however, the Agency should ensure that the labeling can get to the user quickly enough so that users can adequately control the pest. In addition, the labels for products granted an emergency exemption tend to be for a specific crop/pest combination and so may be less burdensome to download than longer pesticide labels.

States may register additional uses for special local needs for their state through Section 24(c). These labels tend to be for a specific site or set of sites and thus may not be as long as section 3 labels. The process is different for 24(c) registrations (i.e., the state approves a use and the Agency reviews it after the fact). 40 CFR § 162.153(e)(4) requires states to ensure that the supplemental labeling is available within 45 days of approval. Some states may already make the labels available on their websites. Web distribution of labeling may make it more feasible for 24(c) labels to be provided on the web for all states. Depending on the website design and search features, this may benefit tribes or others who may try to determine which 24(c)s are available in the states.

All of the registration types and products described in the statute could be eligible for participation in web distributed labeling. However, there are some concerns and no benefits to including Section 5 EUPs so this group will not be included.

Registrant Options

Registrants may sell their products using all the EPA-approved labeling for the registered product or for a subset of the uses that were registered. The registrant may also choose to have another company or entity sell the products. These products are supplemental distributor products. They must be the same as the registered product, although certain labeling elements,

such as the name of the product, may be different. In addition, some label claims and sites may be deleted from the supplemental distributor labeling.

Both types of products can be accommodated in a web distributed labeling system. For supplemental distributor products, the product must meet the criteria for such products. However, for marketing reasons, the registrant may not want supplemental distributor products to be part of web distributed labeling. Therefore, under a voluntary system, the inclusion of supplemental distributor products may be decided in the individual agreements between registrants and supplemental distributors. Including supplemental distributor labels may be more feasible if the registrants host the website. Otherwise, the Agency may experience a resource burden, depending on the process developed, if supplemental distributor product labels are submitted to the Agency.

Marketing Sectors

Products may be marketed for specific types of uses. Some of these uses are described below. While web distributed labeling is appropriate for some of these products, it may not be for other types.

Agricultural commodities are defined in 40 CFR § 171.2 as "any plant, or part thereof, or animal, or animal product, produced by a person (including farmers, ranchers, vineyardists, plant propagators, Christmas tree growers, aquaculturists, floriculturists, orchardists, foresters, or other comparable persons) primarily for sale, consumption, propagation, or other use by man or animals." Pesticides used in an agricultural setting are used as part of a business. Since agricultural commodities are often grown in rural areas, there is concern that these areas may not have internet access, or that access is not adequate to download labeling. However, fax machines may be an option for obtaining labeling, or the users may have dealers that may be able to provide labeling. In addition, agricultural producers may plan ahead and purchase pesticides before the growing season, giving them adequate time to obtain labeling. The Agency believes that web-distributed labeling is appropriate for agricultural producers, even though there are concerns about adequate technology, since they should be able to access labeling. Pesticide use for these users is likely to be an important aspect of their business so these users have an incentive to follow the labeling directions.

Professional non-agricultural products have not previously been defined by the Agency. EPA has a draft definition of a "professional specialty pesticide":

> A registered pesticide product labeled only for pest control for: (1) turf (includes sports turf and golf courses), lawn, or ornamentals; (2) nursery or greenhouses; (3) structures and institutions (human dwellings both public and private, schools, food handling establishments and their adjacent areas); (4) aquatic vegetation management; (5) right-of-ways; (6) forestry; and (7) public health (mosquitoes, ticks, and other carriers or transmitters of infections, disease or human allergens); with the exception of pesticide products that are: (1) used in the production of an agricultural commodity; (2) labeled only for use in or around a household or residence by a resident; (3) industrial biocides; or (4) antimicrobials used in swimming pools."

For the purposes of web-distributed labeling, professional non-agricultural products have been described as products used in a money-making or business operation, either as part of the business (e.g., control weeds in rights of ways) or because pesticide applications are a necessary component of the business (e.g., to control pests in food handling establishments), or as a public regulatory function (e.g., mosquito control, invasive pest management). In order to minimize confusion over this issue, it is recommended that the definition proposed for professional specialty products apply to professional non-agricultural products, with the exception that industrial biocide and possibly antimicrobials used in swimming pools should also be included in the definition. These additional products (industrial biocides and possibly antimicrobials used in swimming pools) may also be appropriate for web distribution of labeling.

The Agency believes that, as with agricultural products, professional non-agricultural products are used in a business or regulatory setting and thus web distribution of labeling is appropriate for these products. These products are used by individuals who use pesticides in their business or profession and are familiar with regulatory requirements. It is also in the best interest of these users to use the products correctly. In addition, EPA has established methods for communicating with these user groups.

