

William K. Andersen, BE, MD, FAAOS
President, Andersen Sterilizers, Inc.
3154 Caroline Dr
Haw River, NC 27258

Regarding: EPA-HQ-OPP-2013-0244
EPA-HQ-OAR-2019-0178

Shortly after the interim decision came out at the end of March, I reviewed the medical literature and identified numerous peer-reviewed articles regarding human risk of EO exposure from endogenous and exogenous EO. Many of the studies call the EPA's statistical methods based on the IRIS assessment into question. They use the same data EPA used and determine lower risk (or even no added risk) for workplace or bystander EO exposure. There were no articles I could identify that agreed with the EPA's assessment. Although I would assume the literature has been reviewed by EPA experts in the process of writing the PID, I am including a list of the pertinent articles:

CR Kirman, AA Li, PJ Sheehan, JS Bus, RC Lewis & SM Hays (2021) Ethylene oxide review: characterization of total exposure via endogenous and exogenous pathways and their implications to risk assessment and risk management, *Journal of Toxicology and Environmental Health, Part B*, 24:1, 1-29, DOI: 10.1080/10937404.2020.1852988.

Kirman CR, Sweeney LM, Teta MJ, et al. Addressing nonlinearity in the exposure-response relationship for a genotoxic carcinogen: cancer potency estimates for ethylene oxide. *Risk Anal.* 2004;24(5):1165-83. doi:10.1111/j.0272-4332.2004.00517.x

Lynch HN, Kozal JS, Russell AJ, Thompson WJ, Divis HR, Freid RD, Calabrese EJ, Mundt KA. Systematic review of the scientific evidence on ethylene oxide as a human carcinogen. *Chem Biol Interact.* 2022 Sep 1;364:110031. doi: 10.1016/j.cbi.2022.110031. Epub 2022 Jun 30. PMID: 35779612.

G.M. Marsh, K.A. Keeton, A.S. Riordan, E.A. Best, S.M. Benson, Ethylene oxide and risk of lympho-hematopoietic cancer and breast cancer: a systematic literature review and meta-analysis, *Int. Arch. Occup. Environ. Health* 92 (7) (2019) 919–939.

Sheehan PJ, Lewis RC, Kirman CR, Watson HN, Winegar ED, Bus JS. Ethylene Oxide Exposure in U.S. Populations Residing Near Sterilization and Other Industrial Facilities: Context Based on Endogenous and Total Equivalent Concentration Exposures. *Int J Environ Res Public Health.* 2021 Jan 12;18(2):607. doi: 10.3390/ijerph18020607. PMID: 33445726; PMCID: PMC7828163.

C. Valdez-Flores, R.L. Sielken, M.J. Teta, Quantitative cancer risk assessment based on NIOSH and UCC epidemiological data for workers exposed to ethylene oxide, *Regul. Toxicol. Pharmacol.* 56 (3) (2010) 312–320.

M.J. Vincent, J.S. Kozal, W.J. Thompson, A. Maier, G.S. Dotson, E.A. Best, K. A. Mundt, Ethylene oxide: cancer evidence integration and dose-response implications, *Dose Response* 17 (4) (2019), 1559325819888317.

Regards,

William Andersen

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