



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

March 12, 2008

The Honorable Stephen L. Johnson
Administrator
Environmental Protection Agency
Washington, DC 20460

Dear Mr. Johnson:

This letter memorializes the results of the coordinated “regulatory planning and review” process for EPA’s final regulation concerning the national ambient air quality standard (NAAQS) for ozone pursuant to Executive Order 12866.

As you know, on March 6, 2008, pursuant to section 6(b) of Executive Order 12866, I sent to you in writing a memorandum outlining significant reservations about the preliminary draft’s proposal for a secondary (public welfare-based) standard that would have differed from the primary (public health-based) standard in form, though not in effect. (A copy is attached.) On March 7, 2008, EPA’s Deputy Administrator sent me a response in writing. (A copy is attached.) I then promptly advised EPA’s Deputy Administrator of differences between that response and issues that arose during interagency review, and that OIRA was still not in a position to conclude its review of the rule with the proposed secondary standard unaltered. Further consultations ensued.

Pursuant to section 7(a) of the Executive Order, EPA then sought further consideration of this disagreement concerning EPA’s proposed departure from precedent on the form of the secondary standard. That process has assisted us both in further considering the issues and legal determinations involved, and pursuant to section 7(d) of the Executive Order we have been advised of the result of that process, as you requested, to enable your determination.

There are two options that were proposed by EPA and are supported by the record and the Clean Air Act, both of which provide an increase in the protection to public welfare from ozone. The two options are: 1) revising the secondary standard to a seasonal, cumulative form; and 2) revising the secondary standard to be identical with the new primary standard.

The President has concluded that, consistent with Administration policy, added protection should be afforded to public welfare by strengthening the secondary ozone standard and setting it to be identical to the new primary standard, the approach adopted when ozone standards were last promulgated. This policy thus recognizes the Administrator’s judgment that the secondary standard needs to be adjusted to provide increased protection to public welfare and avoids setting a standard lower or higher than is necessary.

I understand that you intend to render your determination today. As usual, my staff is available to work with your staff to meet this deadline.

Sincerely,

A handwritten signature in blue ink, appearing to read "S. Dudley", with a stylized flourish at the end.

Susan E. Dudley
Administrator



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March 6, 2008

MEMORANDUM FOR ADMINISTRATOR STEVE JOHNSON

FROM: Susan E. Dudley 

SUBJECT: Secondary Ozone NAAQS

I am writing with concerns about EPA's preliminary draft final regulation setting national ambient air quality standards (NAAQS) for ozone, submitted for review under Executive Order 12866 on February 22, 2008. Under the draft, EPA would establish, for the first time, a secondary standard for ozone (based on "public welfare") that is different from the primary standard that the draft would establish (based on "public health"). Yet, in the course of interagency review, concerns have been raised that the analysis that accompanies this draft is not adequate to support such a decision. First, the draft would establish a secondary standard without taking into consideration the factors that Congress, in the Clean Air Act, expressly specified as coming within the Act's broad definition of "welfare." Second, the draft does not provide any evidence that a separate secondary standard would be more protective than one set equal to the draft primary standard. This approach is inconsistent with Executive Order 12866, which requires agencies to adhere to certain principles, when not precluded by law.

As you know, in the Clean Air Act, Congress requires EPA to set a secondary standard at a level "requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air." [Sec. 109(b)(2)] The Act defines "welfare" very broadly, by setting forth a non-exhaustive list of criteria which include "effects on economic values and on personal comfort and well-being." Specifically, the Act defines "welfare" as follows:

Welfare includes, but is not limited to, effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being." [Sec. 302(h)]

Executive Order 12866 directs that "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need..." [Sec. 1(a)]

The language of Section 109(b)(2) clearly allows for the balanced consideration of a broad measure of public welfare. Yet, the draft under review would interpret the statute in a way that sets a separate W126 standard of 21 parts-per-million hours (ppm-h) based exclusively on adverse effects of ozone exposure on sensitive vegetation, with a narrow focus on forested lands in specifically-designated areas. EPA has not considered or evaluated the effects of adopting a W126 standard on economic values, personal comfort and well-being, as specifically enumerated in the Act.¹

