

Characterizing the Impacts of Uncertainty and Scientific Judgment in Exposure Limit Development

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There is a misperception by some that exposure limits are precise estimates. In the eyes of risk managers, one discrete value is often considered to be “correct” and all others considered “incorrect.” Exposure limits should be evaluated based on whether the value is derived in a manner “consistent with current principles” or “not consistent.” An analysis of current risk assessment methods was conducted to identify the bases for variability in exposure limits for individual chemicals. The role of scientific judgments, risk policy perspectives, and evolving science methods were evaluated in the context of exposure limit setting methods. A systematic methods analysis shows that important drivers to be considered in evaluating acceptability of an exposure limit include: thoroughness of the review of available data, interpretation of results according to current scientific principles under the regulatory framework being used, and consideration of sufficient sources of variability and uncertainty. Sources of variability that may be encountered in risk assessments performed by different industrial hygienists or toxicology professionals using identical data sets include: selection of the point of departure, uncertainty factors used for data extrapolation, and use of adjustments for toxicokinetics, among others. These and related considerations form the basis of a “quality evaluation” process proposed for assessing the robustness of an exposure limit. Transparency in methods to assure robustness is a core principle embedded in risk assessment methods harmonization. Application of a systematic quality evaluation process provides for more informed use of exposure limits for risk management. A clear understanding of the basis for disparate values can provide useful information regarding the current level of uncertainty in the science and the level of confidence appropriate in using different exposure limits to characterize risk.