

**CAL/OSHA PERMISSIBLE EXPOSURE LIMITS
SECTION 5155 PUBLIC ADVISORY MEETING
MAY 18, 2005
OAKLAND, CALIFORNIA**

Attendees

Kelly	Bailey	Vulcan Materials
Hudson	Bates	Nickel Producers Environmental Research Association (NiPERA)
James	Bresnahan	Bricklayers & Allied Crafts Local 3
Julie	Broyles	California Chamber of Commerce
Ted	Brucker	CalTrans
Thomas	Burke	Petersen Dean
Paul	Burnett	Santa Clara Valley Water District
Orlando	Castellon	Roofers Union Local 81
Hector	Castillo	Latino Engineers, Architect, Developer Society
Joseph	Cattaneo	Glass Packaging Institute
Peter	Chiu	BMI
Glenn	Clifton	Casey-Fogli Concrete
Jacquelyn	Coleman	Petroferm
Jim	Collins	Cal/EPA Office of Environmental Health Hazard Assessment (OEHHA)
Jack	Connors	Toll Brothers
Michael	Cooper	Vishey-Siliconix
Cynthia	Cory	California Farm Bureau Federation
Angus	Crane	American Insulation Manufacturers Association NAIMA
Robert	Crolius	The Refractories Institute
Dave	Danner	Bricklayers & Allied Crafts Local 3
Jerry	Desmond	Desmond & Desmond
Steve	Daly	Rudolph & Sletton for Construction Employers Association
Mike	Dunlap	Operating Engineers Local 3
Judy	Freyman	ORC Worldwide
Mari	Golub	Cal/EPA Office of Environmental Health Hazard Assessment (OEHHA)
Diana	Graham	Mason Contractors Assoc & California Conference of Mason Contractors
John	Hakel	Associated General Contractors (AGC) of California
Adam	Harper	California Mining Association
Sara	Hoover	Cal/EPA Office of Environmental Health Hazard Assessment (OEHHA)
Mark	Harrison	Diepanbrock Harrison
William	Jackson	Granite Construction
Gary	Johnson	Penhall Company
Jim	Kegebein	Health and Safety Consultant
William	Kelly	Refractory Ceramic Fibers Coalition and Unifrax Corporation
Sally	Lagomarsino	Clorox Company
Gene	Livingston	Livingston & Mattesich for American Chemistry Council Silica Panel
Randy	Logsdon	National Cement Company of California
MJ	Marshall	Mason Contractors Association
Marshall	Massie Jr	Operating Engineers Local 3
Chuca	Meyer	Pillsbury Winthrop
Paul	Michalko	State Fund Compensation Insurance Fund
Beth	Mohr	State Compensation Insurance Fund

Nancy	Moorhouse	Teichert Construction/Teichert Materials
Richard	Morford	International Brominated Solvents Association
Jim	Mueller	Petroferm, Inc.
Kathleen	O'Doherty	Hanson Building Materials
Adriana	Oller	Nickel Producers Environmental Research Association (NiPERA)
Nancy	O'Malley	Albemarle Chemical
Todd	Priest	Building Industry Association of Southern California
Patty	Quinlan	University of California San Francisco
Julia	Quint	HESIS California Dept of Health Services
Susan	Ripple	Dow Chemical Co
Sylvia	Rodriguez	Surface Technology Association/Metal Finishing Assoc. of Southern Calif.
Arlene	Rosenbaum	ICF Consulting
Randy	Roth	Nickel Institute
James	Simonelli	California Metals Coalition
Joseph	Shapiro	Unimin Corp
Frederick	Simonelli	California Cast Metals Association
Jeremy	Smith	California Labor Federation
Mark	Stelljes	SLR International Corp
Ed	Stockton	FPL Energy - POSDEF
Larry	Tipton	Southern California Edison
Elizabeth	Treanor	Phylmar Regulatory Round Table
Adrian	Trevino	Gregg Industries, Inc.
Ray	Trujillo	State Building and Construction Trades Council
Doyle	Tyree	J.T.Thorpe & Sons Inc.
Phil	Vermeulen	Engineering Contractors Association
Tom	Walters	Vesuvius, Inc. and Refractory Ceramic Fibers Coalition
Randall	Ward	Cogeneration Ash Council
Lynell	Washington	National Assoc. of Minority Contractors (Southern California)
Willie	Washington	California Manufacturing and Technology Association
Bruce	Watzman	National Mining Association
Rich	Waugh	Thermal Ceramics and Refractory Ceramic Fibers Coalition
Kevin	White	California Professional Fire Fighters
Wanda	Wild	National Association of Women in Construction
Chad	Wright	Laborers Union
George	Yesowitch	Galson Laboratories