Adopting a W126 standard would also deviate from EPA's past practice, which has been to set a secondary ozone NAAQS equal to the primary NAAQS. The preamble to the 1997 final regulation explained the rationale for deciding not to establish a separate secondary standard, despite a similar scientific basis as today, as follows:

The decision not to set a seasonal secondary standard at this time is based in large part on the Administrator's recognition that the exposure, risk, and monetized valuation analyses presented in the proposal contain substantial uncertainties, resulting in only rough estimates of the increased public welfare protection likely to be afforded by each of the proposed alternative standards... In light of these uncertainties, the Administrator has decided it is not appropriate at this time to establish a new separate seasonal secondary standard given the potentially small incremental degree of public welfare protection that such a standard may afford."²

Nothing in the draft or its accompanying analysis supports a different conclusion today. As EPA observed last summer in the preamble to the proposed rule, a secondary (public welfare) standard that is set at a level identical to the primary (public health) standard would provide a significant degree of additional protection for vegetation as compared to the primary standard currently in effect.³ By contrast, the incremental protection that would be associated with a W126 standard is far less certain. EPA has not attempted to make even a rough estimate of the increased public welfare protection associated with adopting a separate W126 standard beyond that achieved by adopting a revised secondary standard equal to the primary standard of 75 ppb. In fact, there is substantial uncertainty in the additional benefits of a separate secondary standard, both in terms of the degree of risk attributable to alternative standards and the degree of protection afforded by a W126 standard of 21. As a result, the draft rule under review does not contain a reasoned basis for concluding that a secondary standard set separate from the primary standard is "requisite to protect the public welfare."⁴

I know you are under a tight deadline for issuing a final rule, and my staff and I stand ready to work expeditiously with you to ensure the draft meets the requirements of E.O. 12866 by your deadline.

¹ EPA's discussion does not include an inquiry into broader effects of a separate secondary standard. See American Trucking Ass'ns v. EPA, 175 F.3d 1027, 1052-53 (D. C. Cir. 1999) ("Legally, then, EPA must consider positive identifiable effects of a pollutant's presence in the ambient air in formulating air quality criteria under § 108 and NAAQS under § 109" and EPA "[should] determine whether . . . tropospheric ozone has a beneficent effect, and if so, then to assess ozone's net adverse health effect by whatever criteria it adopts."), *pet. for reh'g en banc denied*, 195 F.3d 4 (D.C. Cir. 1999), *aff'd in part and rev'd in part on other grounds sub nom. Whitman v. American Trucking Ass'ns*, 531 U.S. 457 (2001)

² National Ambient Air Quality Standards for Ozone, 62 Fed. Reg. 38856, 38877-78 (July 18, 1997) (codified at 40 C.F.R. part 50).

³ In this respect, EPA's discussion is even more constricted than the determination reached in 1997, because the discussion expressly acknowledges that the available information is not adequate to establish a secondary standard based on adverse effects to urban/suburban landscaping (or ornamental vegetation) or the need for additional protection for agricultural crops.

⁴ The Clean Air Act does not require that secondary standards be set at a zero-risk level, but rather at a level "requisite" to protect public welfare – that is, a standard neither more nor less stringent than necessary for this purpose.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 7 2008

DEPUTY ADMINISTRATOR

MEMORANDUM

SUBJECT: Ozone Secondary Standard

FROM: Marcus Peacock

TO: Susan Dudley

Thanks for your memorandum of March 6, 2008 noting two major concerns regarding the adequacy of the support for the proposed W126 secondary national ambient air quality standard (NAAQS) for ozone. EPA appreciates the effort to make this a better and more defensible rule. This memorandum responds to those concerns.

Before going further, it is important to address the context in which the secondary standard is set. EPA cannot consider costs in setting a secondary standard. For instance, Justice Scalia, in speaking for the unanimous Supreme Court in *Whitman v. American Trucking Assns., Inc.*, made clear that EPA cannot consider implementation costs in setting NAAQS – and this prohibition extends even to secondary NAAQS.¹ Thus, the Administrator's standard-setting is constrained. With that observation in mind, this memorandum addresses each of your concerns in turn.

