NATIONAL STONE, SAND & GRAVEL ASSOCIATION

Natural building blocks for quality of life

Ms. Rebecca J. Smith, Acting Director
Office of Standards, Regulations and Variances
Mine Safety & Health Administration
US Department of Labor
1100 Wilson Blvd., Room 2350
Arlington, Virginia 22209-3939

Subject: RIN 1219-AB29 Diesel Particulate Matter

VIA E-MAIL: zzMSHA-comments@dol.gov.
VIA Hand Delivery

Dear Ms. Smith:

The National Stone Sand & Gravel Association (NSSGA) appreciates the opportunity to submit comments to the record regarding the Mine Safety and Health Administration (MSHA) Diesel Particulate Matter (DPM) standard proposed September 7, 2005.

Based near the nation's capital, NSSGA is the world's largest mining association by product volume. Its member companies represent more than 90 percent of the crushed stone and 70 percent of the sand and gravel produced annually in the U.S. and approximately 115,000 working men and women in the aggregates industry. Sale of natural aggregates (crushed stone, sand and gravel) generates nearly 38 billion dollars annually for the U.S. economy. The estimated output of aggregates produced in the first half of 2005 was 1.3 billion metric tons, a 4 percent increase over the same period in 2004 (2.85 b MT). According to the USGS, the significant increases in aggregates production were due to the increase in construction activity, which has increased every year for the past decade. Construction spending amounted to $617.9 billion during the first half of 2005, a 9 percent increase over the same period in 2004.

Aggregates are used in nearly all residential, commercial and industrial building construction and in most public works projects, such as: roads, highways, bridges, railroad beds, dams, airports, water and sewage treatment plants, and tunnels. While the American public pays little attention to these raw natural materials, they go into the manufacture of asphalt, concrete, glass, paper, paint, pharmaceuticals, cosmetics, chewing gum, household cleansers, and many consumer goods. They are used for water treatment at many public utilities.

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The National Stone, Sand & Gravel Association (NSSGA) is committed to safety and health in mines. Safety is, and will continue to be, the number one priority for the aggregates industry. The industry recognizes that its employees are its most valuable asset -- an asset that must be protected for the well being of the industry now and in the future. NSSGA respects the government effort to reduce diesel emissions and has been completely prepared to support any rational program.

Summary

The NSSGA has expressed, since the 2001 diesel particulate matter rulemaking began, a number of important concerns regarding this rule:

- It does not have a sound basis in science regarding health effects.
- The proposed limit of 160 $\mu g/m^3$ total carbon is not supported by the existing data and should be deleted.
- The interim permissible exposure limit of 308 $\mu g/m^3$ elemental carbon should be retained as the final limit.
- There continue to be difficulties with the sampling and analytical method used to determine compliance.
- The issue of total carbon vs. elemental carbon as the standard remains unresolved.
- There is not a well defined relationship between total carbon and elemental carbon on which to determine proper conversion between them should elemental carbon be selected as the final surrogate.
- The September 7, 2005 proposed standard has not satisfied the requirements of the Data Quality Act.
- Feasibility issues, both technical and economic, have not been adequately addressed. Extensions of time without penalty to abate exposures over the limit should be granted to operators demonstrating good faith efforts toward reducing DPM exposures. An appeal process should be incorporated to provide an alternative where legitimate differences exist between the operator and the District Manager.
- Worker rotation as a means to comply, where other administrative or engineering controls are infeasible, should be permitted.
- The multi-year schedule proposed anticipates the more gradual advances in technology that would enable further reductions in the DPM levels. Even so, the interim limit of 308 $\mu g/m^3$ should remain in effect.

NSSGA has previously submitted comments for the record. They are included by reference with these additional comments. Several of NSSGA's comments can be found in the docket at:

RIN 1219-AB29-Comm 28
RIN 1219-AB29-Comm 41 (jointly with MARG and NMA)
RIN 1219-AB29-Comm 49

The present comments will address the important issues included in the above.

Response to MSHA Inquiry

Many members of NSSGA have and will submit comments to the record specifically addressing the proposed rule's effects on their operations and the safety and health of their miners. These comments have addressed the various lines of inquiry raised in MSHA's proposed rulemaking.

