UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: December 1, 2016

SUBJECT: Guidance for Pesticide Registrants on Location of the First Aid Statement and Clarification on Definition of Label "Panel" per 40 CFR 156.68

TO: Persons Responsible for Registration of Pesticide Products

FROM: Michael Goodis 12/1/16
Acting Director, Registration Division
Office of Pesticide Programs

Steve Knizner 12/1/16
Director, Antimicrobials Division
Office of Pesticide Programs

Robert McNally 12/2/16
Director, Biopesticides and Pollution Prevention Division
Office of Pesticide Programs

The EPA has learned that there is a discrepancy in how the "location of first aid statement" per section 156.68 (d) of Title 40 of the Code of Federal Regulations (40 CFR 156.68(d)) is interpreted by both the EPA and those in the pesticide registrant community. The agency has received several inquiries from the states and from the pesticide registrant community regarding the required placement of first aid statements on pesticide containers. The purpose of this memorandum is to clarify the interpretation of the term "panel" in the context of 40 CFR 156.68 and to clarify where first aid statements must appear on pesticide labels based on the product's Toxicity Category. While the agency reviews and approves pesticide labeling, reviewers generally only review a "master" label that contains all information that may be found on labeling. Master labeling may specify how labeling elements will be presented in the marketplace but oftentimes does not. The agency does not routinely review the versions of labels as they appear on containers in the marketplace, nor are these container labels currently posted to the agency's Pesticide Product Label System (PPLS) site (https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1). The labels that are posted to the PPLS are

"master" labeling in Adobe Acrobat Portable Document Format (PDF). Pesticide container labels are reviewed by some states.

The term "panel" is not defined in the 40 CFR. Despite there being no definition, the regulations require first aid statements to appear on the front panel for Toxicity Category I products and any panel for Toxicity Category II and III products (40 CFR 156.68).

In PR Notice 2001-1[1], the EPA interpreted the regulatory text and stated:

"First aid statements for other than Toxicity Category I products may appear on the ***front, side or back panel*** of the label. Any time first aid statements appear on the side or back panel of the label, EPA expects that a referral statement such as 'see side/back panel for additional precautionary statements' will appear on the front panel of the label near the signal word. First aid statements appearing on the side or back panel of the label would then be grouped near the other precautionary labeling, yet be set apart or distinguishable from the other label text" (emphasis added). We have historically interpreted the term "panel" in the 40 CFR 156.68 to mean that portion of a label that is immediately visible on a pesticide product at the time the pesticide is sold or distributed. We are not changing our position regarding where the first aid statements are required to appear. We are clarifying our position that the first aid language must be on a visible panel (front, side or back depending on Toxicity Category) and must not be placed inside multi-page labeling (i.e., "extended text," "accordion," "saddle stitched," "pull-out," "booklet" or other types of formatted labels) that require the user to open a booklet or unfold an extended text label or other type of label where the first aid information is not immediately visible on the product.

Over time, a variety of label types/presentations (extended text labels, saddle-stitched labels, accordion style labels, pull-out style labels, "booklet" and many others) that may not have existed or been considered when 40 CFR 156.68 and subsequent agency guidance was written have become prevalent in the marketplace. This evolution of label types and confusion over where label elements must be placed are complicated by the fact that the EPA does not regularly review the final printed labeling that appears on the packaged products. Instead, we review and approve master labeling that contains all of the required elements to be found on marketplace labels, but does not indicate how these elements will be presented on the product container. We have reviewed master labeling where the label indicates the panel on which the first aid statement will be located via a "referral statement," which is typically noted on the first page of the label. Not all labels submitted for agency review include this type of referral statement.

As such, the EPA has determined that it is appropriate to clarify our interpretation of the term "panel" in the 40 CFR 156.68 and to clarify where first aid statements must appear on pesticide labels based on the Toxicity Category of a product.

We are clarifying in this memorandum that the agency interprets the term "panel" in the 40 CFR 156.68 as a portion of a label that can be immediately visible on a pesticide product at the time the pesticide is sold or distributed. This interpretation does not include information on labels that is only accessible through manipulation of the label by opening a booklet or unfolding accordion

[1] Pesticide Registration (PR) Notice 2001-1: First Aid Statements on Pesticide Product Labels

style pages. This interpretation is consistent with the PR Notice 2001-1, where the agency said the front, side, or back panels were appropriate locations for the first aid statement. The specification of front, side or back panels indicates the agency was not envisioning first aid statements to be found on the inside of a multi-page labeling (such as a label that needs to be peeled open in order to see the first aid statements).

To be clear, regardless of whether "extended text," "accordion," "saddle stitched," "pull-out," "booklet" or other types of formatted labels are used, for products assigned to Toxicity Category I by any route of exposure, the first aid statements must appear on the front panel unless the agency has approved a reasonable variation. By front panel in the 40 CFR 156.68, the agency means on the outer cover of the label format (booklet, accordion, pull-out, etc.), so that it is immediately visible on a shelf to the user or the consumer and the label does not need to be opened to access this information (the same location where the name of the product and the ingredients statement appear). While we will entertain requests for alternative placement on a case-by-case basis, it is unlikely we would allow Toxicity Category I first aid statements to be placed only within a fold-out label format.

The first aid statement for products assigned to Toxicity Categories II or III may appear on the front, side or back panel of the label, which as interpreted above must be visible without manipulation. Thus it would not be appropriate for the first aid statement to only appear enclosed within an accordion, pull-out, extended text, saddle stitched, booklet, or any other style of label format. Registrants may also elect to display first aid statements on any visible panel (front, back or side) of the label for Toxicity Category IV products, although this is not a requirement. If a registrant chooses to list first aid statements for Toxicity Category IV products, this language must also appear on the visible panel.

Because the agency does not generally review labels as they appear in the marketplace, the agency is not asking for pesticide container labels to be submitted at this time. However, the agency is reminding pesticide registrants to comply with the historic and current interpretation of the EPA and the State Lead Agencies that First Aid Statements must be visible on the outside of a pesticide container and incorporate any necessary updates to their pesticide container labels at the next label printing.

We will update the Label Review Manual (LRM) to reflect the current interpretation of "panel" in the 40 CFR 156.68."