Oral Comments Presented to the Science Advisory Board for Review of USEPA's Draft "*Evaluation of the Carcinogenicity of Ethylene Oxide*"

Christopher R. Kirman, M.S.

The Sapphire Group, Inc.

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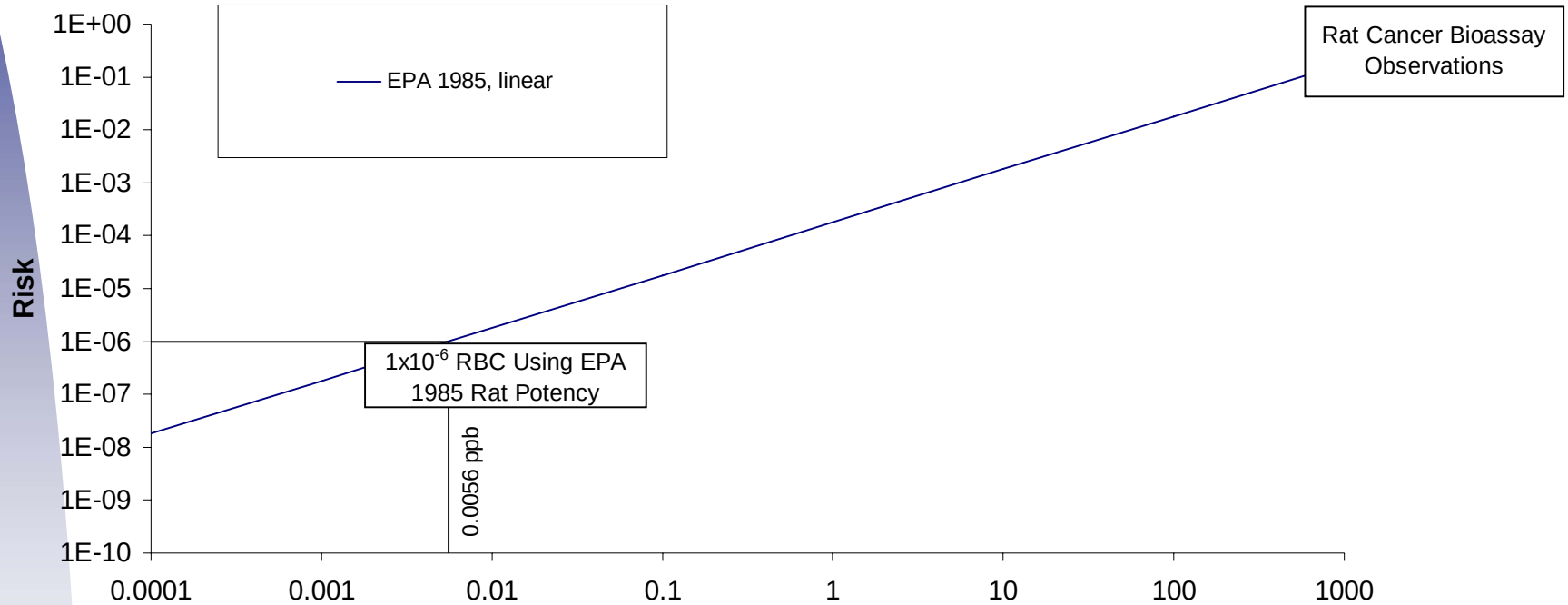
Endogenous Ethylene Oxide Production

