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November 30, 2016

Ms. Sheila McConnell
MSHA, Office of Standards Regulations and
Variances
201 12th Street South
Suite 4E401
Arlington, VA 22202-5452

Re: RIN 1219-AB86
Docket No. MSHA-2014-0031
Exposure of Underground Miners to Diesel Exhaust

Dear Ms. McConnell:

We write on behalf of the Mining Coalition, a group of MSHA-regulated companies in a wide variety of industries that operate mines, quarries, and processing facilities with thousands of employees and vastly different conditions, operations, methods, and practices. All members of the Coalition share with MSHA the goal of protecting the safety and health of the workforce, reported by MSHA as including 221,529 employees at 11,787 regulated facilities.

Many of the facilities regulated by MSHA utilize diesel powered equipment. Some members of the Mining Coalition participated in the Diesel Exhaust In Miners Study (DEMs) that is the underlying basis for the MSHA Request For Information (RFI). The Coalition is proud of the massive reductions in diesel exhaust exposures achieved since the DEMs study was planned and conducted, and it has a deep interest in the RFI. Coalition members will be impacted directly by any new, additional regulations proposed for diesel engines and further exhaust controls, and we urge caution in relying on the current state of the science in supporting the need for such regulations.

The Coalition requested that MSHA extend the time for evaluation and response to the MSHA RFI. While we appreciate the short extension provided by MSHA, we respectfully request that the time for response be extended further to permit evaluation and consideration of the complex and extensive information underlying the RFI. We submit for the record the following list of published studies and critiques, some of which we excerpt below, to

demonstrate the complexity of the scientific record and the uncertainty of its use to support regulatory action (before re-publishing the attached articles, please obtain any necessary copyright permission).

Of course, we realize that there are published opinions contrary to those expressed below that will be used to support regulatory action. Yet, we urge extreme caution in relying on the current state of the published health effects science to support additional diesel engine regulations at this time, particularly because the published science generally does not consider today's far-cleaner diesel engines, fuels and exhaust.

Re: The Diesel Exhaust in Miners Study: A Nested Case-Control Study of Lung Cancer and Diesel Exhaust and a Cohort Mortality Study with Emphasis on Lung Cancer – Boffetta, Paolo Published in Journal of the National Cancer Institute 5 December 2012.

Comment on the Diesel Exhaust in Miner Study – Borak, Jonathan Published in the Annuals of Occupational Hygiene Vol. 55 No.3 Received 15 September 2010 final 16 November 2010.

Meta-Analysis of Lung Cancer Risk from Exposure to Diesel Exhaust: Study Limitations – Crump, Kenny Published in Environmental Health Perspectives September 2014.

Meta-Analysis of Lung Cancer Risk from Exposure to Diesel Exhaust: Vermeulen et al. Respond Published in Environmental Health Perspectives September 2014.

Evaluation of an exposure assessment used in epidemiological studies of diesel exhaust and lung cancer in underground mines Crump, Kenny and Van Landingham, Cynthia Published in Critical Review in Toxicology, 2012:

> *" NIOSH/NCI (National Institute of Occupational Safety and Health and National Cancer Institute) developed exposure estimates for respirable elemental carbon (REC) as a surrogate for exposure to diesel exhaust (DE) for different jobs in eight underground mines by year beginning in the 1940s—1960s when diesel equipment was first introduced into these mines. These estimates played a key role in subsequent epidemiological analyses of the potential relationship between exposure to DE and lung cancer conducted in these mines. We report here on a reanalysis of some of the data from this exposure assessment. Because samples of REC were limited primarily to 1998–2001, NIOSH/NCI used carbon monoxide (CO) as a surrogate for REC. In addition, because CO samples were limited, particularly in the earlier years, they used the ratio of diesel horsepower (HP) to the mine air exhaust rate as a surrogate for CO. There are considerable uncertainties connected with each of these surrogate-based steps. The estimates of HP appear to involve considerable uncertainty, although we had no data upon which to evaluate the magnitude of this uncertainty. A sizable percentage (45%) of the CO samples used in the HP to CO model was below the detection limit which required NIOSH/NCI to assign CO values to these samples. In their preferred REC estimates, NIOSH/NCI assumed a linear relation between C0 and*