- *Would you be able to meet the interim levels of the 5 year phased-in approach after 2007?*

Based on their experiences in implementing controls to reduce exposure to DPM, our members are largely skeptical that they will be able to positively achieve the levels as described in MSHA's proposed 5-year plan. Any phased-in approach would be founded on assumptions that technologies will be developed within the given time frame that will make compliance both technologically an economically feasible for operators. The original draft of this rule was founded on a similar set of assumptions that have proven to be wholly inaccurate. As such, this approach offers only a short-term relief for the industry while disregarding the greater issues associated with the fundamental basis of the rule.

- *Is there any new cost data regarding the use of diesel particulate filters for reaching the 160 ug/m3 limit?*

What many NSSGA members are experiencing is that they do not have any way of establishing the true current costs of diesel particulate filters because, setting aside the direct costs and questionable results related to filter usage, the filters affect equipment in ways that are adverse but cannot be readily quantified. Both short term and long term difficulties have been experienced, and our members do not believe that adequate technology exists to resolve the problems currently. Neither do they have reason to be confident about availability of reliable affordable technology over the next five years.

- *Could you meet the final limit with or without ventilation?*

As previously noted, mining conditions for NSSGA members vary significantly mine to mine. However, a notable characteristic of underground stone mines is their large open spaces (room and pillar mining) that are ventilated naturally. To introduce forced ventilation in mines presently ventilated naturally would entail enormous costs in mine structures that would be needed to direct the ventilation inside the mine. Similarly, mandates for controls could force mines out of business. This, in turn, would result in loss of jobs and loss of economic benefits, including the benefits of having stone available in areas where surface mining is not practical or environmentally feasible.

- *Would the phased-in approach permit you to effectively use alternative fuels as a control measure?*

As a group, NSSGA members have not found alternative fuels to be something that could help them meet a reduced DPM standard. The industry has always been based on operating traditional diesel equipment. Underground stone mines are located where diesel fuel supplies are available. Due to unavailability of alternate fuels, our members do not have sufficient experience as a group to comment on how an attempt to change over to such fuels could be made and there is little confidence that alternative fuels suitable and cost effective for stone mines will be available anytime in the near future.

- *What is your replacement cycle for substituting low emitting engines?*

Many NSSGA members rely on equipment that they have operated successfully and safely for many years. Members have not perceived any adverse health effects from diesel equipment usage. Many factors go into selection of equipment, most importantly its suitability for specific mine functions, its safety and durability, its ease of operation, and its characteristics for protecting against noise and dust exposure. The same is true with respect to selection of replacement engines and parts. The stone industry does not believe that health problems related to DPM below current limits have been proven in stone mines and NSSGA does not believe the burden is on it to demonstrate how soon its members can discard perfectly good and appropriate equipment for other equipment possibly less suited to the work. The cost of equipment replacement to address an alleged health risk that has never been proven, with respect to large open underground stone mines, in the opinion of NSSGA, is not warranted based on any current scientific knowledge.

- *If compliance difficulties exist, is there a problem created by requiring miners to wear respiratory protection until exposures are controlled?*

Miners can wear respiratory protection equipment if mines cannot meet the current limit. However, they should not be forced into continual usage of cumbersome or uncomfortable equipment to meet reduced limits that have not been proven necessary, appropriate or achievable.

- *For mines where respiratory protection would be required for meeting each of the interim limits, should a medical evaluation program for wearing respirators be included in the standard?*

Medical evaluations for use of respiratory equipment are an integral part of current regulations that mandate that such protection be provided in accordance with American National Standards Institute (ANSI) standards, which are incorporated into the regulations by reference. There is no need for further regulation on this issue.

- *Is the proposed phase-in schedule beginning with the 2006 limit technologically feasible?*

NSSGA believes that the phase-in schedule is inappropriate and wholly infeasible and it has no sense that there is reliable help available. The current limit should not be reduced.

Data Quality Act

This new rulemaking opens the record to new and additional information. As such, all of the scientific information relied upon to promulgate a standard for Diesel Particulate Matter for underground mines should be subject to the Data Quality Act. See Attachment # 1 for a complete discussion of this issue.

NSSGA supports sound science as the basis for federal policies, particularly in the areas of health and safety where invalid rules not only threaten the economic survival of its members but can also adversely impact the protection of their workers. Peer review of the science upon which regulators rely is absolutely critical to the advancement of science. That is why prominent medical journals and public health agencies support openness in the scientific process and utilize peer review, and that is why the federal government must follow suit.

