



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

June 26, 2014

EPA-CASAC-14-004

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: CASAC Review of the EPA's *Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards*

Dear Administrator McCarthy:

The Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel met on March 25 - 27, 2014, to review the EPA's *Second Draft Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards*, hereafter referred to as the Second Draft PA. This letter highlights the chartered CASAC's consensus advice, followed by consensus responses to the charge questions from the Agency. Individual review comments from the CASAC Ozone Review Panel are also attached.

Overall, the Second Draft PA is an excellent summary of information needed to judge the adequacy of the current National Ambient Air Quality Standards (NAAQS) for ozone and to consider alternative standards. The information on emissions, atmospheric chemistry and common patterns of ozone concentration is presented clearly and is appropriately characterized. "Background" ozone (i.e., ozone that originates from precursors from natural sources or anthropogenic international emissions) is extensively and appropriately characterized, although in our consensus responses to charge questions, we have some technical comments that should be addressed to improve the coverage of this issue. The Second Draft PA is not clear as to how background estimates might impact the primary and secondary standards and whether these impacts may differ regionally. The Second Draft PA cites a 2002 court decision (*American Trucking Associations, Inc. v. EPA*, 283 F.3d at 379) that allows the EPA to consider relative proximity to peak background levels when evaluating alternative standards but it also cites a case where the court said "attainability and technological feasibility are not relevant considerations in the promulgation of the NAAQS" (*American Petroleum Institute v. Costle*, 665 F. 2d at 1185). The Second Draft PA was silent as to how the EPA intends to navigate between these two legal guidelines when considering background ozone in a policy and standard-setting context. This question became an important issue in the CASAC deliberations as we listened to public comments regarding

high background levels in the intermountain Western United States.

In addressing the adequacy of the primary standard, the Second Draft PA presents scientifically sound information on the health effects evidence for each major effect category: lung function decrements, pulmonary inflammation, respiratory symptoms, respiratory morbidity and respiratory mortality. The CASAC finds scientific justification that current evidence and the results of the exposure and risk assessment call into question the adequacy of the current standard. Furthermore, there is clear scientific support for the need to revise the standard. The CASAC supports the scientific rationale presented in the Second Draft PA on these points.

The CASAC concurs with the staff's justifications in the Second Draft PA for retaining the current indicator (ozone), averaging time (maximum daily 8-hour average) and form (annual 4th highest maximum daily 8-hour average, averaged over three years) for the primary standard. The indicator of ozone is appropriate based on its causal or likely causal associations with multiple adverse health outcomes and its representation of a class of pollutants known as photochemical oxidants. The current 8-hour averaging time is justified by the combined evidence from epidemiologic and clinical studies referenced in Chapter 4. The CASAC concurs that the ozone standard should be based on the fourth highest, daily maximum 8-hour average value (averaged over three years). This averaging time provides programmatic stability by allowing for atypical meteorological conditions that can lead to abnormally high ambient ozone concentrations while providing health protection.

The CASAC further concludes that there is adequate scientific evidence to recommend a range of levels for a revised primary ozone standard from 70 ppb to 60 ppb. The CASAC reached this conclusion based on the scientific evidence from clinical studies, epidemiologic studies, and animal toxicology studies, as summarized in the Integrated Science Assessment (ISA), the findings from the exposure and risk assessments as summarized in the HREA, and the interpretation of the implications of these sources of information as given in the Second Draft PA. However, as noted below, we believe there is an important distinction in our finding and advice regarding the upper bound level of 70 ppb as compared to that of EPA staff as given in the Second Draft PA.

In reaching its scientific judgment regarding a recommended range of levels for a revised ozone primary standard, the CASAC focused on the scientific evidence that identifies the type and extent of adverse effects on public health. The CASAC acknowledges that the choice of a level within the range recommended based on scientific evidence is a policy judgment under the statutory mandate of the Clean Air Act. The CASAC advises that, based on the scientific evidence, a level of 70 ppb provides little margin of safety for the protection of public health, particularly for sensitive subpopulations. In this regard, our advice differs from that offered by EPA staff in the Second Draft PA. At 70 ppb, there is substantial scientific evidence of adverse effects as detailed in the charge question responses, including decrease in lung function, increase in respiratory symptoms, and increase in airway inflammation. Although a level of 70 ppb is more protective of public health than the current standard, it may not meet the statutory requirement to protect public health with an adequate margin of safety. In this regard, the CASAC deliberated at length regarding advice on other levels that might be considered to be protective of public health with an adequate margin of safety. For example, the recommended lower bound of 60 ppb would certainly offer more public health protection than levels of 70 ppb or 65 ppb and would provide an adequate margin of safety. Thus, our policy advice is to set the level of the standard lower than 70 ppb within a range down to 60 ppb, taking into account your

judgment regarding the desired margin of safety to protect public health, and taking into account that lower levels will provide incrementally greater margins of safety.

