U. S. Environmental Protection Agency
Office of Transportation and Air Quality

August 28, 2001

Mr. Thomas Richichi
Beveridge & Diamond, P.C.
1350 I Street, N.W., Suite 700
Washington, D.C. 20005-3311

Dear Mr. Richichi:

This is in response to American Trucking Associations Inc.'s (ATA) March 16, 2001, petition for reconsideration of the final rule, "Heavy-Duty Engine and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements Rule," (66 FR 5002 (January 18, 2001)).

After careful review of all of the issues raised in the petition, the Environmental Protection Agency (EPA) has decided against reconsidering the final rule. EPA did not commit procedural errors, we provided fair notice to the public throughout the rulemaking process, and the final rule is a logical outgrowth of the proposal. In addition, ATA has not presented any new evidence that would warrant reopening the rulemaking at this time. The enclosed document presents EPA's comprehensive response to the issues presented in the petition for reconsideration.

This rule, which will significantly reduce harmful exhaust emissions from heavy trucks and buses, is an important public health program. I am committed to ensuring that this program is implemented in a smooth and timely manner. I urge you to reconsider your opposition to certain parts of the program so that we may move forward as partners to make this a reality.

Sincerely yours,

Christine Todd Whitman

Enclosure

RESPONSE TO AMERICAN TRUCKING ASSOCIATIONS' REQUEST FOR RECONSIDERATION OF THE PHASE 2 FINAL RULE (HEAVY DUTY ENGINES AND TRUCKS)

I. Introduction

On December 21, 2000, the Environmental Protection Agency (EPA) issued a final rule setting more stringent standards on emissions of oxides of nitrogen (NOx) and particulate matter (PM) from heavy-duty highway engines and trucks beginning in model year 2007 (the "phase 2 final rule"). The final rule also requires that highway diesel fuel contain lower sulfur levels beginning in mid-2006. The final rule was published in the Federal Register on January 18, 2001 (66 FR 5001).

On March 19, 2001, the American Trucking Associations (ATA) submitted a petition to EPA requesting reconsideration of the phase 2 final rule based on the Agency's reliance on the July 2000 draft Health Assessment Document ("HAD") for Diesel Exhaust and the Clean Air Scientific Advisory Committee ("CASAC") Review of EPA's Health Assessment Document for Diesel Exhaust ("CASAC Review Document").

As discussed in detail below, EPA is denying ATA's request for reconsideration. ATA has provided no evidence that EPA committed any procedural error in its final rule. ATA has also provided no evidence that any of its objections are "of central relevance to the outcome of the rule."

II. Statement of Facts

The Notice of Proposed Rulemaking (NPRM) for the Phase 2 rule (65 FR 35430, June 2, 2000) contained an extensive discussion explaining the Agency's reasons for believing that the proposed emission standards and fuel sulfur restrictions would benefit public health and welfare, and the air quality need for further reductions in emissions from heavy duty vehicles and engines. 65 FR 35439-35456. EPA reviewed the adverse health and welfare effects of emissions from these engines and the air pollution situation that would likely exist without the rule. Such health and welfare effects include effects from short-term and long-term exposures to ozone and PM exceeding existing NAAQS and exceeding levels shown to be linked to adverse effects on human health. EPA also discussed the nature and extent of potential cancer and noncancer risks associated with exposure to diesel exhaust. Finally, EPA discussed the effects of these emissions on visibility, air toxics, acid deposition, eutrophication, nitrification and POM deposition.

Regarding EPA's view that diesel exhaust is linked to cancer and non-cancer health effects (see discussion at 65 FR 35446-47 and Draft Regulatory Impact Analysis (Draft RIA), Doc. No. III-B-01,[1] at II-80 - II-101), the NPRM stated that EPA's current position is that diesel

[1]All references to document numbers are for EPA Air Docket number A-99-06.

exhaust is a likely human carcinogen and that this cancer hazard exists for occupational and environmental levels of exposure. EPA noted and cited to approximately thirty studies showing increased lung cancer risks associated with diesel exhaust, and other studies providing support for this view. On average, the studies indicated that lung cancer risks were increased by 33 to 47 percent. Based on these studies and other information, EPA discussed the potential range for environmental cancer risks from diesel exhaust. EPA noted that several other organizations, including California EPA, the International Agency for Research on Cancer, and the National Institutes for Occupational Safety and Health, had described diesel exhaust as a "potential" or "probable" human carcinogen. EPA also discussed in detail its concern regarding the noncancer effects of diesel exhaust. EPA noted that its current draft of the HAD was being revised based on comments from CASAC, and that it was subject to further CASAC comments.

