

**Clarification for  
Chemical Assessment Advisory Committee (CAAC)  
for the IRIS Evaluation of Ethylene Oxide**

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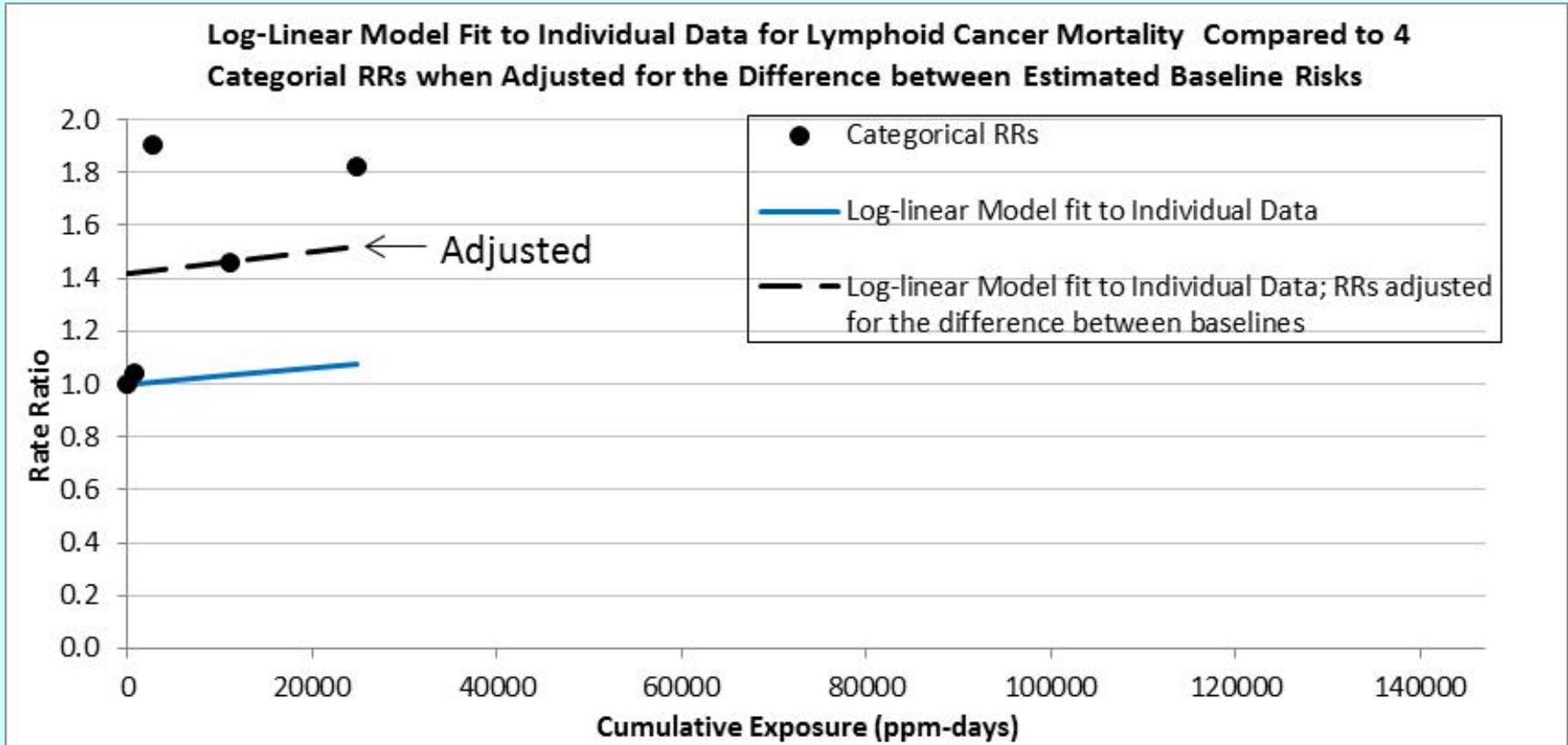
**On behalf of the American Chemistry Council (ACC)**

**November 18-20, 2014**

The individual data  
are **NOT** supralinear  
for either breast cancer mortality  
or lymphoid cancer mortality.