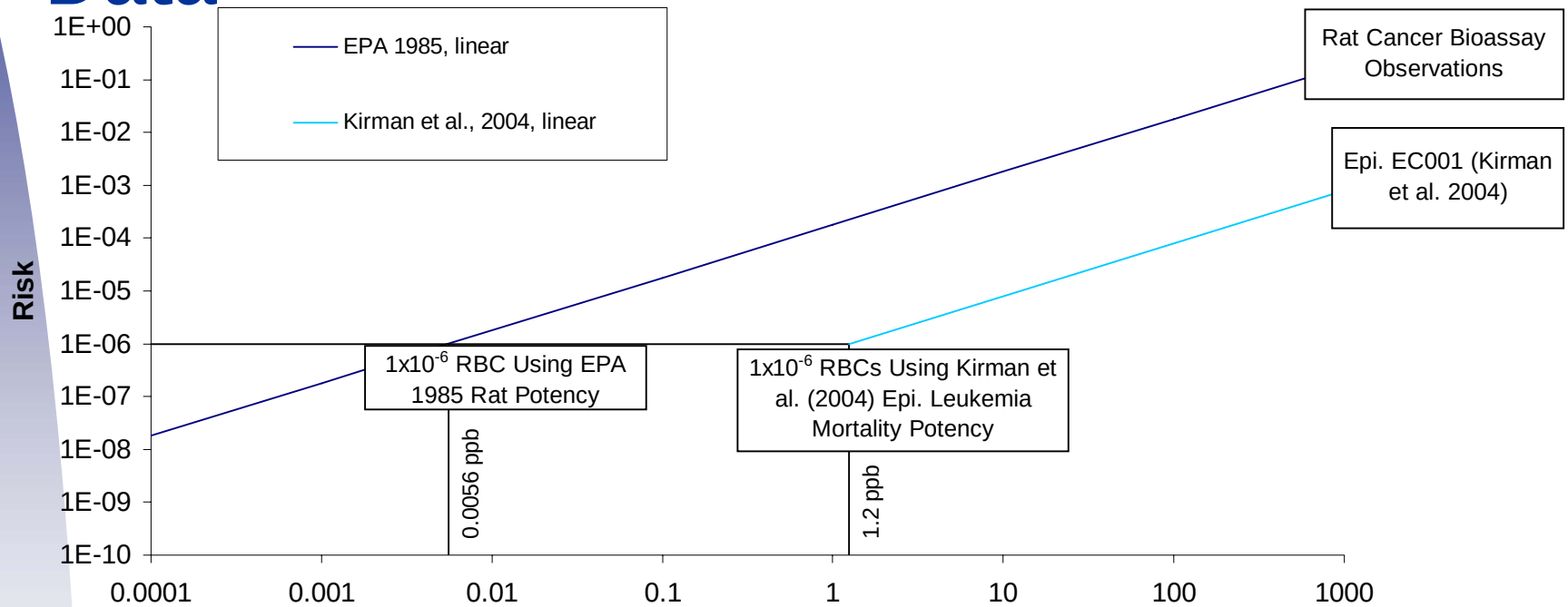
- Naturally occurring ethylene oxide can be detected in the atmosphere
- Ethylene oxide is produced within the body by the epoxidation of endogenous ethylene
  - Humans produce 0.471 nmol/hr-kg bw (Csanady et al., 2000)
  - Rats produce 11.2 nmol/hr-kg bw (Csanady et al., 2000)
  - Influenced by dietary unsaturated lipids and by intestinal bacteria
- *How does EPA's new de minimis ($1x10^{-6}$) concentration compare to atmospheric and endogenous exposures, and to previously determined risk-based concentrations?*