Cal/OSHA Meeting Staff

Len Welsh, Acting Chief, DOSH
 Steve Smith, Supervising Industrial Hygienist, DOSH
 Bob Barish, Senior Industrial Hygienist, DOSH
 Tom Mitchell, Senior Industrial Hygienist, Cal/OSHA Standards Board

Other Cal/OSHA staff in attendance

Deborah Gold, Senior Industrial Hygienist
 Scott McAllister, Senior Industrial Hygienist

MEETING SUMMARY

Len Welsh, Acting Chief, thanked attendees for their interest and participation in the day's meeting. He expressed his belief that the public advisory process as a pre-rulemaking activity is important because it allows for informal discussion of issues and offers the potential for working out difficult problems in a manner that can be satisfactory to many parties often at odds. He urged attendees to keep an open mind and refrain from polarization and to use the opportunity for informal discussion to explore the need for new or amended PELs based on health outcomes and feasibility.

Bob Barish explained the agenda for the meeting and Steve Smith explained the background of the PEL advisory process. Len Welsh expressed appreciation for the work of the PEL Advisory Committee of technical experts which developed the recommended PELs to be discussed in the meeting. He noted that today's meeting was necessitated by that committee's recommending PELs below the ACGIH for a number of substances with widespread employee exposure such as crystalline silica and nickel. He noted that the ACGIH TLVs from which the PEL Advisory Committee starts its work are standards recognized throughout the world. He said that today's meeting was like that held March 30, 2004 for another set of substances for which the PEL Advisory Committee made recommendations below the TLV.

Before opening the meeting Bob Barish asked for a show of hands of the different sectors present, employers, employees, academics etc. Employers and employer representatives were the most numerous source of attendees.

Coal Dust (bituminous)

The first substance to discuss on the agenda was coal dust (bituminous). The PEL Advisory Committee had recommended a PEL of 0.1 mg/M³. The TLV is 0.9 mg/M³ while the current PEL in 8 CCR 5155 is 2 mg/M³. The first speaker on coal dust was Tom Hall of the University of Oklahoma Health Sciences Center speaking on behalf of the National Mining Association. He stated that the ACGIH TLV reflected the NIOSH rationale for coal dust. He supported adoption of the TLV rather than the recommendation of the PEL Advisory Committee. He said that coal dust was a very well-studied hazard and that since the 1970s there has been extensive medical surveillance. He also said there is extensive data on exposures. He said that these data have shown that the incidence of coal worker pneumoconiosis is at the level of the unexposed general population and therefore he did not see a need for a standard below the TLV. He noted that even though California does not have any active bituminous coal mines employees can be exposed to coal dust at cogeneration plants and in cement manufacturing. He said the exposures at these locations were limited primarily to employees loading coal with front end loaders. He also felt that at an exposure level of 0.1 mg/M³ there could be significant measurement interference from ambient levels of respirable particulate.

The next commenter on coal dust was Randall Ward representing the Co-Generation Ash Council. Mr. Ward indicated that his organization had only recently become aware of the day's meeting and the recommendation for coal dust of the PEL Advisory Committee. He asked that additional time be allowed for his organization to develop their comments. Len Welsh suggested to Mr. Ward that if his organization submits additional comments it would be helpful if they included information on costs and feasibility of compliance with the Advisory Committee's recommendation.

Allyl glycidyl ether, glyoxal, methyl n-butyl ketone, methyl vinyl ketone

Bob Barish asked if there was anyone present who wished to comment on the PEL Advisory Committee recommendations for any of these substances. No one came forward to comment.

Crystalline Silica

The next substance for discussion was crystalline silica for which the PEL Advisory Committee had recommended a PEL of 0.01 mg/M³. Numerous attendees indicated that they wished to comment on this substance and the Advisory Committee's recommended PEL.

The first speaker was Gene Livingston who indicated that his law firm represented a coalition of employers opposed to any lowering of the current PEL of 0.1 mg/M³. He introduced the coalition's primary technical presenter Kelly Bailey, an industrial hygienist and health and safety manager for Vulcan Materials. Mr. Bailey indicated that his employer is the largest producer of sand and gravel in the United States with 76 locations throughout the United States and approximately 1300 employees. Mr. Bailey indicated that his company has collected 14,000 silica air samples measuring employee exposure, with 98% of these being below the current PEL of 0.1 mg/M³. He said further that medical screening of employees since the 1980s

