

# **Diesel Exhaust Developments: What Do Mining Companies Need To Know?**

Edward Green  
Sherrie A. Armstrong  
Crowell & Moring LLP

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# Introduction

- 2012 diesel exhaust scientific developments could lead to more stringent regulation of exposure in miners
- Industry and individual companies are monitoring these developments
- On June 8, MSHA issued a Request for Information on exposure of underground miners to diesel exhaust

# Presentation Roadmap

- How did we get here? The history of regulatory interest in diesel exposure
- What's new?
  - Diesel Exhaust in Miners Study (DEMS)
  - Reanalysis Efforts
  - Regulatory Developments
- Where are we going?



# The Regulatory Landscape

- MSHA
- NIOSH
- NCI
- IARC
- HEI
- Other agencies of note:
  - EPA
  - OSHA



## Early Regulatory Activity

- 1975 - NIOSH sent a warning letter to MSHA's predecessor agency about the potential health effects of diesel exhaust for underground coal miners, including the possibility of carcinogenicity
- 1986 - NIOSH Report "Evaluation of the Potential Health Effects of Occupational Exposure to Diesel Exhaust in Underground Mines"

## Early Regulatory Activity

- 1988 - NIOSH Central Intelligence Bulletin 50 concluded that “potential occupational carcinogenic hazard exists in human exposure to diesel exhaust”
- 1988 - MSHA Advisory Committee Report on standards and regulations for diesel-powered equipment in underground coal mines

## Early Regulatory Activity, cont'd

- 1988 - EPA sets standards for particulate matter (PM) from heavy-duty diesel trucks and buses
- 1988 - IARC classified diesel exhaust as a probable human carcinogen
- 1990 - EPA imposes limits on diesel fuel sulfur content

## Early Regulatory Activity, cont'd

- 1997 - EPA finalized various emission standards for newly manufactured diesel locomotives and locomotive engines
- 1998 - EPA issues more stringent standards for non-road diesel engines used in construction, agricultural, and industrial equipment. Those standards were tightened again in 2004.
- 1995 & 1999 - HEI Diesel Working Group conducted reviews of the existing literature, but cautioned that the existing studies had limited utility for quantitative risk assessment



## Early Regulatory Activity, cont'd

- 1996 – At an HEI Workshop on Diesel Exhaust, MSHA official asserts that since underground miners had more exposure than any other occupational group, MSHA would regulate their exposure
- 1998 – MSHA proposes rules governing DPM exposure of underground metal and nonmetal mines and underground coal miners

# Current DPM Rules

- Midnight rulemaking in 2001
- For underground metal/non-metal mines and coal mines
  - MSHA concluded that even short term exposures to concentrations of DPM like those observed may result in serious health problems
  - MSHA emphasized that “surface miners are entitled to the same level of protection as other miners”

## Current DPM Rules, cont'd

- The DPM Rules, 30 C.F.R. §§ 57.5060 – 57.5075, are mandatory and enforceable
- Coal standards impose tailpipe emission limit (2.5 grams per hour)
- Metal/nonmetal standards impose PEL of  $160_{TC} \mu\text{g}^3$  measured as eight-hour equivalent full shift concentration

## Diesel Exhaust in Miners Study (DEMS)

- Joint effort NIOSH-NCI
- Two-part retrospective study:
  - (1) Mortality study of 12,315 surface and underground workers at 8 non-metal mines (the cohort study)
  - (2) Nested case control study
    - 198 lung cancer deaths and 562 controls



Debra Silverman with the recruitment poster for the Diesel Exhaust in Miners Study.

## DEMS, cont'd

- 8 study mines volunteered
  - 3 potash, 1 limestone, 3 trona, 1 salt
- Respirable Elemental Carbon (REC) used as diesel exhaust surrogate
- Historical estimate of exposure back to the time when the mines started using diesel

## DEMS, cont'd

- Analyses were both unlagged and lagged to exclude recent exposure occurring within last 15 years
- Nested case control study adjusted for smoking; cohort did not

## DEMS Results

- Conclusion: exposure to diesel exhaust caused a statistically significant increase of risk of death from lung cancer
  - Found increasing risk of lung cancer in relation to increased REC exposure, lagged 15 years
  - Above the rate of cancer attributable to smoking or normally found in the population
  - Among heavily exposed workers, the risk of dying from lung cancer was approx. 3 x greater than that for workers in the lowest

# The Truckers Study

- Also completed in 2012
- Built on peer-reviewed publications for the period of 1971-2000 and subsequent epidemiological analyses
- Examined the risk of lung cancer in relation to quantitative estimates of personal exposure to submicron elemental carbon in a large cohort of 31,135 workers employed in trucking facilities across the United States.





## The Truckers Study, cont'd

- Used SEC (submicron elemental carbon) as a surrogate for diesel exhaust
- Individual smoking data not available
- Found weak associates and evidence of trends in hazard ratios for cumulative SEC, lagged 5 and 10 years, and lung cancer in the cohort excluding mechanics. Those associations and trends were strengthened when adjusted for duration of employment, used as a proxy for “healthy worker survival bias.”

