Staff Paper #29
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DECISION-MAKING CRITERIA

Background:

EPA may find, on the basis of available, reliable data used to complete an appropriately refined risk assessment, that the risk from registered uses of a pesticide exceeds the safety standard. In that case, EPA will need to begin a process to reduce risks to meet the safety standard and will need a method to equitably select those uses and/or tolerances that should likely remain (with or without revision) and those that should not. To initiate discussion on a method for choosing among competing uses, EPA developed possible decision-making criteria that were discussed with TRAC members. These criteria were presented in the context of a tolerance reassessment for pesticides sharing a common mode of action, however, the same criteria may be used to choose among competing uses in several contexts as described below.

TRAC Discussion:

TRAC members provided comments to clarify or expand some of the decision-making criteria. The TRAC also recommended that the draft list of criteria be grouped by category of criteria (i.e., toxicity, dietary exposure, importance to agriculture, public health benefits, non-dietary exposures, and other considerations) and that a set of guiding principles for applying the criteria be developed. Based on these recommendations and comments on the list of criteria, the attached paper was developed.

Although the TRAC discussions identified a number of challenges that would be posed in applying the decision-making criteria, the TRAC did not make specific recommendations as to what type of methodology or process should be used in applying a set of decision-making criteria or how such criteria should be weighted relative to each other. However, there does appear to be consensus that the criteria do not readily lend themselves to a strict quantitative approach.

One issue raised by some TRAC Workgroup #2 members was related to a pesticide's importance to agriculture and availability of alternatives. Some members of the TRAC expressed concern that while alternatives might be available, not all such alternatives would in fact be "reasonable" alternatives. Based on this discussion, the following statement for comment was developed by some members of TRAC Workgroup #2 to clarify what is meant by "reasonable" alternative to a pesticide:

> A "reasonable" alternative to a pesticide that may be under consideration for action under FQPA is one that is *cost effective* to the grower, meaning that the cost of using the alternative pesticide should not disproportionally increase the overall cost of producing the crop when compared to the use of the pesticide being replaced".

The alternative should be one that can be applied acording to label rates without destroying important *beneficial biota* and should be effective considering the other *ecological and*

environmental impacts of the problem. In fact, it is important for EPA and USDA to consider the *entire health of the system* surrounding the commodity in a particular region before making a determination as to whether "reasonable" alternatives are available. For example, the sole alternative should be a product that is not unusually *resistance-prone*, thereby potentially causing the need for other emergency uses. EPA and USDA should consider any *site-specific and regional issues* that may impact the effectiveness of the alternative. Potential impacts of the switch to the alternative on *other pests* relevant to the commodity should be considered. And generally, some *economic, environmental and sociological analysis* of the risks associated with use of the alternative should be completed.

The *sociological adaptation* needed to use the alternative should be considered, meaning that the education and training of applicators, and the monitoring of effectiveness by workers and the grower should be considered in determining a reasonable alternative. The product should also be known to be *reliable in actual field application*.

Finally, the product should be available in *adequate supply* (with adequate shelf life) to meet the anticipated demand, including the possible demand associated with an epidemic year of known pests.

In summary, some of the major factors for consideration of a "reasonable" alternative are the time, help, equipment and cost of using the alternative.

How Decision-Making Criteria Could be Used:

The sample decision-making criteria presented by the EPA to the TRAC have potential relevance beyond tolerance reassessment for pesticides sharing a common mode of action. Such decision-making criteria could be used to choose among competing uses in a variety of contexts where a "reasonable certainty of no harm" finding cannot be made, such as:

- in choosing among competing uses for an individual pesticide,
- in choosing among multiple chemicals used on a single commodity, or
- in choosing among multiple commodities and multiple chemicals in the context of a cumulative dietary risk assessment.

Next Steps:

The EPA will be considering the comments of the TRAC and continue to work with USDA and others to define key criteria and the process for applying such criteria to the tolerance reassessment of the organophosphate pesticides. As these decision criteria are finalized and the process for applying them developed, they will be made available for public notice and comment.