


Defining Assessment Factors (e.g., exclusion/inclusion criteria)

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ASSESSMENT FACTORS

“[Assessment factors] can also be used as part of a broader evaluation of a body of evidence that is collectively evaluated through a process typically referred to as a *weight-of-evidence* approach.”

“When EPA considers using information for a particular purpose, careful judgment is applied to evaluate the information for quality and relevance in the context of the specific Agency action being developed .”

Tier 1: *applicability and utility*

1. Did the study evaluate effects of the chemical of interest or its metabolites known to be formed in humans?
2. Did the study evaluate effects in the tissue (organ) of interest or cells derived from this tissue?
3. Did the study evaluate cellular, biochemical or molecular effects relevant to the mechanism under consideration?
4. Did the study include information sufficient to determine what species were studied?
5. Does the publication include original data?

Will be applied to all searches for mechanistic evidence

Tier 2: *clarity, completeness, soundness*

6. Did the study employ dose-/concentration-response design?
7. Does the study contain sufficient number of replicates within each experimental group to evaluate significance of the effect?
8. Does the study report variability within each experimental group/condition?
9. To what extent the study clearly and completely describes both the experimental details and results?

Will be applied to the mechanisms with large databases