# Lymphoid Cancer Mortality

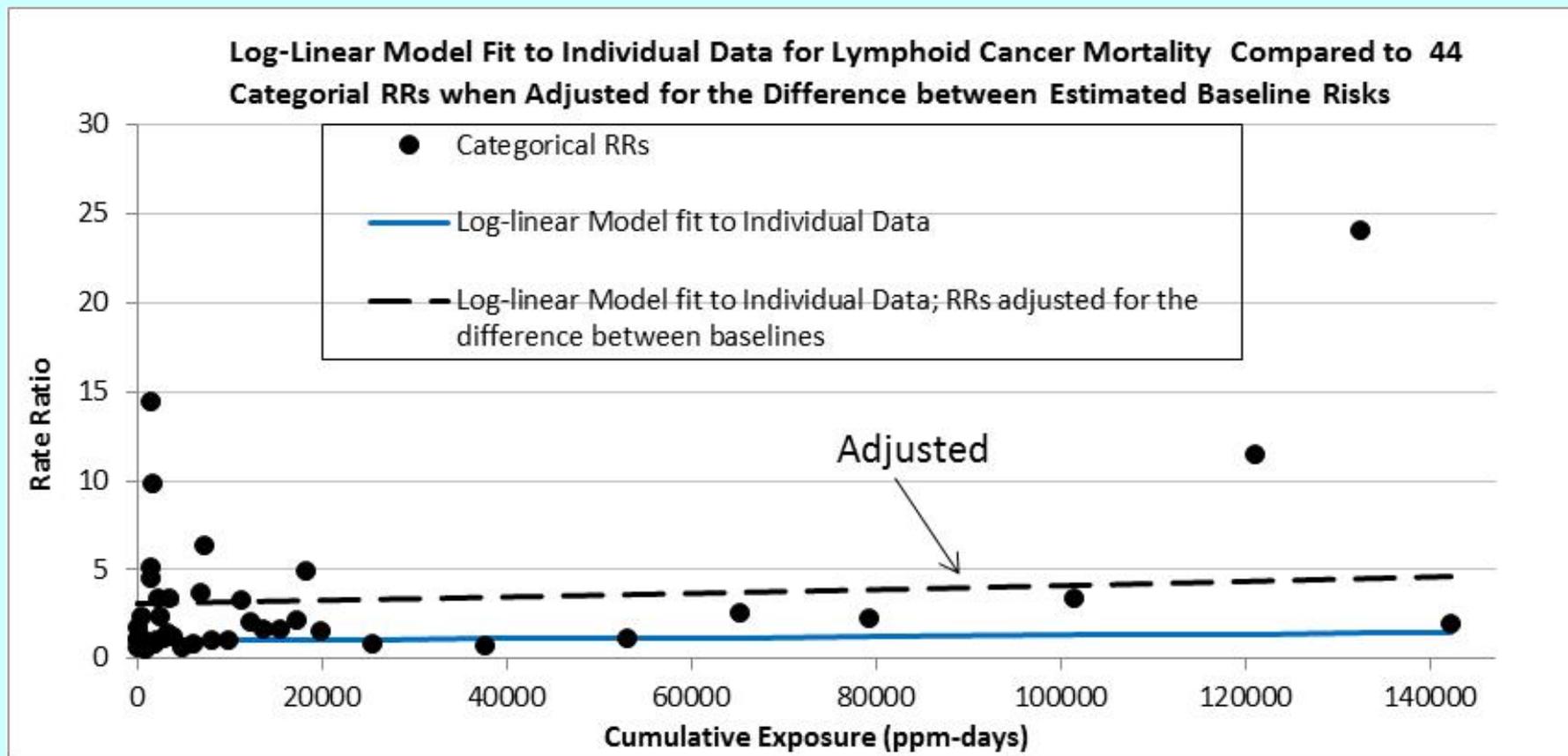
The problem with evaluating the Log-Linear Model fit to the individual data using this picture is that the 5 categorical RRs are NOT the individual data.