REC, although they provided no credible support for that assumption. Their assumption of a stable relationship between HP and CO also is questionable, and our reanalysis found a statistically significant relationship in only one-half of the mines. We re-estimated yearly REC exposures mainly using NIOSH/NCI methods but with some important differences: (i) rather than simply assuming a linear relationship, we used data from the mines to estimate the CO—REC relationship; (ii) we used a different method for assigning values to nondetect CO measurements; and (iii) we took account of statistical uncertainty to estimate bounds for REC exposures. This exercise yielded significantly different exposure estimates than estimated by NIOSH/NCI. However, this analysis did not incorporate the full range of uncertainty in REC exposures because of additional uncertainties in the assumptions underlying the modeling and in the underlying data (e.g. HP and mine exhaust rates). Estimating historical exposures in a cohort is generally a very difficult undertaking. However, this should not prevent one from recognizing the uncertainty in the resulting estimates in any use made of them."

Reanalysis of the DEMS Nested Case Control Study of Lung Cancer and Diesel Exhaust: Suitability for Quantitative Risk Assessment Crump et. al. Published in Risk Analysts, Volume 35, No. 4, 2015:

"The International Agency for Research on Cancer (IARC) in 2012 upgraded its hazard characterization of diesel engine exhaust (DEE) to "carcinogenic to humans." The Diesel Exhaust in Miners Study (DEMS) cohort and nested case-control studies of lung cancer mortality in eight U.S. nonmetal mines were influential in IARC's determination. We conducted a reanalysis of the DEMS case-control data to evaluate its suitability for quantitative risk assessment (QRA). Our reanalysis used conditional logistic regression and adjusted for cigarette smoking in a manner similar to the original DEMS analysis. However, we included additional estimates of DEE exposure and adjustment for radon exposure. In addition to applying three DEE exposure estimates developed by DEMS, we applied six alternative estimates. Without adjusting for radon, our results were similar to those in the original DEMS analysis: all but one of the nine DEE exposure estimates showed evidence of an association between DEE exposure and lung cancer mortality, with trend slopes differing only by about a factor of two. When exposure to radon was adjusted, the evidence for a DEE effect was greatly diminished, but was still present in some analyses that utilized the three original DEMS DEE exposure estimates. A DEE effect was not observed when the six alternative DEE exposure estimates were utilized and radon was adjusted. No consistent evidence of a DEE effect was found among miners who worked only underground. This article highlights some issues that should be addressed in any use of the DEMS data in developing a QRA for DEE."

Influence of Alternative Exposure Estimates in the Diesel Exhaust Miners Study: Diesel Exhaust and Lung Cancer Crump, Kenny S., Van Landingham, Cynthia, and McClellan, Roger O. Published in Risk Analysis 2016:

"The landmark Diesel Exhaust in Miners Study (DEMS) studied the relationship between diesel exhaust exposure (DEE) and lung cancer mortality of workers at eight nonmetal mines who were followed from beginning of dieselization of the mines (1947–1967) through December 31, 1997. The original analyses quantified DEE exposures using exposure to respirable elemental carbon (REC) to represent DEE, and CO as a surrogate for REC. However, this use of CO data, and the CO data themselves, have numerous shortcomings. We developed new estimates of REC exposures using historical data on use of diesel equipment, diesel engine horsepower (HP), mine ventilation rates, and the documented reduction in particulate matter emissions per HP in diesel engines from 1975 through 1995. These new REC estimates were applied in a conditional logistic regression of the DEMS nested case-control data very similar to the one applied in the original DEMS analyses. None of the trend slopes calculated using the new REC estimates were statistically significant ($p > 0.05$). Moreover, these trend slopes were smaller by roughly factors of five without control for radon exposure and factors of 12 with control for radon exposure compared to those estimated in the original DEMS analyses. Also, the 95% confidence intervals for these trend slopes had only minimal overlap with those for the slopes in the original DEMS analyses. These results underscore the uncertainty in estimates of the potency of diesel exhaust in causing lung cancer based on analysis of the DEMS data due to uncertainty in estimates of exposures to diesel exhaust.

