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Dr. Holly Stallworth
Designated Federal Officer (DFO)
Science Advisory Board Staff Office
USEPA Headquarters
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Re: Comments by the American Petroleum Institute to the Clean Air Scientific Advisory Committee, April 2, 2009 Consultation: Draft Plan for Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment

Dear Dr. Stallworth:

The American Petroleum Institute (API) represents nearly 400 member companies involved in all aspects of the oil and natural gas industry. API is pleased to submit the following comments to the Clean Air Scientific Advisory Committee (CASAC) regarding the April 2, 2009 consultation on the Draft Plan for Particulate Matter National Ambient Air Quality Standards: Scope and Methods Plan for Health Risk and Exposure Assessment (REA). Please provide these comments to the CASAC panel and post on the meeting Web site. These comments are in addition the ones supplied by David W. Heinold, CCM, Sr. Air Quality Meteorologist, AECOM Environment, on API's behalf.

The following comments relate to Chapter 3 - SCOPE AND APPROACH FOR THE HEALTH RISK ASSESSMENT of the document. Specifically API offers the following comments:

3.2.2 Selection of Health Effects Endpoint Categories

The REA should not attempt quantify health endpoints for which the causal evidence is only suggestive

In the draft REA plan, EPA suggests they are considering quantifying health endpoints for which the causality is "suggestive". We disagree with this approach. In the causality framework for NAAQS pollutants, EPA considered the evidence as "suggestive" if only one observational epidemiology study shows a "positive" association, even when bias, chance, and confounding with other pollutants in the study itself cannot be ruled out, and when results of other studies are inconsistent. Currently, EPA considers any observational epidemiology

study to be “positive” when the study reports any single coefficient above 1.000, even if the coefficient is not statistically significant and if a myriad of other coefficients in the study are below 1.000, and even if the coefficient for the pollutant of concern is markedly reduced by inclusion of other pollutants or model specifications. This approach guarantees that if any observational study has been conducted on any given health endpoint, EPA will conclude that the evidence for a causal association is at least suggestive. This extremely low causal hurdle should not be used to justify quantifying health effects. Specifically, EPA should not quantify birth outcomes (infant mortality, low birth weight) since the health effects data are far too inclusive to justify such an approach. We question EPA to appropriately characterize the uncertainty of health effects that are only suggestive. Currently, EPA makes no distinction whatsoever between health effects that have been determined to be causal versus those which are likely causal.

3.2.3 Specification of Concentration-Response Functions

In their criteria to select epidemiology studies for risk assessment, EPA must include additional guidance for selecting specific concentration response functions within studies for use in the REA.

In their guidance for selecting studies, EPA provides a number of study selection criteria. However, EPA does not provide any guidance on how they will select specific concentration response functions (CRFs) from within studies. In observational epidemiology, rather than define a specific analytic approach up front, it is common to provide risk estimates using various method specifications. Examples include: different methods and degrees of freedom for smoothing functions for time-varying factors, various methods for adjusting for meteorological factors, various lag times, and various adjustment for co-pollutants. However, other than a vague mention to model fit, which provides no information on biological plausibility, EPA does not provide guidance on they will select various CRFs presented within published studies. Rather, in the past, EPA has trended towards the use of the highest CRFs for use in risk assessment.

We recommend that EPA develop criteria for selecting specific CRFs. As an initial step, we recommend that EPA discontinue the practices of: 1) using CRFs that are not statistically significant; 2) selecting the highest estimates from amongst those provided using various alternate model specifications; and 3) ignoring the results of negative studies.

As an example, in the draft REA, EPA places high emphasis on the results of Ostro et al. (2007). The results of Ostro et al. (2007) were significantly higher when a non-parametric penalized spline model was used versus a parametric natural spline model. Also, changing the degrees of freedom from 4 to 8 resulted in a reduction of the CRF to a level that was not statistically significant. EPA’s selection of the “appropriate” CRF should not be guided by selecting the highest CRF, but should rather capture the full range of results from this study.

EPA also places high reliance on the results of Franklin et al. (2007). In this study, the results at lag 1 were much higher than at lag 0. Many of the results presented were not statistically significant and should be excluded from the REA. Franklin et al. did not adjust for confounding pollutants. The results across cities were highly heterogeneous raising the question of if it was appropriate to combine the results in a meta analysis. Again, EPA should not select only the highest results but present the full range of results from this study.

In the list of chronic studies, EPA ignores the study by Janes et al. (2007) that provides a different spectrum of risks, mostly not statistically significant, from chronic exposure to PM. EPA should not exclude a study from the REA on the basis of null findings as this approach skews the risk assessment towards over-estimating the risks.

EPA must also appropriately use the epidemiology study selection criteria they have provided.

From inspection of the studies EPA plans to use, they have violated their own study selection criteria. For example, EPA states that a study selected for use in the REA must be based on direct measurement of PM2.5 rather than a surrogate measure such as airport visibility data. We agree with this criterion. However, EPA has selected the study by Laden et al. 2006 for use in the REA, even though the update of the Harvard Six Cities study presented in this paper was based on a surrogate measure of exposure, PM10 and airport visibility data. Similarly, EPA states a preference for excluding studies that rely on ecological-defined variables. However, EPA has selected the chronic study by Eftim et al. (2008) for use in the REA, even though this study relied on an ecological-defined variable, population based COPD rates, to control for smoking, a critical confounding factor.

For any questions about these comments, please contact me at 202-682-8568 or steichent@api.org.

Sincerely,

/s/

Attachments

cc: Howard Feldman – API (feldman@api.org)
Beth Hassett-Sipple – EPA (hassett-sipple.beth@epa.gov)