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April 17, 2006

Via Electronic Filing and Hand Delivery

Environmental Protection Agency
EPA West Building
Room B102
1301 Constitution Avenue, NW
Washington, DC

Re: Docket ID No. EPA-HQ-OAR-2001-0017
National Ambient Air Quality Standards for Particulate Matter; Proposed Rule, 71 Fed. Reg. 2620 (January 17, 2006), and
Docket ID No. EPA-HQ-OAR-2004-0018, Revisions to Ambient Air Monitoring Regulations, Proposed Rule, 71 Fed. Reg. 2710 (January 17, 2006)

Dear Sir or Madam:

The National Mining Association ("NMA") appreciates the opportunity to comment on the Environmental Protection Agency's ("EPA") proposed revisions to the Particulate Matter ("PM") National Ambient Air Quality Standard ("NAAQS"). 71 Fed. Reg. 2620-2708 (January 17, 2006) and the Proposed Air Monitoring Regulations as referenced above. NMA is a trade association of mining and mineral processing companies whose membership encompasses producers of most of the United States' metals, coal, uranium, and industrial and agricultural minerals; manufacturers of mining and mineral processing machinery equipment and supplies; and engineering consulting, transportation and financial institutions that provide services to the mining industry.

The proposed rule addresses two categories of particulate matter: fine particles ("$PM_{2.5}$"), which are 2.5 micrometers in diameter and smaller; and coarse particles ("$PM_{10-2.5}$" or "PMc"), which are smaller than 10 micrometers in diameter but larger than $PM_{2.5}$. While these comments focus primarily on EPA's proposed coarse particle standard, the last section of the comments address the Monitoring Rule.

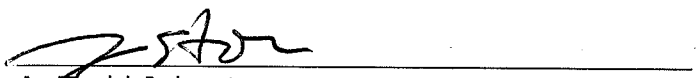
Many of NMA's member companies are located in the western U.S. where windblown, fugitive dust comprises a large fraction of coarse particulate matter. As such, NMA has a particular interest in this rulemaking, which proposes a National Ambient Air Quality Standard that would subject sources of fugitive coarse PM to stringent health-based ambient standards.

For the reasons discussed more fully in the attached comments and exhibits, there is not a sound or adequate basis for the adoption of a coarse PM standard at this time. NMA supports the alternative of not adopting a coarse PM standard for ambient exposure. There has never been a valid coarse PM NAAQS in the past, and coarse PM health effects have not been the basis for past controls of fugitive dust. Continued control of fugitive dust from mining operations is not dependent on the adoption of a coarse PM NAAQS. If, however, EPA chooses to implement a coarse PM NAAQS, EPA must exclude coarse PM from agricultural and mining sources. Such exclusion is necessary to remain consistent with the scientific evidence, and the determinations of EPA, Congress and the Courts concerning these sources since the inception of the Clean Air Act.

Sincerely,

Harold P. Quinn, Jr.
Sr. Vice President & General Counsel

Tawny Bridgeford
Assistant General Counsel



A. Todd Johnston
Director, Air Quality

National Mining Association

Comments on

EPA's Proposed Revisions to

the National Ambient Air Quality Standards

for Particulate Matter

71 Fed. Reg. 2620 (Jan. 17, 2006)

and on

EPA's Proposed Revisions to the

Ambient Air Monitoring Regulations

71 Fed. Reg. 2710 (Jan. 17, 2006)

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GLOSSARY

µm	micrometers, equal to one one-millionth of a meter.
1982 CD	Air Quality Criteria for Particulate Matter (EPA 1982)
1996 CD	Air Quality Criteria for Particulate Matter (EPA 1996)
2004 CD	Air Quality Criteria for Particulate Matter (EPA 2004)
BACT	Best Available Control Technology, referring to the control technology-based level of air pollutant emissions which must be achieved by any source which must obtain a PSD permit under the program for the Prevention of Significant Deterioration.
BS	British Smoke, a measure of the darkness of PM collected, estimated at approximately PM3.5-4.5, prior to modern PM controls.
CAA	Clean Air Act
CASAC	The Clean Air Scientific Advisory Committee, which reviews EPA proposals for ambient air quality standards and provides advice and reactions to EPA.
CO	Carbon Monoxide
D_{50}	Due to the engineering difficulties of designing a sampling instrument with an absolute size cutoff, PM samplers are designed to have a 50% collection efficiency at a specified size (e.g., 10 microns), which then results in increasing collection efficiencies (up to ~100%) of smaller particles and decreasing collection (down to 0%) of larger particles. This is commonly referred to as the "D_{50}" of the particular sampler, e.g., D_{50}=10µm.
NAAQS	National Ambient Air Quality Standards
NMA	National Mining Association
OSHA	Occupational Safety and Health Administration.
PM	Particulate matter

PM_{coarse}	Coarse particulate matter, consisting of crustal material, including dust from surface mining, construction, agriculture, forestry and wind erosion (as well as sea salt and plant particles). Nearly all PM_{coarse} has an aerodynamic diameter greater than 1 μm, but EPA's rule was $PM_{2.5}$ as a size indicator to distinguish between PM_{fine} and PM_{coarse}.
PM_{fine}	Fine particulate matter, consisting of such products of combustion as the atmospheric conversion of combustion gases such as sulfur oxides and nitrogen oxides into sulfates and nitrates, tobacco smoke and soot. Almost all PM_{fine} has an aerodynamic diameter of 1 μm or less, but EPA's rule uses $PM_{2.5}$ as a size indicator to distinguish between PM_{fine} and PM_{coarse}.
$PM_{2.5,}$ $PM_{3.5,}$ PM_{10}, etc.	Particulate matter collected by an instrument with a 50 percent sampling efficiency at the aerodynamic sampling diameter specified by the sub-number in micrometers; e.g., PM_{10} is the PM collected by an instrument with a 50% sampling efficiency at a particle size of 10 μm. (See definition of D_{50}).
PNOR	Particles not otherwise regulated, used by OSHA to mean non-chemical specific air-borne particles, for certain sizes of which OSHA has adopted workplace standards.
PSD	Prevention of Significant Deterioration, referring to an EPA program designed to prevent deterioration of the air quality in areas in which levels of pollution are below the NAAQS.
SP	EPA's "Staff Paper" – EPA's staff review, analysis and recommendations of PM NAAQS based on the CD.
TSP	Total Suspended Particulate Matter, as measured by an EPA reference instrument, which captures PM with aerodynamic diameters in the range of PM_{25} to PM_{45}, based on wind speed and direction.
TWA	Time Weighted Average.

I. Executive Summary

- EPA's proposal of an "urban-type" coarse PM standard is not based on sound science. In fact, EPA concedes that there are powerful reasons for not adopting a coarse PM standard.

- Because coarse PM falls out of the atmosphere over relatively short distances, and is a "local" pollutant, central monitor data is not representative of population exposure and thus cannot support the conclusions of the studies that assume such representative and uniform exposure.

- Epidemiological studies that rely on monitored air quality data from central monitors that are not representative of population exposure are fundamentally flawed.

- The 70 $\mu g/m^3$ concentration level is arbitrary and capricious, and without rational basis.

- The PM_{10} concentration level of 150 $\mu g/m^3$ cannot be the touchstone for equivalence because it is fundamentally flawed as a coarse standard.

- The evidence cannot sustain a finding of equivalence. Indeed the evidence indicates that there is in fact no such equivalent $PM_{10-2.5}$ concentration level.

- Basing a coarse PM standard on PM_{10} is unlawful under the *American Trucking* case. At any given location, whether 70 $\mu g/m^3$ is equivalent to 150 $\mu g/m^3$ will depend (arbitrarily) on how much $PM_{2.5}$ is present.

- The exclusion of coarse PM from agricultural and mining sources is consistent with the preponderance of the scientific evidence and the longstanding practice and determinations of EPA, Congress and the Courts.

- The preponderance of the scientific evidence continues to demonstrate that fugitive dust from agricultural and mining operations presents no substantial health or welfare concerns.

- In order to ensure that the proposed exclusion continue the longstanding exclusion of fugitive dust from agricultural and mining sources from consideration as part of the PM NAAQS, we have some suggested revisions to the exclusion language and related definitions.

- EPA correctly determined that there was not an adequate basis to set a distinct secondary PM coarse standard.

- EPA's proposed rule to implement fine PM NAAQS includes crustal and other coarse PM dusts that should be excluded from PM2.5.

- EPA's failure to extend the notice and comment period to allow consideration of the additional studies EPA has indicated it is reviewing denies NMA due process.

II. Introduction

The National Mining Association ("NMA") appreciates the opportunity to provide testimony on the Environmental Protection Agency's ("EPA") proposed rule, which seeks to revise the National Ambient Air Quality Standards ("NAAQS") for particulate matter ("PM"). NMA is a national trade association of mining and mineral processing companies whose membership encompasses producers of most of the United States' metals, coal, uranium, and industrial and agricultural minerals; manufactures of mining and mineral processing machinery, equipment and supplies; and engineering consulting, transportation and financial institutions that provide services to the mining industry.

The broad contours of economic impact of PM_{10} regulation of PM_c sources, particularly on western surface mining, have been considered in several proceedings, such as the adoption of PM_{10} Prevention of Significant Deterioration (PSD) "increments," and EPA's decision not to include surface coal mines in the PSD permit program. In those proceedings, EPA determined that a typical western surface mining operation would be prohibited by the PM_{10} increments. In the later proceeding, EPA determined not to include coal surface mines as listed PSD "major" sources, because the environmental benefit from doing so was outweighed by the adverse economic impact. 54 Fed. Reg. 48870 (November 28, 1989).

As discussed below, the proposed coarse PM standard is roughly twice as stringent as the PM_{10} standard for sources operating in the arid west. Because mines are already required to control coarse PM through a variety of technology and management requirements little more can be done to comply other than scale back or shut down operations. The impacts of a coarse PM standard to energy and commodities markets, not to mention the communities and ancillary businesses that depend on mining, would be substantial, sending ripple effects throughout the economy.

NMA's comments are premised upon mining operations that apply Best Management Practices ("BMPs") or Best Available Control Technology ("BACT") to minimize dust emissions. These BMPs include watering roads or applying other dust suppressants to them, limiting speeds on haul roads, wetting down process materials, and other site specific operational practices. NMA's comments go to the irreducible, minimal impacts of such dust that remain after applying BMPs. Technology-based, reasonable and feasible fugitive dust controls measures have been in the past, and must continue to

be in the future, the basis for controlling fugitive coarse PM from mining operations.

The amounts of fugitive dust remaining after BMPs from mining operations have never been demonstrated to have adverse impacts on health at ambient levels. Because such dust has been generally agreed by health experts not to have substantial health or welfare effects at ambient concentrations, historically it has not been included in making determinations of ambient compliance. Over the last more than 30 years, EPA has excluded such dusts in making "attainment" determinations of compliance with the PM NAAQS, has determined not to list surface mines because of the lack of such effects, created the "fugitive dust exemption" to exclude it from ambient determinations under the Prevention of Significant Deterioration ("PSD") program, discounted it under its "rural fugitive dust policy," and excluded it under various "natural events" policies from being considered in determining compliance with the PM NAAQS. The overwhelming scientific consensus on the lack of substantial health or welfare effects from such dusts over the last 30 years has been detailed and documented in the comments the National Cattlemen's Beef Association has filed with EPA, and on which NMA has collaborated (*See* NCBA Comments dated July 9, 2002, Exhibit A at pp. 3-22, and the consensus on exclusion of such dusts from ambient determinations by EPA, the courts and Congress. *Id.*) The proposed rule's exclusion of coarse PM from agriculture and mining operations from the coarse PM NAAQS continues EPA's historic, scientifically-based, policy and practice of excluding such coarse PM from the PM NAAQS.

III. Current Requirements to Control Fugitive Dust

As discussed below, the proposed rule's exclusion of coarse PM generated by mining sources continues EPA's historic, scientifically-based policy and practice of excluding such coarse PM from the PM NAAQS. Such exclusion, however, does not eliminate the existing regulatory framework for controlling coarse PM from mining operations. In fact, coarse PM emissions from mining operations, which are generally referred to as fugitive dust, are subject to pervasive regulation on the federal, state, and local level. These laws control fugitive dust through the use of various control technologies, best management practices, and numeric emissions limitations.

On the federal level, coarse PM from mining operations is regulated under the Surface Mining Control and Reclamation Act (SMCRA), the Clean Air Act (CAA), and the Occupational Safety and Health Act (OSHA)(as enforced by the Mine Safety and Health Administration (MSHA)). Surface coal mining permit applications under SMCRA must include a plan for fugitive dust control practices as part of the air pollution control plans. 30 C.F.R. § 780.15. These plans must implement minimum environmental protection performance standards for stabilization of surface areas to "control erosion and air pollution attendant to [such] erosion." 30 C.F.R. § 816.95. The New Source Performance Standards under Section 111 of the CAA set technology-

based emissions standards for particulate matter and opacity for various facilities, including breakers, crushers, conveyors, bagging operations, and loading stations, located within coal preparation plants, metallic mineral processing plants, and nonmetallic mineral processing plants. Furthermore, OSHA health standards provide another regulatory control on PM emissions by setting a "total dust" standard (~ PM_{100}) at 15,000 $\mu g/m^3$, as well as a "respirable fraction" standard ($PM_{3.5}$) at 5,000 $\mu g/m^3$, for "Particles Not Otherwise Regulated" (PNOR) and inert or nuisance dust. 29 C.F.R. § 1910.1000, Tables Z-1 and Z-3. These regulatory requirements will continue to apply to the mining industry irregardless of the status of the coarse PM NAAQS. For additional details on these requirements, *see* **Exhibit 1.**

On the state level, state-specific emission standards and permit requirements control fugitive dust from mining operations. For example, Nevada prohibits sources from handling, transporting, or storing any material in a manner that allows controllable PM to become airborne. NAC § 445B.22037. Prior to constructing, repairing, demolishing, or using an unpaved or untreated area, sources must implement an "ongoing program using the best practicable methods to prevent [PM] from becoming airborne." *Id.* Such methods include "paving, chemical stabilization, watering, phased construction and revegetation." *Id.* Furthermore, before disturbing or covering five acres or more of land or its topsoil, sources must obtain "an operating permit for surface area disturbance to clear, excavate, or level the land or to deposit any foreign material to fill or cover the land." *Id.* This surface area disturbance permit includes a fugitive dust control plan. Similar emission standards and permitting requirements for fugitive dust apply in other states. For additional details on these requirements, see **Exhibit 1.**

IV. Historical Basis for the PM NAAQS

The critical feature of the Particulate Matter NAAQS, namely its concentration term, has, from its inception, been based primarily on "British Smoke," ("BS") measurements. 52 Fed. Reg. 24642-45 (July 1, 1987); 62 Fed. Reg. 38659 (July 18, 1997). BS is a measure of the "blackness" of smoke produced by combustion appearing on a filter paper. The concentration term of virtually all of the PM NAAQS promulgated from the Clean Air Act's enactment forward and in effect from 1970 through 1997, was the BS data from a 1952 London smog, stagnation incident. It found associations with adverse health effects at 24-hour concentrations that EPA estimated were equivalent to 500 $\mu g/m^3$ of PM_{10} (in combination with high levels of sulfur oxides), and, for instance, in 1987, took approximately 1/3 of this amount, namely 150 $\mu g/m^3$ as the basis for the PM_{10} standard. *Id.* 62 Fed. Reg. at 38659.