Concern: Focus of Effects Evaluation

The first concern is that the proposed W126 standard is based exclusively on effects of ozone exposure on sensitive vegetation and does not consider or evaluate the effects of a W126 standard on economic values, personal comfort and well-being. In essence, the concern is that the standard does not provide a balanced consideration of all of the factors included in the definition of welfare in the Clean Air Act (CAA) § 302(h). EPA believes the record in this rulemaking addresses this concern.

As in all NAAQS reviews, EPA must first update the air quality criteria to reflect the best and most current science. Per CAA section 108(a)(2), the air quality criteria are to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air," specifically including information on "any known or anticipated adverse effects

¹ 531 U.S. 457, 471 n.3 (2001) ("EPA may not consider implementation costs in setting the secondary NAAQS.").

on welfare." EPA has been mindful of the welfare effects encompassed by the Act.² As in all reviews, the nature and depth of information available on welfare effects has necessarily focused our attention on those effects for which we have adequate information to inform a decision on a quantitative ambient air quality standard.

Welfare effects have been addressed in this review. For instance, Chapters 9 through 11 of the Criteria Document evaluate a broad array of ozone-related welfare effects for which relevant information was available, including effects on vegetation and natural ecosystems; economic values (related to effects on vegetation and ecosystems); climate change; and man-made materials. Additionally, the Staff Paper (Chapters 7 and 8) and the proposal recognize an array of welfare-related effects defined in the CAA and note that the ozone-related effect categories of most concern at concentrations typically occurring in the U.S. include adverse effects on agricultural crops, trees in managed and unmanaged forests, and vegetation species growing in natural settings. These documents also recognize that ozone can affect other ecosystem components such as soils, water, wildlife, and habitat. Further, these documents recognize that increasing protection for vegetation from ozone-related effects would improve the protection afforded to ecosystems and their related public welfare categories.³ In sum, the quantitative assessments in this review focus on commercial and natural vegetation (including economic values associated with impacts on commercial crops⁴), and the qualitative assessments focus on ecosystem effects, including evidence of potential ozone-related alteration of ecosystem structure and function as well as effects on ecosystems services such as carbon sequestration.

A concern is that EPA has not considered economic values and effects on personal comfort and well-being. EPA agrees it must consider both the beneficial effects of an air pollutant as well as its adverse effects, and must assess the net impact on public health of a pollutant such as tropospheric ozone. However, in this review, EPA is not aware of any information indicating beneficial effects of ozone on public welfare, and we are not aware of any information that ozone has beneficial effects on economic values or on personal comfort and well-being.⁵ All of the information in the record seems to indicate otherwise. The effects considered are those attributable to the presence of the pollutant in the ambient air; EPA cannot consider any benefit, regardless of magnitude, that could be attributed to avoiding the cost of implementing a revised NAAQS. That EPA has focused attention where there is the most adequate information in the record should not be confused with failure to consider relevant effects.

² Under CAA § 302(h), welfare effects include, but are not limited to, effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.

³ In addition, these documents recognize that (1) ozone-related damage to man-made materials and the economic consequences of that damage are too poorly characterized to directly inform standard setting, and (2) although there has been research on ozone-related impacts on climate in recent years, further advances in monitoring and improvement in modeling are needed before such considerations can inform standard setting.

⁴ This analysis on economic values is presented in chapter 7 of the Staff Paper. This information was not highlighted in the proposal due to a decision not to focus on impacts on agricultural crops as a basis for the proposed decision, consistent with concerns raised in the interagency process for the proposal.

⁵ The secondary standard will protect vegetation in areas that society has decided to preserve as protected areas as well as vegetation that has aesthetic value to the public. To the extent this falls within personal comfort and well-being, then EPA has considered this effect.

In sum, EPA considered the cognizable welfare effects in this NAAQS review to the extent allowed by law. In future reviews the Agency may receive more and better information on welfare-related effects, to the extent that information is available.

