Guidelines for Considering Racial Variation During DSD Development

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Humans vary in the absorption, distribution, metabolism, and excretion of chemicals, which may result in variability in their responses to chemicals. Some of this variation may be mediated by genetic differences, and therefore it is possible that certain racial or ethnic groups may show similar variation in their response to toxicant exposure because of the presence of specific genetic characteristics in those groups. The Toxic Effects of Solvents and Vapors chapter in Casarett and Doull's Toxicology (2008) discusses potentially sensitive subpopulations and endogenous and exogenous factors that may play a role in variability in their responses to chemicals. Risk assessment models attempt to predict human risk to toxicant exposure; however, these models cannot always account for the wide variety of human responses, including those that may be attributable to genetic differences that vary by race. Most dose-response assessments have inherent uncertainty because the process requires some scientific judgment, use of default assumptions, and data extrapolations. The TCEQ currently uses an intrahuman uncertainty factor (UF_H) to account for the variation in susceptibility among members of the human population (i.e., interindividual or intraspecies variability). Default factors of up to 10 have been commonly applied to account for these sources of uncertainty and variability. When sufficient data exist, decisions are made based on chemical-specific data and chemical-specific adjustment factors (CSAFs) are used to account for interspecies differences and human variability in toxicokinetics and toxicodynamics (Section 3.11.1 of the RG 442 guidelines).

When sufficient evidence is available to suggest that racial variability plays a role in the occurrence of a specific effect, the TCEQ has taken that information into account in derivation of toxicity factors. Currently, data on race with respect to variability in responses to environmental toxicants are rare. However, the question of whether there is evidence for racial variation that may inform the toxicity factor derivation has not been explicitly considered in the assessment. This new guidance directs that, as part of our literature search and review of the available data, we will look for any evidence of racial variability in toxicodynamics or toxicokinetics of the chemical response. If there is significant evidence that shows a particular race is more sensitive to a chemical's effect(s), this information will be taken into consideration when deriving the chemical toxicity factors. When there is no available evidence or data, we will continue to use the current methodology to account for interindividual variability which is a consistent practice within the scientific regulatory community that derive toxicity factors. Also, because our methodology includes a UF_H (often assigned a value of 10), the TCEQ has confidence that our default methods are likely protective of people of different racial backgrounds.

Based on experience in evaluating data for toxicity factor derivation, there often is little information available on racial variation in responses to toxicant exposure. Therefore, the TCEQ encourages more research on and reporting of racial variability in toxicant responses, as it will allow the scientific regulatory community to more accurately predict human risk to environmental toxicants.

Reference

Casarett, L. J., Doull, J., & Klaassen, C. D. (2008). Casarett and Doull's toxicology: The basic science of poisons. New York: McGraw-Hill Medical Pub. Division.