Lack of Sound Science for the 160 µg/m^3 TC Standard

The comments previously submitted at RIN 1219-AB-29-COMM 41, containing the study by the highly respected Jonathan Borak, PhD, provide an excellent summary of the state of the science regarding diesel particulate matter. Dr. Borak covers the question regarding lung cancer as well as non-cancer endpoints that may result from exposure to diesel particulate matter. The question is raised as to whether it is even possible to perform a quantitative risk assessment based on the data available in the literature regarding DPM. Answering the question, Dr. Borak points out that quantitative risk assessment is not possible because there is a general lack of exposure data in the relevant epidemiological studies. No new information has been added to the DPM database to permit meaningful quantitative risk assessment. Dr. Borak's comments go on to point out many other shortcomings of the existing body of literature relevant to DPM for the mining industry.

To help answer this question, NIOSH/CDC initiated a long-term study to evaluate the health effects of DPM in miners. This study is still not completed. A preliminary report of the data by Dr. Gerald Chase concluded that the pattern of lung cancer deaths showed no increased risk compared to populations of the same demographics whether the reference populations were from the entire U.S. or the states or counties where the study was conducted.

Any decision regarding the effects of DPM and subsequent permissible exposure limit should await completion and analysis of this study. It will provide the most definitive data to date regarding health effects of DPM to miners.

Interim Exposure Limit of 308 µg/m^3 EC

The interim limit should become the final permissible exposure limit. The body of scientific literature does not support even this number, but as it has already been agreed to in a previous settlement agreement, it should be retained as the final limit rather than another lower limit based on an inadequate database for DPM quantitative risk assessment.

As noted elsewhere in these comments, the technology for reaching lower levels is not available or is infeasible. This is especially true for the smaller companies of the aggregates industry-a significant portion of the total underground aggregate mining community.

Sampling and Analytical Issues

There continue to be significant concerns about the measurement of DPM. Specifically, the lack of accuracy and precision prevent an adequate assessment of DPM for both compliance purposes and performing quantitative risk assessment. The paper "Exposure of Miners to Diesel Exhaust Particulates in Underground Nonmetal Mines"[1] provides the results of a study containing over 800 samples from 7 nonmetal underground mines including one limestone mine. This study concluded that using Total Carbon as a way to estimate exposure to DPM in underground mines was inappropriate.

Elemental Carbon (EC) provides an improved sampling and analytical method over Total Carbon (TC) even though there is no direct relationship between lung cancer and elemental carbon. NIOSH has undertaken a study to evaluate the conversion factor appropriate to move from TC to EC. Their work has not been published at this time, but in response to a question on the accuracy below the 308 $\mu g/m^3$ interim limit at a recent meeting of the Kentucky Crushed Stone Association, NIOSH researchers indicated that the variability increased with lower measured exposures.

This lack of accuracy and precision at lower levels suggests that the interim 308 $\mu g/m^3$ EC should be maintained as the final permissible exposure limit.

Total Carbon versus Elemental Carbon

Neither Total Carbon (TC) nor Elemental Carbon (EC) themselves are linked to lung cancer related to DPM. As Dr. Borak suggests in his previous comments, "...if DPM can cause human lung cancer, it is probably due to exposure to certain specific organic components. Most studies have not measured the organic fraction (organic carbon or OC) of DPM and none have attempted to measure the potential specific carcinogens." The data show that TC and EC are poor predictors of OC, thus making for large uncertainties in the exposure assessments needed to sustain a quantitative risk assessment. Dr. Borak puts this more directly: *"...historical studies have used the wrong exposure metric for predicting lung cancer risks."*

The NSSGA remains of the opinion that the risk of lung cancer is not supported by the available data. Neither TC nor EC are good surrogates for assessing exposure of miners to DPM risks and the lack of adequate exposure measurements prevents quantitative risk assessment. Further, as discussed elsewhere, there remain sampling and analytical difficulties that prevent adequate exposure measurement.

