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**U.S. Environmental Protection Agency  
Office of Pesticide Programs (OPP)**

**"Minimum Application Rates" Issue Paper  
OPP Synopsis and Discussion of Comments Received**

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

**“MINIMUM APPLICATION RATES” ISSUE PAPER  
OPP SYNOPSIS AND DISCUSSION OF COMMENTS RECEIVED**

**Background**

In November, 2006, the Office of Pesticide Programs (OPP) Labeling Committee invited comment on a short issue paper dealing with minimum use rates on labels. Application rates are specified in the “Directions for Use” section of pesticide labels to inform the user of the appropriate amount of product to apply, and in some cases to establish a maximum allowable rate, while minimizing risks to human health and the environment. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 2(ee) permits the use of a pesticide product “at any dosage, concentration, or frequency less than that specified on the label unless the labeling specifically prohibits deviation from the specified dosage, concentration or frequency.”

Application amounts are typically stated on product labels as either a specified rate or a range of rates. However, occasionally there are products which place minimum application rates on product labels in addition to the specified application rate. This is often in the form of “Do not apply at less than...” a specified amount. A minimum application rate stated in this way gives the appearance of being an enforceable requirement, i.e., that it is not allowable to apply an amount lower than what is stated.

Under some circumstances, such a statement may be false and misleading if it is not a required term and condition of the product’s registration.

Placing minimum application rates on product labels is not addressed in FIFRA outside of section 2 (ee). Currently, EPA’s Office of Pesticide Programs offers guidance on the topic in the Label Review Manual, which reads:

*Some proposed labels will contain various use restrictions desired by the registrant, (e.g., “Do not tank mix this product with [their competitor’s products],” or “Do not use this product for formulating other products,” or other similar restrictions). Unless there is some risk based reason for such use restrictions, such statements are not generally acceptable on product labels because they are false and/or misleading-*

In the Minimum Application Rates Issue Paper this question was raised to stakeholders: If registrants wish to place minimum application rates on product labels, should they be allowed to do so if the reason is not risk-based or to ensure efficacy?

**Synopsis of Comments**

Below is EPA’s summary of the principal points made by the commenters, which were mostly state regulators and pesticide registrants. These are EPA’s interpretive summaries, and do not capture many details or differences among the individual comments received.

Comments were received from one registrant, two trade associations, one professional organization, and three state/regional regulatory agencies.

- Most comments received were in support of allowing minimum application rates to be stated on labels. Of these, one felt that there is “no downside as it relates to consumers” while the majority of the comments felt that minimum application rates are appropriate if they are “justified by some appropriate environmental, human safety, public health, resistance management or other risk mitigation basis.”
- Over half of the comments stated that minimum application rates were appropriate to reduce the risk of pest resistance.
- Three of the comments stated that the registrant should have data to support minimum application rates if the restriction is due to efficacy. In addition, one set of comments focused specifically on the need to ensure efficacy of hospital disinfectants. Currently, EPA does require testing that includes identifying minimum use rates and contact times on the labels for use of these products.
- One comment specified that the issue isn’t whether or not minimum application rates should be allowed on labels, but whether enforcement officials should attempt to enforce a minimum rate.

### **Clarification of EPA Position**

In reviewing the comments submitted in response to the Minimum Application Rates issue paper, EPA feels that the majority of comments were in support of stating minimum application rates on labels in certain situations. For certain justified reasons, these rates should be enforceable. EPA believes that enforceable minimum application rates are warranted in two situations:

1. When there is a risk that reduced application of the product may result in increased pest resistance to the active ingredient.
2. When there is documentation that a product’s efficacy is substantially compromised under a certain application rate.

If one of these reasons can not be documented, the minimum application rate should be stated in advisory language, and should follow the enforceable application rate. The Agency recognizes that occasionally a registrant may wish to state minimum application rates for marketing reasons, such as to limit a grower’s tank mix options. In these instances, absent one of the documented reasons described above, mandatory language may be misleading and, if so, would not be acceptable.

### **Next Steps**

EPA believes that the Label Review Manual (LRM) is the appropriate means to communicate the Agency’s position, as it is a guidance document used internally by Agency label reviewers, and also externally by industry stakeholders. The Agency will enhance Chapter 11, Directions for Use, in the LRM to more accurately convey EPA’s position on this issue. The current LRM guidance is very brief, as cited above, and would benefit from a more thorough explanation of the issue with acceptable examples provided.