Comparison: EPA's 1985 Potency Based on Rat Data



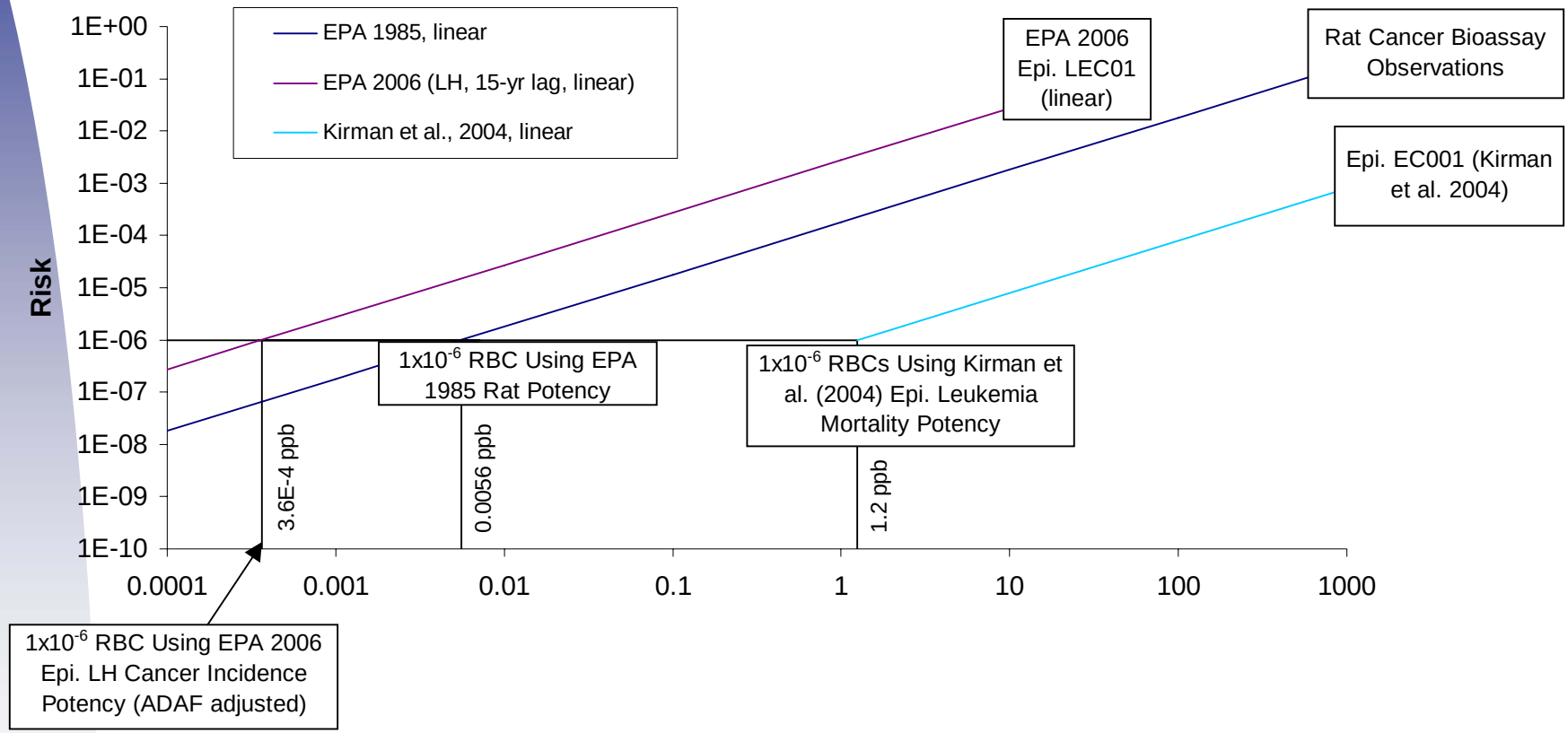
Concentration (ppb)

