

US EPA ARCHIVE DOCUMENT

EARLY ASSESSMENT FOR OP USES WITH VERY LOW RISK CONTRIBUTION AND/OR HIGH PUBLIC VALUE

Background:

While decision-making criteria can be used to choose among competing uses for retention in the cumulative OP risk cup, there may be some uses that can be identified early on as posing only negligible risk or of such high public value that they should be guaranteed retention in the risk cup before the decision-making criteria are applied to the bulk of the OP chemical-crop uses. In order to initiate discussion and solicit feedback from the TRAC Workgroup #2 on this concept, a Staff Paper was developed outlining how such an approach might work, and listing questions for the TRAC Workgroup #2 to consider.

TRAC Discussion:

The Staff Paper listed different criteria that could be used to define “negligible risk.” The TRAC discussed and commented on these possible definitions. Some comments included a suggestion that negligible risk be defined as having non-detectable residues even at highly exaggerated application. Some TRAC members also stressed that any negligible risk definition also address contributions from water, worker and ecological risk, and not just food consumption, in order to be retained in the risk cup.

TRAC Workgroup members were also given the opportunity to provide written comments on the Agency’s draft paper and several comments were submitted. These comments supported development of an early assessment tool, recommended that no single criterion should be dispositive and that all of the criteria need not be satisfied for a “negligible contribution to risk” finding, and that truly negligible risk should be sufficient even in the absence of a high or unusual value although uses with high public value might qualify for early assessment even if risk posed was “low” rather than “negligible.” The comments also noted that there was no scientific basis for categorically excluding foods in the top 20 food commodities eaten by children if such uses posed a negligible contribution to risk, and that it was unclear how the “opportunities for risk mitigation” translated into early retention in the risk cup. One commentator stated that it may be unlawful under FIFRA to guarantee a place in a risk cup, and that “EPA should instead focus its attention on the development of policies which remove or exempt uses from consideration when filling the risk cup.” Overall, however, the TRAC and individual commentators recognized that some form of narrowing would be useful and necessary.

How an Early Assessment Might Work:

If a suitable definition of “negligible risk” and/or “high public value” can be formulated, then the Agency could make some early decisions which could provide certain OP chemical-use combinations with a “guaranteed” spot in the cumulative OP risk cup and provide some greater

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measure of certainty for the regulated community with respect to those uses. Such early assessment would also allow the Agency to narrow the range of OP chemical-use combinations which might be subject to a set of decision-making criteria and decision-making process for OP tolerance reassessments.

Next Steps:

The Agency is preparing to define elements of an early assessment for public notice and comment.