Lung Cancer and diesel exhaust: an updated critical review of the occupational epidemiology literature Gamble, John F., Nicolich, Mark J. and Boffetta, Paolo Published in Critical Review in Toxicology 2012:

"A recent review concluded that the evidence from epidemiology studies was indeterminate and that additional studies were required to support the diesel exhaust-lung cancer hypothesis. This updated review includes seven recent studies. Two population-based studies concluded that significant exposure-response (E-R) trends between cumulative diesel exhaust and lung cancer were unlikely to be entirely explained by bias or confounding. Those studies have quality data on life-style risk factors, but do not allow definitive conclusions because of inconsistent E-R trends, qualitative exposure estimates and exposure misclassification (insufficient latency based on job title), and selection bias from low participation rates. Non-definitive results are consistent with the larger body of population studies. An NCI/NIOSH cohort mortality and nested case-control study of non-metal miners have some surrogate based quantitative diesel exposure estimates (including highest exposure measured as respirable elemental carbon (REC) in the workplace) and smoking histories. The authors concluded that diesel exhaust may cause lung cancer. Nonetheless, the results are non-definitive because the conclusions are based on E-R patterns where high exposures were deleted to achieve significant results, where a posteriori adjustments were made to augment results, and where inappropriate adjustments were made for the "negative confounding" effects of smoking even though current smoking was not associated with diesel exposure and therefore could not be a confounder. Three cohort studies of bus drivers and truck drivers are in effect air pollution studies without estimates of diesel exhaust exposure and

so are not sufficient for assessing the lung cancer-diesel exhaust hypothesis. Results from all occupational cohort studies with quantitative estimates of exposure have limitations, including weak and inconsistent E-R associations that could be explained by bias, confounding or chance, exposure misclassification, and often inadequate latency. In sum, the weight of evidence is considered inadequate to confirm the diesel-lung cancer hypothesis."

Health effects research and regulation of diesel exhaust: an historical overview focused on lung cancer risk Hesterberg, Thomas W. et al Published in Inhalation Toxicology 2012:

"The mutagenicity of organic solvent extracts from diesel exhaust particulate (DEP), first noted more than 55 years ago, initiated an avalanche of diesel exhaust (DE) health effects research that now totals more than 6000 published studies. Despite an extensive body of results, scientific debate continues regarding the nature of the lung cancer risk posed by inhalation of occupational and environmental DE, with much of the debate focused on DEP. Decades of scientific scrutiny and increasingly stringent regulation have resulted in major advances in diesel engine technologies.

The changed particulate matter (PM) emissions in ***"New Technology Diesel Exhaust (NTDE)"*** *from today's modern low-emission, advanced-technology on-road heavy-duty diesel engines now resemble the PM emissions in contemporary gasoline engine exhaust (GEE) and compressed natural gas engine exhaust more than those in the "traditional diesel exhaust" (TDE) characteristic of older diesel engines. Even with the continued publication of epidemiologic analyses of TDE-exposed populations, this database remains characterized by findings of small increased lung cancer risks and inconsistent evidence of exposure–response trends, both within occupational cohorts and across occupational groups considered to have markedly different exposures (e.g. truckers versus railroad shop workers versus underground miners). The recently published National Institute for Occupational Safety and Health (NIOSH)-National Cancer Institute (NCI) epidemiologic studies of miners provide some of the strongest findings to date regarding a DE-lung cancer association, but some inconsistent exposure– response findings and possible effects of bias and exposure misclassification raise questions regarding their interpretation. Laboratory animal studies are negative for lung tumors in all species, except for rats under lifetime TDE-exposure conditions with durations and concentrations that lead to "lung overload." The species specificity of the rat lung response to overload, and its occurrence with other particle types, is now well-understood. It is thus generally accepted that the rat bioassay for inhaled particles under conditions of lung overload is not predictive of human lung cancer hazard. Overall, despite an abundance of epidemiologic and experimental data, there remain questions as to whether TDE exposure causes increased lung cancers in humans. An abundance of emissions characterization data, as well as preliminary toxicological data, support NTDE as being toxicologically distinct from TDE.*

Currently, neither epidemiologic data nor animal bioassay data yet exist that directly bear on NTDE carcinogenic potential. A chronic bioassay of NTDE currently in progress

will provide data on whether NTDE poses a carcinogenic hazard, but based on the significant reductions in PM mass emissions and the major changes in PM composition, it has been hypothesized that NTDE has a low carcinogenic potential. When the International Agency for Research on Cancer (IARC) reevaluates DE (along with GEE and nitroarenes) in June 2012, it will be the first authoritative body to assess DE carcinogenic health hazards since the emergence of NTDE and the accumulation of data differentiating NTDE from TDE."