Comparison: Kirman et al. (2004) Potency Based Upon Epidemiology Data



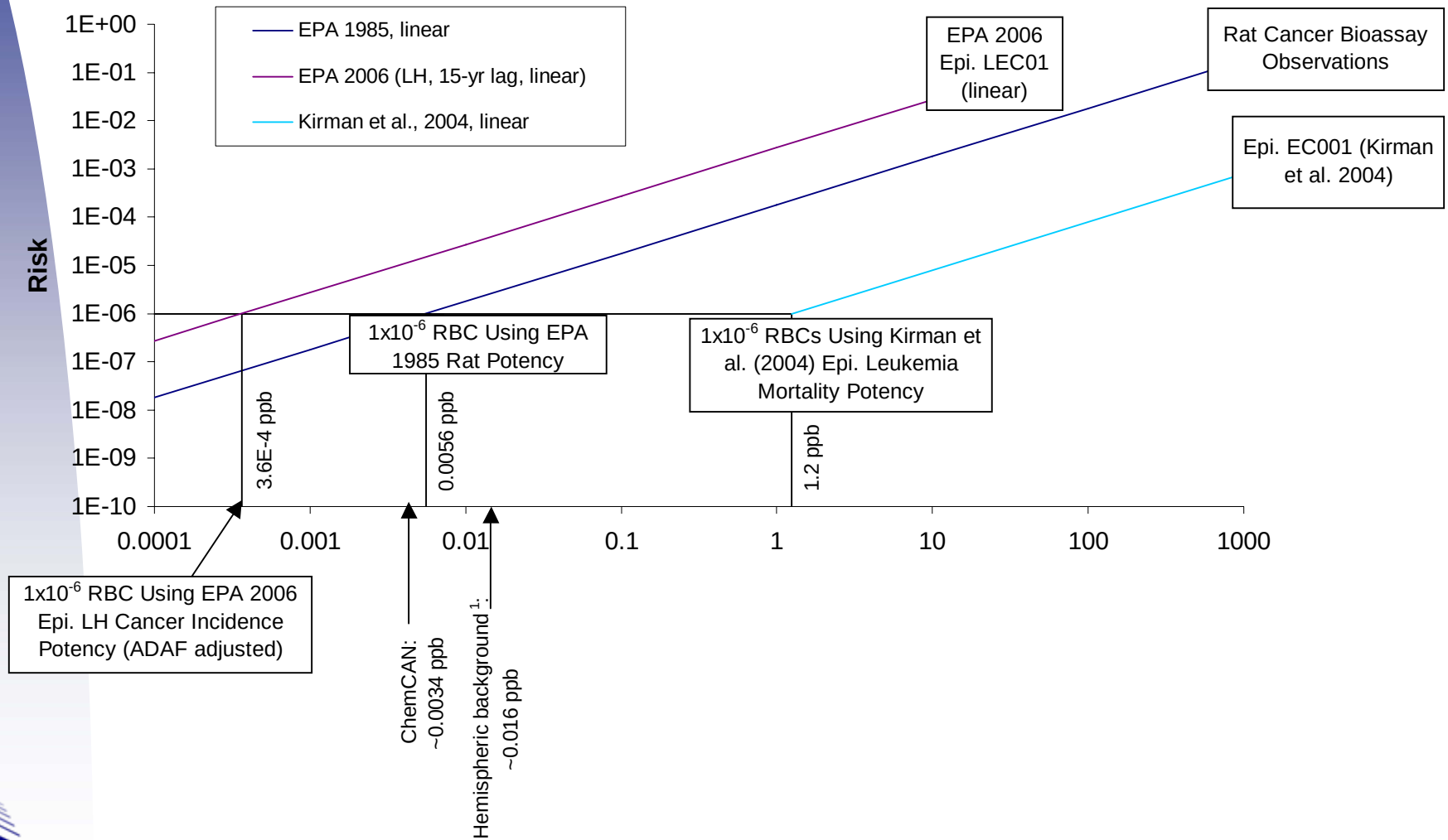
Concentration (ppb)