had identified no cases of silicosis in California. He said that there is no health basis for a 90% reduction in the PEL, and that even if there was there would be significant cost, feasibility, and measurement issues with a PEL of 0.01 mg/M³. Mr. Bailey referred to written comments on the recommended PEL submitted by the Silica Panel of the American Chemistry Council. These included an analysis by Patrick Hessel indicating that risk assessment studies for silica used by the PEL Advisory Committee are based on extrapolation from higher levels of exposure and do not take account of lung clearance and dose rate effects from high levels of exposure. He noted that the Hessel critique of risk assessment studies also cited relatively low levels of increased disease that could be difficult to distinguish from background levels, and misclassification of exposure groups and resultant over-estimates of risk. Mr. Bailey went on to describe difficulties with analysis of air samples for silica at levels which would be only slightly above the analytical limit of detection or reliable quantitation which would make it difficult not only for OSHA personnel to take meaningful measurements but also for employers to reliably determine if they are in compliance. Mr. Bailey stated further that information from the OSHA Integrated Management Information System (IMIS) on workplace inspections for silica indicated that from 1979 to 1995 in over 100,000 air samples, over 30% were over the current PEL. He suggested in conclusion that most silica-related disease is the result of exposures greater than the current PEL of 0.1 mg/M³ and so rather than focusing on lowering the PEL, OSHA and Cal/OSHA should focus on increasing compliance inspections to reduce exposures to reliably below the current PEL.

The next speaker was Bill Jackson, safety and health director for Granite Construction. He suggested that the recommendation of the PEL Advisory Committee was not justified on the basis of necessity as there was no evidence provided of a problem with silicosis in California. Mr. Jackson said that he examined the Workers Compensation Insurance history of Granite Construction since 1952 and found no claims for silicosis. He noted that his employer had collected many air samples for silicosis and found employee exposures to be extremely variable, part of the variability reflecting different levels of effectiveness of control measures. Len Welsh asked how exposures are controlled. Mr. Jackson responded that dust control with water was often used, but sometimes was not feasible. Steve Smith noted that the Title 8 Mine Safety Orders indicate that employers are required to comply with the TLV. Mr. Jackson responded that his employer uses an action level of 0.05 mg/M³ for silica exposure.

Jim Collins, a toxicologist in the Office of Environmental Health Hazard Assessment in Cal/EPA, asked if Granite Construction followed its workers for silicosis after they left employment. Mr. Jackson responded that if an employee believes they have developed silicosis after they leave the company they can file a workers compensation claim but that the company had not had any.

The next speaker was Julianne Broyles of the California Chamber of Commerce representing a number of employer groups including the California Farm Bureau, the California Grape and Tree Fruit League, and the Construction Materials Association. She urged that the PEL for silica not be reduced. She said that a recent Centers for Disease Control report indicated that silicosis mortality has been in a long-term decline over the last 20 years. She said that there were 24,000 lawsuits filed related to silicosis or exposure to silica in 2003 and she was concerned with the impact of lowering the PEL for silica on these cases with AB 1127 allowing use of compliance with Cal/OSHA regulations as evidence in lawsuits.

The next speaker was Cynthia Cory of the California Farm Bureau Federation. As an argument against lowering the PEL she noted the many new regulations faced by agricultural employers, including those to reduce air emissions of dust. She said that a recent study from UC Davis had found that some harvesting operations exposed workers to levels of silica above the 0.01 mg/M³ level recommended by the PEL Advisory Committee.

The next speaker was Mike Dunlap, safety director of Local 3 of the Operating Engineers Local Union No. 3. He said that silicosis was grossly underreported because of its long latency period, usually not developing until after retirement. He supported a reduction in the PEL for silica. He said that the equipment and science to control silica exposures has evolved significantly since the current PEL for silica was adopted decades ago.

Diana Graham, an analytical chemist with the law firm of Keller and Heckman representing the Masonry Contractors Association said that federal OSHA was working on revising its risk assessment for silica and that it was anticipated to be released in the spring of 2006. She reiterated concerns with analysis of air samples for silica in the range of the PEL Advisory Committee's recommendation.

Jim Bresnahan, president of Bricklayers and Allied Craftworkers Local 3 (Northern California) spoke next. He said that over 3,000 members of his local are regularly assigned to use dry saws to cut cement blocks. He displayed one of the saws and explained the process for its use. He said that the saw is frequently used indoors with no ventilation. He said that at least 50 retirees from his union needed portable oxygen as a result of silicosis resulting from use of the dry saw. He was also concerned with the potential for take-home exposure from workers clothes. He said that action needed to be taken to prohibit and prevent dry sawing of concrete blocks and other masonry materials that could result in silica exposures. He said that contractors were not controlling exposures to silica.