Concern: Protectiveness of Secondary Standard

A second concern is that the draft rule does not adequately support the notion that the proposed secondary standard would be more protective than one set equal to the draft primary standard. The memorandum indicates various concerns over the incremental benefits of the W126 standard as compared to a secondary standard set equal to the primary.

As an initial matter, the legal status of a secondary standard differs from that of a primary standard. By definition, the primary and secondary standards are *separate* legal actions based on separate criteria. There is no presumption that the secondary standard should be the same as the primary standard. EPA has the same burden to demonstrate that the secondary standard meets the criteria of section 109(b) of the CAA whether it is the same as or different from the primary standard.

In most prior NAAQS reviews EPA has set the secondary standard the same as the primary. But this has been the result of the state of the evidence in each review and reflected the judgment exercised by the Administrator as to the proper course to follow under those circumstances.⁶ In this review, as in others, EPA has evaluated the information available, and then made a judgment as to the appropriate standard that satisfies the criteria of section 109(b).

In this case, EPA evaluated two alternative standards: one with an 8-hour form and level the same as the primary, the other with a form reflecting biologically relevant patterns of exposure and a level appropriately associated with that form. At this point, EPA believes that a secondary standard that is distinctly different in form and averaging time from the 8-hour primary standard is necessary. While a different conclusion on this issue was reached in the last review, the current conclusion is based on new information, which strengthens the information available in the last review.

The draft final preamble discusses this new research and improved analytical methods. For instance, EPA's updated vegetation exposure and risk assessments reduce the uncertainties upon which the previous decision was based. Most notably, new research and methods have increased our confidence in several key aspects of this review:

- New research has strengthened the basis for the conclusion that ozone-related vegetation and ecosystem effects are best characterized by an exposure index that is cumulative and

⁶ Where EPA has judged it appropriate to set a separate secondary standard, it has done so. When the initial PM standards were set in 1971, the secondary standard (based on visibility protection) was set at a lower level (150 $\mu\text{g}/\text{m}^3$) than the primary standard (260 $\mu\text{g}/\text{m}^3$). When the initial SO_2 standards were set in 1971, the secondary standard was set a different level and averaging time (3-hour) than the 24-hour and annual primary standards.

seasonal in nature, and that revising the current standard in part by adopting such a form is necessary and appropriate.

- New research has strengthened understanding of ozone-related effects on vegetation and ecosystems by providing quantitative information across (1) a broader array of vegetation effects (extending to mature tree growth stages and to linkages between stress-related effects such as ozone exposures at the species level and at higher levels within forested ecosystems); and (2) a more diverse set of field-based research study designs. These new studies include not only additional chamber studies, beyond those available in the last review, but also new free air and gradient field-based studies which provide important support to the quantitative estimates of impaired tree growth and crop yield loss based on chamber studies. These new studies address one of the key data gaps cited in the last review.
- New analytical methods used to characterize exposures of ozone-sensitive tree and crop species further address uncertainties in the assessments done in the last review. These methods include the use of a new multi-pollutant, multi-scale air quality model that contains techniques for simulating atmospheric and land processes that affect the transport, transformation, and deposition of atmospheric pollutant and/or their precursors on both regional and urban scales.

In light of the available information, EPA believes that ozone-related effects on vegetation are clearly linked to cumulative, seasonal exposures and are not appropriately characterized by the use of a short-term (8-hour) daily measure of ozone exposure. Thus, analyses that attempt to estimate the incremental protection that would be afforded by a W126 standard relative to a secondary standard identical to the 8-hour primary standard do not seem to provide as sound a basis for reaching a decision as to what standard is requisite to protect public welfare. EPA's assessment relies on a biologically relevant ozone measure and, then, incorporates this measure into the selected secondary standard.

Conclusion

In sum, EPA appreciates the concerns raised but believes they have been addressed in the existing proposal. If your office still has concerns I ask that they be articulated by tomorrow (Saturday) afternoon, given the court-ordered deadline we all face. This will allow time to elevate any issues so that they may be addressed consistent with Executive Order No. 12866.