

Web-Distribution of Labeling Work Group Discussion Paper: Container-Affixed Label and Web-Distributed Labeling

Issues

When considering a system that could dynamically deliver state-specific and crop/site-specific labeling to pesticide users via the Internet or a toll-free number, what labeling elements

1. must appear on the label affixed to the container?
2. should appear in the labeling affixed to or accompanying the container?
3. could benefit the user by being delivered using a streamlined, dynamic method?

Premise

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”¹ 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 [EPA, USDA, DoI, DHHS], State experiment stations, State agricultural college, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.” Although not common, current labeling sometimes uses a reference to other enforceable documents that do not accompany the container, as evidenced by the Worker Protection Standard and Bulletins Live (for threatened and endangered species and their habitats).

Many people have voiced criticisms of the quality of the labeling currently on many pesticide products. 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. Moreover, pesticide companies do not all follow a consistent approach to the organization and presentation of information in labeling. Further, to reduce printing costs, the labeling information can appear in smaller font sizes. Critics argue therefore that users may have trouble finding and reading all relevant portions of a product’s labeling. They further argue that, if the current system could be changed to address these factors, users’ compliance with labeling requirements could improve.

A new web-distributed labeling system could provide simplified labeling to users. Under the new system the user would be required to obtain a copy of labeling 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. The user would be required to comply not only with restrictions appearing in the label affixed to the container and in labeling accompanying the container, but also with those in the additional labeling available from a referenced internet source or toll-free number. The user would be expected to obtain and follow labeling referenced on the container potentially generating that labeling using a search function for querying items such as state and site.

¹ While the statutory definition of “labeling” encompasses both attached and unattached materials, the remainder of this paper generally uses “labeling” as those labeling materials that are distinguishable from the attached label on the container.

Additional queries, such as county of application or application method, can generate greatly simplified labeling since most 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 by other applications methods. This web-distributed labeling system should improve compliance with protective measures and proper use. The users ultimately would have in their possession all pertinent labeling information.

This new system requires decisions be made regarding which types of information would appear on the label affixed to the container, which would appear in labeling accompanying the container, and which would be available through other sources (i.e. internet, mail, and fax). This issue paper proposes a partitioning of label and labeling elements according to whether they would be either “affixed to the container,” “physically accompanying the container,” or in “web-distributed” labeling. It presents a proposed breakdown of the location of different labeling elements that might best serve the user, registrant, or EPA. The proposed approach is guided by the following principles:

- The location of label and labeling elements required by statute and current regulations would not change;
- Both the label affixed to the container and labeling physically accompanying the container would contain all information necessary for the safe storage, handling, and disposal of the container;
- Both the label affixed to the container and labeling physically accompanying the container would contain basic information necessary to offer safety to any person who might come into contact with the product, for example through handling the container or by using the product;
- The label affixed to the container and labeling physically accompanying the container would contain little or no additional information so that the types of information described above would be prominent and easy to understand; and
- Basic identifying and safety information on the label or in the labeling physically accompanying the container would be repeated in the labeling available from the referenced sources.

What information must appear on the label affixed to the container?

In FIFRA § 2(q) and 40 CFR Part 156, specific label elements are defined as being required to be affixed to the container without which the product is considered misbranded. Thus, the following elements must be found in the label affixed to the container. (* required only by regulation, ** required by statute and regulation).

Required by statute and/or regulation and must be affixed to the container.²

1. *Directions for use or a reference statement to directions for use found elsewhere in labeling
2. *Use classification (Restricted Use Product statement)
3. *Violation of federal law statement
4. *Product registration number
5. *Signal word
6. *WPS referral statements
7. *Storage and disposal requirements
8. **Product establishment number
9. **Brand/product/trademarked Name
10. **Ingredient statement
11. **Net weight or contents
12. **Skull & crossbones/POISON and statement of practical treatment if highly toxic
13. **Name and address of producer, registrant or person for whom produced
14. **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)

In addition to the existing requirements outlined above, under web-distributed labeling a container label would 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 include in the web-distributed labeling. This statement should be obvious to any person handling a pesticide in order to ensure compliance with both label and labeling requirements. Following is an example of what such language requiring users to obtain and comply with web-distributed labeling may look like:

15. *You must obtain additional labeling from <http://pesticidelabeling.gov> or by calling 1-866-LABELING. 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.*

In addition, to facilitate state-EPA-registrant registration synchronicity, it may be necessary to include a *unique identifier* in addition to the product registration number; this is not required today. (A unique identifier may be necessary if the registrant decided, for marketing or other reasons, to sell or distribute a registered pesticide with more than one version of its labeling for the same registration number. Logically it should appear with the registration number on the product container label.)

² Additional requirement for labels of products for export only ** “Not Registered for Use in the United States of America.”

What other types of information should be part of the labeling affixed to or physically accompanying the container?