Re: The Diesel Exhaust in Miners Study; A Nested Case-Control Study of Lung Cancer and Diesel Exhaust, a Cohort Mortality Study with Emphasis on Lung Cancer, and the Problem of Diesel McClellan, Roger O. Published in JNCI 5 December 2012 (*Editorial Letter of analysis DEMS study).*

Evaluation of carcinogenic hazard of diesel engine exhaust needs to consider revolutionary changes in diesel technology McClellan, Roger O., Hesterberg, Thomas W., and Wall, John C. Published in Regulatory Toxicology and Pharmacology Received 23 February 2012 Online 27 April 2012:

"Diesel engines, a special type of internal combustion engine, use heat of compression, rather than electric spark, to ignite hydrocarbon fuels injected into the combustion chamber. Diesel engines have high thermal efficiency and thus, high fuel efficiency. They are widely used in commerce prompting continuous improvement in diesel engines and fuels. Concern for health effects from exposure to diesel exhaust arose in the mid-1900s and stimulated development of emissions regulations and research to improve the technology and characterize potential health hazards. This included epidemiological, controlled human exposure, laboratory animal and mechanistic studies to evaluate potential hazards of whole diesel exhaust. The International Agency for Research on Cancer (1989) classified whole diesel exhaust as – ''probably carcinogenic to humans''. This classification stimulated even more stringent regulations for particulate matter that required further technological developments. These included improved engine control, improved fuel injection system, enhanced exhaust cooling, use of ultra low sulfur fuel, wall-flow high-efficiency exhaust particulate filters, exhaust catalysts, and crankcase ventilation filtration. The composition of New Technology Diesel Exhaust (NTDE) is qualitatively different and the concentrations of particulate constituents are more than 90% lower than for Traditional Diesel Exhaust (TDE). We recommend that future reviews of carcinogenic hazards of diesel exhaust evaluate NTDE separately from TDE."

Diesel motor exhaust and lung cancer mortality: reanalysis of a cohort study in potash miners Mohner, Matthias, Kersten, Norbert, and Gellissen, Johannes Published in Eur. J. Epidemiol Received: 30 November 2011 Accepted 12 February 2013 Published online 19 February 2013:

"The aim of the reanalysis is to reassess lung cancer risk associated with occupational exposure to diesel motor exhaust in potash miners, while controlling for potential confounders such as smoking and previous occupational history. Our investigation is

based on a cohort study of nearly 6,000 German potash miners, who were followed up from 1970 to 2001. The reanalysis also takes into account the employment periods before potash mining, in particular uranium mining. Different approaches (nested case–control study and Cox model) were used to adjust for confounding. The exposure estimates were recalculated, lagging the exposure by 5 years. Exposure groups were defined by tertiles of cumulative respirable elemental carbon (REC) exposure estimates and occupational categories, where exposure was estimated originally by representative measurements of total carbon for different occupations. The highest REC concentration was measured for production workers, about twice as much as for other occupations. The reanalysis revealed that while about 4 % of all study subjects had worked earlier in uranium mines, 10.3 % of later lung cancer cases did so. Although their absolute number was small, the corresponding relative risk estimator was significantly elevated. Our analysis did not show any notable association between cumulative REC exposure and lung cancer risk. Introducing cumulative REC exposure as a continuous variable into the conditional logistic regression model yielded an odds ratio of OR = 1.04 [0.70–1.53]95 % adjusted for smoking and previous employment. The study results give no evidence for an association between REC exposure and lung cancer risk. Only for very high cumulative dose, corresponding to at least 20 years of exposure in the production area, some weak hints for a possible risk increase could be detected. The study underlines the importance of assessing the entire occupational history in occupational studies, especially if the supposed dose–response-relationship is weak."

