

Summary of Meeting Items

Event Title: Meeting Request on EtO Assessments

Date: August 19th, 2019

Time: 2:00 PM – 3:00 PM

Keywords: IRIS, EtO Assessment

Attendees:

Jennifer Sass – Natural Resources Defense Council (NRDC)
Elena Craft – Environmental Defense Fund (EDF)
Richard Denison – EDF
Emma Cheuse – Earth Justice
Michelle Mabson – Earth Justice
Kathleen Riley – Earth Justice
John Walke – NRDC
Jennifer Jinot – University of California San Francisco (UCSF)
Sarah Siskind - Miner, Barnhill & Galland, P.C.
Howard Hu – University of Washington
Jonathan Emmanuelle – Hart McLaughlin & Eldridge, LLC
Pam Nixon – People Concerned About Chemical Safety
Deborah Thomas – Romanucci & Blandin, LLC
Kris Thayer – EPA/ORD/NCEA
Tina Bahadori – EPA/ORD/NCEA
Madison McGovern – EPA/ORD/NCEA
James Avery – EPA/ORD/NCEA
Paul White – EPA/ORD/NCEA
Yu-Sheng Lin – EPA/ORD/NCEA
Ravi Subramaniam – EPA/ORD/NCEA
David Bussard – EPA/ORD/NCEA
Andrew Kraft – EPA/ORD/NCEA
Belinda Hawkins – EPA/ORD/NCEA
Wayne Cascio – EPA/ORD/NHEERL
Amanda Fitzmorris – EPA/ORD
Amy Vasu – EPA/OAR/OAQPS
Darcie Smith – EPA/OAR/OAQPS

Summary of Meeting Activities:

- The focus of the meeting was 2016 IRIS assessment of ethylene oxide (EtO).
 - The IRIS assessment received two rounds of public comment and peer review.
- Jennifer Sass (NRDC) expressed concern over the Texas Commission on Environmental Quality (TCEQ) draft assessment of EtO, particularly its focus on lymphoid cancer only and not breast cancer, and the treatment of incidence versus mortality in the assessment.
 - EPA described IRIS's treatment of incidence and mortality studies.

- EPA explained that both forms of cancers were considered important to hazard characterization and quantitative risk assessment. Lymphoid cancer had higher values than breast cancer, and both were expressed as incidence in the assessment.
- Elena Craft (EDF) inquired about the dose-response model used in assessments of EtO.
 - EPA explained that the choice of models was a critical aspect of the IRIS EtO assessment.
 - EPA referenced the portion of the IRIS assessment (Figure 4.3, page 4-21 in the assessment) that described which models were chosen and why, addressing issues raised during the assessment’s public comment period.
 - Throughout assessment development, EPA and the SAB received public comments. The final assessment represents this input as well as feedback from the SAB.
- Jennifer Sass (NRDC) asked how EPA/IRIS handles endogenous exposure.
 - EPA recognized the relevance of endogenous exposure to EtO and discussed this in the assessment.
 - EPA clarified that the IRIS assessment estimates risk above background exposure (which would include endogenous exposures).
- Howard Hu (University of Washington) asked EPA to comment on the Marsh et al. (2019), paper, which expressed that risk due to exposure was not as extreme as was put forward in the IRIS assessment.
 - EPA responded that internal risk comparison was not included in the Marsh et al. (2019) paper to examine patterns of exposure/risk relationships.
- Howard Hu asked EPA if the Bogen et al. (2019), paper, which evaluated historical exposure to EtO, was considered in the IRIS assessment.
 - EPA explained that the paper was useful in illustrating a different modeling approach for estimating historical exposure but lacked data to support key assumptions.
- Howard Hu asked for additional discussion of the shape of the dose-response curve and the 2-piece Spline model.
- Emma Cheuse (Earth Justice) expressed appreciation for the robustness of the 2016 IRIS assessment. She also expressed concerns about the draft TCEQ EtO assessment and the American Chemistry Council (ACC) EtO Request for Correction (RfC) and asked for ORD comments on the RfC process.
 - EPA explained the RfC is assigned to OAR; IRIS is not working on the RfC at this time.
- John Walke (NRDC) commented that OAR has ongoing rulemaking proposals, which rely on IRIS assessments. Assessments hold Congressional and media interest, and an Agency decision to not rely on a current IRIS assessment would have significant implications.
- Michelle Mabson (Earth Justice) asked for clarification of estimates of lymphoid cancers.
- Emma Cheuse requested information on additive cancer risks, protein adducts, and the role of cellular repair in endogenous exposure.
 - EPA stated the IRIS assessment provides material on mutagenicity and carcinogenicity, including a mechanistic discussion supporting direct acting mutagenic carcinogen characterization.
 - EPA observed that cellular repair processes are indeed important in limiting genetic damage to the organism, but, broadly, may not prevent risk - either from the development of “background” disease in the population or from the effects of added exposures to carcinogens.
- EPA informed participants of the IRIS process for posting meeting notes in order to increase transparency and accessibility and explained notes will be circulated for review—Jennifer Sass will provide EPA with email addresses—before posting.