Comparison: EPA 2006 Potency Based on Epidemiology Data

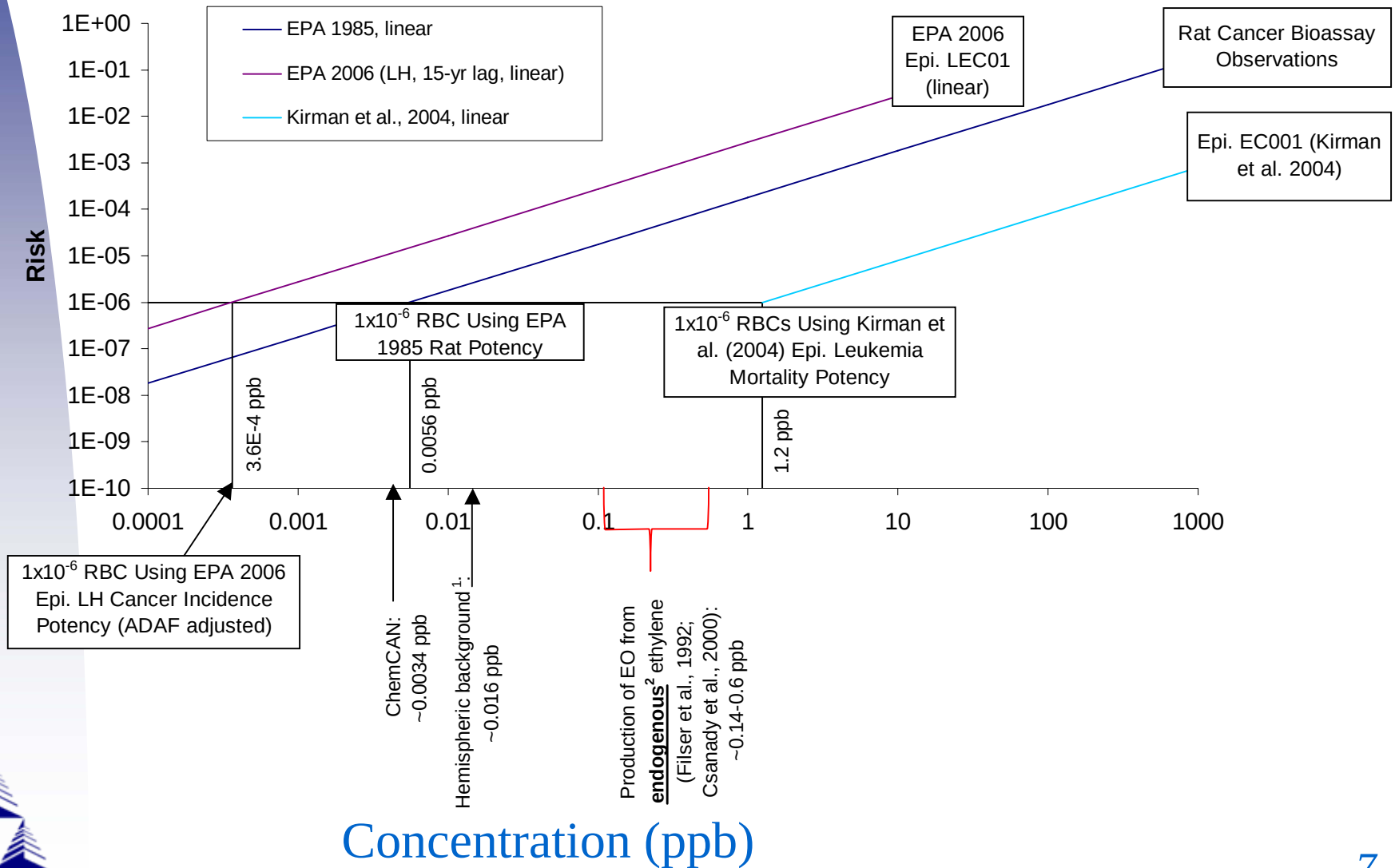


Concentration (ppb)

Comparison: Atmospheric Background



Comparison: Endogenous Production



A Large Cancer Potency Estimate for Ethylene Oxide is Inconsistent with the Weight of Evidence

- Given that…
  - ethylene oxide is considered to be a weak mutagen,
  - ethylene oxide is considered to be a weak animal carcinogen,
  - the epidemiology evidence for ethylene oxide is weak

  Does it make sense that EPA's cancer unit risk value for ethylene oxide (1.5×10^{-3} per ug/m^3) is:
    - **~680-fold** larger than the value for benzene (2.2×10^{-6} per ug/m^3)?
    - **~170-fold** larger than the value for vinyl chloride (8.8×10^{-6} per ug/m^3)?