The 1987 PM NAAQS. In 1987, EPA excluded particles above PM_{10} from the PM NAAQS, based on the clear lack of health effects evidence from such

particles at ambient concentrations. However, PM_{10} still included coarse PM above the BS size indicator, on the possibility that further research and studies might show substantial health effects due to the fact that such particles had the potential to penetrate into primarily the upper airways of the human respiratory system. The particulate material above PM_{10}, between PM_{10} and TSP (PM_{35}-PM_{45}), was discarded from the standard. There was no evidence indicating that that material was producing adverse health effects, yet it was constituting most of the mass in arid, western atmospheres. Including it in the standard distorted and misdirected control efforts, producing no substantial environmental benefit. Several health scientists, environmental and industry groups argued that the particle indicator for the PM NAAQS should have been PM_1 or $PM_{2.5}$, because including particles above those sizes departed from the evidence of adverse health effects on which the PM NAAQS were based, and diluted and misdirected control efforts to particles with no substantial health or welfare effects.

We submit that after years of study, the clear, preponderant weight of the evidence continues to support EPA's historic conclusion that fugitive dusts at ambient concentrations do not present substantial health concerns that would justify the adoption of a coarse PM ambient air quality standard. The best and only indicator necessary for an ambient air quality standard for particulate matter is that which best represents fine PM.

The 1997 PM NAAQS. In 1997 EPA recognized the fundamental difference between fine and coarse PM, and created a fine $PM_{2.5}$ standard. While EPA initially proposed not to adopt a 24-hour coarse PM standard, in the final rule it did adopt such a standard. That coarse PM_{10} standard was, however, set at 150 $\mu g/m^3$. The only concentration data discussed as the basis for this standard was from two epidemiology studies, both of which involved concentration levels well above 1000 $\mu g/m^3$ and included both fine and coarse PM. (Hefflin et al.,1991; Gordian et al., 1996) 62 Fed. Reg. 38652, 38679 (July 18, 1997).

The 1997 coarse PM_{10} standard was vacated and set aside as confounded, because it included both fine and coarse PM.[1] While the court in that case noted that there was evidence to support a coarse PM standard, it found that EPA's action in setting the concentrations of both the fine and coarse PM standards constituted an unconstitutional delegation of legislative authority. Because the coarse PM standard was vacated, the Supreme Court did not

[1] EPA since then has suggested that as result of the court's ruling, the 1987 PM10 standard "springs back" and has issued notices to that effect. For the very same reasons that the American Trucking Ass'n court vacated the 1997 standard, the 1987 PM10 standard would be invalid. It is just as confounded by inclusion of PM2.5 as the 1997 standard. EPA itself understands this since its Proposed Rule requests comment on whether to retain the current PM10 standard, while noting that retaining the standard would also include modifying "the standard to exclude the double-counted PM2.5 contribution." 71 Fed. Reg. at 2673.

address its concentration or other aspects of it. The result is that there has never been a valid coarse PM standard based on coarse PM evidence, nor a sustaining rationale of any kind connecting the 150 μg/m^3 PM_{10}-based level of the concentration term of that standard with any health studies based on coarse PM effects at those concentrations.

V. EPA's Proposed Revisions to the PM NAAQS

On January 17, 2006, EPA published its proposed revisions for the PM NAAQS. 71 Fed. Reg. 2620 (Jan. 17, 2006). The coarse PM standard it proposed is a 24-hour $PM_{10-2.5}$ standard "qualified so as to include any ambient mix of $PM_{10-2.5}$ that is dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources."[2] 71 Fed. Reg. at 2620. The indicator for this standard "excludes any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources." *Id.* In addition, it states that "[a]gricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting this standard." *Id*. at 2698-99. The concentration term of the proposed 24-hour coarse PM standard is 70 μg/m^3. That level, EPA says, is intended to provide a "generally equivalent level of protection" to the current 24-hour PM_{10} standard.

VI. EPA's and CASAC's Controversial Review on Remand of the Vacated Coarse PM_{10} Standard

CASAC's review of the coarse PM standard over the last three years has been marked by controversy, abrupt and unexplained changes of position, last-minute changes in possible theoretical bases for such a standard, and an unprecedented failure by CASAC even to review EPA's Final Staff Paper and reach "Closure" on its scientific basis for the coarse PM standard before that document and its recommendations to the EPA Administrator were finalized and released. CASAC reviewed that scientific basis only after the document had become final.

After several years of review and deliberation, several members of CASAC, including its then Chair and its leading health scientists, had expressed the view that EPA's Criteria Document and drafts of its Staff Paper did not provide an adequate basis for a coarse PM standard. Indeed, CASAC's May 11, 2005 draft letter to the Administrator recommended that "the setting of this [coarse PM] standard be set aside until further deliberations on the appropriate metric can be made." **Exhibit B.**

[2] EPA determined that an annual PM10-2.5 standard was not justified because of the lack of any clear evidence linking health effects to long term exposure to coarse PM. 71 Fed. Reg. at 2668-69.

At its April 2005 meeting, CASAC had suggested a potential new rationale for a coarse PM standard that EPA might substitute for its past, unsuccessful efforts to provide a basis for a coarse PM standard. This new concept was based not on the health effects of coarse PM, but its possible contamination by toxic urban contaminants that might be absorbed and carried by coarse PM in urban areas. EPA was urged to substitute this new concept for the years of work that had gone into the Criteria Document and two drafts of its Staff Paper that CASAC had found wanting. After a teleconference on its May 11, 2005 draft letter on May 18, 2005, CASAC wrote a final letter to the EPA Administrator stating that although "the evidence for a standard for coarse-mode particles was weaker than for the $PM_{2.5}$, the Panel agreed that a 24-hour NAAQS for $PM_{10-2.5}$ was appropriate, especially in urban areas, with caveats to make exceptions for those types of rural dusts thought to have low toxicity." EPA-HQ-OAR-2001-0017-0393 at 2.

EPA's Final Staff Paper. EPA issued its final Staff Paper on PM NAAQS revision at the end of June 2005. It recommended an "urban" coarse PM standard. Significantly, the Staff Paper noted that the studies and data on which it based its proposal were weak, uncertain, limited, and not even adequate to support a health risk assessment that could serve as the basis for a quantitative concentration level, due to the nature and magnitude of uncertainties associated with the risk assessment. Final Staff Paper, June 2005 at 5-69; 71 Fed. Reg. at 2662. EPA-HQ-OAR-2001-0017-0391 at 5-69. That remains the case. EPA also stated that a coarse PM standard might be based on providing protection somehow "equivalent" to the current 24-hour PM_{10} standard. 71 Fed. Reg. at 2670-71.

VII. EPA's Proposal of a Coarse PM Standard Is Not Based on Sound Science

The new concept for development of a coarse PM standard is a novel one, based on CASAC's initial suggestion that it be grounded on its potential role in urban areas (where the hypothesis posits that, white not harmful itself in other areas, it has the potential to combine with other substances that may be hazardous, such as industrial emissions, construction emissions, or mobile source emission components). It was first put forward at CASAC's meeting in April of 2005, EPA-HQ-OAR-2001-0017-0387 and now articulated in some detail with a proposed rationale in the January 17, 2006 Federal Register notice. The notice also asks for comment on a number of alternatives, including the alternative of not adopting a coarse PM standard at this time. We submit that the science does not justify adopting a coarse PM standard at this time, for the reasons we have articulated before, for the reasons articulated by EPA in the preamble to the rule, and because the key epidemiological studies relied on suffer from a fatal flaw—they are based on monitoring data that is not representative of exposures to coarse PM experienced by the populations involved in the studies.

A. Previous Comments

We submit that EPA has not provided the scientific support to demonstrate that a coarse PM standard is necessary to protect public health or welfare, even for urban-type coarse PM, which typically includes other contaminants. In fact, as EPA itself notes, when PM fine or other criteria pollutants are considered, even the marginal statistical associations in a few anomalous, one-pollutant studies disappear. 71 Fed. Reg. 2671-2672. See the following prior comments of NCBA and which we incorporate herein by reference, for a thorough discussion of the evidence on which EPA apparently relies and which it has itself characterized as "very limited at this time and that there are potentially quite large uncertainties inherent in interpreting the available evidence for $PM_{10-2.5}$." 71 Fed. Reg. at 2671:

- March 8, 2006 Comments of Tamara McCann Thies on Behalf of National Cattlemen's Beef Association Regarding EPA's Proposed Revisions to the National Ambient Air Quality Standards for Particulate Matter at Public Hearing in San Francisco, California. EPA-HQ-OAR-2001-0017-1165 including attached Exhibits A & B.
- March 8, 2006 Comments of Jay Truitt on Behalf of National Cattlemen's Beef Association Regarding EPA's Proposed Revisions to the National Ambient Air Quality Standards for Particulate Matter at Public Hearing in Chicago, Illinois. EPA-HQ-OAR-2001-0017-1004.
- October 25, 2005 Electronic Correspondence to Jon Scholl et al. from Tamara McCann Thies Regarding Coarse PM and Agriculture. EPA-HQ-OAR-2001-0017-0433 and 1030 to 1030.5.
- October 20, 2005 Materials from Agriculture Group Meeting with Stephen Johnson, EPA Administrator. EPA-HQ-OAR-2001-0017-0617.
- October 19, 2005 Letter to Mr. Bill Wehrum, Acting Assistant Administrator for Air & Radiation from Robert T. Connery on Behalf of National Cattlemen's Beef Association Regarding Potential Coarse PM Mortality Effects. EPA-HQ-OAR-2001-0017-0461 to 0462.
- August 11, 2005 National Cattlemen's Beef Association Comments on the June 2005 EPA OAQPS Final Staff Paper. EPA-HQ-OAR-2001-0017-0426.
- August 10, 2005 Letter to CASAC from Dr. Jonathan Borak on Behalf of National Cattlemen's Beef Association Regarding Proposed NAAQS for Coarse Particulate Matter. PA-HQ-OAR-2001-0017-0427, 0456 and 0460.

- May 4, 2005 Letter to CASAC from Dr. Jonathan Borak on Behalf of National Cattlemen's Beef Association Regarding Criteria Document and OAQPS Staff Paper (2d Draft). EPA-HQ-OAR-2001-0017-0427 and 0459.
- March 30, 2005 Comments on the EPA OAQPS Staff Paper (2d Draft). **Exhibit C**
- September 29, 2004 Comments on August 2004 Draft of Chapter 9 of the Air Quality Criteria Document for Particulate Matter. **Exhibit D.**
- July 30, 2004 Comments on June 2004 Draft of Chapter 9 of the Air Quality Criteria Document for Particulate Matter. **Exhibit F.**
- November 4, 2003 National Cattlemen's Beef Association Comments on the August 2003 EPA OAQPS Staff Paper (1st Draft). EPA-HQ-OAR-2001-0017-0225 to 0226
- August 29, 2003 Comments on Fourth External Review Draft Air Quality Criteria Document for Particulate Matter. **Exhibit F.**
- July 9, 2002 Comments on Draft Air Quality Criteria Document for Particulate Matter. **Exhibit A.**

B. EPA Concedes There are Powerful Reasons for Not Adopting a Coarse PM Standard

EPA relies on four studies that it says establish statistically significant associations between coarse PM and health effects, and provide the support necessary for demonstrating the necessity of controlling coarse PM to a concentration of 70 $\mu g/m^3$, 71 Fed. Reg. 2670-72. Those four studies are Detroit (Ito 2003), Toronto (Burnett, 1997), Phoenix (Mar 2003), and Coachella Valley (Ostro 2003). EPA states that these studies show significant associations of coarse $PM_{10-2.5}$ with mortality and morbidity at this concentration. The severe problems that militate against any reliance on these four studies are not mentioned in EPA's discussion of its basis for the proposed coarse PM standard. However, in a later discussion of a possible "alternative interpretation" of the health evidence, EPA does acknowledge the fatal flaws in the four studies. Because of EPA's admission that these essential scientific studies do not support its proposal, EPA's treatment of these four key studies bears full quotation and careful consideration:

> Having decided to propose the 24-hour $PM_{10-2.5}$ standard described above, the Administrator recognizes that there are important views on the information relating to the effects of coarse fraction PM that warrant consideration. For example, **an alternative interpretation of the available health evidence presented in the Criteria**

Document and the Staff Paper questions the conclusions about $PM_{10-2.5}$ associations drawn from one-pollutant models. This interpretation of the available epidemiological evidence suggests that the results from one-pollutant $PM_{10-2.5}$ models are confounded by fine particles and gaseous co-pollutants.