With respect to the secondary standard, the CASAC concurs with EPA's identification of adverse welfare effects related to ecosystem services, food and fiber products from crops, and damage to resource use from foliar injury. The CASAC concurs that tree species relative biomass loss, foliar injury, and crop yield loss are appropriate surrogates of adverse welfare effects. The CASAC further supports the causality determinations of the ISA between exposure to ozone and adverse welfare effects. The CASAC supports the scientific conclusion in the Second Draft PA that the current secondary standard is not adequate to protect against current and anticipated welfare effects of ozone on vegetation. We recommend retaining the current indicator (ozone) but establishing a revised form of the secondary standard to be the biologically-relevant W126 index accumulated over a 12-hour period (8 a.m. – 8 p.m.) over the 3-month summation period of a single year resulting in the maximum value of W126 (henceforth W126). The CASAC recommends that the level associated with this form be within the range of 7 ppm-hrs to 15 ppm-hrs to protect against current and anticipated welfare effects of ozone. The CASAC does not support a level higher than 15 ppm-hrs. For example, at 17 ppm-hrs, the median tree species has 6% relative biomass loss, and the median crop species has over 5% yield loss. These levels are unacceptably high. These combinations of indicator, form, averaging time, and level are scientifically justifiable given evidence of current and anticipated welfare effects as captured in the Second Draft PA, and supported by the ISA and the second draft of the WREA.

In reaching its scientific judgment regarding the indicator, form, summation time, and range of levels for a revised secondary standard, the CASAC has focused on the scientific evidence for the identification of the kind and extent of adverse effects on public welfare. The CASAC acknowledges that the choice of a level within the range recommended based on scientific evidence is a policy judgment under the statutory mandate of the Clean Air Act. Specifically, the Clean Air Act grants discretion to the Administrator to specify a standard that is "requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air" (Section 302(h), 42 U.S.C., §7602(h)). As a policy recommendation, separate from its advice above regarding scientific findings, the CASAC advises that a level of 15 ppm-hrs for the highest 3-month sum in a single year is requisite to protect crop yield loss, but that lower levels provide additional protection against crop yield loss. Furthermore, there are specific economically significant crops, such as soybeans, that may not be protected at 15 ppm-hrs but would be protected at lower levels. A level below 10 ppm-hrs is required to reduce foliar injury. A level of 7 ppm-hrs is protective of relative biomass loss for trees and offers additional protection against crop yield loss and foliar injury. Therefore, 7 ppm-hrs is protective of ecosystem services. Thus, lower levels within the recommended range offer a greater degree of protection of more endpoints than do higher levels within the range.

The CASAC does not recommend the use of a three-year averaging period for the secondary standard. We favor a single-year period for determining the highest three-month summation which will provide more protection for annual crops and for the anticipated cumulative effects on perennial species. The scientific analyses considered in this review, and the evidence upon which they are based, are from single-year results. If, as a policy matter, the Administrator prefers to base the secondary standard on a three-year averaging period for the purpose of program stability, then the level of the standard should be revised downward such that the level for the highest three-month summation in any given year of the three-year period would not exceed the scientifically recommended range of 7 ppm-hrs to 15 ppm-

hrs. For example, if in a three-year period the highest three-month summation during a one year period is 15 ppm-hrs, and the corresponding lowest value associated with a three-year average of the highest three-month summations in each year is 13 ppm-hrs, then the appropriate level for the three-year average would be 13 ppm-hrs to protect against a peak one year level of 15 ppm-hrs. The final Policy Assessment should quantify the ratio of the three-year average of the highest three-month summations in each year to the highest three-month summation in the highest year. This ratio should be used to determine what downward adjustment from the three-month summation in one year recommended here is needed if a three-year form is selected.

The CASAC recommends that EPA facilitate research needed for the next review of the ozone NAAQS. For the health-based standard, we note that the Second Draft PA outlines key uncertainties and research that needs to be addressed for future reviews of the health-based standards. Specifically, we underscore the need for research to address the characterization of the exposure-response function; the identification of population thresholds; the role of co-pollutants and temperature in modifying or contributing to ozone effects; alternative modeling specifications; population-based information on human exposure for at-risk populations; time-activity data to improve population-based exposure and risk assessment; and the characterization of background levels.