Steve Daly, a certified industrial hygienist with Rudolph & Sletton spoke on behalf of the Construction Employers Association. He said that he endorsed the comments of Kelly Bailey of Vulcan Materials. He said that the risk assessment studies used by the PEL Advisory Committee in reaching their recommendation were based on exposure measurements made with the impinger sampling method and these sampling results were then converted to gravimetric results with resulting uncertainties that have not been adequately quantified and validated. He said that the NIOSH sampling method was only validated down to a level of 0.025 mg/M³.

Julia Quint a toxicologist in the California Department of Health Services Occupational Health Branch asked if the PEL Advisory Committee's recommendation was anticipated to eliminate all cases of silicosis. Bob Barish responded that the recommended level was based upon studies indicating an increased risk of silicosis in the range of 1 death in 1,000 employees exposed over a lifetime at 0.01 mg/M³ of respirable dust. He said the PEL Advisory Committee assessment did not include the potential increased risk of lung cancer at 0.01mg/M³.

Chad Wright representing the Laborers International Union said that his organization represented approximately 50,000 current and retired employees in California many of whom are or were exposed to airborne crystalline silica in operations such as tunneling, cutting concrete, and sandblasting. He said that the union supported the recommended lowering of the PEL. He said that his review of the scientific literature indicated that approximately 1.5 million American workers are currently being exposed to silica and that deaths from silicosis in recent years numbered around 200. He said that while recognizing that enforcement continued to be an issue in assuring that exposures do not exceed the current PEL, a recent NIOSH Hazard Review reported that epidemiologic studies indicate that the current PEL, and the NIOSH REL of 0.05, are inadequate to prevent silicosis as well as other diseases such as lung cancer.

Joe Shapiro of Unamin, Inc. spoke next. He said that Unamin is a large producer of sand and has collected many air samples (approximately 10,000) to measure employee exposures to crystalline silica. Mr. Shapiro offered to provide the sampling information to the Division. He said that since 1980 his company had had no new cases of silicosis develop among workers. He said Unamin's goal was to keep all employee exposures below 0.05 mg/M³. However he said that of the samples collected about 6.2% were above the current PEL for bagging operations, that this was the most difficult operation for which to reliably control exposures below the PEL.

Wanda Wild an owner of a small contracting company (12 employees) representing the National Association of Women in Construction spoke against the recommended PEL. She said exposures to silica in her company are from concrete cutting. She said her company does not have any data on employee exposure levels but employees are trained to wear respirators for protection. She said she did not want silica control to be the problem that puts her small company out of business. She was concerned with strict enforcement of use of respirators because they can impair visual field and also she is not able to be constantly present at the worksite to ensure respirator use. She said that the current PEL for silica was not being enforced and so questioned whether there was truly a need to lower the PEL when the current limit is not being adequately enforced.

Inell Washington representing the National Association of Minority Contractors concurred with the comments of other employer representatives objecting to the recommendation to reduce the PEL for silica and comments that the problem is mostly an enforcement issue. Glen Clifton safety director of Casey-Fogli Concrete of Hayward, California said he believed the current PEL is strict enough and was at times difficult to comply with. He said his company does concrete grinding, drilling and abrasive blasting. He said their employees need to and do use respirators for concrete drilling and grinding. He said he believes they are doing what's needed to protect their employees. Bob Barish asked if they used or were aware of any engineering control measures for concrete grinding. He said they use concrete grinders equipped with HEPA dust collection systems which are very effective in controlling dust levels. Adam Harper representing the California Mining Association urged review of information from Patrick Hessell mentioned by Kelly Bailey and others and a general re-review of the data used by the PEL Advisory Committee. He was concerned with measurement methods limitations and the feasibility of engineering controls to meet both the recommended and current PELs.

Jan Simonelli representing the Cast Metals Association said that bonded sand can help reduce exposures in foundries. She felt that the foundry industry was adequately protecting workers to the current PEL and there was no need to reduce it. Willie Washington representing the California Manufacturing and Technology Association echoed the comments of others objecting to reducing the PEL. He felt that education of employees was most key to safety and that while the potential for measuring exposure levels was progressing the ability to control exposures to those lower levels were not, and as a result employers are being burdened with an impossible task. He said there was more need for evidence of necessity to lower the PEL, he said the science did not exist to support the recommended PEL. Hector Castillo representing the Latino Engineers, Architects, and Developers Society said there was no evidence of a need to reduce the PEL. He said the members of his organization were not aware of any cases of silicosis among their workers.

