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August 10, 2005



(Names have been removed in order to protect the privacy of the individuals submitting the complaint.)

The Honorable Elaine L. Chao U.S. Department of Labor Frances Perkins Building 200 Constitution Avenue, NW Washington, DC 20210

Assistant Secretary David G. Dye Mine Safety and Health Administration 1100 Wilson Boulevard Arlington, VA 22209

Deputy Director Jay Mattos
Program Evaluation and Information Resources
Mine Safety and Health Administration
1100 Wilson Boulevard
Arlington, VA 22209

Re: MSHA Diesel Exhaust Rule: Petition For Expedited Data Quality Act Corrections

Dear Secretary Chao, Assistant Secretary Dye, and Deputy Director Mattos:

The MARG Diesel Coalition¹ respectfully submits this Petition for expedited correction of information disseminated by the Mine Safety Health Administration ("MSHA") in their Federal Register Notices of June 6, 2005, "Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners" (70 Fed. Reg. 32868-32968) and January 19, 2001, "Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners" (66 Fed. Reg. 5706-5755).

We urge expedited review, correction of the record, and the grant of our concurrent Petition For An Emergency Stay (Exhibit 1), pending withdrawal of the January 19, 2006 Total Carbon (TC) future Final Limit, published in 2001. We also urge your concurrence with Congressional requests and appropriations report directives that any final limit be informed by the CDC NIOSH/NCI multi-million dollar study of the potential health effects of diesel exposure on 14,000 former and current miners, expected to be completed in 2006-7. See e.g., Exhibits 2-5.

¹ The Coalition, composed companies and their trade associations, is a party in the underlying rulemaking proceeding and a party in the circuit court of appeal challenges to the rules sought to be corrected by this Petition.



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I. INTRODUCTION AND SUMMARY

The scheduled January 19, 2006 160 TC Limit neither provides health or safety benefits, nor is feasible to measure or comply with by the regulated parties. When the 2001 rule was rushed to print on the last day of President Clinton's Administration, it was filled with errors that have consumed enormous resources to attempt to correct, including its reliance on total carbon as a surrogate for diesel exhaust and its feasibility conclusions. Both of these 2001 conclusions are acknowledged as wrong by the DOL/MSHA June 6, 2005 rule amendments, but the needed corrections are incomplete, necessitating this Petition.

The June 6, 2005 DOL/MSHA rule amendments adopt a replacement "Interim Limit" based on Elemental Carbon, a new diesel exhaust surrogate. The 2001 rule TC Interim Limit was found to be incapable of accurate measurement by the June 6th amendments, and thus not feasible, contrary to the 2001 rule conclusion. Of course, since the TC Interim Limit was not feasible, neither is the January 19, 2006 TC Final Limit feasible of accurate measurement, and a rule that is not feasible provides no safety and health protection whatsoever and should be withdrawn.

As described below, the June 6, 2005 rule amendments also provide additional compelling reasons for the withdrawal of January 19, 2006 Final Limit of 160 micrograms of Total Carbon. MSHA found that there is insufficient evidence of the industry's ability to feasibly comply with a limit below the Interim Limit and thus the January 19, 2006 Limit does not meet the compliance feasibility requirements of Mine Act.

Withdrawal of the future Final Limit is required by law, including the feasibility mandates of § 101(a)(6) of the Mine Act, and § 101(a)(9), prohibiting a reduction in protection from that provided by an existing standard, because: (1) the new 308 Elemental Carbon limit adopted and implemented by settlement agreement, and again by the June 6, 2005 Federal Register amendments, was deemed by MSHA to provide protection from diesel exhaust, and as a standard that could be measured accurately, and for which compliance is feasible; (2) the future January 2006 Limit, if implemented, will reduce the protection provided by the 308 EC limit since MSHA has declared that total carbon can not be measured accurately, and thus is not feasible; and that there is insufficient evidence that the industry can feasibly comply with a limit lower than the 308 EC Limit.

A limit that cannot be measured, and for which compliance is not feasible, reduces and in fact eliminates the protections offered by a limit that is feasible and can be measured. Failing to delete the 160 TC limit will divert limited safety and health resources of both MSHA and industry, thereby reducing further the protections offered under existing standards. Moreover, as explained below, MSHA data and admissions prove that the 160 TC Limit can not be "converted" to EC because there is no stable correlation of EC to TC at this level, and because once filters are applied to engines to achieve the 308 EC Limit, exhaust characteristics change and create even further instability and variability in EC/TC predictability, rendering conversion impossible.



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Regrettably, MSHA took no action on the Final Limit in the June 6th rule amendments. The failure to delete the January 19, 2006 rule in the June 6, 2005 rule amendments creates an urgent need for its withdrawal now, or for a stay pending its withdrawal based on the grant of this Petition for correction of the record. Moreover, the June 6, 2005 Federal Register notice repeats and extends significant errors with major impacts on public policy that were originally set forth in the 2001 Federal Register notice and also are the subject of this Petition for Correction.

Unless stayed until withdrawn, the MSHA January 19, 2006 Final Total Carbon limit creates regulatory confusion in light of the Agency's June 6, 2005 admission that total carbon can not be accurately measured. More importantly, it creates a significant risk of job loss if it is permitted to go into effect, as shown by the MSHA June 6th admission that there is insufficient evidence of the industry's ability to feasibly comply with a limit below the interim limit. 70 Fed. Reg. at 32916. Importantly, both recent MSHA conclusions contradict the basis of the original 2001 rule and necessitate Data Quality Act corrections of the record on important public policy matters, and deletion of the 2006 Limit.

We emphasize the need for correction of the record, and withdrawal of the Final Limit; not a "phase-in" or another "compromise" limit that has no health benefit or risk basis, as are rumored to be under consideration by MSHA. Neither of these two alternative approaches would be based on sound science and engineering, and would thus not achieve the needed Data Quality Act corrections and meet Mine Safety Law mandates, as demonstrated below.

II. THE MARG DIESEL COALITION IS AN INTERESTED PARTY.

The MARG Diesel Coalition is an informal group of companies and their trade associations. The Coalition is an interested party because the Final Rules will have a significant adverse impact on its members. Some Coalition members operate facilities that are the subject of a massive, multimillion dollar study by the National Institute of Occupational Safety and Health (NIOSH) and the National Cancer Institute (NCI). The study was designed ten years ago to determine whether diesel exhaust causes health effects, particularly lung cancer, and if so, what exposure level is safe. The study covers 14,000 current and former employees, most of them employees of Coalition members, and the results are expected to be released in 2006-2007. The Congress, through its appropriations reports and letters to the Secretary, has instructed that the study "inform" the final MSHA limit. MARG and other industry groups encouraged MSHA to comply with this logical instruction from Congress and challenged the MSHA rules in court when MSHA did not do so. While that proceeding currently is stayed, an expedited Data Quality Act correction can avoid unnecessary litigation and comply with the mandates of the President and Congress.



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III. THE INFORMATION QUALITY GUIDELINES APPLY TO MSHA'S JUNE 6, 2005 RULE AND THE JANUARY 19, 2001 RULE.

The DOL's Information Quality Guidelines ("Guidelines") provide, in part, that where agencies disseminate "information of a scientific, financial, or statistical nature, they should use sound statistical and research methods to develop and analyze the data." DOL Guidelines at 4. Pursuant to the OMB and DOL Guidelines, "[i]f an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties." 67 Fed. Reg. 377; DOL Guidelines, Appendix I at ¶ 12-13. The OMB and DOL Guidelines define "influential" to mean "the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions." 67 Fed. Reg. at 372; DOL Guidelines, Appendix I at ¶ 9. The DOL has further identified influential information in rulemaking to mean "scientific, financial, or statistical information that the agency believes will have a clear and substantial impact on the resolution of one or more key issues in an economically significant rulemaking, as that term is defined in section 3(f)(1) of Executive Order 12866." DOL Guidelines at 6.

In this case, MSHA disseminated a significant amount of information as part of its Final Rules on Diesel Particulate Matter that had a clear and substantial impact on the resolution of the agency's decision-making and will significantly and adversely impact government policy regarding diesel engines, a critical component of the economy. The information disseminated in the final rule also will have significant adverse impacts on the domestic mining industry, already faced with competitive challenges by unregulated foreign producers, threatening the domestic supply of the metals and minerals critical to the economy and the nation's defense.

The importance of MSHA's publication is evidenced in the attached June 20, 2000 letter from a bipartisan group of United States Senators, led by Senator Harry Reid (D-NV) and Larry Craig (R-ID), that urged coordination by MSHA with OSHA and EPA, and that MSHA's rule be

² Section 3(f)(1) of Executive Order 12866 defines "significant regulatory action" to mean "any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." One mine alone estimated the cost of MSHA's rule at \$110-114 Million over a ten-year period, 70 Fed. Reg. at 32934, and there are about 200 mines impacted. If the diesel exhaust limit precedence is applied to trains, trucks and construction, the costs will be in the billions. While MSHA disagrees with industry cost estimates, MSHA estimates are based on errors (e.g., equipment availability, costs, and exposure limit feasibility) that need correction. And, while MSHA admits that its compliance cost estimate for Stillwater in its 31-Mine Study used to justify feasibility was less than 1/20th of the actual Stillwater budget (\$110-114 million), 70 Fed. Reg. at 32943, MSHA speculates hypothetical controls, equipment, plans and methods to salvage its flawed assessment.