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[1] Cohen, HJ, Borak, J, Hall, T, Sirianni, G, Chemerynski, S,; *Exposure of Miners to Diesel Exhaust Particulates in Underground Nonmetal Mines*; AIHA Journal 63:651-658 (2002)

Feasibility Issues

Since the 2001 rulemaking, many limitations as to the feasibility of compliance with the final limit have been identified which continue to the present – not the least of which is the lack of "practical mine worthy filter technology," which, as MSHA acknowledged in its most recent rulemaking, is a key factor in the industry's inability to comply with the final limit. In its proposed rulemaking on September 7, 2005, MSHA acknowledged that the industry "is encountering economic and technological feasibility issues" as it strives to reduce levels below the interim limit. As stated in the Preamble: "The applications, engineering and related technological implementation issues that we believed would have been easily solved by now are more complex and extensive that previously thought."

NSSGA member companies have submitted comments to MSHA on their experience with control measures. Control technologies considered included alternative fuels (e.g. low sulfur, biodiesel), improved mine ventilation, new equipment acquisitions, engine replacement and maintenance procedures. These practical comments should carry considerable weight with respect to technological feasibility and the economic impact of various technologies that have been tried.

With respect to diesel particulate filters (DPF), they would be a last resort due to the complications of use that could have adverse effects on the engine performance. It has also been shown that diesel particulate filters generate other potentially harmful emissions such as nitrogen dioxide. DPF use may also have negative economic impacts on underground mining operations. The technology may not be easily retrofitted to existing equipment and require expensive alterations. The use and maintenance may increase the costs of mining operations especially if the filters require frequent change out and/or regeneration.

Biodiesel, one alternative fuel, has been widely touted as an effective solution to DPM emissions and exposures in mining conditions. It has been shown to be effective at reducing DPM emissions in some situations. Unfortunately, there are presently supply problems in many parts of the country making its viability as an option limited in scope. Seasonal usability during the cold months may preclude its use under many conditions even if it were available. There may be adverse effects on engine performance and maintenance that need careful consideration before selecting biodiesel as an alternative technology. Biodiesel is significantly more expensive and may have an adverse economic if the current tax credit is no longer available.

Environmental cabs are effective. However, they can not be retrofitted to all mining equipment. Further, there are some jobs in underground mines where miners work outside of equipment and cabs would provide them no protection.

In the real world of underground mining, it will likely take a combination of control technologies to maintain exposures below the current interim level of 308 $\mu g/m^3$. This may involve considerable experimentation by individual mines because of the highly varied combination of equipment, ventilation design and mining operations. In fact, the mining environment is constantly changing resulting in high variability in the effectiveness of the controls selected.

The use of alternative or low sulfur fuel, solid maintenance practices, new equipment, operator training, mine ventilation and experimental fuel catalyst systems do not provide enough control to ensure that miners will never be exposed to DPM levels above 160 $\mu g/m^3$ TC. Without any evidence that they will create a healthier environment for the miners, it is hard to accept all those tangible negatives in pursuit of an unproven promise of protection.

Special Extensions

Given the substantial difficulty mine operators will have with compliance given the lack of available, feasible controls, the special extension procedure is critical. Consequently, in addition to (or as appropriate in lieu of) the provisions for special extensions in the rule already, the following provisions should be included:

- Special extensions should be available for the entire mine for those circumstances in which a mine, as a whole, cannot achieve compliance through implementation of available, feasible controls.

- The rule should require the District Manager to issue a written decision on special extension applications within 60 days of receipt of the application. As currently written there is no specified limitation on how long the District Manager may take to make a determination. Given how long the application process may take, even with the 60 day decision making deadline, and the operator's need for a determination within a reasonable time, the rule should provide some certainty to operators as to when they will have a decision from the district office. Sixty days should be more than adequate for the district office to make a determination on the application.

- In the interest of due process, the District Manager should be required by the rule to specify in detail in writing to the operator the bases for the District Manager's determination on the application.

- Again, in the interest of due process, the rule should provide the operator with the opportunity to appeal the District Manager's decision to the Administrator of Metal/Nonmetal and to file such an appeal in the event the District Manager does not issue a timely decision on the application. The time for appeal should be set in the rule such that the operator will have 15 days of receipt of the District Manager's decision to file an appeal. In the event the District Manager does not issue a timely decision, the rule should provide the operator with 75 days of the date the application was received by the District Office in which to file its appeal with the Administrator. The rule should provide that the operator's notice of appeal shall consist of a short statement by the operator of the reasons for the appeal. Upon filing of an appeal, the District Manager should be required to forward the application and the District Manager's decision to the Administrator for review in the appeal.