The key $PM_{10-2.5}$ epidemiologic results discussed in the Criteria Document and Staff Paper are drawn from one-pollutant models; i.e., $PM_{10-2.5}$ is the only variable used in the statistical model reflecting exposure to air pollution. **There are four studies cited in these documents as being suggestive of a statistically significant role for $PM_{10-2.5}$ in the reported associations: Ito (2003), Burnett et al. (1997), Mar et al. (2003), and Ostro et al. (2003).** However, there is strong evidence that adverse health effects similar to those observed in these studies, including both cardiovascular and/or respiratory health effects are associated with exposure to $PM_{2.5}$. The authors of several of these studies focus on fine particles (and in some cases one or more of the gaseous pollutants) as playing an important role in 'explaining' the association between PM and various health endpoints. For example, in these key epidemiologic studies, the correlation coefficients between $PM_{2.5}$ and $PM_{10-2.5}$ concentrations range from moderate to high (i.e., 0.4 to 0.7), which increases the likelihood that associations between health effects and $PM_{10-2.5}$ identified in one-pollutant models may instead simply reflect the effects of exposure to $PM_{2.5}$ rather than independent health effects. With the positive correlations between pollutants and similar health effects, **it generally would be appropriate for any assessment of the effect of exposure to $PM_{10-2.5}$ to control for exposure to the $PM_{2.5}$.**

In this light, it is important to review how the authors of the four key $PM_{10-2.5}$ epidemiology studies have accounted for co-pollutants in their analysis. Ito (2003) noted significant estimates of the health effects of associations in one-pollutant models, but **in a two-pollutant model with $PM_{2.5}$ the $PM_{10-2.5}$ associations lost statistical significance. Burnett et al. (1997) concluded that the effect of $PM_{10-2.5}$ in a one-pollutant model could be**

explained by gaseous co-pollutants. Mar et al. (2003) found $PM_{10-2.5}$ to be positively associated with adverse health effects in a one-pollutant model, but also **found similar associations with a range of other air pollutants**. In addition, Mar et al. (2003) noted that even though all PM mass metrics included in the study were associated with an excess risk of cardiovascular death, the strongest associations were with $PM_{2.5}$, followed by PM_{10} and $PM_{10-2.5}$. **Ostro et al. (2003) used a one-pollutant model to estimate the association between $PM_{10-2.5}$ on mortality using an effectively linear construct of PM_{10} (as observed in Indio, CA) to represent $PM_{10-2.5}$ for the entire study area. By using such a construct of PM_{10}, the estimated associations simply reflect a PM_{10} association (i.e., the construct does not provide additional information on the effect of $PM_{10-2.5}$)**. Moreover, roughly 75 percent of the cardiovascular mortality in this study occurred in or near Palm Springs, CA and PM characteristics differ significantly between Palm Springs and Indio (e.g., average PM_{10} concentrations are roughly 30 percent lower in Palm Springs and $PM_{2.5}$ represents a higher fraction of PM_{10}, with a correlation coefficient between $PM_{2.5}$ and $PM_{10-2.5}$ of 0.46 in Palm Springs). Thus, the Ostro et al. (2003) study suggests a positive association between PM_{10} monitored in Indio and mortality in Palm Springs, but **some view this study as offering little basis for attributing significant mortality association to $PM_{10-2.5}$ as observed in either city.**

The Criteria Document and Staff Paper also present and discuss other epidemiology studies in support of the proposal for both the $PM_{2.5}$ and $PM_{10-2.5}$ standards (as shown in Figure 2 and discussed in Section III.A above): Burnett (1997), Fairley (2003), Ito (2003), Lipfert et al (2000), Mar et al (2003), Moolgavkar (2000), Sheppard et al (2003), Thurston et al (1994), Burnett (2000, 2003), Klemm and Mason (2003), and Schwartz and Neas (2000). However, these studies report positive statistically significant associations with $PM_{2.5}$ that are more consistent and robust than the associations thus far identified for $PM_{10-2.5}$. Indeed, **several of these and other studies that specifically considered $PM_{10-2.5}$, but did not find statistically significant**

associations, including Schwartz et al (1996), Thurston et al. (1994), Sheppard et al. (2003), Fairley (2003), Schwartz et al (1996) and Lipfert et al. (2000). With respect to mortality effects in the Six-City study, Schwartz et al. (1996) concluded that the PM associations (in the six metropolitan areas – including Steubenville) were specifically associated with $PM_{2.5}$, with little additional contribution from the $PM_{10-2.5}$. Sheppard et al. (2003) noted that bias in model selection and reporting can result in inflated excess risk estimates for PM. Fairley (1999) noted that $PM_{10-2.5}$ effects become negative and insignificant when modeled jointly with $PM_{2.5}$. Lipfert et al. (2000) showed insignificant effects for $PM_{10-2.5}$ in one- and two-pollutant models with O_3. The authors also caution against drawing casual interpretations from results when comparing health effects from one region in a metropolitan area to air quality observations in another region. In addition, several of these studies also report positive, statistically significant associations with one or more of the gaseous pollutants. **Both Thurston et al. (1994) and Burnett et al. (1997) reported substantial confounding with gaseous co-pollutants in Toronto, and Thurston et al. (1994, p. 282) reported that "it seems clear that these apparent associations were merely a statistical by-product of interpollutant confounding resulting from the shared day-to-day variations in dispersion conditions."** In addition, Burnett et al. (2000) concluded that gaseous pollutants played an important role in explaining the effect of urban air pollution on health. Similarly, Moolgavkar (2000) concludes that gases were more strongly associated with respiratory effects than PM in Los Angeles.

Taken as a whole, evidence from $PM_{10-2.5}$ epidemiologic studies could be interpreted to suggest that one-pollutant $PM_{10-2.5}$ models suffer from bias due to omitting co-pollutants in the statistical model, especially given the much stronger evidence (discussed above) that these effects are associated with exposure to $PM_{2.5}$. As noted by many of the aforementioned authors, while significant health associations may be noted for coarse fraction PM in one-pollutant models, the actual association may be

> insignificant from zero due to confounding co-pollutants. Of course, the Administrator must conclude in the final rule that the evidence about the health effects of $PM_{10-2.5}$ is sufficiently robust to finalize a standard for $PM_{10-2.5}$.
>
> The Administrator, recognizing notably large uncertainties in the underlying evidence and information that formed the basis for this proposal as well as the challenges associated with moving toward a new $PM_{10-2.5}$ indicator and a related new monitoring network, solicits comment on this and other alternative interpretations of the available health evidence and alternative policy responses. Several such alternative interpretations and policy responses are discussed below.

71 Fed. Reg. at 2671-2672. (Emphasis added.)

What should be clear is that the rationale for the proposed coarse PM standard is not at all supported by the four studies. This passage states that "it generally would be appropriate for any assessment of the effect of exposure to $PM_{10-2.5}$ to control for exposure to the $PM_{2.5}$." In the primary study on which EPA placed reliance to support an "urban" $PM_{10-2.5}$ standard, namely that of Detroit (Ito 2003), it notes that when $PM_{2.5}$ is considered "the $PM_{10-2.5}$ associations lost statistical significance." In the Toronto study (Burnett 1997), the apparent association of health effects with coarse $PM_{10-2.5}$ "disappeared after adjustment for O_3, NO_2, and SO_2." In addition, the Toronto study did not find statistically significant associations between monitored cardiac and respiratory effects and coarse particulate matter. In Phoenix (Mar 2003), only single pollutant models were used, and only a "marginally significant ($p<.10$)" association was found. Anomalously, Mar 2003 found no significant association between total mortality and $PM_{2.5}$, contrary to virtually all of the other epidemiological studies cited by EPA. Any reliance on the Coachella Valley (Ostro, 2003) study also seems entirely unjustified. Not only does it attribute deaths in Palm Springs to exposure measured in the city of Indio, but it finds no association between fine PM and health effects, contrary to virtually all other EPA studies. In addition it models 24-hour concentrations for the 75% of the period for which it has no $PM_{2.5}$ monitoring data.

Even more misleading is the preamble text's treatment of the Six Cities Study as supportive of a finding of an association of coarse PM with mortality and morbidity as a basis for its proposed coarse PM standard. 71 Fed. Reg. 2655, col. 3. Buried in a footnote to this passage, EPA admits that upon reanalysis to correct errors, "the association for Steubenville was not statistically significant in most models reported in the two reanalyses . . ." 71 Fed. Reg. 2655, col. 3, fn. 49. Indeed, in the Schwartz review of the

effects of coarse PM in the Six Cities Study, as well as the reanalyses, no significant associations with mortality were found in five of the six cities, and in the one city where coarse PM was a significant proportion of the PM_{10} measured, Topeka, Kansas, there was a negative association with mortality. (Schwartz, 1996). The original Six Cities Study likewise did not find associations with morbidity in five of the six cities, and only with cough in one of the six cities, St. Louis. Surely it is misleading by omission to cite the Six Cities Study for the proposition that it supports findings of associations with mortality and morbidity.

Even more egregious is the failure to consider and weigh the far larger number of studies with much larger and more powerful databases and longer duration that specifically considered $PM_{10-2.5}$, but did not find statistically significant associations. (Schwartz 1996), (Thurston 1994), (Sheppard 2003), (Fairley 2003), (Schwartz 1996), and (Lipfert 2000).

Any fair and sound scientific weighing of the evidence on coarse PM would, we submit, determine that the preponderance of that evidence does not support the finding that a coarse PM standard at the current 24-hour PM_{10} concentration level of 150 $\mu g/m^3$, or the proposed 24-hour $PM_{10-2.5}$ concentration level, is necessary to protect public health. The preponderance of scientific evidence does not show any significant association with health effects at ambient concentrations. Those few studies purporting to show an association with coarse PM health effects either do not support that characterization, or are fatally flawed, and are contrary to virtually all of the other evidence considered.

C. A Detailed Review of the Cited Studies Reveals Numerous Deficiencies that Undermine EPA's Scientific Justification for the Proposed Coarse PM Standard.

Beyond EPA's own acknowledged deficiencies in its scientific basis for the coarse PM standard, Dr. Jonathan Borak of Yale University School of Medicine, has conducted a detailed review of EPA's cited studies. Dr. Borak's qualifications included expertise in toxicology, epidemiology and occupational health exposure to pollutants. His first review dated May 4, 2005, Ex. I of the limited studies that EPA cited as showing an association of coarse PM with morbidity found "a general lack of scientific support for a proposed NAAQS for $PM_{10-2.5}$," while his second review dated August 10, 2005, Ex. J of additional studies cited by EPA in its Staff Paper, found that such studies "do not sustain quantitative risk assessment." He also noted that:

> Important data deficiencies currently obstruct the setting of such a [coarse] PM standard, noting that "further "data and research are necessary to determine whether there is a need for a coarse PM [standard] to address public health risks at ambient

concentrations, and to characterize the indicator and concentration.

Dr. Borak has now supplemented his reviews of the EPA's Criteria Document and Final Staff Paper, and completed a thorough, detailed review and analysis of the scientific rationale and basis, as well as the underlying studies, on which EPA relies to support its recommendation of a coarse PM standard. It is contained in his letter to EPA dated April 17, 2006, attached as **Exhibit H.** Dr. Borak's conclusion is as follows:

> There is significant paucity of scientific support for the Proposed Coarse PM NAAQS and the scientific studies cited by EPA in support of the NAAQS suffer from significant methodological limitations.
>
> Although EPA repeatedly acknowledges that the database suffers such limitations, it persists in presenting the accumulated data as sufficient to justify the Proposed NAAQS. But in addition to those acknowledged by the Agency, a detailed review of the cited studies reveals numerous deficiencies that EPA has either not recognized or chosen to ignore.
>
> Unlike many other EPA risk assessments that thoughtfully sorted strong from weak studies, emphasizing evidence from the former and discounting that from the latter, EPA in this case seems unwilling to discard any "finding" that might somehow be construed as not supporting its NAAQS. That leads to important inadequacies in the justification and support of its proposed policy.
>
> The majority of findings presented as supporting evidence derive from the methodologically weakest studies, while the methodologically most robust studies yield essentially no support. EPA relies on the least rigorous of analytical approaches (e.g., single pollutant models vs. multi-pollutant models), minimizes or ignores potential confounding (e.g., URI events inducing asthma attacks, gaseous co-pollutants) and, as discussed above, by misrepresenting study findings.
>
> A detailed, balanced reading of the evidence indicates no basis to justify regulating of $PM_{10-2.5}$, only arguments and hypotheses that mainly reflect biological plausibility rather than empirical findings. The general lack of evidence persists even at exposure levels substantially higher than those

> considered health relevant in the Proposed Coarse PM NAAQS.
>
> I find insufficient scientific justification for the adoption of the Proposed Coarse PM NAAQS.

Ex. H at pp. 15-16.

D. Because Coarse PM Falls Out of the Atmosphere Over Relatively Short Distances, and is a "Local" Pollutant, Central Monitors Do Not Reflect or Even Approximate the Exposure of Residents in Surrounding Communities and Metropolitan Areas, and Thus Cannot Support the Conclusions of Studies That Assume Such Representative and Uniform Exposure.

The case EPA attempts to make in support of a coarse PM standard relies on deposition of coarse PM particles in the lung, toxicology in animals at high concentrations showing mechanisms for health effects at high concentrations, and EPA's assertion that those circumstances make the results of the epidemiological studies it selectively cites in support of its proposed coarse PM standard plausible. EPA recognizes the high spatial variability of coarse PM over short distances and the fact that coarse PM is a local pollutant, but contends that these considerations go only to the "precision" and not to the validity of its conclusions and reliance on the epidemiological studies. 71 Fed. Reg. 2660.

NMA submits that the spatial variability of coarse PM renders even the few, limited, uncertain epidemiological studies that have been cited by EPA invalid, as well as imprecise. Exposure to a local coarse PM source in downtown Indio simply has nothing to do with a patient living several miles away in Palm Springs admitted for a respiratory condition or indeed dying of such a condition.

1. Central Monitor Data is Not Representative of Population Exposure.

The epidemiological studies relied on by EPA typically use data from one monitoring site, or in a few cases the average of a couple of air quality monitoring sites, to show whether or not there is a relationship between levels of $PM_{10-2.5}$ and health effects. An assumption inherent in all of these studies is that the levels of $PM_{10-2.5}$ measured at the central monitoring station is the same or similar to the levels to which the persons studied were exposed—that the central monitoring station data is representative of the levels of $PM_{10-2.5}$ across the geographical area studied. This basic assumption is fundamentally at odds with available data, and with the way coarse particles behave.