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informed by the best available scientific evidence, including the pending study of diesel exhaust by NIOSH and NCI, funded by the Congress and subject to the direct oversight of the House Committee on Education and the Workforce. Their letter echoed the instructions of the Senate and the House contained in the attached Labor HHS appropriation report. Unfortunately, MSHA did not heed those instructions and its errors continue in the information disseminated in its June 6, 2005 Rule, requiring correction.

Given that the June 6, 2005, Final Rule for DPM exposure includes, and is based on consideration of the entire rulemaking record, 70 Fed. Reg. at 32870, including the record for the DOL/MSHA January 19, 2001 rule on the same subject, all information disseminated in the January 21, 2001 rule also is subject to DQA review, including the looming January 19, 2006 limit on total carbon which provides no protection and requires expedited correction to prevent confusion and job loss.

IV. THE DIESEL EXHAUST "FINAL" LIMIT—CORRECTION NEEDED

MSHA's June 6, 2005 Federal Register notice, at 70 Fed. Reg. 32870, states:

[E]vidence in the current DPM rulemaking record is inadequate for MSHA to make determinations regarding revision to the final DPM limit [160 micrograms of total carbon, scheduled to become effective on Jan. 19, 2006, pursuant to 30 Fed. Reg. 57.5060(b), promulgated on Jan. 19, 2001].

This statement must be corrected to state:

[E]vidence in the current DPM rulemaking record is overwhelming and requires MSHA to delete the final DPM limit since it is not capable of accurate measurement, not supported by sound scientific evidence as providing protection against significant risks nor providing significant benefits, and is not technologically feasible."

Extensive support for this correction is contained in the rulemaking record and described below, but the following uncontested facts should suffice as reasons to act expeditiously to correct the record:

• MSHA's June 5th Federal Register admission that total carbon cannot be measured reliably due to interferences, 70 Fed. Reg. at 32871, resulted in the Agency deleting the "Interim Standard" of 400 micrograms of Total Carbon and adopting a "settlement" standard of 308 micrograms of Elemental Carbon. Yet, MSHA failed to delete or stay (pending deletion) the corresponding January 19, 2006 160 microgram Total Carbon limit.



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- There is no elemental carbon "equivalent" to the January 19, 2006 160 microgram Total Carbon limit because: (1) MSHA data demonstrates that no accurate conversion factor exists for the highly variable ratio of total carbon to elemental carbon (TC/EC) at levels below the Interim Standard; and (2) once diesel equipment is modified to capture particulate matter to reach the Interim Standard, the unpredictable ratio of TC/EC becomes even more unstable, creating massive variability that can not be overcome to establish an EC equivalent to TC. See e.g. 70 Fed. Reg. at 32897 concluding "statistically significant differences in the mean EC:TC ratios between mines and between differing sampling days within mines."
- MSHA's June 5th Federal Register admission that its selected, original surrogate for diesel particulate (total carbon, "TC") can not be measured accurately, and MSHA's change to a new surrogate (elemental carbon, "EC"), undermines the agency's 2001 justification for its diesel exhaust rules, including the exposure limits. The 2001 MSHA statements regarding statutorily mandated determinations of risks, benefits, impacts, and feasibility were all based on the selected regulated substance, total carbon, as a surrogate for diesel exhaust. 66 Fed. Reg. 5706-5755. Yet, MSHA has failed to delete, or stay pending rulemaking to delete, the January 19, 2006 total carbon limit adopted by the 2001 publication, and discredited by its June 6, 2005 Federal Register notice.
- Current MSHA sampling data published on its web site demonstrates that 90% or more of the regulated industry cannot comply with the January 19, 2006 limit.
 The June 5th Federal Register notice "acknowledges that the current DPM rulemaking record lacks sufficient feasibility documentation to justify lowering the DPM limit below 308 EC μg/m³ at this time." 70 Fed. Reg. at 32916. Yet, MSHA failed to delete the January 19, 2006 final limit or correct its 2001 Federal Register conclusion that the final limit is feasible.
- MSHA's June 5, 2005 Federal Register notice sets forth revised and new scientific arguments to rebut critiques of the agency's risk assessment, and sampling and analysis system underlying the 2001 rule. While these new MSHA scientific declarations provide the foundation for its significant public policy decisions, MSHA relied on incorrect data and information in a manner that is not reproducible, transparent, nor free from bias, and did not subject its analysis of risk and sampling accuracy to independent peer review. Thus, the MSHA risk assessment and sampling and analysis declarations should be corrected.

V. CORRECTION NEEDED REGARDING TECHNOLOGICAL FEASIBILITY

The statement: "MSHA has established that it is technologically feasible to reduce underground miners' exposures to the DPM interim permissible exposure limit (PEL) of



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308 micrograms of EC per cubic meter of air $(308_{\rm EC}\,\mu\rm g/m^3)$ by using available engineering control technology and various administrative control measures" should be corrected to read, "MSHA has established that it is technologically feasible for some mines to reduce underground miners' exposures to the DPM interim permissible exposure limit (PEL) of 308 micrograms of EC per cubic meter of air $(308_{\rm EC}\,\mu\rm g/m^3)$; but that the entire industry can not feasibly comply with the final permissible exposure limit of 160 micrograms of total carbon, by using available engineering control technology and various administrative control measures."

MSHA conclusions in the DPM rules regarding feasibility are contradicted by its own data base and its acknowledged need for the provisions providing mine specific feasibility extension for the interim standard. (30-37% of the industry is not in compliance with the Interim Standard and 90-95% of the industry is not in compliance with the Final Standard). The MSHA incorrect conclusion is based, in large part, upon incorrect assumptions, speculation, and inaccurate data disseminated as part of an MSHA designed "31-Mine Study" and an MSHA created computer model ("The Estimator"). The 31-Mine Study and the Estimator (See 70 Fed. Reg. at 32919; see also 66 Fed. Reg. 5709) fail to meet the "reproducibility" standard required for disseminating influential information. See 67 Fed. Reg. at 378; DOL Guidelines, Appendix I at ¶ 10 (reproducibility standard requires an agency to ensure that information disseminated by it is sufficiently transparent in terms of data and methods of analysis that would be feasible for replication). Neither was independently peer reviewed. Contrary to MSHA's description, a review of the 31-Mine Study, by self selected personnel in its sister agency NIOSH, is not "independent peer review." Similarly, contrary to MSHA's assertion, a review of the Estimator for publication in a mining magazine does not constitute the needed independent peer review for use of the Estimator to determine feasibility of compliance for a mine or for the industry, due to the incorrect assumptions in the Estimator described herein. The information disseminated also fails to meet the "transparency" and bias free standards required under the guidelines. 67 Fed. Reg. 377; DOL Guidelines, Appendix I at ¶ 12-13. See infra at §§ V-IX. For these reasons, MSHA has violated the Information Quality Guidelines by grounding its conclusions regarding feasibility on the 31-Mine Study and the Estimator.

V (A). The MSHA "Estimator" And The "31-Mine Study" Are Neither Transparent Nor Reproducible, Suffer From Bias, Were Not Independently Peer Reviewed, And Information Based On Them Requires Correction.

In both its 2001 and 2005 Final Rules, MSHA explains that its computer model "Estimator," was used as the basis to determine the feasibility of the rules. 70 Fed. Reg. at 32919. The Estimator was used with specified input data to mathematically calculate predicted total carbon levels and determine computer simulated compliance feasibility (both technical and economic) for

³ 70 Fed. Reg. 32915.



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individual mines and the entire industry. Among the input data are assumed ventilation air flows that do not reflect reality or actual MSHA measurements, and assumptions regarding the perfect mixing of ventilation air to achieve dilution of exhaust particulate, another assumption that does not reflect reality or actual measurements. These violations of the Data Quality Act's reproducibility and transparency requirements were admitted by MSHA. 70 Fed. Reg. at 32920 ("commenter observation ...imperfect mixing and ventilating air ...a valid criticism....").

The Estimator also predicts particulate emissions both before retrofitting equipment and afterwards, and was used to determine feasibility of compliance for individual mines and the entire industry based on assumptions that retro-fit filters are available for and would fit all of the equipment in the fleet, and operate as efficiently and effectively as assumed by MSHA. "[T]he methodology for the technical feasibility analysis required all major emission sources at a given mine ... to be provided with the same DPM controls...." 70 Fed. Reg. at 32919. These assumptions also do not reflect reality, as MSHA was forced to admit in the June 6, 2005 amendments that contradict the Estimator (and 31-Mine Study) feasibility determinations. See e.g., 70 Fed. Reg. at 32916 stating that there is "insufficient" evidence of feasibility. Yet, MSHA has not corrected its declarations regarding the Estimator that was the foundation for significant public policy decisions.

An alternative use of the Estimator was reported by MSHA to use "actual" MSHA emission measurements, but the measurements were limited and non representative of routine mining conditions that can vary greatly at each mine from day to day, and from mine to mine throughout the industry, and suffered the same accuracy defects that required MSHA to change the surrogate to Elemental Carbon. 70 Fed. Reg. at 32920. In fact, in the 31-Mine Study MSHA voided 25% of the samples it collected, rendering the study itself suspect even without the considering the invalidity of the Estimator's use. Most importantly, the remaining assumptions of the Estimator, described above, continue to contradict reality, even if input emission measurements were representative, which they were not.