The hidden impact of a healthy-worker effect on the results of the Diesel Exhaust in Miners Study Mohner, Matthias Published in Eur J Epidemiol Received 3 March 2016 Accepted 9 May 2016 (Published online 25 May 2016) *(Letter suggesting a reanalysis of the DEMS data).*

Diesel Engine Exhaust and Lung Cancer Mortality: Time –Related Factors in Exposure and Risk Moolgavkar, Suresh H. et al Published in Risk Analysts Vol. 35, No. 4, 2015:

"To develop a quantitative exposure-response relationship between concentrations and durations of inhaled diesel engine exhaust (DEE) and increases in lung cancer risks, we examined the role of temporal factors in modifying the estimated effects of exposure to DEE on lung cancer mortality and characterized risk by mine type in the Diesel Exhaust in Miners Study (DEMS) cohort, which followed 12,315 workers through December 1997. We analyzed the data using parametric functions based on concepts of multistage carcinogenesis to directly estimate the hazard functions associated with estimated exposure to a surrogate marker of DEE, respirable elemental carbon (REC). The REC-associated risk of lung cancer mortality in DEMS is driven by increased risk in only one of four mine types (limestone), with statistically significant heterogeneity by mine type and no significant exposure-response relationship after removal of the limestone mine workers. Temporal factors, such as duration of exposure, play an important role in determining the risk of lung cancer mortality following exposure to REC, and the relative risk declines after exposure to REC stops. There is evidence of effect modification of risk by attained age. The modifying impact of temporal factors and effect modification by age should be addressed in any quantitative risk assessment (QRA) of DEE. ***Until there is a***

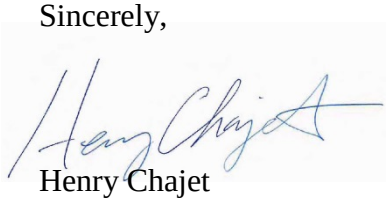
better understanding of why the risk appears to be confined to a single mine type, data from DEMS cannot reliably be used for QRA."

Diesel exhaust in miners study: how to understand the findings? Morfeld, Peter Published in the Journal of Occupational Medicine and Technology 2012:

> *"The Diesel Exhaust in Miners Study (DEMS) is an outstanding epidemiological project on the association between occupational diesel exhaust exposures, measured as long-term respirable elemental carbon (REC) estimates, and lung cancer mortality in a large cohort of US miners. Two articles published recently (Attfield et al. (J Natl Cancer Inst Epub, 2012), Silverman et al. (J Natl Cancer Inst Epub, 2012)) dsescribed the epidemiological findings. These papers are expected to have considerable impact on the evaluation of the carcinogenic potential of diesel exhaust and, furthermore, on occupational and environmental limit value discussions related to diesel motor emissions and particle exposures. DEMS found remarkable exposure-response relationships between REC exposure estimates and lung cancer mortality - conditional on a pronounced effect of surface vs. underground work on lung cancer risk. If this risk factor is ignored the estimated REC-lung cancer association is attenuated substantially. The authors relied on this risk factor in their main analyses. However, this factor "surface/underground work" remained unexplained. The factor lead the authors to introduce unusual cross-product terms of location and smoking in adjustment procedures and even caused the authors to hypothesize that high REC exposures are protective against lung cancer excess risks due to smoking. To understand the reliability of these conclusions, we should ask basic questions about the data collection process in DEMS: Did the mortality follow-up procedures suffer from errors like those that affected the NCI formaldehyde cohort study? Are the REC and/or smoking data reliable, and are these data collected/constructed in such a way that the procedures allow valid comparisons between surface and underground workers? Without clarifying the issues raised in this Commentary the Diesel Exhaust in Miners Study remains to be difficult to interpret."*

On behalf of the Mining Coalition, we thank you for your consideration and inclusion in the record of this letter and the attached, published scientific articles.

Sincerely,



Henry Chajet
Counsel to the Mining Coalition