1.42 = Intercept of Categorical RRs estimated from rate ratios for log-linear slope fit to individual data

# Lymphoid Cancer Mortality

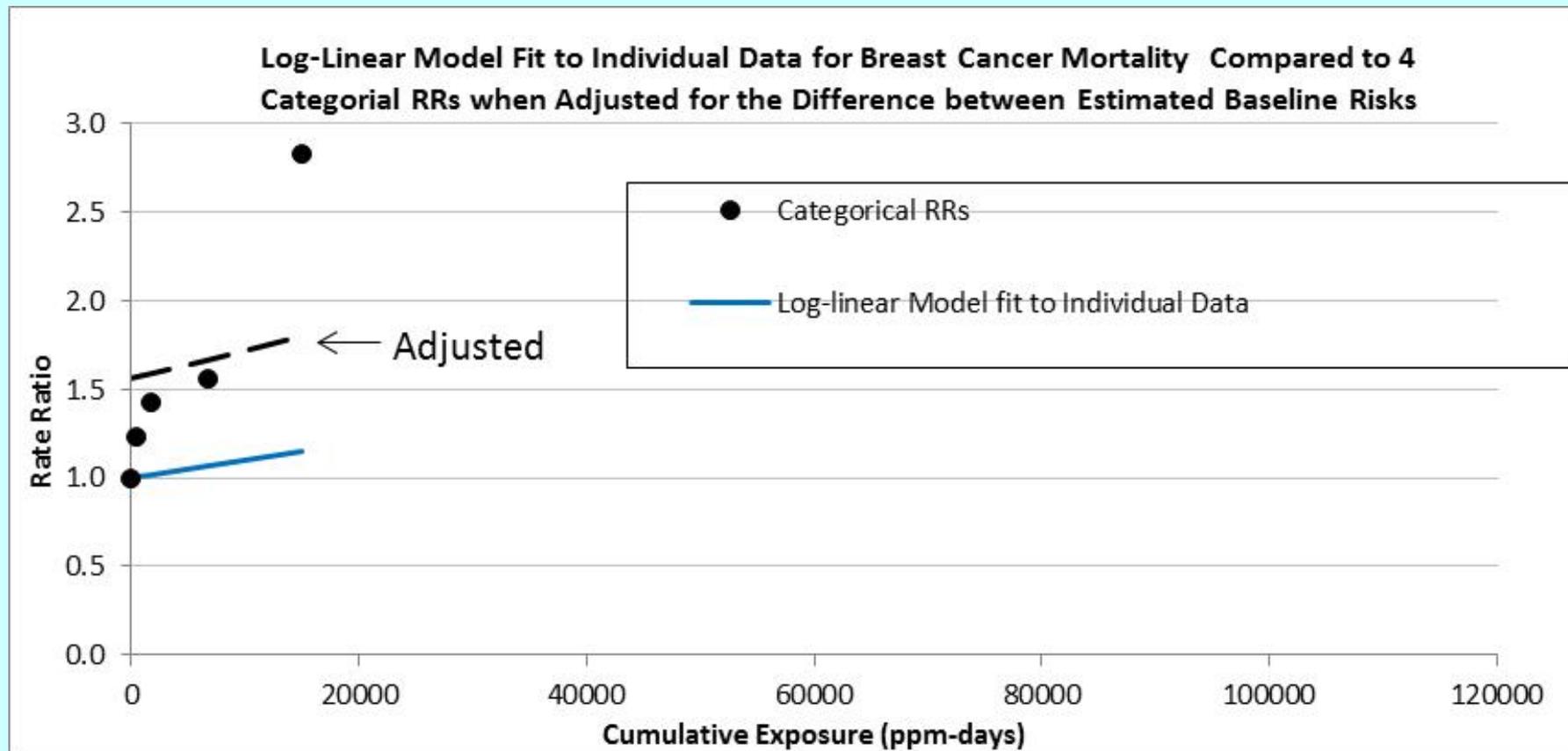
44 categorial RRs are closer to the individual data.



3.11 = Intercept of Categorical RRs estimated from rate ratios for log-linear slope fit to individual data