EPA encouraged all parties with an interest in the rulemaking to offer comments in this rulemaking on all aspects of the rule. The period for comment would extend until August 14, 2000.

In July, 2000, EPA produced a revised draft of its HAD. In an August 11, 2000 Federal Register notice associated with a separate proceeding, EPA solicited comment on the draft HAD. Comments were to be filed with the National Center for Environmental Assessment. 65 FR 49241. EPA also placed the revised draft HAD in the docket for the Phase 2 rule on September 28, 2000.

In response to its NPRM on the phase 2 rule, EPA received numerous comments related to the issue of the human health risks associated with diesel exhaust. Many of the comments were in agreement with EPA's analysis regarding diesel exhaust. Some, however, voiced disagreement with EPA's views on the issue. See EPA Response to Comments Document, Doc. V-C-01, Issues 2.1(J)(2), 2.1(J)(4), 2.1(L), 2.1(M). Some of these comments specifically addressed disagreements regarding EPA's draft HAD and regarding EPA's reviews of the scientific evidence linking diesel exhaust to cancer. ATA's comments in this rulemaking did not address the HAD or the subject of whether there are risks to human health from diesel exhaust.

In a public meeting on October 12-13, 2000, CASAC verbally approved EPA's HAD, while indicating its concerns on certain issues. Richard Moskowitz, a representative of ATA, attended the meeting on both days. See Attachment A.

On December 21, 2000, EPA received, and placed in its docket, CASAC's formal letter of December 19, 2000 concluding its review of EPA's draft HAD (Doc. No. IV-A-44). CASAC's letter of December 19, 2001 indicates that the Committee reached unanimous closure on the Health Assessment Document on October 13, based on assurances that key revisions would be made as agreed by EPA and that attention would be given to the numerous minor issues raised by the Panel. The Executive Summary of CASAC's accompanying report (CASAC Report) identifies and summarizes the key revisions that EPA agreed to make in October 2000. This included modifications to the derivation of the reference concentration (RfC) for non-cancer

health risk and a modification of the types of evidence supporting the designation as a likely human carcinogen. It also included agreement on the use of two approaches to characterizing non-cancer health risk, one using an RfC approach, and the other linking risks from ambient diesel particulate matter to the NAAQS for fine particulate matter. It was also agreed that it was appropriate to discuss a range of possible cancer risk values related to diesel exhaust in order to provide a perspective on the possible significance of the lung cancer hazard from environmental exposures, but that this should be accompanied by clear caveats and disclaimers concerning the uncertainty of the risk, the use of the risk perspective values, and the fact that the possible lower end of the risk range includes zero (CASAC Report, Executive Summary at 1-2).

In its final rule preamble, EPA again discussed in detail the air quality reasons for promulgating the rule. 66 FR 5011-5027. EPA's final air quality analysis continued to show the need for further reductions in PM and NOx emissions from diesel engines and trucks to protect human health and welfare. Regarding diesel exhaust, EPA again noted the numerous studies specific to diesel exhaust emissions that indicate possible links to adverse human health effects, including carcinogenicity and respiratory system toxicity. EPA again stated that its review of the published literature found about 30 epidemiological studies showing increased lung cancer risk associated with diesel emissions. EPA noted that its draft HAD evaluated many of these studies.

EPA also reviewed risk assessments in the peer-reviewed literature regarding worker exposed to diesel exhaust. EPA recognized the significant uncertainties in these studies and did not use these estimates to assess the possible cancer unit risk associated with ambient exposure to diesel exhaust, or develop its own cancer unit risk. Given the absence of a cancer unit risk, EPA provided a risk perspective that discussed possible risks in order to gauge the lung cancer hazard from diesel exhaust. EPA also again noted the noncancer-related health effects associated with diesel exhaust.