EPA repeatedly acknowledges that the reported air quality data relied on in the epidemiological studies is not representative of the level of exposure to coarse particulate matter experienced by the populations involved in the studies. Uncertainty about measurements:

> is an important consideration in evaluating the air quality concentrations with which a statistical association is reported. The air quality levels reported in these studies, as measured by ambient concentrations at monitoring sites within the study areas, **are not necessarily good surrogates for the population exposures that are likely associated with the observed effects in the study areas or that would likely would be associated with effects in other urban areas across the country. The concentrations measured at one particular site may over- or under-estimate air quality levels in other parts of the area**.

71 Fed. Reg. at 2660 (emphasis added). "[I]n interpreting the results of epidemiologic studies, it is difficult to determine how well $PM_{10-2.5}$ concentrations measured at ambient monitoring stations characterize the magnitude of population exposures to thoracic coarse particles." 71 Fed. Reg. at 2660-61. And again, the agency notes that:

> This close examination of air quality information generally reinforces the view that exposure measurement error is potentially quite large in these $PM_{10-2.5}$ studies. As a consequence, the air quality levels reported in these studies, as measured by ambient concentrations at monitoring sites within the study areas, **are not necessarily good surrogates that are likely associated with the observed effects in the study areas or that would likely be associated in other urban areas across the country.**

71 Fed. Reg. 2670 (emphasis added).

Given that the purported associations between PM coarse and health effects is small to begin with, 71 Fed. Reg. at 2659, the logical conclusion should be that the lack of a demonstrable connection between the monitored ambient data and the level of exposure of the subject population is a fatal flaw that precludes reliance on the studies for any connection between PM coarse and health effects. EPA acknowledges that:

> At relatively low levels of air quality, population exposures implied by these studies as being associated with the observed effects likely become more uncertain, **suggesting a high degree of caution in interpreting the group of morbidity studies as a basis for identifying a standard level that would protect against the observed effects**.

71 Fed. Reg. at 2670 (emphasis added). But, enigmatically, EPA's forges ahead with its proposal despite this fatal flaw.

Despite its own caution that the "substantial uncertainties associated with this limited body of evidence suggest that it should be interpreted with a high degree of caution," 71 Fed. Reg. at 2661, EPA appears to suggest that because the uncertainties can cut both ways -- with actual exposure being sometimes higher and sometimes lower than the levels measured at monitoring sites -- somehow this cancels out the problem. It cites the Coachella Valley where the measurements in Indio used in the Ostro study were allegedly **higher** than levels in Palm Springs, where some of the subject patients lived, suggesting that effects might have been associated with lower levels than measured; whereas in Detroit, the measured concentrations at Windsor used in the Lippman study (Lippman, et al, 2000, Association of Particulate Matter Components with Daily Mortality and Morbidity in Urban Populations, Health Effects Institute, Research Report Number 95) appeared to be **lower** than in Detroit where the subject population lived. 71 Fed. Reg. at 2660. EPA fails to grasp the simple truth most of us learned from our mothers and fathers, that two wrongs don't make a right. The agency does not offer any thoughtful or principled method whereby one might analyze these apparently contradictory study results and emerge with a sensible conclusion based on the empirical data. It just plunges ahead to propose a $PM_{10-2.5}$ standard without in any way attempting to cope with the lack of reliable population exposure data, or otherwise attempting to address this fatal flaw.

We submit herewith an analysis by Mr. Gale Hoffnagle of TRC that delves more deeply into the fact that $PM_{10-2.5}$ data from central monitors is not at all representative of levels across large geographical areas and therefore not representative of population exposures. **Exhibit G.** Mr. Hoffnagle explains the physical processes that cause particles to remain aloft and the processes that cause them to deposit out and settle to the ground, and reports the results of an analysis using EPA's approved ISC, empirically-based fugitive particulate matter modeling that predicts that 99% of 10 micron particles emitted at ground level (e.g., from paved roadways, cattle operations or surface mines), fall out within 400 meters of the source; and that 99% of 2.5 micron particles fall out within 1,000 meters of the source. This and other evidence cited by Mr. Hoffnagle shows that, for the range of particles measured by the proposed $PM_{10-2.5}$ NAAQS, levels measured at central

monitoring sites are representative only of sources within less than 1/3 of a mile for ground level sources of particulate emissions, and within 2/3 of a mile for 10 meter elevated sources.

The authors of the epidemiological studies, not being schooled in the physics or behavior of PM in the ambient air, have apparently simply assumed that measurements at central monitoring sites are representative of the levels of coarse PM to which subjects are exposed across an entire city or metropolitan area. But in truth, **the authors do not know what are the levels of coarse PM to which these subjects are exposed.** Because the health effects purportedly found in a handful of studies are so small, and therefore so highly dependent on the accuracy of the assumed exposure levels, the fact that coarse particles rapidly settle out of the ambient air leads to only one conclusion -- there is **no basis for assuming the study populations are in fact exposed to the measured level.**

2. The PM Monitoring Data is Not Representative

EPA's own analysis confirms that ambient PM levels vary dramatically from one location to another within the same city, and that data from one monitoring site, or average values from a couple of sites, are not representative of area-wide population exposures. EPA Staff obtained and evaluated information from several cities with multiple monitoring stations in which key epidemiological studies were conducted. Ross, Updated Information on Air Quality Monitoring Data for Thoracic Coarse Particles Used in Epidemiologic Studies (June 30, 2005) (Ross 2005) EPA-HQ-OAR-2001-0017-0395. Data for recent years was gathered by EPA from multiple sites, but data for the epidemiological studies gathered in earlier years were limited to single sites or averages from a couple of sites. The EPA information clearly illustrates the variability of PM concentrations from site to site within the cities where important epidemiological studies were conducted.

Mr. Hoffnagle analyzes these data, as well as additional data from monitors in Salt Lake City. He cites EPA's own criteria for when spatial averaging of multiple monitoring stations may be used to measure compliance with the NAAQS for $PM_{2.5}$, and notes that most monitors in the key epidemiological study cities **do not meet the criteria**. EPA does not allude to these criteria in its evaluation of the epidemiological studies—for reasons not disclosed, it ignores the criteria, and ignores its own concession that data from a central monitor is not a good surrogate for area-wide exposures, and thus allows itself to be deceived by the mirage that coarse particulate matter is associated with health effects.

The proposed rule, in fact, would tighten the criteria for spatial averaging. Thus, anomalously, while EPA would make it **more difficult** to rely on average values to determine NAAQS compliance, in the epidemiological context it finds it **not at all difficult** to rely on the assumption that average

exposures across a wide area are represented by a single data point. This is another example of the puzzling contradictions inherent in EPA's proposal.

EPA's data (Ross, 2005) shows that in 2003 in Phoenix, the annual mean concentration at the JLG Supersite was 28.4 $\mu g/m^3$, at West Phoenix it was 36.6 $\mu g/m^3$, and at each of 3 other sites it was 62 $\mu g/m^3$. Thus, within the same metropolitan area different values from different sites differed by a factor of two.

Another example is data from St. Louis (one of the cities involved in the Harvard Six Cities study) which show that 2001-2003 mean $PM_{10-2.5}$ concentrations at different sites within the St. Louis metropolitan area varied by more than a factor of two. *Id.*

A further example is Detroit, where EPA staff found that in 1999-2003, concentrations from the two central Detroit sites were "appreciably higher, by about two- to three-fold, than those at the Windsor monitors". (Windsor monitoring data being the basis for the study reported in Lippman, et al, (2000). Association of Particulate Matter Components with Daily Mortality and Morbidity in Urban Populations. Health Effects Institute, Research Report 95.) *Id.* See Mr. Hoffnagles's analysis at Exhibit G for more examples that $PM_{10-2.5}$ concentrations vary widely within a single city.

These and other dramatic differences in particulate levels noted by Ross are based on **annual average** values. As Mr. Hoffnagle points out, **daily values show far greater differences**, and it is daily values on which epidemiological studies rely. This fact simply compounds the magnitude of the error inherent in EPA's assertion that coarse particulate matter is associated with health effects.

3. Epidemiological studies that rely on monitored air quality data from central monitoring stations that are not representative of population exposures, are fundamentally flawed.

EPA has acknowledged that monitoring data is not a good measure of PM levels to which study populations were exposed. But the agency nonetheless relies on the epidemiological studies to assert a need for a coarse PM standard. We have searched in vain for an explanation of why these studies should be relied on for this purpose, despite the acknowledged problems. EPA simply glosses over the issue. After noting that the population exposure problems suggest a "high degree of caution", the preamble observes that the Staff Paper's recommendation to consider a thoracic coarse standard at least down to 50 $\mu g/m^3$ "takes into account the conclusion that this evidence is particularly uncertain as to population exposure". 71 Fed. Reg. at 2670. It is difficult to ascertain *how* the recommendation has taken into account the flaws in the studies. Had the flaws been taken into account, EPA would not have proposed a coarse particle standard. EPA evidently has ignored the flaws.

Dr. Jonathan Borak, in a letter to the Administrator submitted concurrently with these comments, a copy of which is attached as Exhibit H, adds further cautionary notes regarding the adequacy of the exposure assessments that underlie the epidemiological studies. First, he notes that, because coarse particles settle out of the air rapidly, coarse PM measurements at relatively distant monitoring sites, or at sites relatively distant from target populations, should be viewed with caution. Second, he notes that PM 10-2.5 measurements obtained using the "difference method" are prone to larger errors than direct measurements using dichotomous samplers; that the best quality exposure assessments, using dichotomous samplers, have found no significant health effects from coarse particles; that lesser quality studies using the difference method find only marginal associations in some cases, and that the lowest quality assessments, those that rely on PM10 as a surrogate for PM10-2.5, are the studies most relied on to support the proposed coarse particle standard.

All of these factors cumulatively underscore that the fundamental epidemiological assumption, that data from one or two monitoring sites represents exposure of the target population on an area-wide basis, is contradicted by empirical fact, and therefore fatally flawed.

Because of this fatal flaw, there is no logical alternative but to disregard the purported health associations found in these studies.

VIII. The 70 µg/m^3 Concentration Level is Arbitrary and Capricious, and Without Rational Basis

After EPA asserts that the health evidence demonstrates a need to establish a NAAQS for $PM_{10-2.5}$, the question remains, what is the appropriate level of such a $PM_{10-2.5}$ NAAQS? For the 24-hour fine particle $PM_{2.5}$ standard, EPA relies primarily on recent short-term epidemiological exposure studies to quantify the level of the standard, with risk assessment data playing a qualitative supporting role. 71 Fed. Reg. at 2648-50. For the 24-hour coarse particle standard, however, neither the epidemiological studies nor the risk assessment are deemed adequate for quantifying the standard, so EPA must reach for an alternative method for doing so.

First, EPA explains the limitations of the quantitative risk assessment:

> While one of the goals of the $PM_{10-2.5}$ risk assessment was to provide estimates of the risk reductions associated with just meeting alternative $PM_{10-2.5}$ standards, the nature and magnitude of the uncertainties and concerns associated with this portion of the risk assessment weigh against use of these risk estimates as a basis for recommending specific standard levels.

71 Fed. Reg. at 2662. Interestingly, one of the concerns described was that "the $PM_{10-2.5}$ levels measured at ambient monitoring sites in recent years may be quite different from the levels used to characterize exposure in the original epidemiologic studies based on monitoring sites in different locations, thus possibly over- or underestimating population risk levels."[3] *Id*.

Second, although EPA chooses to rely on the admittedly "limited" and "uncertain" epidemiological studies to assert a need for **some** PM coarse standard, such studies are deemed by the agency to be inadequate to **quantify** a PM coarse standard:

> [T]he Staff Paper focuses on relevant U.S. and Canadian epidemiologic studies . . .. As an initial matter, the Staff Paper recognizes that these individual short-term exposure studies provide no evidence of population thresholds, or lowest-observed effects level. **As a consequence, this body of evidence is difficult to translate directly into a specific 24-hour standard that would protect against the range of effects that have been associated with short-term exposures.**

71 Fed. Reg. at 2669. EPA notes that "[i]n considering the [epidemiological] evidence, the Staff Paper notes the **significant uncertainties and limited nature of the available evidence.**" *Id.*. In its discussion of this evidence, EPA briefly explores whether, despite these uncertainties and limitations, this evidence might serve as a basis for quantifying a standard, and looks at the "upper end of the distributions of daily $PM_{10-2.5}$ concentrations in the relevant studies in terms of the 98^{th} and 99^{th} percentile values." *Id.* Based on a perusal of the epidemiological studies, EPA points out various uncertainties associated with the studies, including uncertainties related to the fact that "exposure measurement error is potentially quite large in these $PM_{10-2.5}$ studies", 71 Fed. Reg. 2670, and observes that "the Staff Paper concludes that this evidence suggests that EPA could consider a standard for urban thoracic coarse particles at a $PM_{10-2.5}$ level at least down to 50 $\mu g/m^3$, in conjunction with a 98^{th} percentile form." *Id.* But in the end the agency does not, in fact, rely on the upper end concentrations in the epidemiological studies to establish a standard. Acknowledging that "**this evidence is particularly uncertain** as to population exposures," *id.* (emphasis added), EPA decides there is a better basis for quantifying a $PM_{10-2.5}$ standard:

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[3] This causes us to wonder again why EPA believes the evidence demonstrates a need for a coarse PM standard. If the variation of PM concentration levels from one location to another precludes use of the risk assessment, (based on epidemiological evidence) to set a standard, it seems it likewise should preclude use of the evidence to conclude there is a need for a standard. **See Exhibit G**

> Another view that reflects a more cautious or restrained approach to interpreting the limited body of $PM_{10-2.5}$ epidemiologic evidence would be to judge that the uncertainties in this whole group of studies as to population exposures that are associated with the observed effects are too large to use the reported air quality levels directly as a basis for setting a specific standard level... The Staff Paper concludes, therefore, that it is reasonable to interpret the available evidence as supporting consideration of a short-term standard for thoracic coarse particles, so as to provide **generally 'equivalent' protection to that afforded by the current PM_{10} standards....**

Id.(emphasis added).

In the final analysis, the EPA "provisionally concludes that the selection of a level that **provides generally equivalent protection to that provided by the current PM_{10} standards** is an appropriate policy response to the very limited body of evidence that is available at this time." 71 Fed. Reg. at 2671 (emphasis added).

