

**February 27, 2018**

**First Aid Guidance: Response to Public Comments on *EPA's Guidance for Pesticide Registrants on Location of the First Aid Statement and Clarification on Definition of Label "Panel" per 40 CFR 156.68.* (Docket ID: EPA-HQ-OPP-2016-0545)**

**Summary**

This document summarizes the U.S. Environmental Protection Agency's (the Agency, EPA) response to public comments on EPA's memorandum 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.

*EPA's Guidance for Pesticide Registrants on Location of the First Aid Statement and Clarification on Definition of Label "Panel" per 40 CFR 156.68* was posted to the docket on December 7, 2016, for a 30-day public comment period. In December 2016, the Agency received four requests for an extension of the comment period for an additional 60 days. The Agency accepted the requests. The docket comment period was extended to March 7, 2017. EPA received nine comments to the public docket from the following entities: Sunshine Makers, Inc.; Nufarm Americas, Inc.; The Scotts Company; Bonide Products, Inc.; CSPA; Valent USA; American Chemistry Council; Crop Life America; and RISE.

While the verbatim public comments are not noted in this document, the full public docket comments are available on the docket. The public comments are summarized below followed by the Agency's response.

**Past Practice**

- The Office of Pesticide Program's (OPP's) interpretation of the regulation is not accurate because EPA has been approving the current configurations for over 30 years (including OPP and State personnel).
- Registrant community unaware of any EPA or state enforcement actions based on the current placement of FIRST AID statements.
- The current locations of First Aid statements have not been known to cause difficulty or injury (no incident reports).
- State personnel have more experience with container labels and they have been approving them for a long time.
- FIRST AID statements have been appearing on "any panel" for decades.
- Since 1975 (when EPA promulgated its labeling requirements following FIFRA's amendment in 1972) there are a lot of new labeling types in the market place. However, there is nothing in the history of EPA's labeling regulations to suggest that "any panel" for Category II and III pesticides must mean the portion of the label that is immediately visible.

**Previous Guidance**

- There is no definition of panel in the 40 CFR and no requirement that the FIRST AID language be immediately visible.

- Pesticide Registration Notice 2001-1 states that FIRST AID for tox II or III products can appear on the front, side, or back panel of the label.
- The Label Review Manual (LRM) states that registrants can use booklets where it's not feasible to fit an entire label on the actual container. Neither the PRN or the LRM explicitly require the FIRST AID statements to be immediately visible to the user.
- The Label Consistency Q&A page also has a question regarding moving label language to the inside of a booklet via non-notification. The inquirer proposes a referral statement that clearly signals its intent to move the FIRST AID statements inside the booklet. EPA's answer was that it can be done, but just via amendment.

### **Process for Providing EPA's interpretation**

- The Agency has not conducted an adequate analysis of the impact to all of industry and the regulatory agencies involved.
- The proposal is a change in the regulations and should be subject to a regulatory impact analysis and to formal rulemaking.
- No evaluation done to demonstrate that OPP's proposal is the best alternative or would benefit the public in any way.
- Agency has failed to answer "what problem is the Agency attempting to correct?"
- EPA has failed to demonstrate that first aid statements contained within the multi-page labels has resulted in users not timely and easily locating first aid information when needed.

### **Practicality**

- Impossible to fit visible first aid on a consumer product along with information on how to use the product.
- UPC barcodes are also required to be a certain size, and there simply isn't enough room.
- Many products come in multiple sizes; could mean a reconfiguration of over 1,000 labels for some companies.
- The amount of information required on pesticide labeling is too voluminous to put on a container without using a booklet style label.
- The "base" panel is permanently affixed to the container and therefore users must open booklet to see the statements.
- Redesign of container labels and label printers would be required.
- If required to change location of FIRST AID statements, registrants will likely go back to a previous format of using text rather a table, as is currently used so as to address space issues. The text format would contradict research and findings of the Consumer Label Initiative regarding good product stewardship.
- Discussion of Consumer Label initiative in 1996 which focused on FIRST AID statements. The location of the FIRST AID statements was not a focus on the research though. Consumers felt it was important information and wanted to be able to find it, but it was not information that consumers used to make a purchase decision.
- By using a referral statement, the users know where to find FIRST AID Statements.
- EPA should not address the positioning of one precautionary statement without considering its impact on the placement on a pesticide label of other precautionary statements.