MSHA admits that the Estimator, and the 31-Mine Study which used the Estimator, together were used to conclude that the rule is feasible. 70 Fed. Reg. at 32919. Given the Data Quality Act violations that produced the Estimator conclusions, and the MSHA reversal on the feasibility of the Final Limit, the conclusion of the Estimator's validity must be corrected.

MSHA's Estimator violates the Data Quality Act mandates because the information upon which it is based is false, not reproducible nor transparent, bias, and was not subjected to independent peer review for its use to determine feasibility. The limited review reported by MSHA of Estimator for publication in a mining magazine did not constitute independent peer review of the Estimator's use to determine feasibility with the unrepresentative data input and assumptions utilized. The MSHA Federal Register quote of an industry comment stating that the Estimator's math was valid, is an example of the Data Quality transparency problems that must be corrected. A correct mathematical model that assumes data that does not exist in reality is the basis of



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MSHA's feasibility conclusions. When primary assumptions of models do not correspond to reality, but they are portrayed as supporting major public policy decisions, they violate Data Quality Act mandates. As a result, the information published by MSHA regarding the Estimator and the technological and economic feasibility conclusions based on the Estimator, require correction.

Not only does the Estimator and the 31-Mine Study wrongly assume that diesel exhaust filters exist that can be retrofitted on the entire existing fleet of mining equipment, it assumes that they will successfully reduce DPM by 80% or more, and would therefore constitute the primary means of feasible compliance with the Rule. Prior to the 2001 Final Rule, there had been no mine worthiness application testing of any diesel exhaust filter. While it is true that a few diesel exhaust filter prototypes were subjected to limited tests pre 2001 for mining machines, and a few more now exist and worked in initial tests conducted over the last three years; many failed, some introduced significant new hazards, and it is not true that they "fit" or "work" on the entire fleet of equipment, as assumed by MSHA's Estimator and 31-Mine Study.

An example of the failure of the Estimator and the need for data quality act corrections, is shown by the testing performed at the Stillwater Mine in partnership with NIOSH, MARG and others, described in the June 6, Federal Register notice. MSHA speculates, without actual evidence, expertise, or experience, that there are feasible filters for equipment that could not be retrofitted in the NIOSH sponsored testing (due to the size of the filters, the equipment's horsepower, and/or the duty cycle of the equipment that was not compatible with the filters). MSHA further speculates that it can obtain feasible compliance at substantial cost savings to Stillwater's carefully calculated costs, which were based on actual testing, operating experience and expertise.

MSHA's explanation for the many filter failures reported by Stillwater, and almost all companies, was both wrong, and identical: it was the fault of the user or the manufacturer and MSHA would have selected or used them differently (70 Fed. Reg. at 32924-26). When installed filters undergoing NIOSH sponsored testing and oversight released dangerous levels of Nitrogen Dioxide, causing mine evacuations under the watchful eye of NIOSH researchers, MSHA blames the mine operator without any proof or substance, and disagrees with NIOSH which carefully documented the filter caused NO2 hazards (compare 70 Fed. Reg. at 32928 reporting the NIOSH cause to 70 Fed. Reg. at 32929 speculating—"it is likely"—that company conditions caused the event).

The extensive MSHA Federal Register speculations of the reasons for filter failures have not undergone independent peer review, are not transparent, nor reproducible, and suffer from suspected bias since they likely were drafted by the same personnel that concluded that the 2001 rule was feasible. Bias in defending the 2001 rule is expected since the original chairman of the MSHA committee that drafted the rule, Thomas Tomb, testified under oath to his conflict of interest that led to the rule: overlapping drafting duties at the American Conference of



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Governmental Industrial Hygnists and MSHA, where he acted secretly, without independent peer review or even identification until his deposition was taken in a lawsuit. See infra at \(\times \times III.

In addition to these faulty assumptions, and the lack of transparency and bias underlying the MSHA rule, it relies on faulty data input into the Estimator program. Even though ventilation quantities are one of the most important input factor for DPM control and the use of the Estimator, the ventilation quantities used in the Estimator calculations were more than double those ventilation quantities reported in the MSHA data base (as reported by the on-site sampling teams). This is an obvious flaw in the use of the Estimator to determine feasibility that violates the transparency mandates of the Data Quality Act. Other extensive Estimator failures requiring correction are noted in MARG comments in the rulemaking record, and in MARG's report on the 31-Mine Study, which are incorporated by reference herein.

V (B). MSHA's Use Of Non-Representative Sampling Is A Violation Of The Data Quality Act And Results In Information That Requires Correction.

In reaching its conclusion regarding feasibility, MSHA has disseminated additional data that relies on non-representative sampling in violation of the Information Quality Guidelines. MSHA assumed that DPM sample results in isolated sections of the mines in the 31-Mine Study are representative of DPM exposure levels in hundreds of thousands of locations over perhaps millions of miles of underground tunnels, resulting from thousands of pieces of diesel equipment in almost 200 mines. MSHA then voided 25% of the samples collected in the 31-Mine Study "mostly because of potential interferences," and eliminated four mines from the study. 70 Fed. Reg. at 32890. MSHA then uses this non-representative data throughout its justification for the June 2005 Rule. MSHA's baseline samples reported in the June 6 Federal Register do not cure this defect since they are similarly non representative and MSHA conclusions to the contrary have not undergone independent peer review for their statistical validity.

For the January 2001 Rule, MSHA used data from other industries, from outdated sources, and from faulty and limited sampling, to support the rule, and speculated massive industry DPM exposures, which it used to analyze risk. 70 Fed. Reg. at 32889 (mean concentration of 808 micrograms, up to 3500 micrograms; compared to 2001-2 measured exposures that MSHA does not report in the same manner, but for which the mean was 75–500 micrograms, for the 304 samples not voided by MSHA).

MSHA speculation as to industry TC levels in the 2001 Rule, and attempts to justify that speculation in the June 2005 rule, do not meet Data Quality Reproducibility and Transparency standards. Plainly, this sampling database was not, and is not today representative of the mining industry, which has varied conditions and fleets of diesel equipment (dictated by the uncontrollable variables of the earth's mining conditions and the material being mined), and DPM exposures far different that those which MSHA speculated.



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Moreover, the mean levels of DPM reported by MSHA do not represent hazards, feasibility of achieving reduced DPM levels, or feasibility of compliance with the MSHA rules. The MSHA rule measures compliance based on a single sample, regardless of its risk estimates based on hypothetical long-term exposures. The MSHA rule measures DPM by its use of a single surrogate, regardless of its risk estimates, at best based on complex mixtures of diesel exhaust with unstable ratios of the surrogate to other components. The MSHA rule measures compliance with a measurement system that is inaccurate and not feasible for the surrogate that MSHA used to justify the rule. The MSHA use of non-representative sampling is pervasive throughout the justification for the rule and constitutes a lack of transparency, and non-reproducible results, based on science that was not subjected to independent peer review, but was used to make major policy decisions impacting diesel engines across the economy. See e.g., 67 Fed. Reg. at 378; DOL Guidelines, Appendix I at ¶ 10 (reproducibility standard requires an agency to ensure that information disseminated by it is sufficiently transparent in terms of data and methods of analysis that would be feasible for replication).

The resulting information that MSHA relied upon requires correction, including: (1) the 2001 reported industry diesel exhaust levels which are contradicted by the 2005 Federal Register data reports; (2) the reported risk associated with the speculative 2001 exhaust levels which MSHA declares remains unchanged by the 2005 corrections; and (3) the reported 2001 feasibility conclusions for sampling and analysis and compliance, which MSHA admits were proven incorrect, but which were not fully corrected by the June 6, 2005 Federal Register notice.

V (C). The MSHA Conclusion That Its Sampling And Analytical Method Is Accurate, Was Not Subjected To Independent Peer Review, Is Not Transparent Nor Free From Bias, Is Not Reproducible, Is Wrong, And Requires Correction.

MSHA concluded that it demonstrated the feasibility of the sampling-and-analytical method it created and used for risk analysis, feasibility analysis, and to enforce the Final Rule. The conclusion requires correction because it is wrong, not based on sound science, not transparent, free from bias, and was not subjected to independent peer review.

A sampling-and-analysis method is the equivalent of a ruler that must produce accurate and consistent results to be considered feasible. With respect to the measurement of a substance for industrial hygiene purposes, 'accuracy' is defined as the true value of the amount of the substance being measured. To determine the accuracy of a method, it is first necessary to have a 'standard' against which the method can be compared. (An example is the silica standard, provided by the National Bureau of Standards, that allows measurements of silica to be compared to a 'true value' in order to determine whether the Permissible Exposure Limit (e.g., 100 micrograms per cubic meter of silica) has been exceeded). No such standard exists for elemental carbon; thus it is not possible to determine or ensure the accuracy of its measurement.



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In calculating its Error Factors for this method, MSHA assumes that there are no related methodological inaccuracies, an assumption that is factually unsupported and logically absurd. We are aware of no analytical method that is without some element of inaccuracy and the MSHA assumption defies reason. Thus, the MSHA statements that their method is accurate and feasible cannot be supported scientifically, have not and cannot be tested, and are certainly incorrect. Accordingly, MSHA statements that its method is accurate and feasible must be seen as reflecting unsubstantiated and incorrect conclusions that require correction under the Data Quality Act.