There are three fundamental problems with this "equivalence" approach that render the EPA's proposed coarse particle standard invalid:

1. The PM_{10} standard is not a valid foundation on which to base an "equivalent" coarse standard.

2. The evidence cannot sustain the conclusion that the proposed $PM_{10-2.5}$ standard is in fact equivalent to the current PM_{10} standard. Indeed, the evidence indicates that there is in fact no such equivalent $PM_{10-2.5}$ standard.

3. Basing a coarse particle standard on the current PM_{10} level is invalid under the *American Trucking Association* case.

A. The PM_{10} Concentration Level of 150 µg/m^3 Cannot Be the Touchstone for Equivalence Because It Is Fundamentally Flawed as a Coarse Standard

Because of the paucity and uncertainty in the underlying health data, EPA fundamentally premises its proposed 70 ug/m3 concentration level on equivalence to the "current" PM10 standard of 150 ug/m3. But equivalence to 150 ug/m3 of PM10 would be a logical basis for a coarse standard only if the 150ug/m3 level were rooted in coarse particle evidence. EPA apparently believes that the underlying health evidence for the 150 ug/m3 level is well established and needs no further discussion since it provides none in the Proposed Rule. However, further examination of the process by which EPA

selected the 150 ug/m3 concentration level in 1987 and again in 1997, reveals that the 150 ug/m3 level is grounded primarily in evidence of effects of fine particles, and therefore cannot reasonably be the foundation for a coarse particle standard. As discussed further below, the 150 ug/m3 concentration level does not meet the legal standard set by the U.S. Supreme Court in the *American Trucking Association* case, nor would any "equivalent" level that is set based on that concentration level.

1. Legal Requirements for Setting Concentration Level

Before discussing how EPA arrived at the 150 ug/m3 concentration level, it is important to understand the legal requirements that EPA must follow in setting the level. In 1999, the D.C. Circuit Court in *American Trucking Association* vacated the 1997 PM10 coarse standard because the indicator was flawed. With respect to the appropriate concentration level of the standard, the Court held:

> We note, however, that whatever levels the agency ultimately selects for coarse particle pollution will need to comply with the requirements set forth in Part I of this Opinion.

175 F.3d 1027, 1055 (1999). Part I of that Opinion was the Court's finding that EPA's authority to set a concentration level was too broad and amounted to an unconstitutional delegation of legislative power. Id at 1034. However, the U.S. Supreme Court held that EPA's authority to set a concentration level was not unconstitutionally broad and was appropriately limited: EPA is required, the Court stated, "to set air quality standards at the level that is requisite – not lower or higher than is necessary – to protect the public health with an adequate margin of safety." Slip op. at 15 (emphasis added). This language, thus, sets the standard against which both EPA's selection of the 150 ug/m3 level and any "equivalent" level must be measured.

2. In 1987, EPA Did Not Set the 150 ug/m3 Concentration Level Based on Coarse PM Health Data

In setting the original 150ug/m3 level for the 1987 standard, EPA relied primarily on London smog data from the 1950s as measured by British Smoke -- a measure of blackness and not of coarse PM – more similar to fine PM than coarse PM in terms of chemistry and size. 52 Fed. Reg. 24642 (July 1, 1987).[4] At the time, the 1987 PM10 standard was intended to be a "fine"

[4] EPA has subsequently indicated that it derived the 150 ug/m3 level by taking the 500 ug/m3 levels measured in the London episode and applying a factor of 3 for a margin of safety, see 1996 CASAC testimony of John Bachmann; 62 Fed. Reg. at 38659 (July 18, 1997), though a review of the 1987 preamble does not necessarily support this

PM standard, inasmuch as it was reducing the size of the regulated PM from TSP to the respirable fraction. Because of this, there was no evidence regarding any health effects from the coarse fraction of PM10. Also, EPA's discussion of the appropriate level at which to set the standard focused on ensuring that the standard was as stringent as possible, rather than whether the concentration level was lower than necessary, in violation of the requirement set forth by the U.S. Supreme Court.

3. In 1997, EPA Did Not Consider Whether the 1987 150 ug/m3 Concentration level Was Lower than Necessary, Nor Did it Rely on Coarse PM Health Data.

In 1997, EPA decided to establish separate PM indicators for fine and coarse PM, and focused its consideration of an appropriate concentration level on the fine PM because that fraction was viewed as the fraction most clearly associated with the adverse health effects observed in the PM10 studies: "the preponderance of the available evidence suggests that strategies to control fine particles will more effectively reduce population exposure to substances associated with health effects in the recent epidemiological studies." 62 Fed. Reg at 38667. EPA's premise with respect to the coarse fraction was that "coarse fraction particles are more likely linked with certain effects at levels **above those allowed by the current PM_{10} standards**." Id. at 38665 (quoting 1996 EPA Staff Paper at p.7-45)(emphasis added).

"[T]he new function of PM10 standards was to protect against potential effects associated with thoracic coarse particles in the size range of 2.5 to 10 um (62 FR 38,677)". Final Staff Paper, June 30, 2005, at 5-47. But there were no health studies on the effects of thoracic coarse particles. The decision to use PM10 as a surrogate for coarse particles "was based in part on the recognition that the only studies of clear quantitative relevance to health effects most likely associated with thoracic coarse particle used fugitive dust studies in areas that substantially exceeded the PM10 standards. . . . In essence, EPA concluded at that time that it was appropriate to continue to control thoracic coarse particles, but that the only information available upon which to base such standards was indexed in terms of PM10" *Id.* If EPA previously had relied on coarse particle data as a basis for its PM10 standard, in 1997 EPA abandoned any such reliance on previous data:

> **The original quantitative basis** for the level of the current 24-hour PM10 standard (150 ug/m3) **is no longer appropriate**. Instead, the staff found that the main quantitative basis for a short-term standard is provided by the two recent community studies of exposure to fugitive dust (Gordian et al., 1996;

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straightforward calculation. The 1987 preamble does, however support that British Smoke data was in large part the basis for the concentration level of the PM10 standard.

> Hefflin et al., 1994). Because these studies reported multiple large exceedances of the current 24-hour standard and because of limitations in the studies themselves, the staff concluded that they provide **no basis to lower the level** of the standard below 150 ug/m3. Moreover, staff concluded that none of the qualitative literature regarding the potential effects of short-term exposure to coarse particles provides a basis for a lower standard level.

62 Fed. Reg. at 38679 (July 18, 1997) (emphasis added).

Thus, as of 1997, the *only* data purporting to suggest an association between coarse particles and health effects were two studies that did not measure coarse particles. As for these two studies, EPA acknowledged they had "limitations" and reported "multiple large exceedances" of the 150 ug/m3 level. Beyond EPA's own criticism of these studies, they suffered from numerous additional problems, as detailed in NCBA's March 30, 2005 comments to CASAC, Exhibit C, and as further discussed in Dr. Borak's comments, Exhibit H. In fact, the levels at which effects were observed in Hefflin were 1035 to 1689 ug/m3, many times larger than the 150ug/m3 level.[5] And beyond the problems with the studies themselves, They were not used by EPA to try to **quantify** an appropriate PM10 concentration level for a coarse PM standard, but only to ascertain whether they demonstrated a need to make the previous PM10 standard more stringent—the previous standard that admittedly had been based on evidence that was "no longer appropriate".

EPA's sole focus was whether the 150 ug/m3 level might be **higher than necessary**, but undertook no analysis of the question of whether the 150 ug/m3 might be **"lower than necessary to protect public health.**" *American Trucking Association* at 15 (emphasis added). For this reason alone, the 150 ug/m3 standard PM10-as-coarse-particle standard is fundamentally flawed. Moreover, EPA's reliance on studies, "that reported multiple large exceedances of the current 24-hour standard [150ug/m3]," 62 Fed. Reg. at 38679, without any discussion of the disparity between those levels and the selected 150ug/m3 level, demonstrates that EPA did not undertake the requisite level of analysis necessary to meet the U.S. Supreme Court's test for a valid NAAQS.

4. The 150 ug/m3 Concentration Level Violates the US Supreme Court's Legal Standard for Setting NAAQS Concentration Levels

Of course, we now know that the D.C. Circuit ruled that the use of PM10 as a coarse particle standard was invalid. *American Trucking Associations v. EPA,*

175 F.3d 1027, 1054 (D.C Cir. 1999). Therefore, EPA proposes a coarse particle standard measured by PM10-2.5. Nonetheless, EPA bases its proposed PM10-2.5 standard on "equivalence" to PM10, so the question remains, at this time is PM10 a bona fide basis for a coarse PM standard? As of 1997, the only remaining thread cited by EPA to link PM10 levels with effects from coarse particles were the Gordian and Hefflin studies, and even these had not been used to actually *quantify* an appropriate coarse standard. In the current review, Gordian and Hefflin have, at best, been relegated to the second team. "[S]taff concludes that continuing to rely principally on health effects evidence indexed by PM10 is no longer appropriate, since more directly relevant studies, indexed by PM10-2.5, are also now available." Final Staff Paper, June 2005, at 5.48. Instead, staff concluded it is appropriate to base a revised standard "principally on the currently available evidence and air quality information indexed by PM10-2.5, but also considering evidence from studies using PM10 in locations where PM10-2.5 is the predominant fraction." Thus, if Gordian and Hefflin continue to have any relevance, their relevance is distinctly secondary to studies using PM10-2.5 data.

What do we learn from this history of PM10? We see that, in the beginning, the 1987 PM 10 standard was based primarily on evidence of fine particle effects, not coarse. In 1997, EPA concluded that the original 1987 basis for quantifying a PM10 standard was inappropriate, and that the main 1997 bases for quantifying a PM10 standard were the Gordian and Hefflin studies (in truth, the Gordian and Hefflin studies were used only to evaluate whether the 1987 standard should be lowered, not to evaluate what a proper coarse particle standard should be). Now, we are told that more recent studies based on measurements of PM10-2.5 are the best available data and that we should not principally rely on PM10 studies such as Gordian and Hefflin to set a coarse PM standard. Finally, as noted above, the more recent studies are determined by EPA to be too uncertain to use them "directly as a basis for setting a specific standard level".

As a result, EPA has reverted to equivalence to the 1987 PM10 concentration level to quantify the level of the proposed 70ug/m3 coarse particle standard. Thus, anomalously, EPA's path leads us full circle, back to the 1987 PM10 level that never was primarily a coarse particle standard in the first place, and the original quantitative basis for which has since been discredited. At one and the same time, EPA tells us that the best evidence we have regarding health effects of coarse particles are the recent studies based on PM10-2.5 data; that this best evidence is not good enough to use to quantify a coarse particle standard; and therefore to quantify a coarse particle standard we should use evidence that is less than the best and that EPA, itself, already has discredited as no longer appropriate. This is an amazing story, which we submit may fairly be summarized as "we decided the best evidence isn't good enough, so instead we have relied on the worst." This approach makes a mockery of EPA's stated legal obligation under § 109(b)(1) of the CAA that "for a discrete set of pollutants and based on

published air quality criteria that reflect **the latest scientific knowledge** the EPA must establish uniform national standards at a level that is requisite to protect public health from the adverse effects of the pollutant in the ambient air." *American Trucking Ass'n* at 13(emphasis added).

B. The Evidence Cannot Sustain a Finding of Equivalence

Even if, contrary to the foregoing, we assume the 150 $\mu g/m^3$ standard for PM_{10} is a valid point of departure from which to derive an "equivalent" $PM_{10-2.5}$ level, the evidence does not support the assertion that 70 $\mu g/m^3$ is an equivalent level. EPA argues that a $PM_{10-2.5}$ level of approximately 70 $\mu g/m^3$, in terms of a 98^{th} percentile form, would be roughly equivalent on average across the U.S to the "current" PM_{10} standard level of 150 $\mu g/m^3$, in terms of the current one-expected exceedance form. 71 Fed. Reg. 2670. But this assumes that similar circumstances exist in every city, every state and every region across the country, and that the ratio of $PM_{10-2.5}$ to PM_{10} is the same everywhere.

In fact, EPA's analysis, which compared $PM_{10-2.5}$ data with PM_{10} data in various regions across the country, shows a high degree of variability in the ratio. Schmidt, et al. (2005), Analyses of Particulate Matter (PM) Data for the PM NAAQS Review, Output A.7, Docket EPA-HQ-OAR-2001-0017-0398 (Schmidt 2005). For example, the ratio of the means of $PM_{10-2.5}$, 98^{th} percentile form level, to PM_{10}, expected exceedance form level, varies from approximately 0.31 to 0.56 across seven regions of the country. *Id.* at 10 of 19. The ratios of the 95^{th} percentile levels for $PM_{10-2.5}$, 98^{th} percentile form, to PM_{10}, expected exceedance form, varies from approximately 0.46 to 0.67 across the same seven regions. It should be noted that these ratios are based on annual average measurements, and therefore show far less variability than would be seen on a 24-hour basis. Not only do equivalence levels vary widely across the country, but EPA's own analysis show that equivalent $PM_{10-2.5}$ levels for a high percentage of existing monitoring sites would be above 70 $\mu g/m^3$. The median equivalence level is 66 $\mu g/m^3$, and the 75 percentile level is 81 $\mu g/m^3$, which means that between 25% and 50% of existing sites have EPA-calculated equivalence levels above 70 $\mu g/m^3$. Schmidt, 2005, Output A.7 at 12 of 19.

Mr. Hoffnagle reports data from Salt Lake City showing that the PM coarse equivalent to PM_{10} at 150 $\mu g/m^3$ would be between 127 and 133 $\mu g/m^3$, and data from Wyoming showing that the proposed NAAQS for $PM_{10-2.5}$ would be significantly more stringent than the current PM_{10} NAAQS. Exhibit G.