- The Administrator should be required by the rule to issue a final decision for the agency within 30 days of receipt of the appeal.

- Special extensions should not be limited to only one year in length. Under the current rule, operators may obtain multiple one-year extensions, but must file a completely new application each year in order to obtain another one-year extension. This process is unduly burdensome for the operator, and presumably would be for the agency as well. NSSGA, therefore, believes that it would be a better use of everyone's resources, industry, labor and government alike, if the regulation provided for a special extension of whatever length would be appropriate based on the application submitted, with provision for an annual review of the extension where it is to last for more than one year. The annual review could consist of a much shorter submission by the operator informing the agency as to whether any of the circumstances forming the basis for the extension have changed since the extension was granted or the last annual review was completed.

Respiratory Protection

To reduce the possibility that miners may be required unnecessarily to wear respiratory protection, the rule should provide for MSHA to resample a miner's exposure if the operator takes action to abate a violation for overexposure within 5 days of notification of the violation. If the resampling shows no overexposure, the miner would not be required to wear respiratory protection.

To reduce the amount of time that any given miner must wear respiratory protection, in the event exposure cannot be reduced below the effective limit, the standard should provide that the mine operator may assign other miners who shall wear respiratory protection to work in the affected area.

Rotation of miners as an administrative control to reduce exposures and therefore achieve compliance with the exposure limit, without having to require miners to wear respiratory protection, should be permitted in circumstances where there are no other administrative or engineering controls that would be feasible.

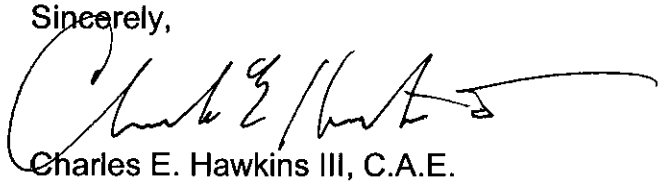
Replacement Engines

NSSGA members expect that there will be circumstances in which a replacement engine will have to be installed in existing diesel equipment in an underground mine. In order to accommodate this, the rule should provide that an operator may install a replacement engine of the same type into existing diesel equipment where the affected occupations are within compliance with the applicable DPM PEL.

Conclusion

Thank you for the opportunity to make the concerns of the NSSGA known to MSHA during this comment period. We look forward to a satisfactory resolution to these issues during the standard setting process.

Sincerely,



Charles E. Hawkins III, C.A.E.
Executive Vice President & Chief Operating Officer

Received 2/16/06
MSHA/OSRV

Data Quality and Peer Review Considerations

In 1980, Congress enacted the Paperwork Reduction Act (PRA) based on the federal government's growing demand for data from small businesses, individuals and other governmental entities. 44 U.S.C. §3501. In 2000, Congress adopted the Data Quality Act (DQA) [1], to amend the PRA and help ensure that information disseminated by the federal government satisfied certain quality standards. The Office of Management and Budget established procedures to establish DQA criteria and to guide agency implementation of the law.[2] The DQA procedures apply to all agencies that are subject to the PRA; thus, MSHA is among the covered governmental entities.

The DQA guidelines apply to a wide array of government information dissemination activities, including the promulgation of rules such as the DPM proposal under consideration by MSHA. Covered "information" includes "any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. [3] Inherent in the "Quality" concept are data utility, objectivity and integrity. Specifically, with regard to "objectivity," OMB established that:

a) The information must be presented in the proper context and the agency must identify sources along with supporting data or models so the public can assess for itself whether there is reason to question the objectivity of the sources;
b) The substance of the information disseminated must be accurate, reliable and unbiased;
c) The agency must provide full, accurate and transparent documentation concerning the information;
d) Sound statistical research methods must be used to generate original and supporting data and to develop analytical results; and
e) Information that meets OMB's definition of "influential scientific information" must also be reproducible to demonstrate its objectivity, because such data have a substantial impact on public policies and important private sector decisions.[4]

Under the DQA, an agency is directed, 'to the degree that an Agency action is based on science,' to use '(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods

[1] Public Law 106-554 section 515; 42 U.S.C. 300g-1(b)(3)(A). This law is alternatively referred to as the "Information Quality Act" but will be referred to in these comments as the DQA.
[2] See *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies*, 67 Fed. Reg. 8452 (February 22, 2002).
[3] 67 Fed. Reg. at 8460.
[4] 67 Fed. Reg. at 8459-60.

