



**IRIS Assessment on Ethylene Oxide:  
Public Comments to EPA Panel  
9/30/14**

Committee members:

Thank you for allotting me this time to present briefly on the EPA IRIS assessment of ethylene oxide. I am speaking on behalf of the Breast Cancer Fund, the only national organization focused solely on *preventing* breast cancer. We do that by working to eliminate our exposure to toxic chemicals and radiation linked to the disease.

We commend the Assessment authors for their unwavering conclusion that the scientific evidence on ethylene oxide exposures demonstrates that “there is strong confidence in the hazard characterization of ethylene oxide as ‘carcinogenic to humans’”. This conclusion is drawn after a careful evaluation of the human epidemiological data with a special focus and analysis of the large NIOSH study examining associations between occupational exposures to ethylene oxide and subsequent incidence and mortality rates.

These occupational data linking ethylene oxide exposure and increased risk for dying from breast cancer are especially significant, given the relative dearth of occupational health data linking particular chemicals (as opposed to occupations), alone or in mixtures, with negative health outcomes – and especially rare in women.

Also important is the appropriate use by the panel of a larger ‘weight of the evidence’ criterion. In the case of ethylene oxide, as carefully reviewed by the panel, there is substantial rodent data implicating ethylene oxide inhalation as a carcinogenic exposure. Furthermore, its carcinogenic mechanism is well established, with the chemical known to be directly genotoxic. Finally, in the final models, the committee has appropriately recognized the importance of modeling low-dose exposures and the assumption of increased early life susceptibility.

To the point of **question 2.a**, we believe that considerations used for model selection and their application in the selection of preferred exposure-response models for breast cancer incidence for the purposes of estimating low-exposure cancer risks and the cancer risks from occupational exposures are clearly and transparently described and scientifically appropriate.

In response to **question 2.b**, we find that the rationale provided for defining the “reasonable models” for low-dose exposures is clearly and transparently described and scientifically

appropriate.

In response to **question 2.c**, the rationale underlying the decision to use the two-piece spline model as well as the method used to identify the knots, both were clearly described, derived from empirical evidence and reflective of the need to address several potential mediating factors.

In response to **question 6**, the addition of new studies in Appendix J appeared to be complete. We agree that the inclusion of these new studies does not substantially alter the findings of the assessment.

In deriving the final exposure-response model to serve as the basis for its regulatory mandate, it is critical that the EPA considers the most valid scientific model for understanding these complex associations. It is also imperative, where any uncertainty exists, that the Agency adopts a regulatory stance that is most attentive to protecting the health and livelihood of the women and men who are exposed to this chemical, primarily through their work environments.

The workers of America deserve no less.

Thank you.

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