Thus, we see that, based on EPA's own analysis as well as other evidence, there is no nationwide "equivalence" level. In the agency's own analysis, therefore, the $PM_{10-2.5}$ level that would be equivalent to the current PM_{10} standard, based on mean values, varies by more that 50%, and would range from 45 $\mu g/m^3$ to 84 $\mu g/m^3$. Of course, setting the standard based on mean values would be designed to ensure that roughly half of all monitored sites

would be subject to a more stringent standard than the current PM_{10} standard. Based on 95th percentile levels, the equivalence values for $PM_{10-2.5}$ would vary from 69 µg/m^3 to 105 µg/m^3. No matter how one slices the data, setting a single equivalence level at 70 µg/m^3 would ensure that many areas of the country would be subject to more stringent requirements than the current PM_{10} standard. Ironically, 70µg/m3 level would impose a PM coarse standard far more stringent than the current PM_{10} standard in areas such as Denver and the arid West where the evidence most clearly does not support a coarse PM standard, while not providing any additional control in areas such as Detroit, Toronto and Seattle where EPA claims epidemiological studies support its position. The data, on its face, makes clear that there is no level of $PM_{10-2.5}$ that is equivalent to the current PM_{10} standard. EPA's establishment of a $PM_{10-2.5}$ standard based on the equivalence method, therefore, is inherently flawed and flies in the face of the agency's own analysis.

It has been suggested that because the proposed standard is expressed in a 98th percentile form, a form which allows more exceedances than the current PM10 standard, the proposed standard is not more stringent than the current PM10 standard. This is not borne out by the facts. The level of the proposed standard is so much more stringent than the existing standard in many areas, that the slightly more flexible and forgiving form of the proposed standard makes little difference because the flexibility is far outweighed by the dramatic increase in how stringent the level of the standard is.

Figure 5 of Mr. Hoffnagle's report incorporates illustrative data from a location in northeastern Wyoming which demonstrates pointedly that, even with the change in form, the number of violations under the proposed standard would increase more than ten-fold compared with the current standard.

Comparisons by Schmidt, et al. show that even using annual average data, the proposed 98th percentile standard would be more stringent than the current PM10 standard for 25% to 50% of monitored sites. Schmidt, 2005.

C. Basing a Coarse Particle Standard on PM_{10} is Unlawful Under the American Trucking Case.

In *American Trucking Associations, Inc. v. EPA,* 175 F.3d 1027 (D.C.Cir. 1999) the court held that when EPA determined that fine PM and coarse PM are separate pollutants and established a standard for fine PM, measured as $PM_{2.5}$, it could not base a standard for coarse PM using PM_{10} as an indicator. The reason was that PM_{10} is inherently confounded by the presence of $PM_{2.5}$. The court reasoned that "using PM_{10} as the coarse particle indicator, instead of $PM_{10-2.5}$, will thus regulate more than just the coarse fraction of PM_{10}, and the amount of coarse particulate pollution permitted will depend (quite arbitrarily) on the amount of $PM_{2.5}$ pollution in the air." 175 F.3d at 1054.

Stated in a different way, the court held that one may not base a coarse PM standard on PM_{10} because PM_{10} is confounded by the presence of $PM_{2.5}$.

In this case, however, because EPA bases its proposed $PM_{10-2.5}$ standard on an alleged equivalence to PM_{10}, it has done precisely what the court held it could not do—it has based a coarse standard on PM_{10}. EPA may argue that it is not doing here exactly what the court in *American Trucking* condemned, which was using PM_{10} as the "indicator" for coarse PM. The agency may point out that it is proposing the use of $PM_{10-2.5}$ as the "indicator", not PM_{10}. It is true that EPA proposes $PM_{10-2.5}$ as the "indicator" for coarse PM. And yet, the concentration level of the proposed $PM_{10-2.5}$ standard is derived directly, solely and entirely from PM_{10}, based on an alleged equivalence to the current PM_{10} standard. But because PM_{10} is inherently confounded by the presence of varying amounts of $PM_{2.5}$, for EPA to derive its proposed $PM_{10-2.5}$ standard from the current PM_{10} standard is to infect the $PM_{10-2.5}$ standard with the same confounding flaw as the standard from which it is derived.

At any given location, whether 70 $\mu g/m^3$ is equivalent to 150 $\mu g/m^3$ depends (quite arbitrarily) on how much $PM_{2.5}$ is present. As Dr. James Crapo, a member of CASAC, stated:

> A critical question is whether or not PM_{10} can be used as a surrogate for health effects of coarse particles. I agree with the court ruling which suggests that regulation of coarse mode particle should be based on data directly on coarse mode particles, not including the $PM_{2.5}$ fraction as would occur if one used PM_{10}. It is possible that the adverse health effects of PM_{10} reflect only the $PM_{2.5}$ effects and that the coarse mode particles add little to health risk.

EPA-HQ-ORD-2005-0004-0039, Exhibit L at B-5. No structure is more sound than the foundation on which it is based. No matter how the agency might try to disguise its action, the unavoidable conclusion is that the concentration level of the coarse standard it proposes is fundamentally based on PM_{10}, which is precisely the approach that the court struck down. It is perhaps easiest to follow this in the form of a logical syllogism:

1. According to *American Trucking,* a coarse standard based on PM_{10} is invalid because of the confounding presence of $PM_{2.5}$.

2. The proposed concentration level of the coarse standard is based on PM_{10}.

3. Therefore, the proposed coarse standard is invalid.

The logic of the foregoing is pointedly illustrated by the data noted above from Schmidt, et al. Different areas of the country have different mixes of coarse and fine PM included in PM_{10}. When it picks a single "equivalent'

coarse standard, EPA ignores this varying mix, just as it ignored the varying proportion of fine and coarse in selecting PM_{10} as a coarse indicator. In this way, the EPA commits the same error condemned by the court.

IX. The Exclusion of Coarse PM from Agricultural and Mining Is Consistent with the Preponderance of the Scientific Evidence, and the Longstanding Determinations of EPA, Congress and the Courts.

As noted above, fugitive dusts have been consistently determined not to present substantial health or welfare effects, and have been excluded from PM NAAQS determinations, PSD and NSR permit applicability determinations, and discounted or not counted under exemptions ranging from the fugitive dust exemption to the rural fugitive dust policy for more than 30 years. These determinations and policies have been upheld by the courts, and endorsed by Congress on several occasions. CASAC counseled EPA to "make exceptions for rural dust thought to have low toxicity" EPA-HQ—OAR-2001-0017-0393**.** This section provides specific reference for this history.

By the time of the CAA Amendments of 1977, it was well-known that coarse PM dusts, generally referred to as "fugitive dust," from natural sources and activities, such as surface mining, agriculture, dirt roads, forestry, construction and earth-moving, routinely exceeded the PM NAAQS in the arid West. In the same Amendments, Congress added the Prevention of Significant Deterioration (PSD) program into the statute, requiring all new or expanded sources of 250 tons/year or more of PM to demonstrate not only that the PM NAAQS were met, but that PSD PM increments, set at levels approximately one-fifth of the PM NAAQS, also were met. 42 U.S.C. §7460-69. It was apparent that if the PM NAAQS and increments were applied to new or expanded activities producing fugitive dust, those activities would be drastically reduced or prohibited because their emissions were projected to exceed those PM standards, even after the application of Best Available Control Technology(BACT).[6]

Based on this uncontroverted assessment, EPA determined that fugitive dust should be excluded from the application of the PM NAAQS and increments ambient air quality impact analyses under the PSD program, noting several factors cited at the time by the mining industry, namely:

> that a large majority of the associated particulate matter is nonrespirable; that mining activity occurs in areas with limited population; that the particulate matter arises at ground level and falls out within very short distances; that visibility is not affected

[6] See studies recited in fn. 3, col. 2, 43 Fed. Reg. 26395 (June 19, 1978) and EPA Region VIII Interim Policy Paper on Air Quality Review of Surface Mining Operations (1978).

> because the light scattering which hinders visibility is caused by smaller particles; and that even after the application of BACT, short-term particulate standards for NAAQS and PSD increments might not be met.
>
> In view of these comments and other studies, EPA has decided to exclude from any air quality impact assessment of a source or modification any fugitive dust that would emanate from it.
>
> * * *
>
> Additional support for this exclusion can be found in the legislative history. It points to the utilization of 'administrative good sense' regarding fugitive dust (*see* S. Rep. No. 95-127, at 98 (1977)) and suggests that Congress did not intend PSD to prohibit surface mines of an economically viable size (*see* H. Rep. No. 95-294, at 165-66 (1977)).

43 Fed. Reg. 26395 (June 19, 1978).

EPA routinely classified "nonattainment" areas exceeding the PM NAAQS due to fugitive dust as "attainment" areas, applying its "rural fugitive dust policy," e.g., 45 Fed. Reg. 78122 (Nov. 25, 1980), 56 Fed. Reg. 37564 (August 8, 1991).

As Judge Leventhal noted in the Court's decision on fugitive PM issues in *Alabama Power Co. v. Costle*, 636 F.2d 323(D.C. Cir. 1979):

> EPA's regulation of fugitive emissions has been of special concern to the mining and forestry industries which contend, without serious opposition, that they are incapable of meeting the strict limitations on the emission of particulate matter set by the PSD provisions.

Id. at 369. The Court in this case held that fugitive emissions could not be included in determining applicability until EPA had performed a rulemaking to include them pursuant to section 302(j) of the Clean Air Act. Perhaps as or more important, the Court noted that:

> EPA has discretion to define the pollutant termed 'particulate matter' to exclude particles of a size **or composition** determined not to present substantial public health or welfare concerns.

Id. at 369-70, fn. 134 (emphasis added). It went on to explain how those particles could remain subject to reasonable controls under other provisions of the Clean Air Act. The Court also vacated the fugitive dust exemption.

Congress, in deciding not to enact a statutory exclusion of fugitive dusts, made very clear that EPA was expected to use its "administrative good sense" to exclude it:

> Because of the imprecision inherent in the total suspended particulates standards, background dust in such States can cause levels in excess of the particulate standards. Fortunately, the logical dilemma posed by the shortcomings of the present particulates standards can be overcome by administrative good sense until such time as modification of the standards are adopted. *The States and EPA have begun to recognize this problem of background particulates and should discount its effects where the problem involves particulates* ***not generally of the substances*** *and respirable sizes thought to affect public health.* The Environmental Protection Agency has used this approach in its current policy, and the committee endorses it. *In calculating baseline levels for the purposes of the nondeterioration requirements, and in making determination of attainment and nonattainment of ambient particulate standards, the committee would expect that this administrative good sense would apply.* (Emphasis supplied). S. Rep. No. 95-127, 95th Cong., 1st Sess. 98 (1977).

EPA came to the same conclusion as the Court and Congress concerning coarse PM from surface coal mining. Following the Court's remand in *Sierra Club v. Gorsuch,* 715 F.2d 653 (D.C. Cir. 1983), EPA proposed to list such mines as sources whose fugitive dust emissions must be included in determining whether they are major stationary sources under the PSD program. It concluded that mine fugitive dust emission should not be included and surface mines should not be listed because of (1) the lack of substantial health or welfare effects from such coarse PM emissions, and (2) the prohibitive effect on the mining industry that including such coarse particle fugitive dust would have. 54 Fed. Reg. 48870 (November 28, 1989).

In summary, EPA's proposal to exclude coarse PM from agriculture, mining and similar sources is in keeping with past determinations of Congress, the courts and EPA itself.

X. The Preponderance of the Scientific Evidence Continues to Demonstrate That Fugitive Dust from Agricultural and Mining Operations Presents No Substantial Health or Welfare Concerns.

Over the last 30 years, the consensus opinion of the many eminent and experienced medical and public health experts in respiratory disease epidemiology, toxicology and clinical treatment has been that coarse PM has never been demonstrated to have adverse health effects at ambient levels. This section summarizes that evidence.

After many years of study, Benjamin G. Ferris, Jr., M.D., a nationally known expert in research on the effects of PM and other criteria pollutants on health, Professor of Environmental Health and Safety, Department of Environmental Science and Physiology, head of the Respiratory Epidemiology Program of the Harvard School of Public Health, and a principal author of the Harvard Six City Study stated this conclusion clearly in an unsolicited letter to EPA Administrator Lee M. Thomas dated August 27, 1987:

> Throughout my forty years of studying the associations between air pollution and public health, which includes my personal involvement and observations of our Harvard Air Pollution Respiratory Health study (Six-City Study), and numerous epidemiological studies reported by a number of excellent investigators, it appears that the fine particle fraction and its reactive constituents comprise the source of potential adverse effects of particulate matter. The fine fraction may include carcinogenic agents, toxic trace metals, and other organic and acidic components associated with combustion processes.
>
> * * *
>
> EPA's fugitive dust policy traditionally reflected the fact that standards for particulate matter were routinely exceeded by coarse particle fugitive dust from natural sources, agriculture, unpaved roads, mining, construction, and other sources, especially in the arid areas of the western U.S.A. **This fugitive dust at the levels measured in ambient air in the western and other parts of the United States over the years has never been documented to have had adverse effects on human health.** We began to realize this from research on particle deposition and clearance, showing that coarse insoluble particles deposited primarily in the upper airways while the fine soluble

> particles deposited primarily in the intrathoracic region. **Toxicological work in animals and clinical studies on humans further support the conclusion that fugitive dust at ambient concentrations poses little risk of adverse health effects to the public.** (Emphasis added).

Chatten C. Cowherd of the Midwest Research Institute, who has spent much of a distinguished scientific career in the study and characterization of PM, and authored much of EPA's work on fugitive dust, stated much the same opinion:

> Fugitive dust emissions, whether from mining, agriculture, or unpaved public roads, consist largely of coarse particles which settle out of the atmosphere close to the source. These particles do not account for any known adverse effects to health or welfare other than localized nuisance problems usually associated with periods of dry, windy weather.

Dale A. Lundgren, an eminent professor, scientist and industrial hygienist, who often advises EPA on PM issues, concluded, after a thorough review, that "coarse particles are not of significant health effect at levels found in the ambient air. . ."

Professor David L. Swift of Johns Hopkins University School of Public Health, one of the country's leading authorities on PM for more than 20 years, also conducted a comprehensive review and weighing of all of the scientific evidence in 1996. He concluded:

> It is concluded that the regulation of CF [coarse fraction] at ambient levels discussed in the SP [EPA Staff Paper] and preamble [to the EPA proposal to revise the PM standard] do not provide any substantial health benefit. By definition, CF is composed primarily of particles which are formed by mechanical processes from larger particles or bulk material. **Such crustal particles, because of their lack of health effects at ambient levels well above the proposed standard,** should be excluded from any PM standard.

We submit that this substantial body of medical and public health expert opinion, as well as the rationale and basis of EPA's practice for more than three decades excluding fugitive coarse PM from PM standard determinations, should be accorded substantial weight.

