

US EPA ARCHIVE DOCUMENT



EPA Follow-up on Previous HSRB Recommendations

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AHETF Closed Cab and Open Cab Airblast Completed Studies

- EPA has determined that the data from these studies represent the “best available data” for these exposure scenarios
- No quantitative changes were made to the data following HSRB review, but additional language was added to the final EPA reviews in response to some recommendations, including limitations on using the data
- Will be used in future risk assessments to assess risks to workers applying pesticides using open cab airblast equipment



AEATF Wipe Study

- HSRB recommended additional statistical analyses (non-detect issue)
- Summary statistics re-analyzed and compared (parametric and non-parametric bootstrap C.I. too)
 - $\frac{1}{2}$ LOQ for non-detects (as originally presented)
 - Exposure based on hands only (all detected)
 - Multiple imputation substitution for non-detects (maximum likelihood method for censored data)



AEATF Wipe Study (continued)

- Ready-to-use (RTU) results
 - 3 methods for handling NDs agree closely (all clothing)
 - Hands represent majority of exposure
- Trigger Spray & Wipe results
 - Both ND substitution methods agree closely (all clothing)
 - Hands-only method agree for “long” clothing
 - Hands-only method represents 2/3 of exposure for “short” clothing



AEATF Wipe Study (continued)

- Parametric versus non-parametric bootstrap confidence intervals (CI)
 - Upper CI for parametric method larger than that of non-parametric method
 - CI width for non-parametric method narrower than that of parametric method



AEATF Wipe Study (continued)

- Conclusions
 - Use dermal whole body rather than just hands
 - Hand values drive exposure; imputation methods for NDs had minimal impact (Wipe Scenario)
 - Parametric upper bound of 95% CI is
 - more conservative than non-parametric
 - appropriate when log normal assumption is valid
 - Wipe data were used to confirm regulatory decision based on CMA data for pending action



Gulson et al. (2010)

- HSRB: there was not adequate information to conclude that the study was conducted in substantial compliance with procedures at least as protective as those in subparts A-L of 40 CFR part 26
- To date, EPA has not pursued collecting the additional ethics information; EPA may do so in the future if there is a regulatory need for the data
- EPA is currently planning to use the *Moiemen et al. (2011)* study, which the HSRB will be reviewing at this meeting



Proposed Revisions to Human Studies Rule

- Comment period closed on April 4, 2011
- 10 comments received
- EPA planning to finalize the amendments as proposed
- Draft final rule package has completed EPA intra-agency review process
- Currently undergoing inter-agency review; submitted for OMB review
- Final rule to be signed by December 2011