- Registrants many times place the first aid statement for Category II and III products on the last page of a multi-page label because the last page is typically securely affixed to the back of the pesticide container. This precaution is taken so that, in the event the booklet is detached from the container, the first aid statement will remain secured to the container.
- By having the placement of FIRST AID on the second page and/or base panel (last page of the label which adheres to the container) addresses the needs of the users.

### **Transition Period**

- If the Agency insists on this interpretation there should be a defining sell-through period of existing label inventory or else product will end up in a landfill.
- If the Agency decides to move forward with proposal there should be a 24-month transition period.
- If EPA moves forward there is a request for time to implement; there are limited number of printing companies that service the pesticide product industry.
- Existing stocks policy should be created; need existing stocks provision of at least 2 years.

### **Financial**

- The proposal is costly and takes time for registrants to implement due to manufacturing aspects which should be considered.
- Compliance costs would be high.
- Adding side and back panel labels to products is often expensive.
- The applicability of the requirements to small-size containers needs to be fully assessed; there are a number of biocidal products packed in small containers; in order to comply with the memorandum, the manufacturers will need to seek exceptions or variations which will incur significant costs.
- The proposal is a new burden on the regulated industry.

### **Other**

- 75%-80% of all labels would be affected (for entire registrant community).
- Registrant community is not arguing that tox category I products must have FIRST AID statements on the front panel of the label.
- Should EPA implement, it should create a list of circumstances that would trigger an exemption (small containers).

### **Agency Response**

The Agency will continue to require that Toxicity Category I products have the first aid statements on the front panel. This requirement is clear in the 40 CFR Part 156.68(d) and PR Notice 2001-1. The 40 CFR Part 156.68(d) reads as follows:

*“Location of first aid statement.* The first aid statements must appear on the front panel of the label of all products assigned to Toxicity Category I by any route of exposure. Upon review, the Agency may permit reasonable variations in the placement of the first aid statements if a reference such as “See first aid statement on back panel” appears on the front panel. The first aid

statements for products assigned to Toxicity Categories II or III may appear on any panel of the label.”

The Agency will continue to require that Toxicity Category I products have the first aid statements on the front panel except in cases where variation has been approved. This requirement is clear as stated in the 40 CFR 156.68(d) and described in PR Notice 2001-1.

Based on the comments received and the wide reliance by the regulated community on an interpretation that “any panel” included inside panels, the Agency will not require the first aid statements for Toxicity Categories II and III products to bear the first aid statements on a visible front, back or side panel (as the Agency memorandum posted to the docket on December 7, 2016, had proposed). The Agency has a number of recommendations for the registrant community to consider when printing their container labels:

1. The Agency strongly recommends that registrants consider placing duplicative first aid language on the very back page of the booklet/accordion/saddle stitch label that is immediately attached to the container in case the booklet/accordion/saddle stitch label is accidentally removed for **Toxicity Category I** products.
2. Regardless of whether a registrant chooses to place the first aid statements for **Toxicity Categories II and III** products on a **visible** front, back, side or inside panel, it is recommended that duplicative first aid language appear on the very back page of the booklet/accordion/saddle stitch label that is immediately attached to the container in case the booklet/accordion/saddle stitch label is accidentally removed. This recommendation is not intended to suggest other information that registrants typically include on the very back page should be moved elsewhere.
3. The Agency recommends that the registrant community consider designing new booklets/accordion/saddle stitch labels that are not easily removed from the containers. Per 40 CFR part 156.10(a)(4) the labels are to be “securely attached” to the immediate container of the pesticide product. However, the Agency believes that in many instances these labels are easily removed which is why many registrants have already chosen to put the duplicative first aid statements on the very last page (as recommended above) of the label that is attached to the container.

Any questions regarding First Aid labeling requirements can be directed to Heather Garvie at 703-308-0034 or [garvie.heather@epa.gov](mailto:garvie.heather@epa.gov).