Members of CASAC and the PM Review Panel have, during the course of CASAC's review, expressed views consonant with those quoted above. Dr. James Crapo of CASAC noted:

> The coarse mode particles are substantially different particulates with regard to their formation, characteristics, and distribution. It is likely that they are substantially different in health effects and there appears to be regional differences in these particles that may have direct impacts on health risk.

Exhibit L at B-5. Dr. Crapo also noted: "It is possible that the adverse health effects of PM_{10} reflect only the $PM_{2.5}$ effects and that the coarse mode particles add little to health risk." Id. *See also* the individual Comments of Dr. Sverre Vedal, EPA-HQ-OAR-2001-0017-0245 at B-41(because of concerns with the underlying health studies, Dr. Vedal concluded, "It is my opinion that proposing a coarse PM standard is premature at this time.")

EPA's proposal to exclude fugitive coarse PM from agricultural and mining sources is, accordingly, well supported by the weight of the scientific evidence and the expert review of that evidence.

XI. Treatment of Fugitive, Coarse Particulate Matter Generated by Agricultural and Mining Sources.

As described in detail above, fugitive coarse PM has historically been excluded from compliance with the PM NAAQS in attainment determinations, under (1) the "fugitive dust exemption," (2) the requirements of section 302(j) with respect to including such dusts in the regulation of major sources in the New Source Review program, (3) the rural fugitive dust policy for enforcement purposes, (4) the "natural" or "exceptional" events policies of federal and state agencies, (5) determinations of federal and state agencies that such PM emissions were not "reasonably quantifiable" and could not be reasonably modeled to predict whether emissions meet the PM NAAQS or PSD increments, and (6) numerous administrative practices following Congressional recognition of the need for "administrative good sense" in not including such fugitive coarse PM in ambient determinations. Taken together, this history establishes that the PM NAAQS have, since their inception, recognized the special circumstances presented by fugitive, coarse PM, and have not included it in ambient determinations. As also discussed above, that status was based on the recognition that fugitive coarse PM does not present substantial health or welfare concerns at ambient levels.

As also recounted elsewhere, there has never been a valid coarse PM standard, nor a valid coarse PM indicator. This proposal of a coarse PM standard responds to the coarse PM_{10} standard vacated and remanded by the court in the *American Trucking Assn.* case. It proposes a new concept for a coarse PM indicator as follows:

> The standard for $PM_{10-2.5}$ includes any ambient mix of $PM_{10-2.5}$ that is dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and excludes any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. Agricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting this standard.

Proposed 40 C.F.R. 50.13(a)(2)(B)(ii), 71 Fed. Reg. 2698-99 (Jan. 17, 2006).

In its discussion of this indicator, EPA states that it is not geographically defined nor geographically limited:

> In short, **the indicator is not defined by nor limited to any specific geographic area**, but includes the mix of $PM_{10-2.5}$ in any location that is dominated by these sources.

Id. at 2668, col. 1. EPA continues:

> With the indicator as defined above, each area in the country would fall into one or the other of these two categories; (1) Either the majority of the ambient mix of $PM_{10-2.5}$ in an area is resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction source, or (2) the majority of the ambient mix is **rural** windblown dust **and** soils and PM generated by agricultural and mining sources.

Id.(emphasis added) This latter passage may create some confusion if the word "rural" is taken to modify and characterize the clause "soils and PM generated by agricultural and mining activities," especially if the "and" is read to be conjunctive rather than disjunctive. We do not believe that interpretation was either intended, reasonable, or consistent with the discussion of EPA's intention or the evidence. We, nonetheless, request clarification to assure that the language stating that the indicator is not geographically defined or limited extends to urban as well as rural ambient mixes of fugitive coarse PM from agricultural or mining sources, and suggest amendatory language to accomplish that clarification below.

We also request that the language of the final rule specifically include crustal material from urban mining activity, such as dust from dirt roads or the handling of sand, gravel and dirt in mining and reclamation at gravel pits or

quarries in urban areas, that are composed of ambient mixes that are majority crustal, mining, or windblown material. This suggestion is, we submit, completely consistent with EPA's determination that "the proposed language reflects that the information supporting the proposed standard for thoracic coarse particles does not support extending controls to thoracic coarse particles from agricultural, mining sources, and other similar sources of crustal material." *Id.*

Likewise, this suggestion is firmly based on the scientific evidence, as characterized by EPA:

> Beyond the urban and rural distinction discussed above, the Staff Paper also considers the extent to which there is evidence of effects with exposure to the ambient thoracic coarse particles in communities predominately influenced by agricultural or mining sources. For example, in the last review, EPA considered health evidence related to long-term silica exposures from mining activities, but found that there was a lack of evidence that such emissions contribute to effects linked with ambient PM exposures (EPA, 1996b, p. V-28). Similarly in this review, there is an absence of evidence related to such community exposures. While crustal and organic dusts generated from agricultural activity can include a variety of biological materials and some occupational studies discussed in the Criteria Document report effects at occupational exposure levels (EPA, 2004, Table 7B-3, p. 7B-11), such studies do not provide relevant evidence for effects at much lower levels of community exposures. Further it is unlikely that such sources contribute to the effects that have been observed in the recent urban epidemiologic studies.

Id. at 2666.

While we think that EPA's intention and the evidence on which it is based are generally clear ("beyond the urban and rural distinction"), several other passages seem to draw a distinction between urban and rural areas, without qualification. For instance, the preamble states in another passage that "the Staff Paper concludes that it is not appropriate to generalize the available evidence of association with health effects that have been related to thoracic coarse particles generally found in urban areas and apply it to the mix of particles typically found in non-urban or rural areas [citation omitted]" and often refers to protection of public health "against effects that have been linked with the mix of thoracic particles generally present in urban areas." *Id.* at 2666-67.

In order to remove any confusion, we suggest the following:

1. That the indicator definition in proposed section 50.13(a)(2)(B)(ii) remove the possible ambiguities discussed above by amending it to read as follows:

> "The standard for $PM_{10-2.5}$ (1) includes any ambient mix of $PM_{10-2.5}$ that is dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and (2) excludes any ambient mix of $PM_{10-2.5}$ that is dominated by (a) rural windblown dust, (b) crustal materials, and/or (c) soils and PM generated by agricultural and mining sources. Soils and fugitive coarse PM generated by agricultural sources and mining sources shall not be subject to control in meeting the standard."

2. That the preamble language clarify the scope of what is meant by mining sources and agricultural sources, and make clear that the indicator excludes their majority ambient mixes in both rural and urban areas. While a footnote states that "[m]ining sources are intended to include all activities that encompass extraction and/or mechanical handling of natural geologic crustal materials," *Id.* at 2666, fn. 66, we suggest the following definition for mining sources:

> "Mining sources" as used in this regulation refers to all activities ordinarily and customarily conducted in and around mining operations that involve the removal of overburden, and the extraction and/or beneficiation of ore or materials from the earth, or its transportation, movement or storage at such operations."

XII. EPA Correctly Determined that there was Not an Adequate Basis to Set a Distinct Secondary PM Coarse Standard

On March 21, 2006, CASAC sent a letter to EPA recommending, *inter alia,* that a secondary $PM_{10-2.5}$ standard be set at the same level as the proposed primary $PM_{10-2.5}$ standard to protect against various irritant, soiling and nuisance welfare and environmental effects of coarse particles. The letter also recommends that the secondary standard not be limited to urban areas. The Proposed Rule on PM NAAQS would adopt a secondary $PM_{10-2.5}$ standard that is identical in all respects to the primary $PM_{10-2.5}$ standard, including the indicator. The Proposed Rule indicates that this standard is intended to be consistent with the level of protection afforded by the current PM_{10} standard.

As with the primary PM10-2.5 standard, we believe the evidence does not support a finding that coarse particulate matter causes adverse welfare or environmental effects at levels found in ambient air. Therefore, we submit no secondary standard should be adopted for PM10-2.5. In addition, however, even if one were to assume that a need for a secondary standard had been demonstrated we submit that, consistent with what has been proposed, CASAC's belated suggestion to apply such a standard to urban areas is without significant support in the record; that there has been no sufficient opportunity or process for EPA staff or anyone else to evaluate such a suggestion; and that even if the evidence showed a need for a secondary standard of some sort, such a standard should parallel the primary PM10-2.5 standard in all respects.

While the Criteria Document and Staff Paper discuss evidence of welfare effects from PM, the Staff Paper concludes that significant gaps in data preclude establishing a distinct secondary standard for any particular size or concentration of particulate matter at this time, based on effects on vegetation and ecosystems, materials or climate and radiative processes. Nonetheless, the Staff Paper recommends consideration of a secondary standard either at the level of the current secondary PM standards (equivalent to the primary $PM_{2.5}$ and PM_{10} standards), or standards from the range of recommended revisions to the primary $PM_{2.5}$ and $PM_{10\text{-}2.5}$ standards. However, a secondary $PM_{10\text{-}2.5}$ standard that does not distinguish between crustal and non-crustal dominated areas establishes a standard beyond the protection of the suite of primary PM standards, which the Staff Paper concluded was not warranted by available information.

While CASAC's March 26 letter states that its September 12 letter recommended a secondary $PM_{10\text{-}2.5}$ standard be set at the same level as the primary $PM_{10\text{-}2.5}$ level, in fact, the September letter merely observed that several members thought that the secondary standard should be expanded to include rural areas:

> Finally, some members of the Panel recommended that a secondary $PM_{10\text{-}2.5}$ standard be set at the same level as used for the (primary) $UPM_{10\text{-}2.5}$ standard. The geographical applicability of this secondary standard should not necessarily be constrained only to urban areas, as the irritant, nuisance soiling, materials damage and ecological effects of coarse particles are not uniquely related to urban contaminants.

September 12 Letter at 5. However, the CASAC recommendation in the September 12 letter did not include a recommendation to set a secondary standard applicable in rural areas. Moreover, a nationwide secondary $PM_{10\text{-}2.5}$ standard is inconsistent with the Staff Paper's conclusion that there is

insufficient evidence to support a distinct secondary standard beyond the protection afforded by the suite of primary PM standards.

Nor does the March 21 CASAC letter point to any specific evidence in the Criteria Document or Staff Paper (as opposed to a general argument about backsliding) that would support a distinct secondary $PM_{10-2.5}$ standard broader than the proposed primary standard.

In contrast, the Proposed Rule appears to read the two prongs of the Staff Paper recommendations as being consistent. The Proposed Rule adopts secondary standards equivalent to the proposed suite of primary PM standards, and concludes that this level of protection is equivalent to the protection of the current secondary PM_{10}standard. In reaching this conclusion, the Proposed Rule recognizes the additional protection afforded by the secondary $PM_{2.5}$ standard for visibility effects and other national and regional programs aimed at addressing vegetation and ecosystem effects.

In the Proposed Rule, the Administrator provisionally concludes that available evidence does not provide a sufficient basis for establishing distinct secondary standards for PM based on potential adverse effects on vegetation and ecosystems, materials or climate and radiative processes. 71 Fed. Reg. at 2681. Instead, the Administrator proposes to revise current secondary $PM_{2.5}$ and PM_{10} standards to address ecosystem and vegetation, materials and climate effects by making them identical to the proposed suite of primary $PM_{2.5}$ and $PM_{10-2.5}$ standards in all respects. 71 Fed. Reg. at 2685. The Administrator believes this would afford at least the degree of protection afforded by current secondary standards, reasoning that the proposed $PM_{10-2.5}$ standard is intended to provide protection equivalent to the current PM_{10} standard in the areas where it applies—typically more densely populated areas where materials damage would be of greater concern. *Id.* Furthermore, the proposed standard is considered in conjunction with protection afforded by other programs intended to address air pollution effects on ecosystems and vegetation, such as the Acid Deposition Program and other regional approaches to reducing pollutants linked to nitrate or acidic deposition. *Id.*

XIII. EPA's Proposed Rule to Implement Fine PM NAAQS Includes Crustal and Other Coarse PM Dusts That Should Be Excluded From $PM_{2.5}$.

A. Background

It has long been recognized that particulate matter falls into a "bi-modal" distribution of coarse particulate matter ("coarse PM") and fine particulate matter ("fine PM"). Fine PM generally has a particle diameter less than 1 µm, while coarse PM typically has a particle diameter greater than 3 µm. However, there is some overlap between fine and coarse PM in the "intermodal" range from about 1 to 3 µm.

Fine and coarse PM vary not only in particle size, but also in chemistry, source and formation:

> The distinction between 'fine particles' and 'coarse particles' is a fundamental one. There is now an overwhelming amount of evidence that not only are two modes in the mass or volume distribution usually observed, but that these fine and coarse modes are usually chemically quite different.

CD (2004) at 2-7 (quoting Whitby (1978)). Thus, while "[m]odes are defined primarily in terms of their formation mechanisms," they "also differ in sources, composition, transport and fate, as well as size." CD (2004) at 2-14. Fine particles are formed primarily by combustion or chemical reactions of gases, and composed of metals and metal oxides, black or elemental carbon, primary and secondary organic compounds, and sulfate, nitrate, ammonium and hydrogen ions. CD (2004) at 2-15. In contrast, coarse particles are formed by the mechanical breakdown of minerals, crustal material and organic debris. *Id.* (See also EPA 1996 PM Criteria Document: "Coarse particles are generated by mechanical processes and consist of soil dust, fly ash, sea spray, plant fragments, particles from tire wear, and emissions from rock-crushing operations. These particles are removed primarily by impaction and settling." (p. 3-6).

Within the intermodal range, the chemical composition of individual particles can usually (though not always) be used to identify the source or formation mechanism, and thereby identify a particle as fine PM or coarse PM. *See* CD (2004) at 2-15. Nonetheless, in 1997 EPA adopted the $PM_{2.5}$ standard, a purely size-based criterion, for separating fine and coarse particles. $PM_{2.5}$ particle size is defined by "size-selective sampling." In other words, the standard refers to particles collected by a sampling device which collects 50% of particles with a diameter of 2.5 μm, and rejects 50% of such particles. CD (2004) at 2-17. (The device must also accept or reject specified percentages of other diameter particles, as specified in federal regulations. *Id.*)

Although compelling arguments—including some from EPA's own scientists—supported selecting 1 μm as the "cut point" or "indicator" for fine PM, EPA chose to use the $PM_{2.5}$ standard, recognizing that it is over-inclusive of coarse PM. Among the considerations that led EPA to choose the 2.5 μm cut point was the fact that limited data on the concentration and composition of intermodal PM mass was available. CD (2004) at 2-25.