According to 40 CFR § 150.3 "r*esidential use* means use of pesticide directly: (1) on humans or pets, (2) in, on, or around any structure, vehicle, article, surface, or area associated with the household, including but not limited to areas such as non-agricultural outbuildings, non-commercial greenhouses, pleasure boats and recreational vehicles, or (3) in any preschool or day care facility."

Web-distribution of labeling may not be appropriate for products registered for general use in residential settings because access to the internet may be limited for much of the general public. In addition, it may be more difficult to communicate and train the general public about obtaining the labeling via the website compared to users who use pesticides as part of their business and thus compliance with labels could be diminished. These users are also less informed about regulatory requirements.

Some professional applicators may apply residential products as part of their business. For web-distribution of labeling, the Agency is concerned with the user of the product rather than the particular use sites registered. However, there is not always a clear way to distinguish whether residential use products will be used by a professional or a homeowner. The Agency does not believe that products used by the general public, such as residential use products, are appropriate for web distribution of labeling.

Some products may be marketed for both the agricultural or professional non-agricultural sector, as well as the residential sector. It would be important for the registrant to make sure that products intended for the residential sector include all information on the attached label.

<u>Other</u>

40 CFR § 150.3 defines *end use product* as "a pesticide product whose labeling (1) includes directions for use of the product (as distributed or sold, or after combination by the user with

other substances) for controlling pests or defoliating, desiccating, or regulating the growth of plants, and (2) does not state that the product may be used to manufacture or formulate other pesticide products. *Manufacturing use products* (MUPs), as defined in 40 CFR § 150.3, "means any pesticide product that is not an end-use product." These products may be used to manufacture other pesticide products.

Formulated end use products are generally the types of products that have been described in the above sections. Since MUPs are used in the pesticide industry, these products could be eligible for web-distribution of labeling but it is not clear if there is any value to including them. Since the labels tend to be shorter than end use products and changes may not occur as frequently, registrants may choose not use web-distributed labeling due to the limited benefits for these products. The Agency would appreciate industry feedback as to whether there is benefit by including MUPs.

Another scope related issue is whether the products included in the system should be limited to containers of a certain size. One common size for commercial products is 2 ½ gallons. Limiting web distribution of labeling to large containers may limit products without the full labeling attached to the container from getting into the hands of consumers.

Overall Product Recommendation

Products that are defined in the statute, with the exception of Section 5 EUPs, should be included in the web distribution of labeling system. The system should be limited to products that are used for commercial, professional or regulatory uses, including agriculture. The Agency will consider use site limitations on the labeling, clearly identifiable professional uses, possibly container size limitations, and the label use directions when determining whether a product is intended for commercial or consumer use.

B. Should the system be mandatory or voluntary?

Voluntary

Under a voluntary system, registrants would decide whether or not to participate, and possibly which products would be included.

One concern with a voluntary system is that products may be sold under two different systems. With the current system, users can use the product according to the labeling that accompanies the product until the pesticide is used up. Under the proposed system, labeling will have a limited lifespan from the date of download, after which users will need to re-download the labeling to continue using the product. The concern is that this could put some products at a disadvantage if they are used for similar situations but one has labeling that may expire within a certain time period and the other can be used indefinitely. In addition, following the rules for two systems could be confusing to users and dealers.

Another concern with a voluntary system is that some of the benefits of web-distributed labeling would be lost. For example, one benefit is that any new precautionary language will get into the

hands of users more quickly. If only some products are using the web distribution of labeling system, then the benefit will not be as substantial since other similar products would have labeling that is valid indefinitely. In addition, it would be more difficult to make the case that changes in label statements could be made across all products at the same time, allowing for a level playing field.

Mandatory

The Agency could also choose to make web distributed labeling a mandatory program. This would ensure that only one system is being used, at least within a category of products. However, this would require rulemaking, which may delay the process. In addition, it may be difficult for the Agency to logistically get the system up and running for all users at one time. It may also cause financial and logistical strain to registrants or other companies in the pesticide industry that do not have the infrastructure to use web-based distribution of labeling for their products.

Voluntary vs. Mandatory Recommendation

There are issues with both a voluntary and a mandatory system. The recommendation is to have voluntary system, at least initially. This will ease the burden on registrants and will allow users to transition to the new system.

C. Are there additional criteria that need to be considered for the pilot project?

A pilot project is planned for 2009. With the pilot, the Agency would like to determine: how well the distribution system works; user acceptance of the distribution system; whether there are compliance problems due to the new system; how the state synchronization issue is worked out; and how the limited lifespan label is accepted.