EPA noted that CASAC reviewed the latest draft of the draft HAD and had found that the Agency's conclusion that diesel exhaust is likely to be a human carcinogen is scientifically sound. CASAC concurred with the draft HAD's findings with the proviso that EPA provide modifications and clarifications on certain topics. The final rule reflects EPA's adoption of revisions on the issues noted above in CASAC's closure letter and report. For example, in the discussion on the range of cancer risk values EPA provided clear caveats and disclaimers concerning the uncertainty of the risk, the use of this range, and the fact that the possible lower end of the risk range includes zero. See 66 Fed. Reg. 5022-23. For a discussion of non-cancer risks and the RfC, see 66 Fed. Reg. 5023. These issues were also discussed in Chapter II of the RIA.

EPA's Response to Comments responded in depth to the comments received regarding the health effects of diesel exhaust, including several references to the scientific literature which were the basis for EPA's views regarding diesel exhaust. See EPA Response to Comments Document, Issues 2.1(J)(2), 2.1(J)(4), 2.1(L), 2.1(M). In particular, EPA states that "[a]vailable data from numerous studies support the Agency conclusion that diesel exhaust is likely to be

carcinogenic to the human lung and that the potential for significant environmental risks attributable to diesel exhaust exposure is of public health concern. It is on this basis that we are taking action to protect the public's health." *Id.* Response to Issue 2.1(J)(2). EPA references CASAC's agreement with its conclusions regarding the identification of a lung cancer and a noncancer respiratory hazard, and also references findings from several other organizations supporting its conclusions regarding diesel exhaust.

ATA's Petition for Reconsideration claims that EPA's docketing of the CASAC review document deprived interested parties of notice and opportunity to comment on the document, or EPA's reliance on it. ATA claims that EPA's reliance on the CASAC review document violates section 307(d)'s command that all materials relied upon by the Agency be placed in the rulemaking docket, because the CASAC document states that there were to be key revisions to the draft HAD that were not reduced to writing. Finally, ATA claims that EPA violated section 307(d) by relying on the draft HAD and CASAC review documents without docketing or responding to comments submitted to a separate docket on the draft HAD.

III. Standard for Reconsideration

Section 307(d)(7)(B) provides the standard for when EPA is required to convene a proceeding for reconsideration under the Clean Air Act. Under that section, if a "person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within [the period for public comment] or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed."

ATA's Petition for Reconsideration primarily raises procedural objections regarding EPA's docketing of certain documents in the record for the Phase 2 diesel rule after the close of the formal public comment period, and the lack of docketing and response to other documents. For ATA to meet the requirements of section 307(d)(7)(B), ATA must first show that EPA committed procedural error.[2] Further, under the Act, an action may be reversed by a reviewing court for procedural error only if:

i) the failure to observe the procedure(s) is arbitrary or capricious; and

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[2]EPA may docket and rely on material submitted after the end of the comment period in promulgating a final rule. *See* CAA section 307(d)(6)(C) ("The promulgated rule may not be based ... on any information or data which has not been placed in the docket *as of the date of such promulgation*. [emphasis added]"); CAA section 307(d)(4)(B)(ii) ("All documents which become available after the proposed rule is published and which the Administrator determines are of central relevance to the rulemaking shall be placed in the docket as soon as possible after their availability").

ii) a specific objection to the procedure employed was raised during the public comment period, or afterwards if the grounds for objection arose only after the comment period and the objection is of central relevance to the outcome of the rule; and
iii) the errors were so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made.

Section 307(d)(9)(D) (paraphrasing cited provisions). *See Air Pollution Control District of Jefferson County, Ky v. EPA*, 739 F. 2d 1071 (6th Cir. 1984). The reference to "central relevance" in 307(d)(9)(D)(iii) above is very similar to section 307(d)(7)(B)'s language that a petition for reconsideration must be granted only if the objection is of "central relevance to the outcome of the rule." EPA believes it should apply the same approach under section 307(d)(7)(B).

