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MEMORANDUM FOR THE ETHYLENE OXIDE INDUSTRY COUNCIL

Re: The Final Toxicological Profile for Ethylene Oxide

The Agency for Toxic Substances and Disease Registry ("ATSDR") has released the final version of the toxicological profile (the "Profile") for ethylene oxide ("EO"). Although some revisions to the Profile respond to comments made by the Ethylene Oxide Industry Council (the "EOIC"), overall the ATSDR did not address certain of the EOIC's most pressing concerns. This memorandum generally summarizes these revisions to the Profile.

The EOIC argued in both its technical comments and a letter to ATSDR's legal department that ATSDR has no statutory authority to issue the Profile because EO has not been found at sites listed on the National Priorities List (the "NPL"). Apparently in response to these comments, ATSDR revised the opening Public Health Statement to read: "[e]thylene oxide has not been definitely identified at any NPL site. However, it has been tentatively identified at three of these sites. As EPA evaluates more sites, the number of sites at which ethylene oxide is found may change." Profile at 1. No other mention of this issue is made in the Profile.

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The EOIC's technical comments also disputed the draft toxicological profile's (the "Draft Profile") assertion that "[t]here is evidence from inhalation data in both humans and animals that ethylene oxide is carcinogenic by this route." Draft Profile at 26. In response, ATSDR softened the Profile's language on carcinogenic effects by expanding this sentence to read: "[t]here is some evidence from inhalation data in both humans and animals that ethylene oxide is carcinogenic by this route. However, the available data in humans are considered to be limited and incomplete." Profile at 26. Further, as suggested by the EOIC, ATSDR revealed the limitations of the Hogstedt study, but did so with only one sentence. "The Hogstedt data are viewed as having certain limitations, however, such as a small cohort size, the small number of deaths that occurred, and uncertainties about the exposure levels." Profile at 26.

The EOIC supplied ATSDR with three studies not cited by the Draft Profile, namely the Gardner, Greenberg and Kiesselbach studies. The Profile incorporates these studies, stating that "[n]o clear excess in any of these cancers, however, was found by Gardner, Greenburg or Kiesselbach." Profile at 26. In Section 2.4 ("Relevance to Public Health"), ATSDR added a similar statement that these studies found no effects. Profile at 40. Finally, in Section 2.2.1.1 ("Death"), the Profile states that these studies indicate that "there is no increase in mortality associated with those exposures." Draft Profile at 12. The Draft Profile claimed that there was no data on lethal effects.

(Of course, the Profile also fails to discuss the very recent NIOSH Report.)

While ATSDR cited the studies which EOIC supplied and presented a more balanced treatment regarding EO's carcinogenicity, the discussion of health effects (Section 2) remains mostly unchanged. The Profile still concludes "[t]here is evidence from both human and animal studies that inhalation exposure to ethylene oxide can result in a wide range of carcinogenic effects." Profile at 40. Further, the Profile states that "this chemical is clearly carcinogenic via the inhalation route." Profile at 46. The Profile does not weigh or analyze those studies which found no carcinogenic effects against the Hogstedt study. Nor does the Profile explain how the limitations of the Hogstedt study should influence any interpretation of the study's results.

ATSDR also did not address many of the EOIC's concerns regarding the Draft Profile's discussion of EO's reproductive effects. The EOIC's comments called for a discussion of the limitations of the Hemminki study. In response, ATSDR added one sentence and revised a second to its otherwise unchanged discussion of reproductive effects. The Profile now notes that "[v]arious limitations have been described in the design and implementation of this study" Profile at 24. The sentence which follows now states that Abrahams observed decreased sperm counts in workers. Id. In the draft profile

this latter sentence noted that "the possibility" of decreased sperm counts "has been proposed." Draft Profile at 25.

It appears that ATSDR failed to revise the Profile in many areas where the EOIC had provided comments, including:

- the Profile should discuss the lack of leukemia and stomach cancers found in the Morgan study and note that only two Hodgkin's cases were found;
- the dose/response relationship of EO with health effects should be clarified;
- the short-term health effects as discussed on pag 4 should not be classified as "not known";
- it should be made clear that carcinogenic effects in animals do not directly equate to human risk;
- there is no evidence of reproductive effects with low levels of EO exposure;
- the appearance of developmental effects in animals does not necessarily indicate a hazard to humans; and
- ATSDR should present all available data on ambient air concentrations of EO to allow citizens to judge their risk for themselves.

ATSDR also did not adopt the vast majority of specific textual changes proposed by the EOIC.

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