A second important consideration in evaluating a sampling-and-analysis method is the ability of the method to provide consistent and reproducible results. This concern reflects the concept of 'precision', i.e., the statistical calculation of the repeatability of the measurement, regardless of its relationship to the true value. Precision is generally calculated as the coefficient of variability (CV) of the method. That concept is built into the NIOSH Accuracy Criteria for industrial hygiene measurements: NIOSH defines an accurate method as one which provides results that are within 25% of the true value, 95% of the time. While this is a generous definition of accuracy that would never be acceptable for rulers, it recognizes the difficulty and substantial variability of industrial hygiene measurements of small quantities of potentially toxic substances that make-up only a small percentage in much larger quantities of air, water or soil.

In its submissions to MSHA, MARG provided data from field trials that it funded demonstrating the imprecision of the method MSHA developed for measuring elemental carbon. The MARG funded study collected side by side samples in 25 baskets of four to five samplers each in underground mines using diesel equipment (the same mines subject to the NIOSH/NCI study of potential health effects) with the same equipment and methods as used by MSHA. The results of side-by-side samples were shocking in their lack of consistency—the imprecision was beyond that even acceptable by the loose NIOSH definition. These data and the accompanying expression of scientific concern, however, were rejected by MSHA based on a biased critique that was not transparent, had not been subjected to independent peer review, and was drafted by the same personnel that invented the MSHA method. 70 Fed. Reg. at 32945-32951.

MSHA's response to the MARG study included a non-peer reviewed statistical analysis of its method that relied on theoretical arguments derived from a Monte Carlo simulation. Beyond being solely theoretical (in contrast to MARG's field-derived data), the MSHA argument relied on a logical tautology. MSHA attributed the MARG findings of the imprecision of the sampling-

^{4 &}quot;MSHA generated a dataset of 10,000 simulated measurements randomly drawn from a log normal distribution..."
[70 Fed. Reg. 32946-7] and used that to argue that field data provided by MARG were "consistent with meeting the NIOSH Accuracy Criterion".

⁵ MSHA generated a theoretical sampling and analysis dataset with a fixed mean and predetermined CV such that the distribution of data points in that set was also necessarily predetermined so "more than 96% of these measurements fell within ±25% of the mean". They then described that finding as showing that the "simulated measurement process satisfied the NIOSH Accuracy Criterion". But that conclusion was predetermined by the



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and-analytical method to "statistical instability" due to small sample size, but failed to indicate an appropriate number of samples that would be acceptable as the basis for challenging their method.⁷

To demonstrate the invalid nature of the MSHA response, we emulated their Monte Carlo simulation. For the hypothetical example used by MSHA ('true' coefficient of variation = 12%), we determined that the proportion of 'baskets' with CV > 12.5% ranged from ~26-37% as the number of measurements ranged from 2-100. Thus the MARG field data fall around the midpoint of this range.

MSHA concluded that it demonstrated the feasibility of the sampling-and-analytical method it created and used for risk analysis, feasibility analysis, and to enforce the Final Rule. The conclusion requires correction to state: "the sampling and analytical method is not accurate, particularly at levels below the 308 EC Limit."

MSHA is wrong in its assertion that the MARG results reflected "statistical instability" due to sample size and this statement should be corrected to state: "based on the MSHA Monte Carlo analysis the MARG data is statistically stable and affirms the inaccuracy and imprecision of the MSHA sampling and analysis method." MSHA also is wrong that their method is consistent with the NIOSH Accuracy Criterion and should be corrected to state the contrary.

There are important data quality implications of the MSHA conclusion and methods. First, the conclusion must be put into the context of a sampling device designed and redesigned by MSHA, and a NIOSH analysis method never used commercially before the 2001 rule was issued. Both were found by MSHA to be feasible in 2001, although fundamental changes were made from 2001 to 2005. 70 Fed. Reg. 32871. The MSHA approach to defending its conclusions poses a substantial risk that a sampling-and-analytical method of unacceptable imprecision could be deemed acceptable for other regulatory and enforcement purposes.

statistics employed by MSHA to construct the example, and the MSHA analysis does not relate to an actual data set drawn from actual sampling and analysis performed according to their rule.

- ⁶ MARG presented empirical data from a published, peer-reviewed study indicating that 32% of 25 sampling baskets with at least four samplers in each had a CV >12.5%, thereby failing to meet the NIOSH "Coefficients of Variation and Accuracy Criteria Requirements" {16989}.
- MSHA failed to note that the NIOSH "Coefficients of Variation and Accuracy Criteria Requirements" do not specify a necessary minimum number of samples. Also, documentation of the NIOSH 5040 Method, adopted by MSHA in this Final Rule, was based on only two 'baskets', one with only seven 'measurement' and the other containing an unspecified number of 'measurements' {18679}.
- ⁸ Using SAS release 8.02, we generated datasets of simulated measurements from a log normal distribution with mean = 126 and a variety of predetermined CV values. For each predetermined CV value, we randomly drew 100,000 'baskets' each containing a predetermined number of 'measurements'. The CVs for those individual 'baskets' were then determined, allowing the number of 'measurements' in each basket to increase from 2 to 100.



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Suppose the 'true' CV of the method was 15%, which is not acceptable according to NIOSH Criteria. Using the MSHA Monte Carlo simulation, we determined the proportion of 'baskets' expected to have a CV ≤12.5%, as the number of measurements ranged from 2-100. Such results would wrongly indicate that the method was acceptable according to NIOSH Criteria. More than 30% of 'baskets' containing 10 'samplers' would have a CV ≤12.5%, as would ~20% of 'baskets' with 20 'samplers', nearly 10% of 'baskets' with 40 'samplers' and about 5% of 'baskets' with 60 samplers. MARG regards this as posing an important and unjustified risk of capricious regulation and enforcement and as providing further evidence that the methods used by MSHA are not feasible, and that their conclusions violate the Data Quality Act requirements. See e.g., 67 Fed. Reg. at 378; DOL Guidelines, Appendix I at ¶ 10 (reproducibility standard requires an agency to ensure that information disseminated by it is sufficiently transparent in terms of data and methods of analysis that would be feasible for replication).

VI. ECONOMIC FEASIBILITY—CORRECTION NEEDED BASED ON VIOLATION OF INFORMATION QUALITY GUIDELINES REQUIREMENTS FOR REPRODUCIBILITY, VALID ASSUMPTIONS AND TRANSPARENCY.

The statement: "MSHA has determined that a PEL of 308 micrograms per cubic meter of air (308_{EC} µg/m³) is economically feasible for the M/NM mining industry should be revised to read, "MSHA has not adequately supported its conclusion that a PEL of 308 micrograms per cubic meter of air (308_{EC} µg/m³) is economically feasible for the M/NM mining industry."

MSHA's conclusion is based on improper sampling, inaccurate data, and incomplete data. For these reasons, as more fully explained above and below, MSHA's stated conclusion does not meet the "reproducibility" standard required for disseminating influential information. See 67 Fed. Reg. at 378; DOL Guidelines, Appendix I at ¶ 10 (reproducibility standard requires an agency to ensure that information disseminated by it is sufficiently transparent in terms of data and methods of analysis that would be feasible for replication).

MSHA's conclusions regarding the economic feasibility of a PEL of $308_{EC} \, \mu g/m^3$ are not based on a representative sampling of all the underground mines affected by this rule. The 185 underground mines impacted by the standard are composed of 24 different major commodities, each of which must be examined from the unique perspective of the market for its products, its existing margins, national and foreign competition, and product commodity market prices. For example, the underground mines in Missouri that produce lead, or the underground mines in Montana that produce platinum, or the underground mines in Nevada that produce gold, are

^{9 70} Fed. Reg. 32939.



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each economically viable only when viewed in light of the international price for their commodities, not their gross sales as used by MSHA to determine feasibility.

MSHA's use of the gross revenue as a measure of economic feasibility is invalid and should not be used to support MSHA's conclusion regarding economic feasibility. This method ignores the fact that international commodity markets determine the viability of mines by setting market prices for their production. For most of the last twenty years, in the mining industry volume and gross sales were an indication of massive losses rather than profitability. For example, gross sales in the hundreds of millions (if not billions of dollars) did not prevent the US underground mining industry today from being a fraction of its size when the MSHA law was passed in 1977 and substantially reduced from the date that MSHA initiated the DPM rulemaking. Competition with unregulated foreign entities, US regulatory costs, and margins have had at least the following effects: 4 out of 5 zinc mines in Tennessee have closed, 6 out of 7 silver mines in Idaho have closed, 2 underground copper mines have closed in Arizona, 3 out of 6 lead mines in Missouri have closed, and 1 of the 2 molybdenum mines in Colorado have closed. The remaining mines in these industries have suffered significant employment cuts, and the many industries that depended on the closed operations, like the metal smelters, refiners, transporters, and service contractors, have closed as well. Some of these, like the thousands of service contractors that provided good paying jobs were regulated directly by MSHA. Thus, MSHA's analysis is flawed to the extent it fails to examine the impact of the additional cost of its regulations on the entire industry and its viability.