When reviewing claims of procedural error under both the Clean Air Act and the Administrative Procedure Act, the courts have emphasized that it is appropriate for agencies to learn from comments and other information received or developed after the proposal and to modify or update its position or the evidence it relies on without further notice and comment as long as the final rule is a logical outgrowth of the proposal. *See Appalachian Power v. EPA*, 135 F. 3d 791, 815 (D.C. Cir 1998); *Natural Resources Defense Council v. Thomas*, 838 F. 2d 1224, 1242-43 (D.C. Cir. 1988); *City of Stoughton, WI v. EPA*, 858 F2d 747, 753 (D.C. Cir 1988); *International Fabricare Institute v. EPA*, 972 F. 2d 384, 399 (D.C. Cir, 1992); *Rybachek v. EPA*, 904 F. 2d 1276, 1286-88 (9th Cir., 1990). *See also Connecticut Light and Power Co. v. NRC*, 590 F. 2d 1011, 1031 (D.C. Cir 1978) ("The agency need not renotice changes that follow logically from or that reasonably develop the rules it proposed originally. Otherwise the comment period would be a perpetual exercise rather than a genuine interchange resulting in improved rules."); *Community Nutrition Inst. v. Block*, 749 F. 2d 50, 58 (D.C. Cir. 1984) ("Rulemaking proceedings would never end if an agency's response to comments must always be made subject to additional comments."). To determine logical outgrowth, courts have examined the specific circumstances, including whether and how the rule changed from proposal to final, how the new information relates to the proposal, the other information in the record, the length of time to comment on the new information, and so on.

Further, a party raising a procedural objection must provide specific objections and a description of how the party would have responded to any late-submitted documents or other information. *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F. 2d 506 (D.C. Cir 1983) ("It is also incumbent upon a petitioner objecting to the agency's late submission of documents to indicate with 'reasonable specificity' what portions of the documents it objects to and how it might have responded if given the opportunity."); *Air Transport Ass'n v. FAA*, 169 F. 3d 1, 8 ("a petitioner objecting to the late submission of documents must indicate with 'reasonable specificity' what portions of the documents it objects to and how it might have responded if given the opportunity." [citations and internal quotations omitted]). Based on this, the petitioner must show that had the alleged procedural error not occurred, it "would have led to

a significant change in the final rule." *Appalachian Power*, 135 F. 3d at 815. *See Union Oil Co. v. EPA*, 821 F. 2d 678, 683 (D.C. Cir 1987) (court found harmless error in EPA's failure to place in docket memorandum regarding the costs and benefits of the challenged rule).

IV. Response to Petition

ATA claims that EPA's docketing of the CASAC review document deprived interested parties of notice and opportunity to comment on either the document itself, or EPA's reliance thereon. ATA also claims that section 307(d) requires that all materials relied upon by EPA be placed in the docket at the time of promulgation and that EPA's reliance on CASAC's review document violated this provision because the CASAC document indicates that its concurrence with EPA's draft HAD was contingent on certain revisions to the draft HAD that were not reduced to writing. Finally, ATA claims that EPA violated section 307(d) by failing to docket and respond in this rulemaking to comments submitted by ATA to another EPA docket on the draft HAD. ATA's petition provides no substantive or technical objections to the draft HAD or the CASAC document.

ATA has not provided sufficient justification to support its request for reconsideration of the rule. EPA therefore rejects ATA's petition. A petition for reconsideration must be granted under section 307(d)(7)(B) only where the person making an objection demonstrates that: 1) it was impracticable to raise the objection within the period of notice and comment or the grounds for objection arose after the period for public comment; and that 2) the objection is of central relevance to the outcome of the rule. EPA believes that for several reasons, ATA's objections are not of central relevance to the outcome of the rule.

First, an objection based on procedural grounds is not of central relevance to the outcome of the rule, and hence would not require reconsideration, if the Agency has not committed any procedural error. That is the case here. ATA had clear and reasonable notice and a full opportunity to raise any substantive objections regarding EPA's analysis of the cancer and noncancer effects of diesel exhaust during the rulemaking. EPA's final rule, and its docketing and discussion of the revised HAD and the CASAC review document, in the circumstances presented here, was a logical outgrowth of the proposal, and no procedural error was committed.