The discussion of crystalline silica concluded with statements from two labor representatives. Ray Trujillo of the State Building and Construction Trades Council said that his union supports efforts to review the PEL for crystalline silica and to update it as necessary to protect worker health. He said that a recent study had reported that construction workers now represent the greatest percentage of employees affected by silica, with about 10% of all silicosis cases. He said that a study by the Center to Protect Workers Rights, a research arm of the national Building and Construction Trades Council, AFL-CIO, found that a review of approximately 30 studies had shown the effectiveness of engineering controls in reducing employee exposures to crystalline silica in a variety of construction operations. He urged in light of this information that Cal/OSHA continue the advisory process on crystalline silica looking at both the exposure level and requirements for engineering control methods. He decried the tragedy of employees working hard for their employers and then finding later in life that they have silicosis and its associated poor quality of life. Referring to previous comments by employer representatives that enforcement of the existing PEL was the major issue, he said that he challenged employers to lobby for more enforcement resources for Cal/OSHA.

Jeremy Smith representing the California Labor Federation echoed the comments of Ray Trujillo and said that the Labor Federation wanted to work with employers to address the problem of exposure to crystalline silica. He challenged employer representatives to work with the Federation to lobby for more funding for Cal/OSHA enforcement activities if they felt that was where the problem is. He said that the Federation applauded the efforts of diligent employers who monitor and control employee exposures to crystalline silica. He said that the Federation doesn't want to hurt small business but rather wanted to work together with employers to address the problem of silica and silicosis.

This concluded the discussion of crystalline silica and the morning segment of the meeting.

LUNCH BREAK

Nickel

The first speaker on nickel was Hudson Bates, a toxicologist with NiPERA the Nickel Producers Environmental Research Association. Hudson Bates noted that there are no nickel producing companies in the United States but there are of course many users of nickel in this country. Hudson Bates noted that NiPERA worked extensively with ACGIH in the 1990s on the current TLV for nickel, in terms of providing information and interpretation of information on the toxicology of nickel. Hudson Bates said that the ACGIH TLV Committee also looked all of the information considered by the PEL Advisory Committee at, but the two groups reached different conclusions with respect to appropriate levels of allowable exposures. Hudson Bates urged that the data be reviewed again and greater consideration be given to the TLVs.

Adriana Oller a toxicologist with NiPERA then gave a technical presentation on nickel. She reviewed the speciation of nickel into soluble and insoluble forms, noting that the water insoluble forms include oxidic and sulphidic forms. She said that the toxicological properties of the different forms of nickel are different, that a single standard as recommended by the PEL Advisory Committee did not accurately reflect the levels of risk of the different forms of nickel. She also said that the Cal/OSHA PEL for nickel in its various forms should be in terms of inhalable, rather than total, particulate, like the TLVs for nickel compounds. She said that the reason for this is that the two main health effects of concern with nickel are respiratory cancer (specifically cancer of the lungs and nose) as well as non-malignant respiratory effects such as lung inflammation and fibrosis. She noted that while studies on nickel toxicology and epidemiology express exposure levels in terms of total particulate, there is sufficient information available comparing total and inhalable exposures to enable conversion from one to the other.

Adriana Oller said that while nonmalignant respiratory effects of some nickel substances have been found in animal studies, they have not been found to be significant in human studies. She said that this could reflect the fact that test animals, particularly rats, can be more sensitive to respiratory effects of particles in general than are humans. She went on to say that data on cancer risk from nickel subsulphide should not be the driving force behind the exposure limits for other forms of nickel. She reiterated that the risk to be addressed with an exposure limit for nickel is cancer, not nonmalignant respiratory effects.

Jim Collins of OEHHA asked about nickel asthma suggested in a European Union risk assessment. Hudson Bates responded that a small number of cases of nickel-induced asthma have been reported from exposure to soluble nickel in primary nickel production operations. He said the number was about 80 cases in 50 years of disease reporting for hundreds of thousands of exposed employees. He noted by contrast that nickel dermatitis is a much more prevalent problem with nickel. He said that there have been three anecdotal reports of asthma associated with exposure to nickel metal, but in those cases there may have exposures to other respiratory sensitizers. He said the European Union has classified soluble nickel as a respiratory sensitizer, but not nickel metal.

Bob Barish asked Hudson Bates if he and NiPERA agreed with the speciation and TLVs for the different forms of nickel. Hudson Bates said that in their deliberations on a nickel TLV in the 1990s ACGIH, like the PEL Advisory Committee, had initially proposed a single TLV for all nickel substances. He said that NiPERA had provided information to the TLV Committee that there should be different TLVs for different forms of nickel.

