



April 22, 2014

CASAC Ozone Review Panel  
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Dear Panel Members:

We are writing on behalf of the American Lung Association and Sierra Club to follow up on several issues raised at your March 25-27 meeting.

**1. Background Levels:** There was considerable discussion on the subject of background ozone levels during the March 26 and 27 sessions. Consideration of background levels is subject to two important limitations under the Clean Air Act. First, the primary NAAQS must specify an ozone level requisite to protect public health with an adequate margin of safety regardless of the source of the ozone. Second, proximity to natural background levels can at most be only one factor in choosing among the final alternatives, and can never justify a standard that allows adverse effects or fails to provide an adequate margin of safety.

On the first point, the law does not allow the NAAQS to protect only against harms presented by ozone attributable to U.S. anthropogenic sources. A person breathing the air is exposed to the total concentration of ozone in the air, including background, and the NAAQS must protect against that total exposure. The fact that background conditions may make attainment of health-protective ozone levels more difficult in some areas is legally irrelevant in determining a requisite level for the primary NAAQS. The U.S. Court of Appeals for the D.C. Circuit so held more than 30 years ago in *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1184-85) (D.C. Cir. 1981) (“Petitioner Houston contends that the ozone standards are arbitrary and capricious because natural ozone levels and other physical phenomena in the Houston area prevent it from meeting the standards ... **Attainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards**”)(emphasis added).

In a subsequent case, the D.C. Circuit did state that, in choosing among 3 alternative levels for the 1997 ozone NAAQS, EPA could consider as one factor the closer proximity of the lowest level under consideration (0.07 ppm) to peak natural background conditions that infrequently occur in some areas. *American Trucking Assns v. EPA*, 283 F.3d 355, 377, 379 (D.C. Cir. 2002) (“[A]lthough relative proximity to peak background ozone concentrations did not, in itself, necessitate a level of 0.08, EPA could consider that factor when choosing among the three alternative levels”). However, the Court found the “[m]ost convincing” reason for EPA’s rejection of that lowest level was “the absence of *any* human clinical studies at ozone concentrations below 0.08.” *Id.* 379 (emphasis in original). Read together with the *American Petroleum Institute* decision and other precedents, *American Trucking* suggests that background can be only a limited factor in deciding where to set the NAAQS. EPA certainly could not set the standard at a level likely to cause adverse effects, or that the Administrator finds does not provide an adequate margin of safety merely because a more protective standard would be closer

to background levels. At most, *American Trucking* indicates only that when faced with material uncertainty in choosing among alternative potential standard levels below the level of likely adverse effects, EPA may consider as one factor the relative proximity to natural background levels in some areas.

Moreover, *American Trucking* dealt only with consideration of natural background conditions. The Court has never allowed EPA to consider proximity to “background levels” where more broadly defined as including the contribution of anthropogenic emissions, whether from U.S. or non-U.S. sources. The Clean Air Act expressly provides for addressing the impact of non-U.S. emissions when *implementing* the NAAQS. Section 179B(a) of the Act specifically requires EPA to approve a state’s implementation plan where the state shows the plan would be adequate to timely attain the NAAQS “but for emissions emanating from outside of the United States,” provided the plan meets all other applicable requirements. 42 U.S.C. §7509a(a). Likewise, section 179B(b) provides for waiver of emission fees triggered by failure of an area to timely attain the ozone NAAQS where the state shows that the area would have timely attained but for emissions emanating from outside the U.S. *Id.* §7509a(b). Thus, Congress specified that the impact of international emissions was to be addressed when implementing – not when setting – the NAAQS.

**2. Risk:** References were made at the meeting to court decisions stating that the NAAQS do not have to eliminate all “risk.” The courts have made these statements simply to note that for non-threshold pollutants, EPA need not set the standard below the lowest level of exposure at which adverse effects could be extrapolated from available data. The decisions do not mean that EPA can set the standard at a level at which available data show adverse effects to members of a sensitive subpopulation (e.g., asthmatic children) are reasonably likely (though not certain), or that fails to provide an adequate margin of safety below that level. Moreover, the decisions do not countenance leaving some portion of the public unprotected from adverse effects, or allowing some adverse effects to persist. The Courts have made clear that the NAAQS must “be set at a level at which there is ‘an absence of adverse effect’ on [] sensitive individuals” such as children, the elderly, and people with respiratory illnesses. *Lead Indus. Ass’n v. EPA*, 647 F.2d 1130, 1153 (D.C. Cir. 1980). And consistent with the Clean Air Act’s “‘preventative’ and ‘precautionary’” approach to setting NAAQS, EPA must protect public health from “not just known adverse effects, but those of scientific uncertainty or that research has not yet uncovered.” *American Lung Ass’n v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) (citation and quotation marks omitted).

A commenter also referred to Justice Breyer’s solo concurring opinion in the Supreme Court’s review of the 1997 ozone and PM NAAQS, but that opinion is merely the view of one justice, not the controlling holding of the Court. Moreover, Justice Breyer did not suggest that EPA could adopt a NAAQS that allows effects that meet clinical criteria for adversity: only that EPA could “avoid regulating risks that it reasonably concludes are trivial in context.” *Whitman v. American Trucking Assn’s*, 531 U.S. 457, 495-96 (2001).

**3. Draft Risk Assessment:** There was some discussion at the meeting as to whether CASAC should express its views on the overall quality of EPA’s Risk and Exposure Assessment and its utility in informing the NAAQS decision. We would strongly encourage CASAC to offer its

views on these matters, and to do so as definitively as possible. In *Mississippi v. EPA* (the Court decision upholding EPA's 2008 primary ozone NAAQS), the Court allowed EPA to effectively discount the results of the agency's Risk and Exposure Assessment based in part on the Court's view that CASAC had expressed reservations about the inputs thereto:

Petitioners also challenge EPA's interpretation of its own risk and exposure assessments. EPA did not rely heavily on them, though petitioners think it should have. These assessments model real-world interactions between a host of variables in order to predict health outcomes based on available data. 2008 Final Rule, 73 Fed. Reg. at 16,441. As such, they adhere to the inviolable law of data analysis, "garbage in; garbage out." That is, as CASAC cautioned EPA, the risk and exposure assessments are only as reputable as the inputs upon which they rely to produce their predictions. Oct.2006 CASAC Letter, at 12; *see also* Letter from Dr. Rogene Henderson, CASAC Chair, to Stephen L. Johnson, EPA Administrator, at D-39 (Feb. 10, 2006), EPA-CASAC-06-003 (discussing similar weaknesses in risk assessment for the secondary NAAQS). In this case, the inputs were the very data whose reliability EPA questioned at lower levels.

*Mississippi v. EPA*, 2013 WL 6486930 at \*13 (D.C. Cir. 2013). Although we believe the Court misconstrued CASAC's comments (which merely advised EPA to revise portions of the risk assessment to better reflect the data and uncertainties), the above-quoted passage highlights the importance of CASAC clearly expressing its views on the risk assessment's overall quality, and its utility as a basis for determining the level of the standard. To the extent CASAC believes that the Assessment is (or with improvement, will be) sufficiently well done and reliable to reasonably inform EPA's NAAQS decision (including as to risks at lower ozone levels under consideration), it would be very helpful for CASAC to clearly so state.

Thank you for your attention to these important issues.

Sincerely,

/s/ David S. Baron  
David S. Baron

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and Sierra Club*