In the NPRM and draft RIA, EPA provided a detailed discussion of the cancer and noncancer health effects of diesel exhaust (see discussion above). EPA cited numerous studies supporting its analysis. EPA also noted in the NPRM that its current version of the draft HAD, which was available electronically at the site noted in the NPRM, was being revised based on comments from CASAC and that EPA's draft designation of diesel exhaust as a likely human carcinogen was subject to further comment by CASAC in 2000. Therefore, the public was on notice at the time of the proposal of EPA's position regarding the health effects of diesel exhaust, and the basis and supporting information for EPA's position. The notice also made clear that updates to the draft HAD could be expected.

ATA had an opportunity to comment on this information during the two and one half month comment period provided by EPA. It chose not to do so. Other parties commented in depth on this issue. In particular, several commenters noted that CASAC had provided comments to EPA asking that EPA revise its draft HAD on certain subjects included in the draft HAD.

EPA completed its next draft of the HAD in July and placed this draft in the docket for this rule on September 28, 2000. ATA therefore had sufficient opportunity to comment in the diesel rule on the revised draft HAD, which was placed in the docket almost three months prior to the promulgation of the rule. Again, ATA chose not to address this issue in this proceeding.

CASAC reviewed the July draft of the HAD at an October meeting at which time CASAC verbally announced its closure on the HAD, based on changes made to that point and assurances that revisions would be made as agreed by EPA. CASAC sent its official written review of the draft HAD on December 19, 2000. EPA placed this document in the docket for the diesel rule on the day EPA received it, December 21, 2000.

EPA's final rule provided a detailed discussion regarding the Agency's analysis of the cancer and noncancer risks to human health of diesel exhaust. The discussion in the final preamble and RIA was similar to and consistent with the discussion in the NPRM and draft RIA. EPA updated both documents to reflect EPA's July, 2000 draft HAD and CASAC's review of the draft HAD. EPA noted that CASAC had found EPA's conclusions that diesel exhaust is likely to be a human carcinogen is scientifically sound. EPA also noted that CASAC concurred with the draft HAD's findings with the proviso that EPA provide modifications and clarifications on certain topics. Regarding CASAC's review of EPA's analysis of noncancer risks, EPA noted that it would revise its draft HAD based on CASAC advice concerning the use of animal data to derive an inhalation reference concentration. EPA noted that the final HAD would be produced in early 2001. As discussed earlier, the letter and review document from CASAC identified and summarized the key revisions that EPA had agreed to make to the draft HAD, in response to CASAC's comments in October 2000, and the final rule fully reflected these key revisions.

In the Response to Comments document for this rule, EPA responded in depth to the comments received in this rulemaking on the issue of diesel exhaust's effect on human health. EPA noted in its responses that EPA had revised its July 2000 draft HAD in response to CASAC's earlier comments and that CASAC had generally accepted the later draft with regard to these changes.

This rulemaking history shows that ATA had more than adequate opportunity to comment on EPA's position regarding diesel exhaust's effects on human health at the time of the proposal. EPA provided a full discussion of its assessment of diesel exhaust's effects and EPA cited to numerous studies supporting this assessment. *See Chemical Manufacturers Ass'n v. EPA*, 28 F. 3d 1259, 1263 (D.C. Cir. 1994) (EPA provided sufficient notice and opportunity to comment on a model where it set out the basis for its model in the NPRM, stated its rationale,

requested comment, addressed significant comments, and revised some modeling parameters based on the comments it received.); *Specialty Equipment Market Ass'n v. Ruckelshaus*, 720 F. 2d 124, 135-36 (D.C. Cir. 1983) (association of parts manufacturers had adequate notice and opportunity to comment on EPA's exclusion of their parts from certification program where EPA's proposal addressed issue of whether they should be included and asked for comment on the issue); *Portland Cement Ass'n v. Ruckelshaus*, 486 F. 2d 375, 392-93 (EPA must make the data and methodology on which a rule is based available to the public); *Air Transport Ass'n v. FAA*, 169 F. 3d 1, 6-7 ("In the rulemaking context, an agency's notice must fairly apprise interested persons of the subjects and issues involved in the rulemaking. ... The question is typically whether the agency's final rule so departs from its proposed rule as to constitute more surprise than notice." [internal quotes and cites omitted]); *Air Transport Ass'n v. CAB*, 732 F. 2d 219 (The final rule was a logical outgrowth of the proposal where the proposal outlined the methods proposed to calculate fees and listed the types of fees it proposed to charge and "these critical elements did not change" in the final rule.)