B. EPA Should Adopt a Mechanism In Its Proposed PM Fine Implementation Rule For Exclusion of Coarse PM Before Making Nonattainment Determinations.

EPA's Proposed Rule to Implement the Fine Particle National Ambient Air Quality Standards, 70 FR 65984 (Nov. 1, 2005) ("Proposed Implementation Rule"), describes requirements that States and Tribes must meet in their implementation plans for attainment of the $PM_{2.5}$ national ambient air quality standards ("NAAQS"). The Proposed Implementation Rule recognizes that despite overlap in the intermodal particle sizes, fine and coarse PM are generally associated with distinctly different sources and formation processes. 70 FR 65922. Despite this recognition, the Proposed Implementation Rule lists a broad range of constituents for fine particles, including "Sulfate (SO_4); nitrate (NO_3); ammonium; elemental carbon; a great variety of organic compounds; and inorganic material (**including** metals, **dust**, sea salt, and other trace elements) generally referred to as "crustal" material, although it may contain material from other sources." 70 FR 65988. (Emphasis added.) It seems clear that EPA is proposing to treat coarse PM dusts such as crustal material as fine PM, and to include it deliberately in fine PM implementation, thus treating it as equivalent to fine PM. We respectfully submit that such inclusion will undermine and confound the PM fine standard by including coarse PM that is without substantial health or welfare effects, and will likewise misdirect control efforts. NMA urges EPA to provide a mechanism for excluding coarse PM from fine $PM_{2.5}$ before making $PM_{2.5}$ nonattainment designations.

Without such a refinement, the $PM_{2.5}$ indicator is likely to impose significant burdens on rural communities, particularly those in the arid western United States that are home to agricultural and mining activities. The Proposed Implementation Rule anticipates most non-attainment areas will be located in the eastern United States and California, and therefore focuses on those regions. 70 FR 65993. In doing so, it disregards the consequences for agricultural activities, including feedlots and ranching, if western and rural communities are determined to be in nonattainment of the $PM_{2.5}$ NAAQS, as a result of the coarse PM contribution captured by the $PM_{2.5}$ indicator. (*See* Pinal County, Arizona study summarized below.)

Table 2 in the Proposed Implementation Rule, 70 FR 65993, shows differences in the composition of $PM_{2.5}$ between urban and rural areas, as well as across various regions of the United States. Notably, crustal material consistently comprises a larger component of $PM_{2.5}$ in rural areas, and in the Desert West, South, East Texas and Northern Plains. Because the mechanical processes associated with coarse PM formation rarely produce particles with diameter less than 1 µm, it is likely that these elevated levels of crustal material in fact represent coarse particles in the intermodal range, which are captured by the over-inclusive $PM_{2.5}$ indicator.

Shortcomings of applying the $PM_{2.5}$ indicator without further refinement through the Proposed Implementation Rule are further illuminated by considering EPA's Proposed Rule on National Ambient Air Quality Standards for Particulate Matter, 71 FR 2620 (Jan. 17, 2006) ("Proposed PM NAAQS Rule"). The Proposed PM NAAQS Rule concedes that "within the intermodal range of 1 to 3 μm there is no unambiguous definition of an appropriate size cut for the separation of the overlapping fine and coarse particle modes." 71 FR 2645. Once again, however, it is asserted that certain policy considerations support the selection of the $PM_{2.5}$. In particular, a regulatory determination that it is more important to capture fine particles more completely under a range of conditions and across the United States, than to avoid coarse-mode intrusion into the fine fraction in some areas. *Id.*

Several flawed assumptions underlie this reasoning. First, it posits a false dilemma that the fine PM definition must be either under-inclusive of the fine mode or over-inclusive of the coarse mode. EPA has an opportunity in the Proposed Implementation Rule, and these proposed revisions to the NAAQS, to retain the $PM_{2.5}$ indicator, while supplementing it with a mechanism to eliminate coarse PM prior to making nonattainment determinations.

At the time the $PM_{2.5}$ indicator was adopted in 1997, little information on the composition of intermodal mass was available, but it was assumed that there was only a small amount of coarse PM intrusion that would be captured in the fine PM measurements. *See, e.g.,* CD (2004) at 2-25, 71 FR 2644. However, more recent information establishes that is such is not the case. The Proposed PM NAAQS Rule recognizes that while there is generally little mass in the intermodal range, in certain circumstances, such as dry, dusty areas, there will be increased coarse intrusion into the intermodal range. 71 FR 2645. This increased coarse PM mass in the intermodal range will be captured by the $PM_{2.5}$ indicator, and without further refinement of the indicator or provision for exclusions from it in implementation, will lead to nonattainment determinations—particularly in western and rural communities—on the basis of coarse PM, which has never been demonstrated to be harmful at ambient concentrations.

The problem is vividly illustrated by the results of an EPA-funded study conducted in Pinal County, Arizona, published in July 2005, "Pinal County Air Quality Control District Source Apportionment Study" Prepared by Pinal County Air Quality Staff (July 29,2005)("Pinal County Study" hereafter, attached to NCBA's comments on the Fine PM Implementation Rule as Exhibit A and incorporated herein, Docket ID No. OAR-2003-0062). The Pinal County Air Quality Control District conducted a source apportionment study to identify sources of elevated particulate matter in an agricultural basin in the heart of the Sonoran Desert, typifying the sort of arid western rural areas that will face the most severe consequences if agricultural or mining activities must be curtailed due to $PM_{2.5}$ nonattainment resulting from high levels of crustal and other coarse PM intrusion. The study gathered data at

a range of sites including downtown and residential locations, as well as areas surrounded by agricultural uses, feedlots and desert environments.

At four of the five locations, geologic soil[7] was, on average, the largest contributor to the $PM_{2.5}$ mass, comprising between 40 and 50%. Pinal County Study at pp. 29, 32, 37 and 40. At the location nearest the feedlot, soil chemically identified as being from the feedlot represented 49% of the average and geologic soil another 24%. *Id.* at 34. These findings suggest that without an implementation mechanism that isolates crustal and other coarse PM material from fine PM, rural communities engaged in agriculture and mining will, like feedlots, almost certainly face significant nonattainment problems under the $PM_{2.5}$ standard. Indeed, the Pinal County Study included one sample from the feedlot site where the measured $PM_{2.5}$ contained 79.8% feedlot dust and 16.2% soil dust, for a total of 96% coarse PM, and the concentration was 183.3 $\mu g/m^3$ – nearly three time the existing primary, 24-hour health standard for fine PM, and more than 5 times the proposed 24-hour primary, health standard for $PM_{2.5}$, namely 35 µg/m3. Pinal County Study at p. 64. During a single month, the Pinal County study measured $PM_{2.5}$ above the proposed $PM_{2.5}$ standard on six days when coarse PM exceeded 68.2% of the fine $PM_{2.5}$, and averaged 78.3% of the $PM_{2.5}$. *Id.*

The Proposed PM NAAQS Rule also provisionally concludes that current studies do not provide a sufficient basis for eliminating any individual component from the fine PM standard. At the same time, however, the Proposed PM NAAQS Rule establishes a new indicator for thoracic coarse particles $PM_{10-2.5}$, which excludes any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. 71 FR 2627. The Proposed PM NAAQS Rule also notes in its discussion of $PM_{10-2.5}$ that certain classes of ambient particles, such as particles of crustal origin, "are relatively non-toxic under most circumstances, compared to combustion related particles," 71 FR 2666 (citing 2004 CD), and that in light of limited evidence, "it is not appropriate to generalize the available evidence of associations with health effects that have been related to thoracic coarse particles generally found in urban areas and apply it to the mix of particles typically found in non-urban or rural areas." 71 FR 2667 (citing 2005 Staff Paper). Thus, given the lack of substantial health or welfare effects from crustal and other coarse PM, and PM found in rural areas, an exception similar to that provided for rural soils and dust generated by agricultural and mining sources under the $PM_{10-2.5}$ standard is likewise appropriate to eliminate coarse intrusion under the $PM_{2.5}$ indicator.

As noted above, in this rulemaking and in the Proposed Implementation Rule EPA has the opportunity to retain the $PM_{2.5}$ indicator, while supplementing it

[7] The study was unable to distinguish between soil from unpaved roads and from agricultural activities, and combined these two sources in the "geologic soil" category. In contrast, soil from feedlots had distinctive chemical markers.

with a mechanism to eliminate coarse PM prior to making nonattainment determinations. Dr. Dale A. Lundgren developed one such methodology for excluding coarse particle intrusion from $PM_{2.5}$ measurements in 1996. Dr. Lundgren's technique, described more fully in the comments and papers attached to NCBA's comments on the Fine PM Implementation Rule as Exhibit B and incorporated herein (Docket ID No. OAR-2003-0062), provides a specific, practical methodology to estimate intrusion of coarse PM into the $PM_{2.5}$ region using only a PM_{10} and $PM_{2.5}$ measurements. Dr. Lundgren has previously proposed that this procedure be incorporated into EPA regulations in order to overcome the cross-contamination and distortion that otherwise occurs when $PM_{2.5}$ is used as the indicator for fine PM. (See March 12, 1997 Comments of the National Mining Association on Proposed Changes to Federal Reference Method for $PM_{2.5}$, included in the materials in Exhibit B.)

XIV. Denial of Right to Notice and Comment.

By letter dated March 24, 2006, we requested that EPA keep the comment period open beyond the April 17, 2006 deadline in order to allow review and public comment on the assessment and evaluation of new scientific studies published since the 2002 closing date of the PM Criteria Document, and the "assessment and summary of the key conclusions" from those studies that EPA promised to place in the rulemaking docket in proposing the rule. 71 Fed. Reg. 2625 (January 17, 2006). EPA had not, on that date, placed the materials in the docket, nor has it done so since, to our knowledge. At its hearing on the proposal in Philadelphia, we understand that the Hearing Officer, Mr. John Bachmann, made reference to this important document and urged participants to watch for it, and review it

We contacted Dr. Erika Sasser of EPA on or about March 17, 2006 to determine when this material would be available. She stated that there is a significant amount of material to cover (the preliminary list includes more than 175 new studies), and that it will not be available in the docket for public review and comment until June 1 at the earliest, and possibly mid- to late-June. As a result there has not been a reasonable opportunity to review and comment on, and cannot be such an opportunity to comment on, these materials prior to the April 17, 2006 comment deadline. Thus, the failure of EPA to grant the required reasonable extension of the comment period beyond April 17, 2006 denies us the right to review and comment upon these materials. That denial violates section 553 of the Administrative Procedure Act, section 307(d)(3) of the Clean Air Act, and the requirements of procedural and substantive due process provides by the Fifth Amendment to the U.S. Constitution.

XV. Monitoring Rule

The proposed Federal Reference Method specifies that ambient $PM_{10-2.5}$ concentrations are to be measured by the "difference method," which separately measures $PM_{2.5}$ and PM_{10} at co-located monitors, and identifies

the difference as $PM_{10-2.5}$. The problem is this method is not an accurate way to measure $PM_{10-2.5}$.

In the first place, $PM_{2.5}$ monitors do not just measure particles 2.5 micrometers in diameter and smaller, nor do PM_{10} monitors just measure particles 10 micrometers in diameter and smaller. Both instruments, due to their design, also collect and measure substantial amounts of larger particles. The error inherent in each instrument is compounded when two erroneous measurements are compared.

As a result, it is not uncommon, in areas where the levels of coarse particles are relatively low, for the instruments to produce negative measurements for $PM_{10-2.5}$, meaning that $PM_{2.5}$ is greater than PM_{10}, a result that is of course physically impossible. Mr. Hoffnagle provides measurement results from Salt Lake City monitors that are real-world illustrations of negative (and therefore inherently inaccurate) results. Exhibit G, Table 1. As noted by Mr. Hoffnagle, the magnitude of some of these errors sometimes exceeds the total exposure levels in epidemiological studies, and therefore cannot be disregarded as insignificant.

The proposed rule regarding new NAAQS for particulate matter is accompanied by the proposed rule regarding ambient monitoring for compliance with the proposed NAAQS. NMA has concerns regarding the proposed monitoring rule because the guidance it provides leaves many questions for interpretation by States and thereby presents a risk of varying interpretations from one part of the country to another. The following are some of our concerns:

1. Monitors must be placed at sites dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and must not be dominated by rural windblown dust and solids and PM generated by agricultural and mining sources.

(a)There is no definition of "dominated", nor any description of the process whereby a determination would be made whether a particular site would be dominated by one type of sources or the other. While we recognize that site-specific judgments may be needed to some extent, we are concerned that in its present state the proposed rule provides very little guidance as to how site-specific judgments should be made regarding this particular criterion. It is not clear

(b)The rule does not define what constitutes agricultural or mining sources. Elsewhere in these comments we propose definitions of mining sources for purposes of the NAAQS rule; we propose additionally that the definition we propose also be incorporated into the monitoring rule.

2. Although the rule specifies criteria for which sources are appropriate for measuring compliance with the NAAQS, EPA nonetheless appears to take the view that data from non-required monitors that do not necessarily meet

all criteria might, after two years of operation, be used to determine non-attainment. 71 Fed. Reg. at 2745-46. Because the siting and operation of monitors is very closely tied to the definition of the urban coarse particulate standard, we submit that only the required monitors meeting all criteria should be used to designate nonattainment.

XVI. Conclusion

For all of the reasons discussed above, we submit that there is not a sound or adequate basis for the adoption of a coarse PM standard at this time. We support the alternative of not adopting a coarse PM standard for ambient exposure. There has never been a valid coarse PM in the past, and coarse PM health effects have not been the basis for past controls of fugitive dust. Continued control of fugitive dust is not dependent on the adoption of a coarse PM NAAQS. Our members will continue not only their efforts at dust control, but will continue to support the improvement of those practices. If, however, EPA chooses to implement a coarse PM NAAQS, EPA must exclude coarse PM from agricultural and mining sources. Such exclusion is necessary to remain consistent with the scientific evidence, and the determinations of EPA, Congress and the Courts concerning these sources since the inception of the Clean Air Act.