The next speaker on nickel was Sylvia Rodriguez representing the Surface Technology Association and Metal Finishing Association of Southern California. She said that together these two associations represent 200 metal finishing and supplier businesses, most of which are family owned and have fewer than 20 employees. She said it was important to consider the cost impact of proposed reductions in the PEL for nickel on these small businesses. She said that about 60% of California metal finishing job shops conduct nickel metal plating, and that it is the most prevalent process in the metal finishing industry. She said that she is the owner of AMEX Metal Finishing, a job shop plating business in Santa Clara, and has been in business 21 years and currently has 41 employees. She said that nickel plating is one-half of her business. She said that she and the associations she is speaking for concur with the comments of NiPERA with respect to speciation of nickel compounds. She said that many Air Quality Management Districts have determined that nickel emissions from electroplating operations are lower than the current TLVs for nickel compounds. She said that engineering control measures are already in use in the electroplating industry including mist eliminators and scrubbers. She said that most California metal finishing operations are complying with the current PEL using the best available technology. She said it was the associations' estimate that the average cost of scrubbers to comply with the PEL Advisory Committee recommended PEL would be \$250,000, not including maintenance and utility costs. She said that these costs would jeopardize the viability of many metal finishing businesses. She urged again that the issues raised by NiPERA be considered along with costs and feasibility of control.

Bob Barish asked Ms. Rodriguez if members of her association could comply with the lower TLV for insoluble nickel. Ms. Rodriguez replied that they could. She said that they had no problem with adoption as PELs of the TLVs for the different forms of nickel.

Mike Cooper an industrial hygienist and member of the PEL Advisory Committee which made the recommendation for nickel said the approach of the committee was to determine the Lowest Observed Adverse Effect Level (LOAEL) and arrive at a PEL with a reasonable safety factor. He asked the NiPERA representatives if they believed the TLV for insoluble nickel at 0.2 mg/M³ (inhalable dust) represented the LOAEL for insoluble nickel. Adriana Oller responded that the TLV for insoluble nickel compounds of 0.2 mg/M³ is consistent with an increased cancer risk of less than 1 case in 1,000 exposed employees and is a no-effect level for noncancer respiratory effects. Adriana Oller also said that even though based on non-cancer endpoints, the TLV for soluble nickel compounds is appropriately lower than the TLV for insoluble compounds. Mike Cooper said that the PEL Advisory Committee's conclusion looking at the same data was that the PEL should be an order of magnitude lower than the TLV.

Bob Barish said that since it appears there is a significant difference in conclusions reached by ACGIH and the PEL Advisory Committee looking at the same data, the Division will go back and review how each group's recommendations were reached from the same information and then decide how to move forward.

Hudson Bates said that while a single PEL for all nickel compounds as recommended by the PEL Advisory Committee may appear attractive in its simplicity, basing that single PEL on the level of risk associated with nickel subsulphide was not appropriate. He said that nickel subsulphide exists only as a by-product of refining of sulphidic nickel ores and so is not present in any California workplaces. NiPERA feels it is unreasonably burdensome for industries where exposures are only to forms of nickel with lower cancer risk, particularly oxidic forms with the lowest cancer risk, to be subject to exposure limits based on the sulphidic form which poses the greatest cancer risk. He noted also that he had been in discussions with OEHHHA about their recommended exposure level (REL) for nickel and noted that it did not address metallic nickel because that is not an environmental release problem but rather limited only to occupational exposures.

Adriana Oller noted that while the National Toxicology Program has said that soluble nickel is a carcinogen, an assessment by TERA.org said that it was not. (Editor's Note: The TERA study was sponsored by the Metal Finishing Association of Southern California, Inc., U.S. EPA, and Health Canada and is available at the website of TERA.org.)

Steve Smith thanked Sylvia Rodriguez for the information she provided on estimated costs for compliance with the recommended PEL. He said that the Division frequently asks for industry description and compliance cost information so what she presented was very helpful. He asked also if there were other major California users of nickel that such information could be obtained from. Attendees said aerospace, semiconductors and hard disc manufacturing were other affected industries.

Ray Trujillo representing the State Building and Construction Trades Council said that if exposures above the PEL recommended by the Advisory Committee could increase risk of cancer, asthma, and other respiratory illness then his

organization supported the PEL Advisory Committee recommendation. He noted that nickel is widely present in industrial plumbing applications, welding rod and base metals.