Two possible projects have been proposed for the pilot. This first is to distribute supplemental labeling for new uses via the website and/or through the fax number system. The second is to do a small scale version of the system, incorporating container label changes, labeling available on the website and/or through fax, and possibly a searchable database. The sections below describe in more detail the two proposed pilot projects, pros and cons for each project, recommended criteria, and issues that need to be resolved before the pilot. The issues will be fully discussed in separate issue papers.

Supplemental Labeling Pilot

The proposed supplemental labeling pilot is intended to distribute labels for supplemental uses via the web. These products already have registered uses and so only the label for the new use would be distributed. The labeling would likely be available to users as a PDF. The container could be stickered to alert users to the website.

Pros:

- Allows the Agency to evaluate whether users will go to the website to get the labeling
- Small in scale

- Labels are short so would not be as burdensome to print
- System could probably be set up by 2009

Cons:

- Does not test the web distribution of labeling system as envisioned by the workgroup
    - May also confuse users as to the vision for web distribution of labeling
- Users often obtain supplemental labeling from the internet so will only legalize a practice that is already occurring

Issues that need to be resolved:

- State synchronicity
- Labeling lifespan
- Need to articulate production issue
- Need to create website/fax system and resolve web hosting issue
- Culture change – how to get participation
- Determine how to collect data and how to assess the pilot

Dynamic labeling pilot

The proposed dynamic labeling pilot would be a smaller scale of the proposed web distributed system. The product container label would only contain those elements considered essential on the label (either required by statute or regulations or as needed for safety) and a reference to the website. The rest of the labeling would be available on an interactive website or by fax. Use of a long label, with the ability to obtain a subset of the label, would demonstrate one benefit of the system.

Pros:

- Allows the Agency to evaluate the proposed system
- Would allow users to give accurate feedback on the proposed system since they may have experience with it

Cons:

- May not be feasible for 2009 due to additional technical and policy issues that need to be resolved
- May require user to print the whole label, which could be burdensome, if the website is not searchable by site

Issues that need to be resolved:

- All of the issues described for the proposed supplemental labeling pilot, PLUS
- Container label vs. labeling from website
- Amended regulations and/or MOUs that allow registrant to do pilot
- Are there additional enforcement considerations?
- Need to develop website with additional capabilities (e.g., searching for crop site function)
- Need to develop coding system

Since this approach may not be fully functioning for the 2009 use season, a demonstration to be used in education and outreach may be possible and could provide an opportunity for initial feedback from potential users.

Criteria for Either Pilot

The number of products and number of companies involved should be limited. However, the number should be large enough to accurately evaluate the system. Limiting the pilot to one or two companies but including several products from each company may be a way to keep the pilot simple but to still have enough products out on the market to evaluate the system. Registrants that already have a good network or outreach on their products may be better suited to the pilot.

There are two options for the types of products to include. If products that are considered lower risk by the Agency are used, risks may be minimized if users do not obtain the labeling. However, if RUPs are used, then the applicators have been trained and/or certified and may be more likely to obtain and follow the labeling.

The pilot should focus on commercial products. Section 3 products and not section 18s and 24(c)s should be used. Section 18 and section 24(c) products already have an established system for distribution and including them in the pilot would have little benefit and could confuse users as to the purpose of the pilot.

For the pilot, the Agency may want to target a subset of sectors (e.g., a certain geographical area and/or a certain sector of agricultural users).

In order to minimize the risk of users applying the product without reading the label, the uses from the previous season should not be changed on the label for the pilot.

The pilot should be voluntary.

A state should be willing to participate in the pilot. If a state is willing to cooperate, issues of state synchronicity may be easier to handle.

RECOMMENDATION:

The scope of web distributed labeling system should include all of the registered products described in the statute, except for Section 5 EUPs, as well as the registrant options described in this paper. The system should be limited to products that are used for commercial, professional or regulatory uses, including agriculture. Residential products should have the full labeling accompanying the product container. However, in addition, registrants may choose to post the labeling for residential products to the website so that consumers may obtain some of the benefits of web distributed labeling, such as viewing text in a larger font size. The Agency will consider use site limitations on the labeling, clearly identifiable professional uses, possibly

container size limitations, and the label use directions when determining whether a product is intended for commercial or consumer use.

The system should be voluntary, at least initially. Once it is established, the Agency may want to reevaluate and decide if a mandatory system is appropriate.

The scope of the pilot should be narrower than the fully functioning system. It is suggested that the companies involved, the number of products, the geographic region, and the sector be limited. It is expected that the pilot will be expanded in future years before the final system is implemented.