Since pesticides in their containers are in the channels of trade, it is important to provide basic safety and handling information about the product that is available to anyone who may come in contact with the pesticide, such as distributors, applicators, handlers, medical providers, or first responders. Having basic handling information related to streamlined information for environmental protection, storage and spills is also important. This is an important liability issue for registrants.

Additionally, 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 following elements would be recommended to be in the label affixed to the container, but at a minimum should appear in the labeling physically accompanying the container.

16. In case of spill – CHEMTREC and manufacturer phone numbers

For marketing or liability purposes, there may be reasons to include manufacturer information or streamlined sections from use directions.

17. Company logo, graphics, or other identifiers

18. General marketing referral to target sites and pests (e.g., for use in landscapes for chinch bugs)

19. Warranty statement

What types of information could benefit from being delivered using a streamlined, dynamic method (Web-Distributed Labeling - referenced by URL)

One benefit of web-distributed labeling is to provide the user with a streamlined container label as well as labeling that contains only the pertinent information for a particular site of application, in a specific state, when using a particular application method. When a pesticide user must read through 40 plus pages of sites/crops, 10 plus pages of application equipment directions, and 5 plus pages of drift mitigation measures when they are using one piece of application equipment on one crop, the labeling becomes “War and Peace.”

By allowing the user to run through a database query, a use-specific label is generated that should be much more readable. For example a search by: 1) Unique identifier, 2) State, 3) Crop/site and 4) Application Method or treatment type (air, ground, chemigation, backpack/hand, shank injection) generates much-reduced user-specific labeling that is specific for the directions, mitigations and precautions needed for that particular use. The search could be further refined by adding other search values, such as county for endangered species with access to Bulletins Live.

- 20. Engineering Controls- expanded section, if warranted
- 21. Environmental Hazards – expanded section, if warranted
 - a. Endangered species
 - b. Site specific concerns
- 22. Resistance Management identifiers
- 23. Storage and Disposal – expanded section, if warranted
- 24. Use Directions (sample list, not exhaustive)
 - a. Worker Protection Standard – apart from the Agricultural Use Box
 - i. REI , especially if multiple crop or application type
 - ii. Early entry worker PPE
 - iii. Prohibition of any entry prior to 4 hours
 - b. Allowable Sites, Crops, Hosts
 - c. Use Requirements
 - i. Type of treatment (band, broadcast, injection, chemigation)
 - ii. Product application rate and limits
 - 1. Rates for target pests
 - 2. Maximum number of applications or annual use-rate limits
 - 3. Timing (growth stage, degree days)
 - iii. Restricted Entry Interval, if multiple
 - iv. Preharvest, grazing/haying, composting, replant, rainfast intervals
 - v. Required adjuvants (buffers, spreaders, antifoaming agents)
 - vi. Formulation and mixing instructions
 - vii. Tank agitation requirements
 - viii. Order of mixing multiple products/adjuvants
 - ix. Spray tank/boom decontamination
 - d. Use Prohibitions
 - i. Tank mixing (Buffers, adjuvants, products, fertilizer)
 - ii. Crop rotation, water usage,
 - iii. Greenhouse applications
 - e. Use Restrictions
 - i. Who may apply (supervised trained technicians, trained handlers)
 - ii. “Do not” statements
 - 1. human exposures, water contamination, edible plants, frozen ground, sensitive sites/crops
 - 2. 1,000 others where known problems exist (air temperature limits, sensitive ornamentals, etc.)
 - iii. Application equipment specific (could be restrictive or advisory) – generate only those precautions by the method they selected.
 - 1. aerial, ground boom, ground injection, chemigation, hand-held high volume/spot

- a. set up (output, droplet size, gallonage, nozzle angle, boom length, boom height)
- b. drift mitigation measures (differs with equipment), such as wind direction, temperature inversions, wind speed, lack of wind, pressure limits and requirement for higher pressures
- c. water source protection measures (check valves for chemigation)
- d. efficacy requirements (droplet size)
- f. Advisory Statements
 - i. Storage and disposal assistance
 - ii. Tank mixing with known combinations
 - iii. Spray adjuvants
 - iv. Off-target management strategies
 - 1. based on application equipment, volumes applied, active ingredient, location of sensitive areas
 - 2. assessing nearby areas
 - v. Resistance Management
 - 1. Mode of action
 - 2. Management approaches
 - vi. Terms and Conditions of Use
 - 1. Inherent Risks of Use
 - 2. Limitations of Remedies

The last three elements that could be included as part of web-distributed labeling would be new to labels.

25. Highlighted, recent changes to web-distributed labeling

26. Download date and expiration date for web-distributed labeling (See issue paper on Lifespan of Web-Distributed Labeling.)

27. Existing stock provision dates if use is no longer supported or planned cancellation