## Significant Data Challenges – DEMS and the Truckers Study

- Dealing with imperfect information – historical estimates of exposure, lack of smoking information as in the Truckers Study
- Diesel technology has changed dramatically, raising the question of the true utility of these backwards-looking studies
- New technology study by HEI found no evidence of gene-damaging effects in rats and mice, and few mild lung effects

# IARC Reclassification

Based on DEMS and the Truckers Study, IARC upgraded its hazard classification of diesel engine exhaust in June 2012 from “probable human carcinogen” to “carcinogenic to humans”



## HEI Work Begins

- HEI convened a panel in 2013 at the request of its sponsors to review the epidemiological studies of diesel exhaust and lung cancer that IARC used in its reclassification: DEMS and the Truckers Study
- Charge: to determine whether the data and results could be used as the basis for a quantitative characterization of the lung cancer risks from exposure to diesel exhaust

## HEI Work Begins, cont'd

- A quantitative risk assessment is significant:
  - Process by which scientists use available evidence to estimate the likelihood and severity of adverse health outcomes that cannot always be observed directly or with complete certainty
  - It is a prerequisite to identifying levels of exposure that would be protective of human health in ambient or occupational settings

## Reanalysis Efforts

- Industry coalition led by the Truck & Engine Manufacturers Association (EMA) sought to conduct “follow on” science, test DEMS data
- Confidentiality concerns prevent unrestricted access to data sets



# DEMS Data Restrictions



- EMA attempted to gain access to the DEMS data for a number of years, stymied by confidentiality concerns
- Ultimately obtained Secure Data Center access- by data use agreement imposed by the State Vital Statistics Database, the data could not be “linked” and had to be viewed in a secure data facility (RDC) to maintain confidentiality
- Linkage could only be done at the National Center for Health Statistics Research Data Center

## Reanalysis Conclusions

- In the DEMS cohort, the reanalysis team found that the positive-association results were driven by the naturally ventilated limestone mine that participated in the study
  - Once those workers were removed from the data, no significant exposure-response relationship existed
- They also concluded that the modifying impact of temporal factors and effect modification by age should be addressed in any quantitative risk assessment



## Reanalysis Conclusions, cont'd

- The reanalysis team also conducted a reanalysis of the nested case-control data
- They found radon was a confounding factor:
  - Without adjusting for radon, their results were similar to DEMS
  - When exposure to radon was adjusted, the evidence for an effect from diesel exhaust was greatly diminished
- They also found no consistent evidence for only-underground miners

## HEI Report

- Peer-reviewed report published November 2015
- Concluded that both the Truckers Study and DEMS were “well-designed and well-conducted” and made “considerable progress” toward addressing limitations of previous work
- Results and data provide a “useful basis for quantitative risk assessments of exposures in particular to older diesel engine exhaust”



## HEI Report, cont'd

- Many contend that the HEI panel has not given equal consideration to the industry-funded reanalysis work; the final report does acknowledge those papers, but they are not a focus
- The HEI Panel had access to the data, albeit the same limited access as was given to the reanalysis team, but declined to conduct a comprehensive reanalysis
- Panel was invited to visit a study mine, but did not do so
- Panel did acknowledge some “key uncertainties and limitations”

# MSHA

- Issued a 2012 diesel exhaust hazard alert with OSHA informing workers that prolonged DE/DPM exposure can increase the risk of cardiovascular, cardiopulmonary, and respiratory disease and lung cancer



## MSHA, cont'd

- RFI issued June 8, 2016
- Asks 28 questions to assist MSHA in determining whether existing DPM standards are sufficiently protective
- Largely focused on coal, but some questions aimed at metal/nonmetal
- Focused on underground operations



## MSHA, cont'd

- Comment period for the RFI ends on September 6 (the agency plans to correct the current September 1 date)
- Timeline for a future rulemaking
- Content of a future rulemaking



# NIOSH

- NIOSH issued a worker notification letter aimed at the participants in the DEMS Study, [http://www.cdc.gov/niosh/pgms/worknotify/pdfs/DEMS\\_NotificationFactSheetWorkerSummary.pdf](http://www.cdc.gov/niosh/pgms/worknotify/pdfs/DEMS_NotificationFactSheetWorkerSummary.pdf)

## NIOSH, cont'd

- In 2014, NIOSH announced at a HEI workshop that it would use DEMS as the basis for a new quantitative risk assessment
- Work appears to be proceeding slowly





## NIOSH, cont'd

- A diesel-silica fracking study is underway at the Health Effects Laboratory Division, Pathology and Physiology Research Branch: “Fracking: Toxicological effects of silica & diesel exhaust exposure” – set to be finished in 2017
- NIOSH field investigations found that many gas extraction workers are exposed to high levels of respirable crystalline silica and diesel exhaust that “substantially exceed” recommended standards

## NIOSH, cont'd

- The rate of gas well drilling has exceeded the pace of the agency's understanding of health effects due to inhalation of crystalline silica and diesel exhaust together
- Focused on fracking, but this study has the potential to inform occupational exposures relative to construction, but could also be relevant to mining

# EPA

- EPA has not signaled whether it will act on the HEI recommendation, but recall that it was one of the sponsors that requested the HEI report



## Conclusion

- In spite of the data limitations, we are likely to see agencies move forward with quantitative risk assessments and rulemakings. Industry and groups need to be aware and engaged.

## Conclusion, cont'd

- Each development is another step down the path to increased regulation of diesel use at mines.
- Tort suits usually use diesel as an “add-on” claim – not a major (current) focus of the plaintiffs bar, but something to watch

# Questions?



Ed Green

[egreen@crowell.com](mailto:egreen@crowell.com)

202-624-2922

Sherrie A. Armstrong

[sarmstrong@crowell.com](mailto:sarmstrong@crowell.com)

202-624-2522