Furthermore, in the 31-Mine Study (upon which MSHA relies to support its economic feasibility study), MSHA used unit prices for commodities that were significantly in error in at least one instance. For example, rock salt for highway de-icing (the primary market for the three rock salt mines included in the study) reportedly sold for about \$20 to \$25 per ton when the analysis was made. Yet the estimates for the revenues and likely annual production levels for the three salt mines seem to indicate that a price of about \$50 to \$70 per ton was used in the analysis.

Moreover, because the 31-Mine Study and the Estimator underlying MSHA's economic analysis was flawed from a technical feasibility perspective (see above), it's corresponding use for economic analysis is not transparent and based on non-reproducible data, later proven invalid.

MSHA's economic feasibility analysis incorrectly assumed that none of the 31 mines would need any major changes to its ventilation system. Moreover, only six of the 31 mines in the 31-Mine Study were allocated any funding by MSHA's analysis for minor ventilation upgrades such as auxiliary fans and ducting, for a total capital cost of \$234,000. In contrast to MSHA's findings, one mine alone in the 31-Mine Study estimates at least \$4.4 million in ventilation changes to achieve compliance. MSHA relies on this erroneous limited ventilation system change assumption despite contradictory conclusions by MSHA itself, and NIOSH, that mine ventilation systems throughout the industry need substantial upgrades to comply with the DPM limits.



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VII. CORRECTIONS ARE NEEDED TO MSHA'S RISK ASSESSMENT INFORMATION AND CONCLUSIONS SINCE THEY WERE NOT SUBJECTED TO INDEPENDENT PEER REVIEW, ARE NOT TRANSPARENT, NOT FREE FROM BIAS AND CONFLICTS OF INTEREST, NOR REPRODUCIBLE.

The statement: "By reducing dpm concentrations in underground mines, the rule will substantially reduce the risks of material impairment faced by underground miners exposed to dpm at current levels." should be revised to read, "By reducing dpm concentrations in underground mines, the rule may or may not reduce the risks of material impairment faced by underground miners exposed to dpm at current levels."

The conclusion by MSHA published on June 6, 2005 that "no change is warranted in the 2001 risk assessment," and the three conclusions reached by the 2001 Risk Assessment (70 Fed. Reg. at 32889), should be corrected to state that "a change is warranted to the conclusions reached by the 2001 risk assessment; the resulting MSHA PELs are not related to health risks and benefits."

VII (A). DOL Standards For Risk Assessment Were Not Met By MSHA.

MSHA has adopted the standards for performing risk analysis that are contained in the Safe Water Drinking Act (SWDA"). DOL Guidelines at Appendix II. Pursuant to DOL and OMB Guidelines adopting the SWDA, "to the degree that an Agency action is based on science," an agency is directed to use "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices." The OMB and DOL guidelines further direct MSHA "to ensure that the presentation of information about risk effects is comprehensive, informative, and understandable." DOL Guidelines, Appendix II.

In reaching its conclusion regarding health risks and benefits justifying the 2001 Rule and the 2005 Amendments, MSHA relied on what it labeled risk assessment, 70 Fed. Reg. 32889; 66 Fed. Reg. 5706-10; but independent scientists concluded MSHA's assessment did not meet standard risk assessment requirements. See e.g., record comments of Dr. Jonathan Borak, Professor at the Yale University Medical School, expert in toxicology and risk assessment, Member of EPA Advisory Board. Regardless of this disagreement, which alone could mandate Data Quality Act correction, the Interim and Final Standards adopted by MSHA were not based on scientific evidence supporting health risks of the regulated substances (which MSHA changed in 2005), at the regulated levels (which MSHA also changed in 2005), nor did MSHA establish a dose/response relationship for either the old or new regulated substance. MSHA's own admission is informative:

^{10 70} Fed. Reg. 32889.



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As MSHA acknowledged in the preamble to the proposed rule, the scientific community has not yet widely accepted any exposure-response relationship between the amount of dpm exposure and the likelihood of adverse health outcomes.

66 Fed. Reg. 5706, 5708 (Jan 19, 2001). MSHA reviewed and updated its risk assessment in the June 6, 2005 rule amendments and concluded that no change was warranted. 70 Fed. Reg. at 32870, 32889, rendering its 2001 and 2005 conclusions subject to review and correction under the DQA.

The quoted admission likely explains why OSHA, EPA, and DOT did not precede, join or follow MSHA's effort to establish a personal exposure limit for the total or elemental carbon component of diesel particulate (for trains, trucks, generators, construction, tunneling and countless other potential exposures). The admission clearly explains why NIOSH and NCI are engaged in a massive study of the potential health effects of diesel exhaust in miners, that MSHA concluded would provide a basis to regulate diesel exhaust when completed (expected in 2006-7). 66 Fed. Reg. at 5710.

In defense of its selected limits, MSHA admits that comments "mistakenly assumed the limits ...were derived from an exposure response relationship..." 70 Fed. Reg. at 32900. Instead, MSHA states that its limits (both new and old, for both EC and TC) "while justifiable by quantifiable adverse health effects, were actually driven by feasibility concerns." *Id.* citing 66 Fed. Reg. at 5710-14. This illogical conclusion is false, and based on incorrect feasibility assumptions that the June 6, 2005 corrections acknowledge.

Moreover, contrary to MSHA's statement, there are no "quantifiable adverse health effects" presented for total carbon or elemental carbon, but instead extrapolations and speculation from EPA ambient air, total fine particulate rules, and the inconclusive, diesel exhaust studies (which suffered from confounding substances or a lack of statistical significance) that led NIOSH and NCI to conduct their health effects study to try to resolve the uncertainties. Since MSHA presents no quantifiable adverse health effects for total carbon or elemental carbon, their risk conclusions are based on a "less is better" regulatory logic, without the ability to identify or quantify the risks of the regulated substances, nor the benefits of the mandated reduction for the regulated substance, which MSHA now admits can not be measured accurately and feasibly.

Moreover, the MSHA risk assessment suffers from a lack of independent peer review. MSHA's claim that they selected and apparently paid two individuals to "peer review" their work, at best creates additional transparency defects since such self selected peer reviewers do not qualify as independent peer review, and the underlying authors and consultants, and their relationship to MSHA and ACGIH, were not disclosed. See e.g., infra at § XII.



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In reaching its conclusions regarding health effects, MSHA ignored the generally-accepted evidence that animal models, particularly rodents, of DPM-induced lung cancer were not applicable to humans and relied on animal models. 66 Fed. Reg. at 5821-50. Second, MSHA further misrepresented or ignored studies that have found there is not sufficient data to provide an adequate basis for quantifying the dose-response necessary for QRA, 11 even while separately admitting that the scientific community generally shared that conclusion.

In addition to deficient data to support a QRA, MSHA's conclusions regarding cancer risk assessments are neither transparent nor reproducible. If exposure metrics are uncertain, then resulting calculations of individual or population dose (derived from those exposure measures) must be uncertain as well. And, if calculated doses are uncertain, then the corresponding dose-response curves, which cannot be more accurate than measured dose, will be still more uncertain. All of this means that MSHA's alleged Quantitative Risk Assessment, which relies on hypothetical and extrapolated measurements, of substances other than the regulated substance, rather than direct measurements of the regulated substance, is neither transparent, reproducible, nor based on accepted science.

First, if DPM is a human carcinogen, then it should be expected to contain at least one specific human carcinogenic agent. Dr Jonathan Borak, a leading toxicologist and risk assessment expert at Yale University Medical School, relied on by the U.S. EPA, commented to MSHA, with supporting peer reviewed scientific studies, that it is generally accepted within the scientific community that such a carcinogen would be found in the organic carbon (OC) fraction of DPM, rather than the elemental carbon (EC) or total carbon (TC) fraction. MSHA disputes this, without any analysis that has undergone peer review. 70 Fed. Reg. at 32898. Moreover, MSHA misstates facts and misquotes scientific materials in reaching its conclusion, errors that independent peer review would have corrected, but now remain for correction under the Data Quality Act.

Because of significant variations empirically observed for the ratios of OC, EC and TC, measurement of either EC or TC could not accurately predict OC and its carcinogenic components. See Figure VI-3 at 70 Fed. Reg. at 32895, which presents massive differences in TC/EC ratios and the MSHA admission on the same page that:

At a confidence level exceeding 95%, the data show statistically significant differences in the mean EC:TC ratios between mines and between differing sampling days within mines."

In other words, neither EC nor TC provides an appropriate basis for measuring exposure to suspected DPM-associated carcinogenic agents, and the very basis of MSHA's risk analysis and

¹¹ See, e.g., Borak Report, 1999 Reports for the Health Effects Institute, HEI Panel, Harskcik presentation at Health Effects Workshop; USEPA Health Assessment Document for Diesel Engine Exhaust.



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resulting limit on its selected diesel exhaust component is wrong and must be corrected. Moreover, that same MSHA created Figure VI-3 at 70 Fed. Reg. 32895 shows a paucity of data at 160 TC and below, and a far greater data spread in this range that in the higher ranges.

MSHA's June 6, 2005 analysis should be corrected to state the impossibility of converting TC to EC in the range of the 160 TC Final Standard due to the wide variability in ratios reported, and the increase in sampling and analytic error expected as the quantity being measured decreases.

