EPA FIFRA SAP January 2007 Review and Report "Worker Exposure Methods"

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The EPA Charge

- Data need
- Dosimetry
- Biomonitoring
- Statistics
  - Normalization by active ingredient amount
  - Within vs. between worker variability
  - Sample size and sample allocation

Panel Response: Data Needs

- Supported the EPA's assessment of the current limitations of the PHED.
- Identified eight limitations of the current PHED data set.
- Emphasized need to develop a database on handler exposure frequency, duration.

Panel Response: PHED Limitations

1. Inadequate QA/QC documentation.
2. Methodology for many studies results in high levels of measurement uncertainty.
3. Large amounts of censored (undetectable) data. Imputed to LOD/2. User not informed.
4. Dermal sampling data incomplete. Requires whole body composition from different individuals and settings.

Panel Response: PHED Limitations

5. High levels of observation clustering. Unknown intra-class correlation.
6. Data often based on short sampling periods. Difficult to scale to full day exposures.
7. Many scenarios have too little data.
8. Scenarios in PHED do not reflect modern work practices and technologies.

Panel Response: AHETF Plan

- Overall, judged to be a reasonable plan.
- Critique
  - Monitoring duration criteria too stringent to capture real-world short-term use scenarios.
  - Biomonitoring data criteria too restrictive (does not allow extrapolation from rat or pig).
  - Air sampling criteria need to be refined.
  - Dermal sampling criteria improvements.

Panel Response: Passive Dosimetry

- Whole body dosimeters recommended.
  - Minimum uncertainty
- Patch dosimeters (if used):
  - High uncertainty
  - Standardize placement.
- Biomonitoring
  - Permit but not require in protocol.
  - Use to measure whole body dosimeter breakthrough.
  - Do not require for acceptance of dosimeter results

Panel Response: Hand Rinse

- Hand wiping underestimates exposure.
- Accept hand rinse method with laboratory data to support models or adjustments.
- Uncertainty due to the effect of rate of adsorption on recovery efficiency.
- Some panel members recommended modeling to adjust hand exposure, others cited confounding by field conditions.

Panel Response: Passive Dosimetry vs. Biomonitoring

"The agreement in the data … is sufficient to support the Agency's conclusion that a passive dosimetry approach can generate data that can be used to develop relatively predictive estimates of worker exposure for a wide variety of scenarios and activities."

Panel Response: Linearity of Exposure to AI Handled

- Linear Model (Exposure = *c* x AI handled) does not always fit the data, exposure mechanisms.
- Under the model, sampling is optimized by varying observation over a large range of AI handled.
- AHETF plan permits measurement of many covariates describing the observational settings.
- Additional research recommended including potential role of other covariates in modeling exposure.

Panel Response: Repeated Measures

- Majority: de-emphasize within-worker variability (repeated measures). Use resources to add clusters and increase sample size.

- Minority: repeated measures are the chance to capture measures of intra-class correlation.

Panel Response: Sample size and allocation.

- Sample size and allocation – Accept AEHTF recommendation given:
  - costs of studies;
  - applicability of linear model, Exposure= c x AiH;
  - precision objectives, factor of k=3 on mean exposure per unit of AI;
  - minimum of 5 clusters of expected 5 workers each
  - review of initial cluster results to establish applicability of model, adapt final sample size for clusters based on accumulating data and fit of model.

Panel Response: Sample Design and Selection

- SAP concerned with purposive nature of sample selection, dependency on model relating exposure to AI handled.
- Appendix C discusses the potential for bias and an alternative stratified (probability sampling) approach.
- High costs of worker exposure measurements seriously constrain sample design options.

Summary

- Panel supported the EPA position on the need for an updated, standardized exposure data-set to replace/supplement PHED.
- Panel supports passive dosimetry, preferring whole body dosimeters.
- Panel recognized large uncertainties in measuring worker exposures. Concerns over exposure model and sample selection.