

42 PERSPECTIVE ON RISKS OF CHLOROFORM IN TAP WATER: IMPLICATIONS OF PHYSIOLOGICALLY-BASED PHARMACOKINETIC MODELING ON REGULATORY TOXICITY CRITERIA. B. D. Kerger, L. B. Walker, M. L. Gargas, D. J. Paustenbach and R. H. Reitz. ChemRisk Division of McLaren/Hart Environmental Engineering Corporation, Irvine, CA and Cleveland, OH.

Estimates of the plausible cancer risk due to chloroform in chlorinated tap water have widespread public health implications. The USEPA Maximum Contaminant Level (MCL) for trihalomethanes, including chloroform, provides an interesting platform for discussion of these implications. The USEPA cancer slope factor for oral exposure to chloroform used from 1976 to 1986 was reduced by a factor of 13-fold based on a reanalysis of existing chronic oral bioassay data. The original, higher cancer slope factor was retained for estimating chloroform inhalation risks. This decision has an unrecognized impact on USEPA regulatory policy in that inhalation exposures to vapors during bathing and other tap water uses now appear to drive the cancer risks (exceeding 1 in 10,000 at the MCL) for common daily exposures. However, recent studies provide important insights on the carcinogenic mechanism and the physiological and pharmacokinetic aspects of human exposure to chloroform and similar chemicals. We used physiologically-based pharmacokinetic (PB-PK) modeling to predict acceptable levels of exposure to chloroform in tap water, supporting an alternative MCL that considers oral, dermal, and inhalation uptake. The internal dose estimates provided by PB-PK modeling suggest that chloroform cancer risks are considerably overestimated by the current USEPA risk assessment approach.

3 STOCHASTIC VS. DETERMINISTIC ASSESSMENT OF CARCINOGENIC RISKS OF LEAD IN SOIL. J C Carlisle and J P Christopher, California EPA, Dept of Toxic Substances Control, Sacramento, CA.

Inorganic lead is classified as a probable human carcinogen by USEPA, but no potency factor has been published. Azar et al (1973) observed kidney tumors in rats exposed to lead acetate in drinking water. This is the best data set for calculating carcinogenic potency because of its many dose levels and large numbers of rats. Using MSTAGE 2.0, we estimated the 95% UCL on Q_1 or Q_1^* and we produced a complete distribution of Q_1 . Conventional deterministic risk assessment could then use as a point estimate of potency either Q_1^* or the likelihood-weighted average of this distribution (Q_1^c), while the distribution of Q_1 could be employed in a stochastic risk assessment. Using the data of Azar et al. (1973), values of Q_1^* were more than fivefold higher than Q_1^c : males - $8.53E-3$ vs. $1.56E-3$ (mg/kg-d) $^{-1}$; females - $1.74E-3$ vs. $3.14E-4$ (mg/kg-d) $^{-1}$. The 50th percentile value of Q_1 was zero for both sexes. CalTOX, a multimedia exposure model, was used to estimate risks in a residential scenario for lead at a nominal concentration of 100 ppm in soil. The range of risks for deterministic and stochastic solutions using Q_1^* , Q_1^c , or the full distribution of Q_1 was surprisingly narrow, ranging from $1.0E-6$ to $1.5E-6$.

544 THE RISK-BASED CRITERIA (RBC) APPROACH TO DECISION-MAKING: INTEGRATION OF THE DATA QUALITY OBJECTIVES (DQO) PROCESS AND QUANTITATIVE RISK ASSESSMENT. J E Storm, D A Nyquist, J R Biesma. Jacobs Engineering Group. Lenexa KS.

To support environmental investigations at a large Superfund site, we were asked to implement EPA's DQO process while assuring decisions would be protective of human health. This resulted in development of an approach to decision-making which is consistent with, but improves upon, EPA's baseline risk assessment (BLRA) approach by allowing risk-based decisions to be made more cost and time efficient. The DQO process is a 7 step planning tool developed by EPA's Quality Assurance Management staff which, when followed, is intended to result in specification of the optimum, statistically-based field sampling plan (FSP) that will accomplish clearly articulated objectives. The objective of this investigation is to implement the DQO process to make statistically defensible, risk-based decisions, as soon as possible, while maintaining compliance with EPA BLRA guidance. The RBC approach developed to accomplish this involves statistical comparisons of contaminant concentrations with pre-established, site-specific risk-based criteria (RBC) using prespecified maximum probabilities of making false (+) and false (-) decision errors. These probabilities are also used in FSP design to assure data collected will be of sufficient quantity and quality to support the specified risk-based, statistical comparison. In this approach the BLRA process is modified, in general, by completing exposure and toxicity assessments prior to design and implementation of the FSP; and, by integrating risk-managers into the risk assessment process, rather than restricting their involvement to review of a final BLRA. This, in turn, is accomplished by assuring decision-maker consensus during DQO development on 1) the conditions of exposure upon which decisions will be based; 2) the site-specific, quantitative acceptable levels of risk/hazard; and 3) the acceptable probabilities of making decision errors. The RBC approach has been tentatively approved by EPA and state regulators for implementation at this site.

545 PREDOMINANT COMPONENTS OF ENVIRONMENTAL CHEMICAL MIXTURES FOUND AT VARIOUS TYPES OF HAZARDOUS WASTE SITES. M M Mumtaz, R E Neft, M Lichtveld, and C Lewis. ATSDR, Atlanta, GA.

The idea of defining a subset of chemicals representative of a larger group has been in use to reduce a complex research problem to a more manageable one. The ultimate goal of this project is to use this approach, based on potential for exposure to human populations, to recommend chemical mixtures for toxicologic research and to develop advanced techniques/tools for performing public health assessments. The data presented here were extracted from an analysis of site-specific data from over 100 sites. The sites were categorized into landfills, chemical companies, solvent reclamation facilities, and manufacturing plants. Considerations were given to on-site/off-site contaminants, completed exposure pathways and allowable values. Hazard quotients were calculated for individual chemicals to define those that occur at highest concentrations. The following were the most commonly found organic and inorganic chemicals: trichloroethylene, vinyl chloride, benzene, 1,2-dichloroethene, perchloroethylene, lead, arsenic, chromium, and beryllium. These results indicate that a relatively small number of the chemicals present at such sites will have a significant impact on the overall recommendations and decisions. Thus, research conducted on a small group of chemicals or simple chemical mixtures could benefit communities living near most of the hazardous waste sites nationwide.