EPA's submissions to the docket following the proposal were a logical outgrowth of the proposal. EPA's proposal specifically referred to the ongoing CASAC process and noted that EPA would revise its draft HAD based on previous CASAC comments. EPA's docketing of the revised HAD updated the information in the proposal regarding that process and ATA had a reasonable opportunity to comment on the revised HAD.[3] EPA's docketing of CASAC's review document was also an updating of information in the proposal on the same issue. EPA's analysis on the issue of the health effects of diesel exhaust in the final rule were virtually the same as that in the proposal in all major aspects.

ATA argues that "[w]here, as here, EPA places materials in the docket after the close of the public comment period, Section 307(d) has been violated." This is a misreading of the statute on its face and of the considerable judicial precedent recognizing the ability of an agency to supplement the docket as appropriate to provide updated information in its final rule. Section 307(d)(6)(C) states that "[t]he promulgated rule may not be based (in part or whole) on any information or data which has been placed in the docket as of the date of such promulgation." An obvious corollary to this rule is that the promulgated rule may be based on information or data which was placed in the docket as of the date of promulgation. Here, EPA has not relied on any materials that were not in the docket as of the date of promulgation.[4]

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[3] ATA also had an opportunity to comment on the CASAC's actions at the October 12-13 meeting in this rule. ATA had actual knowledge of the events at the meeting. Richard Moskowitz, a representative of ATA, attended the meeting on both days. See Attachment A. *Cf. Union Oil Co. v. EPA*, 821 F. 2d 678, 682-83 (D.C. Cir 1987) (Court rejected procedural argument regarding lack of notice where "petitioners received actual notice sufficient to permit them to present their objection to the Agency.")

[4] In a footnote, ATA claims that EPA's docketing of the CASAC report on the date of signature violated section 307(d)(6)(C). ATA seems to argue that EPA's decision was fixed

Moreover, the Courts have been clear in allowing the Agency to revise its proposed regulations in its final rule and/or supplement its data and information in the docket, as long as such revision or information is a logical outgrowth of the proposal. The final rule is a logical outgrowth of the proposal here because EPA's proposal provided ATA with a full opportunity to comment on the issues related to diesel exhaust and to EPA's draft HAD, EPA docketed the revised HAD and ATA had a reasonable opportunity to comment on it, and CASAC's report basically confirmed EPA's views in the proposal and draft HAD. EPA's analysis in the final rule was consistent with and similar to the analysis presented in the proposal, reflecting updates and modifications consistent with CASAC's comments but containing no major changes from the proposal. *See International Fabricare v. EPA*, 972 F. 2d 384, 399 (Court rejected petitioners' notice-and-comment claim where EPA had proposed the use of a particular testing method, petitioners commented that test method hadn't been sufficiently tested, and EPA supplemented record with further studies confirming the reliability of the test procedure. "Because petitioners had fair notice of, and full opportunity to comment on, the issue actually decided by the EPA, we reject [petitioners'] request.... In relying on [the new information], the EPA did no more than provide support for the same decision it had proposed to take."); *Appalachian Power*, 135 F. 3d 791, 814-815 (EPA's reliance on test runs of model performed after end of comment period constituted a logical outgrowth of proposal.); *Natural Resources Defense Council*, 838 F. 2d 1224, 1242 ("EPA can obviously promulgate a final regulation that differs in some respects from its proposed regulation.... A contrary rule would lead to the absurdity that ... the agency can learn from the comments on its proposals only at the peril of starting a new procedural round of commentary....[T]he agency's final rule must only be a 'logical outgrowth' of its proposed rule." [citation and internal quotes omitted]); *BASF Wyandotte Corp. v. Costle*, 598 F. 2d 637, 644-45 (1st Cir. 1979) (it is "perfectly predictable" that an administrative agency will collect new data after the proposal 'in a continuing effort to give the regulations a more accurate foundation" and "[t]he agency should be encouraged to use such information in its final calculations without thereby risking the requirement of a new comment period"); *Community Nutrition Inst.*, 749 F. 2d 50, 58 (no procedural error where USDA relied on two studies completed after the comment period which were not made public before final rule because studies "expanded on and confirmed information concerning [information] which Secretary had summarized [in the proposal]...The supplemental studies were specifically addressed to ... alleged deficiencies [that commenters raised regarding studies in the proposal] and confirmed the earlier studies' conclusion....[Responses to comments may] take the form of new scientific studies without entailing [new procedural requirements], unless prejudice is shown."); *City of Stoughton v. EPA*, 858 F.2d 747, 753 (no procedural error where "EPA set out its position early on ... [Petitioner] not only had the opportunity to comment on the [contested] issue, in fact it and other commenters specifically addressed that very issue. EPA specifically responded to the comments. Concededly, the Agency in its responses placed additional reliance on a 1984 study ... brought to