MSHA incorrectly concludes that the potential carcinogenic role of OC, as described by Dr Borak, was "speculative." 30 Fed. Reg. at 32988. MSHA based its conclusion on an inaccurate understanding of a publication by Ichinoses et al. <u>Id</u>. However the report by Ichinoses actually supports Dr Borak's conclusion, and rebuts MSHA. Ichinoses explains his findings as follows:

"The mechanism of lung carcinogenesis induced by diesel exhaust is not fully understood. However, it is thought that the carcinogenic compounds present in DEP may contribute to the development of lung cancer induced by diesel exhaust since carcinogenic compounds such as benzo[a]pyrene and nitro-polyaromatic hydrocarbons could form DNA adducts which are involved in carcinogenesis... We have recently found that O_2 and OH were enzymatically generated from DEP by the following process: soot-associated quinone-like compounds are reduced to the semiquinone radical by cytochrome P450 reductase, and these semiquinone radials reduce O_2 to O_2 ... which causes DNA damage in vitro."

Thus, Ichinoses proposed that the carcinogenic agent might be "carcinogenic compounds present in DPM" such as PAHs and nitro-PAHs or "soot-associated quinone-like compounds"; both types of compounds are found in the OC fraction of DPM. These authors, incorrectly cited by MSHA, directly contradict MSHA's conclusion, and demonstrate why MSHA's selected surrogates are the wrong substances to regulate and do not relate to the risk, if any, of lung cancer.

The MSHA Final Rule, 790 Fed. Reg. at 32911, quotes at length from the National Toxicology Program (NTP) Tenth Report on Carcinogens.¹³ The NTP statement indicates agreement with Dr Borak's comments, i.e., that the most likely human carcinogenic agents in DPM are organic compounds (e.g., PAHs and nitro-PAHs) that would be measured as OC, but not as EC. The more recent NTP Eleventh Report on Carcinogens affirms that view.¹⁴ It is noteworthy that neither

¹² Ichinose T, Yajima Y, Nagashima M, et al: Lung carcinogenesis and formation of 8-hydroxy-deoxyguanosine in mice by diesel exhaust particles. *Carcinogenesis* 18:185-192, 1997.

¹³ National Toxicology Program: Tenth Report on Carcinogens. Research Triangle Park, NC: US Department of Health and Human Services, 2003.

^{14 &}quot;Diesel exhaust contains identified mutagens and carcinogens both in the vapor phase and associated with respirable particles. Diesel exhaust particles are considered likely to account for the human lung cancer findings



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proposes inflammation-induced reactive oxygen species as the cause of lung cancer in humans. Thus, the MSHA defense of its selection of the wrong substance to undergo risk assessment, or be regulated, is incorrect, "speculative," lacks transparency and must be corrected.

If DPM exposure can cause human lung cancer, data suggests that it is probably due to exposure to certain specific organic components. MSHA has not looked at studies that measure the organic fraction (organic carbon or OC) of DPM and no studies have attempted measure the potential specific carcinogens. This failure would be of little consequence if OC exposure levels were closely related to levels of elemental carbon (EC) or total carbon (TC = OC + EC). However, as MSHA concludes, that relationship is not stable—measurements of EC and TC are now recognized as poor predictors of OC exposure.

Because there essentially are no epidemiological data correlated to OC levels, and because EC and/or TC levels in studies can not accurately predict OC, there are large and important uncertainties in the exposure assessments that MSHA uses to support its risk conclusions. This can be restated simply: Even if MSHA's speculative interpretation of non statistically significant historical studies were appropriate, which it is not, MSHA has used the wrong exposure metric for predicting lung cancer risks. The MSHA conclusions, therefore, require correction under the Data Quality Act to correct the errors resulting from the incorrect risk assessment method, the lack of transparency and reproducibility, the incorrect assumptions, the rejection of accepted science, and the lack of independent peer review.

VII (B). MSHA's Risk Assessment Is Based On Information That Violates Data Quality Act Mandates For Transparency And Lack Of Bias.

Disclosures contained in a deposition transcript included in the 2005 rulemaking record exposed the 2001 Rule, and specifically the Jan 19, 2006 Limit, as suffering from a lack of transparency and bias. MSHA's 2001 rule cited and relied upon an American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV®).

because they are almost all of a size small enough to penetrate to the alveolar region. Mutagenic and carcinogenic chemicals, including polyaromatic hydrocarbons and nitroarenes, have been extracted from these particles with organic solvents, or with a lipid component of mammalian lung surfactant. * * * A variety of mutagens and carcinogens such as PAH and nitro-PAH are adsorbed by the particulates. There is sufficient evidence for the carcinogenicity for 15 PAHs (a number of these PAHs are found in diesel exhaust particulate emissions) in experimental animals. The nitroarenes (five listed) meet the established criteria for listing as reasonably anticipated to be a human carcinogen based on carcinogenicity experiments with laboratory animals." National Toxicology Program: 11th Report on Carcinogens. Research Triangle Park, NC: US Department of Health and Human Services, 2005.

15 Even if DPM exposure mediates a process leading to the formation of mutagenic oxide radicals and it is that process that leads to lung cancer, DPM would best be described as a threshold carcinogen not amenable to linearized risk assessment models. However, the risk assessment models for DPM cited by MSHA rely on linearized models



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Because of the lack of a generally accepted dose-response relationship, some commenters questioned the agency's rationale in picking a particular concentration limit: $160\text{TC} \,\mu\text{g}/\,\text{m}3$ or around $200\text{DPM} \,\mu\text{g}/\text{m}3$. Capping dpm concentrations at this level will eliminate the worst mining exposures, and bring miner exposures down to a level commensurate with those reported for other groups of workers who use diesel-powered equipment. The proposed rule would not bring concentrations down as far as the proposed ACGIH TLV^R of $150_{\text{DPM}} \,\mu\text{g}/\text{m}^3$.

66 Fed. Reg. at 5710. The rule further relies on research conducted by the Chief of the MSHA's dust group, Thomas Tomb (now retired) and his colleague R.A. Haney. 66 Fed. Reg. at 5753, 5905, citing: July 1995. Tomb, Thomas, and R.A. Haney, "Results of Underground Mine Studies to Assess Diesel Particulate Exposures and Control Technologies," *Mining Engineering*, pp. 276-279, March 1995.

The transcript of Mr. Thomas Tomb (MSHA Dust Division Chief) deposition, dated May 23, 2001, revealed that he was the undisclosed chairman of the MSHA DPM drafting committee and the primary author of the ACGIH TLV, using his dual, overlapping positions, and government funds to influence both, and "bootstrapping" one from the other, violating transparency, conflict of interest, and bias policies that when revealed should have been condemned and prohibited, and caused the rule to be cleansed from this undue influence. Unfortunately, neither MSHA nor DOL have addressed this matter even though it has been repeatedly brought to their attention.

MARG also notes that the deposition of Thomas Tomb provides a basis to believe that MSHA entered into a single source consulting contract with a former political appointee, Andrea Hricko (and/or her husband, John Froines, known for his current advocacy role for lower standards on the California Air Quality Board, and his former role in the infamous "Chicago 7," 1960s radical group) to complete the drafting of the rule in time for the rushed Federal Register publication on the last day of President Clinton's Administration. In addition to the corrections needed to the Risk Assessment conclusions and information, MARG urges an investigation into this matter as part of the Data Quality Act inquiry.

VIII. CONCLUSION AND RELIEF REQUESTED.

It is essential for MSHA to revise its Final Rule on "Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners" to delete the January 19, 2006 Limit and appropriately and prominently acknowledge scientific uncertainty and correct the errors



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demonstrated above. The Data Quality Act and its implementing regulations and guidelines demand no less.¹⁶

Detailed, constructive suggestions as to how MSHA may bring the DPM Final Rule into compliance with the Information Quality Guidelines were submitted during the public comment periods that preceded the issuance of the final rules. Although the Information Guidelines do not mandate the precise language suggested, it does require MSHA to fully and honestly disclose scientific uncertainty and error in a manner similar to these suggestions.

The MARG Diesel Coalition, therefore, respectfully urges the Secretary to direct MSHA to stay the Final Limit on "Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners," pending rulemaking to withdraw it, with an accompanying correction of the record so as to bring MSHA into compliance with the Information Quality Guidelines. We also suggest that consideration of the need for any new limit be based on the pending CDC NIOSH/NCI study of potential health effects of diesel exhaust, as instructed by Congress.



(Name removed)

Counsel to the MARG Diesel Coalition

cc: Dr. John Graham, Director, OMB/OIRA
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Robert Friend, Administrator, DOL/MSHA
Edward P. Clair, Associate Solicitor, DOL/MSHA

¹⁶ The needed corrections do not require MSHA to abandon the new 308 EC limit since it is a "settlement" limit, agreed to by all of the parties in the underlying litigation, including MARG, even though MARG expressly preserved its position regarding the invalidity of the rule.

PATTON BOGGS.