# Breast Cancer Mortality

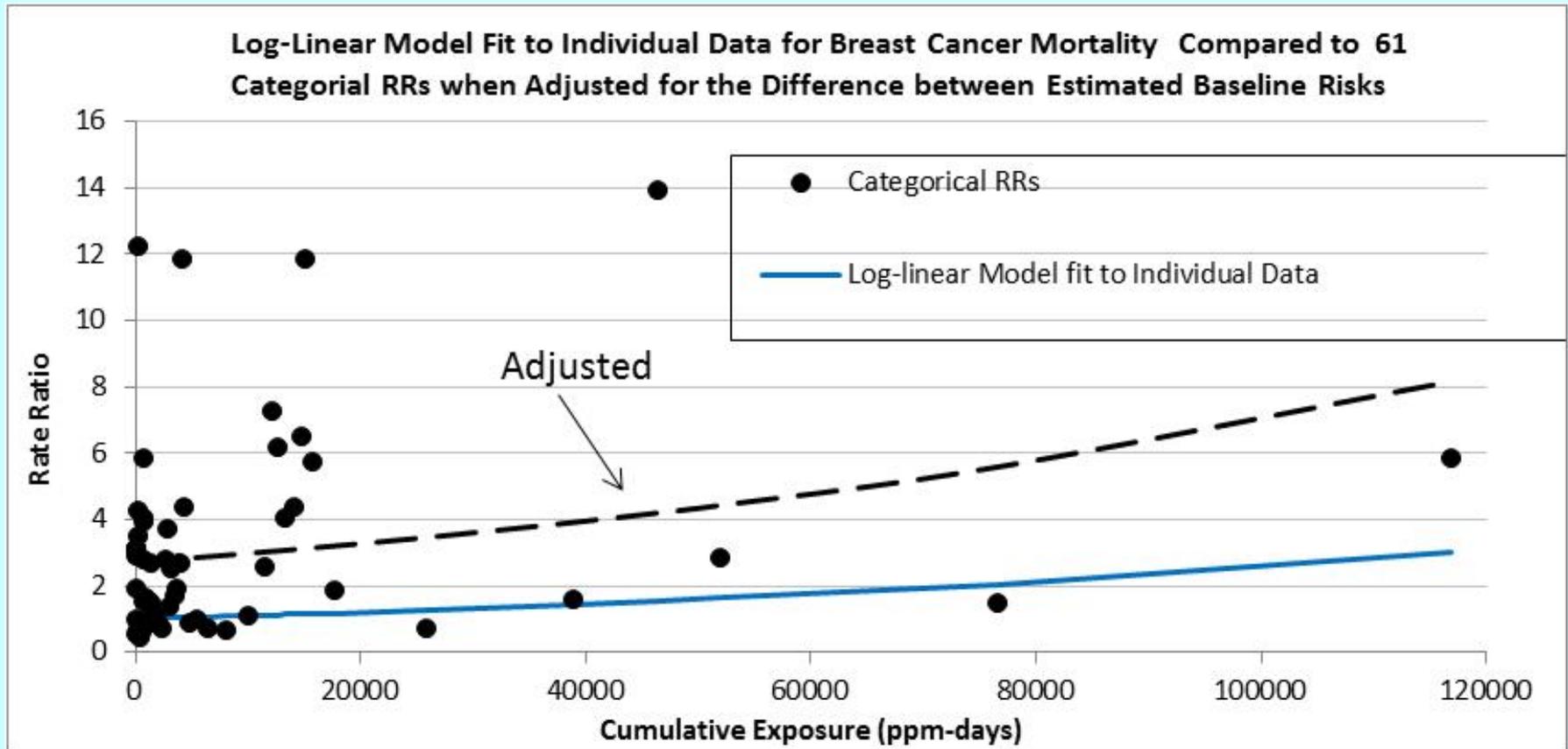
The problem with evaluating the Log-Linear Model fit to the individual data using this picture is that the 5 categorical RRs are NOT the individual data.



1.56 = Intercept of Categorical RRs estimated from rate ratios for log-linear slope fit to individual data

# Breast Cancer Mortality

61 categorical RRs are closer to the individual data.



2.72 = Intercept of Categorical RRs estimated from rate ratios for log-linear slope fit to individual data

# Risk Assessment and Excess Risk Characterization

Valdez-Flores, Ciriaco, Robert L. Sielken Jr., M. Jane Teta, Quantitative cancer risk assessment based on NIOSH and UCC epidemiological data for workers exposed to ethylene oxide. Regulatory Toxicology and Pharmacology 56 (2010) 312–320.

For each of the 12 Endpoints

and each of the 6 sub-cohorts

NIOSH: Males

UCC: Males

NIOSH & UCC combined: Males

NIOSH: Females

NIOSH: Males & Females combined

NIOSH & UCC combined: Males & Females combined,

we calculated EPA's standard points of departure (PoD)

-- Effective Concentrations (ECs)

EC<sub>01</sub> (1/100) to EC<sub>000001</sub> (1/Million)

for 70 years (shown) and also 78 and 85 years

Maximum Likelihood Estimate

95% Two-Sided Confidence Interval

95% One-Sided Confidence Limits