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prior to the date of promulgation. However, the statute on its face allows docketing of information on the date of promulgation, which appropriately acknowledges that an Agency cannot be said to have taken any final action until a rule is promulgated. Only at that time can a decision be said to be fixed.

[its] attention during the comment period, but EPA's conclusion [regarding the disputed issue] has never changed....The statutory requirement for notice and comment on a proposed rule does not automatically generate a new opportunity for comment every time the Agency reacts to the comments. [citation omitted]"); *Rybacheck v. EPA*, 904 F. 2d 1276, 1286 (9th Cir. 1990) ("Nothing prohibits the Agency from adding supporting documentation for a final rule in response to public comments."); *Air Transport Ass'n v. CAB*, 732 F. 2d 219 (no procedural error where agency relied on internal staff studies, not disclosed during notice and comment period, where the methodology was disclosed and no major changes in the final rule occurred.); *Solite Corp. v. EPA*, 952 F. 2d 473, 484-85 (no procedural error where EPA used updated information in final rule where "EPA's methodology ... did not change significantly from the proposed notices to the final rule, and petitioners had ample opportunity to criticize EPA's approach.")

Moreover, ATA has not shown that its objections are "of central relevance to the outcome of the rule," because ATA has made no showing that the objections it would have filed with the Agency would have likely led to a significant change in the outcome of the rule. *See Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 541. ATA has provided EPA with no information regarding how it would have objected to the CASAC document, despite the fact that it had three months following the docketing of that document to provide its specific objections.[5] *See Appalachian Power*, 135 F. 3d 791, 815 ("Although EPA set out its sensitivity analysis in detail in its final Response to Comments, [citations omitted], Appalachian Power has not attempted to identify any defect in that analysis, and hence cannot establish that earlier docketing of the [later] run would have led to a significant change in the final rule."); *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F. 2d 506, 540-41 (D.C. Cir. 1983) ("It is also incumbent upon a petitioner objecting to the agency's late submission of documents to indicate with 'reasonable specificity' what portions of the documents it objects to and how it might have responded if given the opportunity."); *Sierra Club*, 657 F. 2d 298, 399 n.497 (noting that petitioner had eight months after the rule was signed to provide a more complete rebuttal to late-filed data).

Further ATA has provided no indication that any objections it would have raised would have likely led to a significant change in the rule, especially since EPA's analysis of the health effects of diesel exhaust, and the studies underlying EPA's rationale, did not change from proposal to final rule, EPA responded to numerous comments on that issue in the Response to Comments, and EPA's views are consistent with and supported by CASAC. *See Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 541 (no reversible error where objections to new information "are grounded primarily on a single underlying objection [to the new analysis that the petitioner] had ample opportunity to object to...Thus, there is not a 'substantial likelihood' that [petitioner], if given the chance to comment on [the new information], could have convinced EPA to choose a different standard."); *Union Oil*, 821 F. 2d 678, 684

[5] ATA also provided no objections to EPA's revised HAD in this petition. However, even if ATA had provided objections to that document in this proceeding, ATA has not explained how such objections would have had a substantial likelihood of changing EPA's rule.