For the secondary standard, the Second Draft PA also identifies uncertainties and needed research to develop data and better methods for extrapolating results to plant species for which exposure-response functions have not been developed; assessing the effects of ozone on climate (and the effects of climate on ozone); characterizing the effects of ozone on whole ecosystem structure and function; and evaluating how the public judges the adversity of various kinds of ecological effects including foliar injury and estimated reduced tree biomass growth. This policy-relevant research could be conducted in collaboration with other federal and non-governmental organizations to improve our understanding of ozone effects in support of the next review of the ozone NAAQS.

While these scientific research priorities will enhance future scientific reviews of the ozone primary and secondary standards, we also make clear that there is sufficient scientific evidence, and sufficient confidence in the available research results, to support the advice we have given above for this review cycle of the primary and secondary standards.

Although CASAC was not asked to comment about international transport of ozone, we would like to call your attention to this issue as a matter separate from our advice regarding the standard. North American background ozone is defined by the EPA as the ozone that would be present in U.S. surface air in the absence of North American anthropogenic emissions. North American background ozone can be estimated using global models by conducting simulations with North American anthropogenic emissions set to zero. Results indicate that background is only partly natural (lightning, biosphere, fires, stratospheric influence) and is enhanced by anthropogenic sources outside North America. Estimates of this external anthropogenic enhancement are fairly consistent across models [Fiore et al., 2009]. Zhang et al. [2011] estimated that during spring-summer 2006-2008 the mean enhancement from intercontinental pollution and anthropogenic methane is 9 ppb at low-altitude sites and 13 ppb at high-altitude sites (>1,500 m elevation), both roughly one third of the North American background ozone in the respective areas. The authors also indicated that the background ozone is higher than average when ozone concentrations exceed 60 ppb, particularly in the intermountain West. There is currently no international legal agreement on ozone or its precursors that would effectively deal with long-range transport, despite the recommendations by the National Academy of Sciences (2009) and the Task Force

on Hemispheric Transport of Air Pollution (2010) that such an agreement be sought. Given the significant portion of ozone coming from anthropogenic sources outside North America, the CASAC recommends that EPA seek opportunities for international cooperation to reduce long-range transport of ozone.

During the course of the review of the Second Draft PA, the CASAC received public comments focused on costs and implementation issues associated with a possible revised ozone standard, mainly focused on the primary standard. *Whitman vs. American Trucking Associations, Inc.* (2001) decreed that the EPA cannot consider implementation costs in setting the NAAQS. Furthermore, “[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards” (*American Petroleum Institute vs. Costle*, 665 F. 2d at 1185) and EPA need not tailor the NAAQS to fit each region or locale. Thus, cost and implementation issues are not relevant or allowable considerations in setting or revising a NAAQS. Therefore, CASAC did not consider such issues in its scientific review of the current standards or in developing its advice regarding revising the standards. However, the CASAC acknowledges that the Clean Air Act, section 109(d), states that the CASAC shall “advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.” Separate from the standard-setting process, the CASAC would be receptive to a request from EPA to review EPA analyses of “adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards” (42 U.S. Code § 7409). It should be noted, however, that not all of these effects will be “adverse” and any comprehensive assessment would include both adverse and beneficial effects. For example, positive economic effects accrue from implementation of national ambient air quality standards, such as the economic benefit of avoided morbidity and mortality. In response to such a request, the SAB Staff Office would form an *ad hoc* CASAC panel to obtain the full expertise necessary to conduct such a review.

The current approach to review and revision of the primary NAAQS is based on a one-pollutant-at-a-time approach. As the state of science regarding the joint effects of human exposure to multiple pollutants improves, the EPA should consider how review and revision of the NAAQS can be done synergistically for logical, scientifically relevant groupings of criteria pollutants. For example, O₃ and NO₂ are both criteria pollutants that are inter-related via atmospheric chemistry, and human exposure to these pollutants is often in the form of a mixture that includes both, and other pollutants such as particulate matter. The National Research Council and the North American Research Strategy for Tropospheric Ozone have both made detailed recommendations for multipollutant approaches to air quality management, and EPA has been exploring a multipollutant approach for the secondary standards for SO_x and NO_x. CASAC encourages EPA to explore multipollutant approaches for review of the primary standards, and would be receptive to a request by EPA to review planning or methods documents for such approaches.

Overall, we find the Second Draft PA to be adequate for its intended purpose of providing a strong scientific basis for findings regarding the inadequacy of current primary and secondary ozone air quality standards; for scientifically justifiable indicators, averaging times, and forms for alternative revised primary and secondary standards; and for our advice regarding scientifically justifiable ranges of levels for each of the primary and secondary standards. The CASAC appreciates the opportunity to provide advice on the Second Draft PA and looks forward to receiving the agency’s response.

Sincerely,

/signed/

Dr. H. Christopher Frey, Chair
Clean Air Scientific Advisory Committee

Enclosures