

of people exposed to them. The Agency used these four DBPs to calculate an alternative baseline number of annual pre-Stage 2 cancer cases. The calculations use the linearized multistage model and predict 37 cases for the ED₁₀ risk factors and 87 cases for the LED₁₀ risk factors. The ED₁₀ risk factors (also known as the maximum likelihood estimate) are based on the estimated dose that the model predicts will result in a carcinogenic response in 10 percent of the subjects, while LED₁₀ risk factors correspond to the lower 95% confidence bound on the dose that the model predicts will result in a carcinogenic response in 10% of the subjects (LED₁₀ is EPA's more conservative and more commonly used expression of toxicologically based cancer risk). Assuming that DBP risk reductions for Stage 2 for the entire population average 4.2% (corresponding to the reduction in average TTHM levels), Stage 2 cancer cases avoided based on the toxicological data range from 1.7 to 4.0 cases per year. Section 5.2.2.2 of the Economic Analysis (USEPA 2003i) presents a more detailed basis for the derivation of these estimates. It is important to note that these estimates do not include risks from dermal or inhalation exposure nor do they account for many other DBPs (or the mixture of DBPs seen in actual PWSs) for which occurrence or toxicological risk data do not exist.

1. Non-Quantifiable Health and Non-Health Related Benefits

Although there are significant monetized benefits that may result from this rule from the reduction in bladder cancer, other important potential benefits of this rule are not quantified including potential reductions in adverse reproductive and developmental effects and other cancers.

The primary purpose of the Stage 2 DBPR is to address potential adverse reproductive and developmental health effects that might be associated with DBP exposure. EPA concludes that, "the epidemiologic data, although not conclusive, are suggestive of potential developmental, reproductive, or carcinogenic health effects in humans exposed to DBPs" (Simmons et al 2002). EPA does not believe the available evidence provides an adequate basis for quantifying potential reproductive/developmental risks. Nevertheless, given the widespread nature of exposure to DBPs and the priority our society places on reproductive/developmental health, and the large number of fetal losses experienced each year in the U.S. (nearly 1 million (Ventura *et al.* 2000)),

we believe it is important to provide some quantitative indication of the potential risk suggested by some of the published results on reproductive/developmental endpoints, despite the absence of certainty regarding a causal link between disinfection byproducts and these risks. To do this, we have adapted illustrative PAR calculations from several studies on the relationship between chlorinated water exposure and fetal loss and applied these to national statistics on annual incidence of fetal loss.

Specifically, we calculate the unadjusted population attributable risk associated with each of the three distinct population-based epidemiological studies of fetal loss published: Waller et al. 2001, King et al. 2000a, and Savitz et al. 1995. All three are high quality studies that have sufficient sample sizes and high response rates, adjust for known confounders², and have exposure assessment information from water treatment data, residential histories, and THM measurements. Because the populations in these three studies appear to have TTHM exposures significantly greater than those of the general U.S. population, we have chosen to scale the results using Information Collection Rule data to allow us to derive population attributable risks that may be more relevant to the general U.S. population (USEPA 2003i).

These three studies (using unadjusted data to allow for comparability, and scaled to the TTHM levels reported in the Information Collection Rule data base) yield median PARs of 0.4%, 1.7%, and 1.7% (with 95% confidence intervals for each of the studies of 0 to 4%)³. Using the prevalence of fetal loss reported by CDC, the median PARs for these three studies suggest that the incidence of fetal loss attributable to exposure to chlorinated drinking water could range from 3,900 to 16,700 annually. As part of the analysis to evaluate potential reduction in fetal loss for the Stage 2 DBPR, EPA assumed that reductions in risk are proportional to the 28 percent reductions in the number of locations having one or more quarterly TTHM measurements that exceed the study population cut-offs (>75 to >81 ug/l, depending on study). This analysis implies that a range of 1,100 to 4,700 fetal losses could be

avoided per year as a result of the Stage 2 rule.

Caution is required in interpreting the numbers because many experts recommend that population attributable risk analysis should not be conducted unless causality has been established. Causality has not been established between exposure to disinfection byproducts and fetal loss. The estimates presented here are not part of EPA's quantitative benefits analysis, and the ranges are not meant to suggest upper and lower bounds. Rather, they are intended to illustrate quantitatively the potential risk implications of some of the published results.

EPA has not monetized the value of potential reductions in fetal loss, but recognizes that there is a significant value associated with improvements in reproductive and developmental health. In the absence of valuation studies specific to the health endpoints of concern, the Agency typically draws upon existing studies of similar health endpoints to estimate benefits. The "transfer" of the results of these studies to value similar health endpoints must be done carefully and methodically, controlling for differences in the health endpoints and in the relevant populations. Some researchers have attempted to transfer values using sophisticated analytical techniques such as preference calibration methods (e.g., Smith et al. 2002). Regardless of the approach used, "benefit transfer" requires systematic comparison of the differences in the health effects in the studies and those resulting from the regulation. Application of benefit transfer leads to a detailed qualitative examination of the implications of using those studies and potentially to empirical adjustments to the results of the existing studies.

The Agency is investigating further work specific to the case of fetal loss valuation. One possible area of further research is the value that prospective parents attach to reducing risks during pregnancy. In this regard, the substantial lifestyle changes that prospective parents often undertake during pregnancy suggests that reducing these kinds of risks is of value. A second possible area of further investigation would be work on benefit transfer methodologies that address how existing studies can inform the estimation of the benefits of reduced fetal loss.

EPA has not monetized the potential reductions in fetal loss. Without more information and discussion on these subjects the Agency cannot fully consider and describe the implications of relying upon existing studies.

² Use of unadjusted PAR estimates has the effect of removing the adjustments for known confounders, however, EPA believes the unadjusted estimates are adequate for purposes of the illustrative calculations presented here.

³ The negative lower 95% confidence intervals for all three studies was truncated at zero.