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(if the reliability of the method and the nature of the decision justifies use of the data).'" (emphasis added)

The Department of Labor's guidelines implementing the DQA requirements were promulgated on October 1, 2002 (67 Fed. Reg. 61669). OMB subsequently issued the *Final Information Quality Bulletin for Peer Review*,[5] which stated that the peer review requirements were applicable to agency action and information disseminated after June 16, 2005. The Bulletin established that important scientific information must be peer reviewed by qualified specialists before it is disseminated by the Federal government. The Bulletin applies stricter minimum requirements for the peer review of "highly influential scientific assessments" and NSSGA maintains that the information included in MSHA's DPM proposed rule falls within this category and is, therefore, subjected to a heightened level of scrutiny.

Peer review is the process by which experts in a field review and critique studies and papers in an effort to assure the quality of the research. The peer review mandated under the DQA and the OMB Bulletin focuses on verifying the validity of the underlying research upon which agencies rely in making regulatory and policy decisions, or which agencies disseminate as "fact" to the general public through publication in the *Federal Register*, on agency websites, or through other methods of communication. As the General Accounting Office noted when developing the peer review requirements: "[A]ll of the agencies' definitions or descriptions of peer review contained the fundamental concept of a review of technical or scientific merit by individuals with sufficient technical competence and no unresolved conflict of interest." (emphasis added)[6]

In the September 7, 2005, proposal, MSHA states: "We have incorporated into this rulemaking record the previous DPM rulemaking records, including the risk assessment to the January 19, 2001[7] standard." However, there is no mention made of any effort to conform to the requirements of the DQA or the OMB bulletin that was in effect when the September 7th proposal published. However, the OMB Bulletin specifically states:

> If an agency relies on influential scientific information or a highly influential scientific assessment subject to the requirements of this Bulletin in support of a regulatory action, the agency shall include in the administrative record for that action a certification that explains how the agency has complied with the requirements of this Bulletin and the

[5] 70 Fed. Reg. 2664-2677 (January 14, 2005).
[6] See generally, General Accounting Office (GAO), Federal Research: Peer Review Practices at Federal Science Agencies Vary, GAO/RCED-99-99.
[7] *See* 66 FR 5706 (January 19, 2001).

> Information Quality Act. Relevant materials are to be placed in the administrative record.[8]

MSHA has completely ignored these obligations under the DQA, as well as failing to adhere to the related peer review mandates that are now in effect for all Department of Labor rulemaking activities.

As OMB observes: "Peer review should not be confused with public comment and other stakeholder processes. . . . notice-and-comment procedures for agency rulemaking do not provide an adequate substitute for peer review, as some experts – especially those most knowledgeable in a field – may not file public comments with federal agencies." [9]

It is inherently arbitrary, capricious and an abuse of discretion for MSHA to rely upon the non-peer-reviewed 2001 risk assessment and the 2001 rule's purported "scientific evidence" since, as MSHA itself admits, many of the 2001 rule's assumptions concerning both technological and economic feasibility turned out to be flawed.[10] This is the very reason why MSHA subsequently abandoned the use of total carbon as a surrogate for the interim exposure limit in its June 6, 2005, final rule, and has found it necessary to delay the final limit's implementation, opting instead to initiate the instant rulemaking.

The 2001 risk assessment (and the scientific representations in subsequent DPM rulemakings that predated the applicability of the DQA and peer review requirements) relied on a number of published studies as well as on unpublished and/or unreviewed data in making representations concerning both the purported need to this standard as well as on the feasibility issues arising from the interim and final concentration limit (CL) / permissible exposure limits (PELs). [11]

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[8] 70 Fed. Reg. 2673.

[9] 70 Fed. Reg. at 2665.

[10] *See* 70 Fed. Reg. 53282.

[11] Among the studies relied upon in the cost/benefit section of the September 2005 proposed rule are: Saverin et al. (1999), Steenland et al. (1998), Johnston et al. (1997), and the so-called "31-Mine Study" (*MSHA'S Report on Data Collected during a Joint MSHA/Industry Study of DPM Levels in Underground Metal and Nonmetal Mines* (2003)).