2550 M Street, NW Washington, DC 20037-1350 202-467-6000



August 8, 2005

The Honorable Elaine L. Chao U.S. Department of Labor 200 Constitution Avenue, NW Washington, DC 20210

Howard M. Radzely Solicitor, U.S. Department of Labor 200 Constitution Avenue, NW Washington, DC 20210

Re: Petition For An Emergency Stay of the Effective Date of MSHA Jan 19, 2006 Diesel Exhaust Limit

Dear Secretary Chao and Solicitor Radzely:

The MARG Diesel Coalition¹ ("MARG" or "Coalition") respectfully Petitions the Department of Labor (DOL), Federal Mine Safety and Health Administration (MSHA) to publish an immediate, emergency stay of the 160 Microgram Total Carbon (TC) "Final Limit," 30 CFR § 57.5060 (b), for diesel particulate in underground metal and non metal mines, pending rulemaking to accomplish its withdrawal. The Coalition further Petitions the Secretary to base any new final limit on the multi-million dollar study of 14,000 current and former miners underway by NIOSH and NCI, designed to determine if there are potential health effects caused by diesel particulate, and if so, the safe exposure level. The study is scheduled for completion and Congressional review in the House of Representatives Committee on Education and the Workforce in 2006-7. Basing the Final Limit on the study complies with the direction provided by Congress in its appropriations reports, and in bipartisan letters to DOL from United States Senators Reid, Enzi, Thomas, and Craig, and others, attached hereto as Congressional Exhibits 1-4.

Pending completion of the NIOSH/NCI study, and any rulemaking supported by its findings, we further Petition the Secretary to extend the effective date of the 308 Microgram Elemental Carbon (EC) "Interim Limit," adopted on June 6, 2005, 70 FR 32868, and to grant compliance extensions, when feasible controls are not available.

¹ The Coalition is a party in the 2001 and 2005 court challenges to the MSHA diesel exhaust rules and its members operate facilities cooperating in the NIOSH/NCI study of potential health effects discussed herein.



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The looming 160 TC permissible exposure limit (PEL) was set as a future surrogate for diesel particulate on the last day of President Clinton's Administration. 66 FR 5706 (Jan 19, 2001). Unless stayed immediately, it will create confusion among regulated parties because it conflicts with the new June 6, 2005 Elemental Carbon limit. More importantly, the Limit poses a threat of closure for almost 200 mining operations that provide thousands of jobs and critical metals and minerals for the nation's economy and defense.

There are three independent reasons that require a stay, pending rulemaking and deletion of the January 19, 2006 160 Microgram Total Carbon Limit: (1) it is not "technologically feasible" because it cannot be measured; (2) it is not "technologically feasible" for the industry to comply with the Final Limit; and (3) the limit does not meet Congressional mandates.

FEASIBLE CONTROLS DO NOT EXIST TO MEET THE JANUARY 19, 2006 LIMIT

The DOL MSHA June 6, 2005 Federal Register reported that the agency found 30-37% of the impacted mines were not in compliance with the 308 EC Interim Limit. Current MSHA and industry data indicate 90-95% of the industry cannot comply with the 160 TC Final Limit, scheduled for January 19, 2006. MSHA's June 6, 2005 Federal Register notice states:

MSHA acknowledges that the current DPM rulemaking record lacks sufficient feasibility documentation to justify lowering the DPM limit below 308 EC µg/m3 at this time.

70 FR at 32916. Under applicable law requiring feasible standards, this conclusion alone mandates a stay, pending rulemaking to withdraw the Final Limit. Moreover, as requested in our concurrently filed Petition For Data Quality Act Correction, correction of the 2001 Final Rule is mandated by the Act since it declared the 2006 Final Limit feasible, based on incorrect assumptions, inaccurate data and unjustified engineering and scientific conclusions. The extensive diesel exhaust control tests, and the failures reported in the MSHA June 5, 2005 Federal Register notice, as well as the reported MSHA diesel exhaust sampling data base, fully support the need to stay and delete the 2006 Final Limit.

THE JANUARY 19, 2006 FINAL LIMIT CANNOT BE MEASURED AND MUST BE WITHDRAWN

The Final Limit is in direct conflict with the new Interim Limit of 308 Micrograms of Elemental Carbon (EC), adopted by MSHA on June 6, 2005. 70 FR 32868. The new Interim Limit recognizes that the Total Carbon limits are incapable of accurate measurement:



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No reasonable method of sampling was found to eliminate interferences from oil mist or that would effectively measure DPM levels in the presence of ETS with TC as the surrogate.

70 FR at 32871, June 6, 2005. Accurate measurement is required for a rule to be feasible and comply with statutory mandates. This MSHA conclusion independently requires a stay, pending a rulemaking to withdraw the January 19, 2006 Final Limit. Moreover, as requested and documented in our Data Quality Act Petition For Correction, filed concurrently herewith, correction of the 2001 Rule is required since it declared the Total Carbon rule accurate, capable of measurement, and feasible; was based on incorrect assumptions, inaccurate data, and unjustified engineering and scientific conclusions, using information that did not meet Data Quality Act standards.

THE JANUARY 19, 2006 LIMIT DOES NOT MEET CONGRESSIONAL MANDATES

MSHA's diesel particulate limit is a unique regulatory experiment that demonstrates the validity of Congressional mandates to base standards on sound scientific evidence, coordinate actions with other safety and health agencies, and rely on reproducible, transparent, independently peer reviewed science, free from bias and conflicts of interest. MSHA's DPM rules regulate suspected, but unproven health hazards, at levels not associated with scientific evidence of risk:

As MSHA acknowledged in the preamble to the proposed rule, the scientific community has not yet widely accepted any exposure-response relationship between the amount of dpm exposure and the likelihood of adverse health outcomes.

66 FR 5706, 5708 (Jan 19, 2001). This conclusion was reinforced when MSHA affirmed the results of its risk assessment in the June 2005 rule amendments. The conclusion may explain why OSHA, EPA, and DOT did not precede, join or follow MSHA's effort to establish a personal exposure limit for the total or elemental carbon in diesel particulate (for trains, trucks, generators, construction, tunneling and countless other potential exposures). The conclusion clearly explains why NIOSH and NCI are engaged in their massive study of the potential health effects of diesel exhaust in miners that ironically MSHA concluded would provide a basis to regulate diesel exhaust, when completed. 66 FR at 5710.

Regardless of this logical MSHA conclusion, and the Congressional direction for any final standard to be informed by the NIOSH/NCI study and coordinated with OSHA and EPA, on January 19, 2001, MSHA rushed to regulate DPM on the closing day of the outgoing



Secretary Chao and Solicitor Radzely August 8, 2005 Page 4

Administration. MSHA's action was based on: (1) total carbon as a surrogate for DPM, even though it was an unproven surrogate (from both a health effects and measurement perspective); (2) a "less is better" concept, even though "less of what" had not been defined by the science, and how much better, if any, can not be determined; (3) a sample collection and measurement system which did not exist at the time, but was created (piecemeal) from Bureau of Mines and NIOSH research projects resulting in a commercially untested system that ultimately required repeated redesign and reevaluation; and (4) technical and economic feasibility decisions using an MSHA computer model, "The Estimator," which relied on invalid assumptions proven by MSHA's admission that 30% of the industry is not in compliance with the Interim Standard, 70 FR at 32918, and that there is insufficient evidence for the feasibility of compliance with a lower standard, 70 FR at 32916. The lack of feasibility is uncontested and demonstrated by MSHA data showing at least 90% of the industry not in compliance with the January 19, 2006 Limit.

In the four and one-half years since MSHA reached its conclusions, massive implementation experiments resulted in the June 6, 2005 rule amendments that fundamentally changed the rule. While contrary to the opinions of independent scientists, expert physicians and toxicologists, MSHA still asserts that its health risk assessment is correct, even while admitting that compliance feasibility and sampling and analysis conclusions underlying the selected limits were incorrect.

To resolve the DPM issues and stop the continued diversion of limited resources away from other safety and health priorities, the Coalition petitions for the extension of the June 6, 2005 Interim Limit until the completion of the NIOSH/NCI Study Of The Potential Health Effects Of Diesel Exhaust informs the Secretary of the scientific basis for determining if a new, Final Standard should be proposed and adopted.

Your prompt attention to this matter is respectfully requested to avoid confusion, unnecessary litigation, and the significant job losses that would result from implementation of the January 19, 2006 Limit.

 Sincerely	',				
					(Name removed)
Counse	To Th	e MAR(- Diesel	Coalition	

HC:eei

Anital States Senate

WASHINGTON DC 20510-2003

June 30, 2000

The Honorable Alexis Herman United States Department of Labor 200 Constitution Avenue, NW Washington, DC 20210

Dear Secretary Horman,

We are pleased that the Department's Mins Safety and Health Administration (MSHA) is proceeding with its Diesel Particulate Matter rulemaking. It is very important that we protect miners from any potential health risk posed by diesel exhaust. Because other federal agencies have already expressed concern regarding the potential health effects of diesel fitnes, we hope that coordinated actions will be taken to provide the highest level of protection and avoid conflicting standards. It is importative that you proceed with the rulemaking in a manner that ensures the appropriate protection of workers currently exposed to diesel particulate in mines. At the same time we hope you will coordinate MSHA's effort with OSHA's protection of workers in the construction and tunneling industry, as well as the Environmental Protection Agency's (EPA) ongoing efforts to require cleaner diesel engines.

