

October 22, 1990

Some interesting details in the recent Benzene NESHAP.

- The two numerical criteria EPA used as a "first step" in the process were
  - MIR of no greater than "approximately"  $10^{-4}$ , assuming 70 years exposure.
  - Protecting the "greatest number of persons to an individual lifetime risk" of less than  $10^{-6}$  (99% of people within 50 kilometers to  $<10^{-6}$ ).

"A principle that accompanies these numerical goals is that while the Agency can establish them as fixed numbers, the state of the art of risk assessment does not enable numerical risk estimates to be made with comparable confidence. Therefore, judgment must be used in deciding how numerical risk estimates are considered with respect to these goals. As discussed below, uncertainties arising from such factors as the lack of knowledge about the biology of cancer causation and gaps in data must be weighed along with other public health considerations" (page 6).

A two step process is used as outlined in Vinyl Chloride.

- Step 1 is to establish the risk based acceptable level ( $10^{-4}$ ).
- Step 2 is to determine the ample margin of safety to decide "... whether to reduce the risks even further." (page 13 my emphasis).

(\*) In the first step "The EPA will generally presume that if the risk to that individual is no higher than approximately 1 to 10 thousand, that risk level is considered acceptable and EPA then considers the other health and risk factors to complete an overall judgment on acceptability. The presumptive level provides a benchmark for judging the acceptability of maximum individual risk ("MIR"), but does not constitute a rigid line for making that determination." (page 8)

(\*) "It is an estimate of the upperbound of risk based on conservative assumptions, such as continuous exposure for 24 hours per day for 70 years. As such, it does not necessarily reflect the true risk, but displays a conservative risk level which is an upperbound that is unlikely to be exceeded. The Administrator believes that an MIR of approximately 1 in 10

thousand should ordinarily be the upper end of the range of acceptability (page 8-9)".

"The EPA also considers incidence (the numbers of persons estimated to suffer cancer or other serious health effects as a result of exposure to a pollutant) to be an important measure of the health risk to the exposed population. Incidence measures the extent of health risk to the exposed population as a whole, by providing an estimate of the occurrence of cancer or other serious health effects in the exposed population. The EPA believes that even if the MIR is low, the overall risk may be unacceptable if significant numbers of persons are exposed to a hazardous air pollutant, resulting in a significant estimated incidence (page 9-10)".

"Particular attention will also be accorded to the weight of evidence presented in the risk assessment of potential human carcinogenicity or other health effects of a pollutant. While the same numerical risk may be estimated for an exposure to a pollutant judged to be a known human carcinogen, and to a pollutant considered a possible human carcinogen based on limited animal test data, the same weight cannot be accorded to both estimates. In considering the potential public health effects of the two pollutants, the Agency's judgment on acceptability, including the MIR, will be influenced by the greater weight of evidence for the known human carcinogen (page 10)".

"The EPA believes that the level of the MIR, the distribution of risks in the exposed population, incidence, the science policy assumptions and uncertainties associated with the risk measures, and the weight of evidence that a pollutant is harmful to health are all important factors to be considered in the acceptability judgment (page 11-12)".

"In the second step, EPA strives to provide protection to the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million. In the ample margin decision, the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including costs and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors. Considering all of these factors, the Agency will establish the standard at a level that provides an ample margin of safety to protect the public health, as required by Section 112 (page 13)".