Many other studies added to the Administrative Record after the original risk assessment was completed and/or the related 2001 final rule was promulgated (but considered as part of the June 6, 2005, rulemaking on DPM, and were incorporated by reference into the instant rulemaking). These studies, which NSSGA avers are subject to the peer review requirements under the DQA, include, but are not limited to: United States (U.S.) Department of Health and Human Services, Center for Disease Control, National Institute of Occupational Safety and Health, ``The Effectiveness of Selected Technologies in Controlling Diesel Emissions in an Underground Mine--Isolated Zone Study at Stillwater Mining Company's Nye Mine," January 5, 2004; U.S. Department of Labor, Bureau of Labor Statistics, and U.S. Department of Health and Human Services, Center for Disease Control, National Institute of Occupational Safety and Health, ``Respirator Usage in Private Sector Firms, 2001," September, 2003; Chase, Gerald, ``Characterizations of Lung Cancer in Cohort Studies and a NIOSH Study on Health Effects of Diesel Exhaust in Miners," undated, but received by MSHA on January 5, 2004; Pandya et al. (2002); Peden at al. (2002), Sydbom et al. (2001); Gavett and Koren, 2001; Patton and Lopez,

Significantly, even if some of previously disseminated information upon which MSHA now relies was published, OMB clarified in the January 2005 Peer Review bulletin: "prior peer review and publication is not, by itself, sufficient grounds for determining that no further review is necessary."[12] Therefore, MSHA cannot simply infer that no additional peer review was required before disseminating this information through incorporation by reference in the September 7, 2005, proposed DPM rule.

In short, to comply with the DQA, these studies – as well as all other material that has been "incorporated" from the previous rulemakings' administrative records -- must undergo peer review and have the requisite transparency of data and capacity for replication intended by Congress. OMB has specified that when an agency disseminates information supplied by a third party, the requirements of the DQA and peer review apply where, as here, the dissemination is "influential."[13] The term "influential scientific information" means information that the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.

The scientific information forming the basis for MSHA's rulemaking determination will impact mining companies' decisions on equipment purchases, continuation of existing mining operations, establishment of new mines, and whether to remove operations from the United States, among other things. It also impacts the manufacturing sector and may have a significant impact on whether the Occupational Safety and Health Administration follows suit in regulating occupational diesel particulate exposure at millions of tunneling, construction, transportation, and marine operations. Therefore, it is difficult to envision how MSHA could justify exempting this rulemaking from the requisites for "influential scientific information."

The OMB Bulletin requires MSHA to subject such "influential" scientific information to peer review prior to dissemination. MSHA's failure to do so is an incurable defect and requires withdrawal of the proposed rule. The documents cited in the original rulemaking, as well as those scientific analyses added in the June 6, 2005, and September 7, 2005, phases of this rulemaking, are "influential"

2002; Lippmann et al., 2000; Magari et al., 2001; Pope et al., 2002; Samet et al., 2000a, 2000b; Wichmann et al., 2000; Boffetta et al., 2001; Gustavsson et al. (2000); and Pope et al. (2002). *See* 70 Fed. Reg. 32869-70 and 32902-05. MSHA has even relied upon a Polish "literature review" for which no English translation was available (Szadkowska-Stanczyk and Ruszkowska (2000)), and it is a reasonable assumption that this work has not been vetted through the peer review process applicable to new agency rules – especially since MSHA cites it based only upon an "English Abstract." 70 Fed. Reg. 32905.

To comply with the DQA, all of these studies and reports – as well as the prior data that have been "incorporated" from the previous rulemakings' administrative records -- must undergo peer review and have the requisite transparency of data and replicability intended by Congress. The required peer review must be characterized by both scientific integrity and process integrity, according to OMB.

[12] 70 Fed. Reg. 2671.