In this regard, we note that a study currently underway at the National Institute of Occupational Safety and Health (NIOSH) could contribute to a solid foundation for this rulemaking. In particular, the Desert Research Institute (DRI) of Nevada has been chosen by NIOSH to investigate underground mine diesel exposure risks. As you may know, the scientists at DRI are well-regarded for their premier analytical work on matters pertaining to health and safety. We believe that DRI's research will help guarantee the scientific basis for NIOSH's findings and should, therefore, receive exercit consideration.

Moreover, we understand that the work to be completed by DRI in 2001 is responsive to the Senate-House Conference Report which accompanied the FY 2000 Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriation Conference. This directive asks that your rulemaking be "informed" by the NIOSH study. This language also directly references exposure analysis research, which is currently the subject of the DRI's study.

It is important that the MSHA Diesel Rule be scientifically sound and consistent with congressional intent. We believe, therefore, that you should issue your final rule after completion and review of the NIOSH study even though that may temperarily delay the final rule. We are concerned that MSHA would be subject to a strong challenge if the rulemaking procedes the study results.

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PROFESSION MACHINES PAPER

We understand that you intend to issue a final rule by the end of 2000. You should know that we will do everything we can to urge the timely completion of studies by DRI and NIOSH, so that MSHA can proceed as expeditiously as possible. At the same time, we believe it important to make certain that the final rule be informed by the best available scientific information, including the work being done by DRI and NIOSH, as well as ongoing work by OSHA and EPA. We are also urging DRI to proceed as expeditiously as possible with their research in order to confirm to your timetable without jeopardizing the quality of their work.

Thank you for your consideration. We look forward to continuing to work with you to protect the health and safety of the nation's workers.

Sincerely,

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OFFICER

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United States Scrate

WASHINGTON, DC 20510-5004

June 30, 2000

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COMMITTEES:

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The Honorable Alexis Herman United States Department of Labor 200 Constitution Avenue, NW Washington, DC 20210

Dear Secretary Becomen:

I am pleased that the Department's Mine Safety and Health Administration (MSHA) is proceeding with its Diesel Particulate Maner rulemaking. It is very important that we protect miners from any potential health nisk posed by diesel entenst. Because other federal agencies have already expressed concern regarding the potential health effects of diesel funes, we hope that coordinated actions will be taken to provide the highest level of protection and avoid conflicting standards. It is imperative that you proceed with the rulemaking in a manner that casures the appropriate protection of workers currently exposed to diesel particulate in mines. At the same time we hope you will coordinate MSHA's effect with OSHA's protection of workers in the construction and numering industry, as well as the Environmental Protection Agency's (HPA) ongoing efforts to require cleaner diesel engines.

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The Honorable Alexis Herman June 30, 2000 Page 2

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Thank you for your consideration. We look forward to continuing to work with you to protect the health and axisty of the nation's workers.

Sincerely.

Michael B. Bazi

Chairman, Senate Subcommittee on Employment Safety and Training

DIANG THOMAS

Anited States Senate

February 14, 2001

The Honorable Elaine Chao Unite States Department of Labor 200 Constitution Avenue, NW Washington D.C. 20210

Dear Secretary Chao:

on January 19, 2001, the Mine Safety and Health Administration promulgated a final rule establishing a diesel particulate standard for underground mines (30 CFR Part 57). We agree it is extremely important to protect miners from any potential health risk posed by diesel exhaust, but are concerned with the circumstances under which this rule was finalized.

Research is currently engoing through the National Institute of Occupational Safety and Health (NIOSH) and the Desert Research Institute of Nevada (DRI) focused on the investigation of underground mine diesel exposure risks. Congress in the Fiscal Year 2000 Labor Appropriation recognized this engoing research as pertinent to the completion of the rulemaking. We believe this research could ensure the integrity of the rulemaking and the finalization of this rule, absent consideration of the NIOSH/DRI data, to be premature.

Many of the undersigned Senators made this point to the Department of Labor in a letter conveyed June 30, 2000. We recommended the rule be issued following completion and review of the NIOSH study even if that meant temporarily delaying final promulgation. Unfortunately, we received no reply from the Department, except in the form of the final rule as published in the Federal Register. We are concerned that this rule, lacking the input of the NIOSH study, may be scientifically unsound and subject to a strong challenge.

We request that as the Department complies with President Bush's regulatory review plan, this particular rulemaking be stayed or withdrawn pending the completion and analysis of the NIOSH study. We seek only to ensure that the rulemaking is scientifically sound, sufficiently protective of underground mine workers, and complementary of the efforts across the Federal government to protect the public from hazards associated with diesel particulate.

We appreciate your consideration of this request and look forward to working with you to resolve this issue.

Sincerely,

Craig Thomas

United States Senator

106TH CONGRESS
1st Session

HOUSE OF REPRESENTATIVES

REPORT 106-370

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATION BILL, 2000

REPORT

TO ACCOMPANY

H.R. 3037



OCTOBER 7, 1999.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed interview to create compliance profiles for each facility and generate comprehensive "to-do" lists to manage compliance—customized for each facility, and kept current over the Internet. In addition, the system would use the Internet to automatically download, index, view and print Material Safety Data Sheets (MSDS) files. Once tagged, MSDS's would be monitored and user

files would be automatically updated via the Internet.

The Committee has included language carried in the bill since 1976 in one instance and 1979 in the other that restricts the use of funds for certain purposes. First, the bill includes language that effectively exempts farms employing 10 or fewer people from the provisions of the Act except those farms having a temporary labor camp. Second, the bill includes language exempting businesses employing 10 or fewer in industry classifications having a lost workday injury rate less than the national average from general schedule safety inspections.

MINE SAFETY AND HEALTH ADMINISTRATION

SALARIES AND EXPENSES

The bill includes \$211,165,000 for this agency. This is \$17,208,000 below the budget request and the same as the fiscal year 1999 level after adjusting for the one-time funding in 1999 of Y2K activities. This agency enforces the Federal Mine Safety and Health Act in underground and surface coal and metal and non-metal mines.

The Committee wishes to commend the agency and the affected industries for working together effectively, as requested in last year's appropriations cycle, to revise the miner training regulations with respect to the companies engaged in the mining of sand, gravel, surface stone, surface clay, colloidal phosphate and surface limestone. The proposed regulations are currently under review by the Office of Management and Budget and are scheduled to be issued in final form by September 30. In order to ensure that there is a transition period after the regulations are finally issued, the Committee has decided to continue language in the bill prohibiting the use of funds to carry out the training provisions of the Act with respect to these industries until June 1, 2000. The Committee hopes and intends that the agency and the affected industry groups will continue to work together cooperatively to see that there is an appropriate transition period during which the affected industries can become familiar with the new regulations and can see that they are smoothly implemented. If sufficient progress has been achieved by the time the conference committee meets on this bill, every consideration will be given to dropping the prohibition entirely.

The Committee believes that the promulgation of a proposed rule on diesel exhaust should be informed by the ongoing NCI/NIOSH study of Lung Cancer and Diesel Exhaust among Non-Metal Miners. The Committee believes that this rule would be strengthened by the development and use of testing methods that more accurately identify actual toxic properties and exposure effects associated with diesel exhaust and notes that research presently being undertaken could lead to substantial improvements in current test-

ing devices and analytical methods used to measure actual expo-

The Committee is concerned about the possible ramifications of a rulemaking on the use of conveyor belts in underground coal mines. A number of questions have been raised concerning this proposed rule, including concerns about the validity of the testing on which the rule is based and concerns about the amount of time that has elapsed since the rule was originally proposed. The Committee directs MSHA, before the agency issues a final rule on conveyor belts, to carefully examine the record, conduct additional research that may be required to address any significant concerns that have been raised, and to be very sure that any final rule does not have the unintended consequence of creating additional hazards in coal mines.

BUREAU OF LABOR STATISTICS

SALARIES AND EXPENSES

The total funding recommended by the Committee for the Bureau of Labor Statistics is \$394,697,000. This is a reduction of \$26,222,000 below the budget request and is a freeze at the 1999 level after adjusting for the planned reduction in funds for the Consumer Price Index revision. The bill includes \$340,551,000 in general funds for this account and authority to spend \$54,146,000 from the Employment Security Administration Account of the Unemployment Trust Fund. The Bureau of Labor Statistics is the principal fact-finding agency in the Federal Government in the broad field of labor economics. Its principal surveys include the Consumer Price Index and the monthly unemployment series.

The Committee has approved \$6,986,000, the full amount requested by the Administration, for the completion of the Consumer Price Index revision. This revision is critical to the Nation's econ-

omy and to the Federal budget.

DEPARTMENTAL MANAGEMENT

SALARIES AND EXPENSES

The bill includes \$191,131,000 for Departmental Management activities. This is \$66,523,000 below the budget request and is a freeze at the 1999 level after accounting for one-time funding in 1999 for Y2K activities and other one-time funding requirements related primarily to the Clinger-Cohen Act. The bill includes \$190,832,000 in general funds for this account along with authority to transfer \$299,000 from the Employment Security Administration account of the Unemployment Trust Fund. In addition, an amount of \$20,422,000 is available by transfer from the Black Lung Disability Trust Fund. This is \$722,000 less than the budget request and the same as the fiscal year 1999 level.

The Departmental Management appropriation finances staff responsible for formulating and overseeing the implementation of Departmental policy and management activities. In addition, this appropriation includes a variety of operating programs and activities that are not involved in Departmental Management functions, but