Refractory Ceramic Fiber

Tom Walters, introduced himself as President of the Refractory Ceramic Fibers Coalition (RCFC) which has three member companies that produce 95% of all RCF in the United States. He said he would like to be able to have a separate meeting with Cal/OSHA to discuss the scientific findings on health the effects of RCF. He said that the industry was rather small with 100 million pounds annual product with about 10% of that being sold in California, 1000 manufacturing workers in the U.S. total, with no manufacturing in California, and less than 30,000 employees exposed in end uses in the United States. He said that RCF is used primarily as an insulating material in high temperature industrial applications and generally not in lower temperature applications such as residential insulation or pipe lagging. He said that the respiratory hazard of RCF is different chemically and physically from that posed by asbestos and crystalline silica, in part because RCF fibers break transversely (across the width of the fiber) and are more soluble in the lung than asbestos.

Richard Waugh of RCFC described health research findings for RCF. He said that in the 1980s studies were started looking at hazards versus risk of RCF. At that time a large number of somewhat cursory studies were being conducted on the toxicology of manmade mineral fibers including RCF. In one of these studies a tumor was induced in a single test animal with RCF. This prompted the formation of the RCFC to study more closely the risk of RCF. Detailed animal toxicology studies showed that at high levels of exposure RCF did appear to be a respiratory carcinogen. Looking further at these studies it was found that the fibers being used had a high degree of particulate matter which was interfering with pulmonary clearance mechanisms. The tests were repeated with fibers cleaned of particulate matter and no lung tumors were found. He said that these cleaned fibers were more representative of fibers in actual use.

Richard Waugh continued by stating that the animal toxicology studies pointed out the importance of looking at human exposure results. He noted that medical surveillance studies have been funded by the industry for the last 15 years at the University of Cincinnati and are planned to continue until at least 2015. He said that these studies look at current and former workers as far back as 1952. He said that these studies showed no excess mortality related to exposure from all causes, no increase in lung cancer or mesothelioma. A slight increase in urinary cancers has been detected and work is being done to see if that is statistically significant. Richard Waugh stated that although no excess disease or mortality has been found in these studies, an excess of pleural plaques has been found with exposure to RCF. He said that pleural plaques are only an indication of exposure, not disease. He said that no RCF-related disease has been found in those with pleural plaques. He said that risk assessments have only been based on animal studies, extrapolating to humans, because no human disease has been documented. He said that one risk assessment, conducted by Fayerweather, used the linearized multi-stage model and found at exposures of 1 fiber/cc, the excess lifetime risk of developing lung tumors was 3.8×10^{-5} maximum likelihood estimate. He said further that in 1999, a risk assessment by Moolgavkar et al, was conducted and the calculated risk for a worker age 70 worker with 30 years of exposure at 1 fiber/cc was 3.7×10^{-5} for a non-smoker, and 1.5×10^{-4} for a smoker.

Bob Barish asked if the written materials submitted detailed what has been presented. Richard Waugh said they did, but with more detail. He said that work done at the University of Cincinnati contains the longterm data described above back to the 1950s.

Bill Kelly, spoke next. He introduced himself as the president of Unifrax, which he said makes about 40% of ceramic fiber used in the United States. He felt that the minutes of the PEL Advisory Committee discussion of RCF did not address the large body of studies that has been done on this substance. He said leaving aside the results of these studies, that in the interest of worker protection RCFC members developed a product-stewardship program to try to lower exposures to what was reasonably possible to achieve through assistance to producers and users of RCF. Started in 1993 with a consent agreement with EPA under TSCA which he said RCFC asked for, developing a project assurance plan for producers and users. He said that 14,000 air samples have been collected at producer and user companies – this information was reported every 6 months to EPA for five years and is now reported to OSHA and can be shared with the Division if desired. He said the air samples are collected on a random basis consistent with a Quality Assurance Project Plan developed with regulators and other interested parties including organized labor. He said that the product stewardship program started with a target exposure level of 2 f/cc in the early 1990s and now the target is 0.5 f/cc. He said that currently approximately 80% of exposures measured in the product stewardship program are below 0.25 f/cc. He said that with the 0.1 f/cc limit recommended by the PEL Advisory Committee, 50 percent of exposures would be above this level. He said that 72% of RCFC customers could not meet a PEL of 0.25 f/cc

RCFC disagrees with the ACGIH TLV as unreasonable given the level of risk posed by RCF compared with risk levels associated with other TLVs. Mr. Kelly suggested that the cost of compliance with a PEL of 0.1 f/cc for RCF would be \$6 to

\$8 million per year in California. Mr. Kelly said that since this compliance cost almost equals the value of RCF sold in California it would eliminate RCF use in California.

Mr. Kelly reiterated his desire to expose the Division to data that has been developed by RCFC. Bob Barish asked if air sampling data described is for customers or producers. Mr. Kelly said it was for both, noting that the highest exposures found have been in tear out operations.