(Petitioners did not show a 'substantial likelihood' that the rule would have been changed where failure to provide cost-benefit analysis did not affect the "first justification" for the contested regulation).

ATA also claims that EPA's reliance on the CASAC review document violated section 307(d)'s prohibition on reliance on materials not placed into the docket because the CASAC document indicates that there were key revisions that had not been reduced to writing. This claim is factually incorrect and misleading. The letter from Dr. Hopke is a brief overview of the accompanying CASAC review document. The letter states that during the October 2000 meeting of the Committee, numerous comments were offered for additional revisions to improve the draft HAD and that two issues had engendered extended discussion. The letter then describes those issues briefly. The letter then states that the Committee reached unanimous closure on the document based on assurances that key revisions would be made as agreed and attention would be given to the numerous minor issues raised by the panel. The accompanying review document then lays out in detail the key revisions that EPA agreed upon as well as providing other comments that CASAC had on each chapter of the draft HAD. It also attaches the written comments of every individual panelist on the draft HAD. Therefore, the comments from CASAC were in fact made a part of the rulemaking record when the CASAC document was placed in the record. EPA's final rule documents incorporate the key revisions identified by CASAC on the draft HAD.

Finally, ATA is incorrect in its statement that EPA violated section 307(d) by not docketing and responding to comments on the draft HAD provided by commenters in a separate EPA docket. Section 307(d)(3) requires that EPA in its proposal "specify the period available for public comment," as well as "the docket number, the location or locations of the docket, and the times it will be open to public inspection." Section 307(d)(4)(B) requires that EPA promptly place in the docket for the rule "all written comments and documentary information on the proposed rule received from any person *for inclusion in the docket* during the comment period. [emphasis added]" Finally, section 307(d)(6)(B) requires that the final rule contain "a response to each to each of the significant comments, criticisms, and new data submitted in written or oral presentations during the comment period."

This detailed set of requirements provides a specific avenue for persons interested in a covered rule to provide comments to the Agency and for the Agency to respond. It is clear from this language that the comments EPA must respond to are the comments provided on the rule being reviewed. It does not require that EPA respond to comments provided in other proceedings.

EPA provided specific and clear directions in its Notice of Proposed Rulemaking for commenters to provide comments relevant to this rule. EPA listed the contact person for the rule and directed comment be sent to that person or to an E-Mail site where electronic comments could be filed. ATA apparently was aware of the procedure required in providing comments to EPA related to this rulemaking, as it provided such comments to EPA on other aspects of the

rule. However, unlike several other commenters, ATA did not provide any comments to this docket on the issue of diesel exhaust. It was ATA's responsibility to submit any comments to EPA in this rulemaking docket if it wanted EPA to consider them in this rulemaking.

This is not a mere procedural formality. At any given time, EPA is simultaneously working on hundreds of separate actions. Many of these actions may arguably be somehow related to one another. Because ATA did not provide its objections to the appropriate docket, the Agency could not have known that ATA intended those comments to be considered as comments on the Phase 2 rule. EPA cannot reasonably be expected to search through various agency files or dockets separate from the docket for this rule to find comments that may be relevant to a particular action. *See Linemaster Switch Corp. v. EPA*, 938 F. 2d 1299-1305-06 (D.C. Cir 1991) (EPA is under no duty to examine material submitted in a proceeding different from the proposed action to search for potentially relevant data in connection with proposed action).

In this case, ATA was well aware of the existence of a separate docket for the Phase 2 rule and could have easily provided comments to the appropriate place. EPA cannot be said to have ignored ATA's comments in its final rule when the comments were never addressed to this rule. In addition, and as discussed above, ATA has made no showing that any objections raised in the separate proceeding would likely have led to a significant change in this rule, given the full notice and comment provided in this rule, EPA's response to the comments that were filed in this rule, the consistency between EPA's views in the proposal and final rule, and CASAC's support for EPA's views.

IV. Conclusion

For the reasons discussed above, EPA is denying ATA's Petition for Reconsideration. The grounds for mandatory reconsideration under section 307(d) have not been met, and no good grounds have been shown that would otherwise warrant granting of this petition.