[13] 70 Fed. Reg. 2667.

information under the terms of the DQA . By definition, such "influential" releases of information are subject to stricter quality standards and a high degree of transparency.[14]

Although the "31-Mine Study" was "peer reviewed" by NIOSH, it did not undergo the independent, unbiased, external peer review envisioned under the DQA. This is particularly important since NIOSH was itself involved multiple meetings with MSHA and manufacturers of equipment used in the study throughout its course as well as in a "side protocol" of the 31-Mine Study. NIOSH therefore had a professional stake in the outcome of this study, in terms of its acceptance within the scientific community. NIOSH analyzed the laboratory results and its employees recently published some of their findings.[15] Therefore, additional, independent peer review would be required before the findings of the 31-Mine Study could be accepted for the purpose of determining regulatory feasibility under current criteria. This has not been accomplished for much of the so-called scientific evidence that MSHA uses to support its current proposal to reduce the DPM final exposure limits to 160 $\mu g/m^3$ (total carbon).

In addition to ignoring the peer review requirements for the scientific data cited in the current proposed rule and in the prior administrative record that has been incorporated by reference into this proceeding, MSHA has also apparently ignored the requirement that its regulatory impact analysis be externally peer reviewed. In September 2001, the OMB recommended that, for economically significant and major rulemakings, agencies subject Regulatory Impact Analyses ("RIAs") and supporting technical documents to "independent, external peer review by qualified specialists." [16]

Although MSHA claims that this rule is not a "major rule" under the criteria of Executive Order 12866,[17] industry has consistently challenged the agency's self-certification relating to the rule's economic impact since the DPM rulemaking began in the 1990s. MSHA's erroneous assumption in terms of its economic impact has fostered additional problems that extend to the latest modification of the DPM rule, insofar as MSHA has determined there is no need to conduct an initial regulatory flexibility analysis of this proposal; the agency also claims that there is no "significant economic impact on a substantial number of small business entities."[18] This assumption is incredible, in light of the fact that nearly 98 percent of the affected businesses are considered "small" under the Small Business Administration and Regulatory Flexibility Act criteria.

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[14] 67 Fed. Reg. 8460 (February 22, 2002).
[15] *See*, Noll, J. D., Timko, R. J., McWilliams, L., Hall, P., Haney, R., ``Sampling Results of the Improved SKC Diesel Particulate Matter Cassette," JOEH, 2005 Jan; 2(1):29-37.
[16] *See* http://www.whitehouse.gov/omb/inforeg/oira_review-process.html.
[17] 58 Fed. Reg. 51735 (Oct. 4, 1993).
[18] 70 Fed. Reg. 53292.

Because this rulemaking does, in fact, have a significant economic impact on a regulated industry sector (underground metal/nonmetal mines) comprised almost entirely of small businesses, peer review of the agency's economic assumptions is not only appropriate but is mandatory.

Failure to conform fully to the DQA's requirements and the lack of independent peer review for much of the data relied upon and disseminated by MSHA in this rule has subverted and invalidated the entire DPM rulemaking process. The proposed rule is permeated by an aura of illegitimacy because key cited studies have not been subjected to rigorous peer review. Moreover, the pseudo-peer review performed by NIOSH for the critical 31-Mine Study is akin to in-house analysis, and is inadequate under the current statutory requirements because of the inherent bias of the government employees who have peer-review this research that was designed to support their own projects.

When regulatory decisions are made without significant analysis by independent experts, it results in promulgation of regulations based on "junk science," wastes both governmental and industry resources and, ultimately delays the rulemaking process because of the attendant litigation that will undoubtedly ensue if MSHA fails to correct this deficiency now by withdrawing the proposed rule.[19] Data quality is of premier importance in this regulatory process, for without some assurance that the research relied upon is valid, serious questions will be raised about the efficacy and legitimacy of MSHA's actions.

NSSGA supports sound science as the basis for federal policies, particularly in the areas of health and safety where invalid rules not only threaten the economic survival of its members but can also adversely impact the protection of their workers. Peer review of the science upon which regulators rely is absolutely critical to the advance of science. That is why prominent medical journals and public health agencies support openness in the scientific process and utilize peer review, and that is why the federal government must follow suit.

Because MSHA has failed to comply with the statutory mandates in the Data Quality Act, and has improperly elected not to prepare a revised, peer-reviewed Regulatory Impact Analysis for the latest phase of the DPM rulemaking, the proposed rule is irreparably flawed and must be withdrawn.

[19] As OMB states in its January 2005 final peer review bulletin: "[I]nvesting in a more rigorous peer review early in the process 'may provide net benefit by reducing the prospect of challenges to a regulation that later may trigger time consuming and resource draining litigation.'" (internal citations omitted) *See* 70 Fed. Reg. 2668.