Doyle Tyree indicated that RCFC had assisted his company with industrial hygiene monitoring during installations

Julia Quint commended the RCFC representatives on their product stewardship program, particularly assistance with air sampling and control of exposures to downstream users of their products and the collection and presentation of that information. She asked if RCF use was likely to increase, especially as a replacement for asbestos and other insulating materials. Bill Kelly was optimistic that use would increase but said that the cost of RCF limits its application to only the highest temperature, generally industrial applications, and not as a substitute for asbestos.

Steve Smith asked RCFC members if \$6-8 million was their cost estimate to go to a PEL of 0.1 f/cc and if so, what their cost estimate was to go from 0.5 to 0.2. Richard Waugh said that the \$6-8 million figure was to control to 0.1 f/cc. He said that an estimate for compliance with a PEL of 0.2 f/cc could be developed with recalculation from their data.

Ozone

Paul Burnett asked if the proposed PEL applied to ambient air. He said that on some days ambient levels of ozone can exceed the recommended PEL of 0.1 ppm as a ceiling limit. Bob Barish said that this would be looked into and if appropriate taken into consideration in developing the proposed amended PEL for ozone.

1-bromopropane

Rich Morford, introduced himself as Director of the International Brominated Solvents Association (IBSA) and General Counsel for EnviroTech International. He said the annual worldwide usage of 1-bromopropane (1-BP) is 8 to 10 million pounds, with about half of that in the U.S. With restrictions on the use of halogenated solvents, use in California is very limited. There are no 1-BP manufacturers in California, and no uses of 1-BP in adhesives that he is aware of. He said that most use in California use is in aerospace for vapor degreasing. He said that aircraft manufacturers use 1-BP for precision cleaning of aircraft components where they have studied and decided there are no good water based alternatives.

He said that manufacturers had evaluated 150 workplaces for exposures to 1-BP from vapor degreasing and found exposures to be 0 to 25 ppm with an average exposure level of 6 ppm. He said that with that, a 1 ppm PEL as recommended by the PEL Advisory Committee would amount to a ban on 1-BP. He said that 1 ppm would be 1/25th of the PEL for methylene chloride which is a known carcinogen. He said that it was difficult to comment on the PEL Advisory Committee process on 1-BP given what he'd been provided prior to the meeting. He said it was unclear from the minutes of the meeting where 1-BP was considered how the recommendation of 1 ppm was derived or what studies and other references were looked at in the process. He said that the minutes and the summary sheet used by the Advisory Committee listed only a few of the toxicology studies on 1-BP that have been conducted.

Julia Quint said that the minutes of the PEL Advisory Committee refer to her providing the committee with information from the study by National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction (CERHR). She said that document reviewed the database on 1-BP beyond what was specifically referred to in the minutes. Rich Morford acknowledged that the CERHR report of October 2003 did address other studies that he referred to and reviewed much of the then existing database.

Nancy O'Malley of Albemarle Chemical said that her company had participated in the NTP-CERHR review and that she and her colleagues were well aware of its contents and conclusions. She reiterated Mr. Morford's point that there was not much to comment on with respect to the PEL Advisory Committee's deliberations. She said that she had more documents from the Proposition 65 proposal on 1-BP than with respect to the PEL Committee's work. So she did not know how to respond to the Committee's recommendation.

Julia Quint asked Mr. Morford if his group had assessed the NTP document. He responded that Mark Stelljes would respond to that.

Mark Stelljes introduced himself as director of risk assessment and toxicology for SLR International, a UK based company with offices in the Bay Area. He said he has worked on 1-BP since 2000 on behalf of IBSA and EnviroTech. He said that he was probably one of the few people who has read every toxicology study that has been published on 1-BP, and some unpublished as well, and so suggested that he probably knew more about the toxicology of 1-BP than anyone else in the room. He said that in 2001 EnviroTech had sponsored a benchmark dose risk assessment which was published in 2004. (Regul Toxicol Pharmacol. 2004 Oct;40(2):136-50). He said they had evaluated 60 endpoints from 13 different studies and ended up with a benchmark dose low of 156 ppm based on sperm motility in the F1 generation of a 2-generation study that was not listed in the documentation of the PEL Committee's recommendation. He said that EPA in a 2003 Federal Register notice cited the study and independently reached the same conclusion (168 ppm) using the same approach for the same endpoint. He said that EPA in that document recommended an occupational exposure limit of 25 ppm by applying two uncertainty factors of 3 each, one for pharmacodynamics, and one for interspecies sensitive members of the population. He said that raw animal toxicology data he had obtained from the National Toxicology Program in 2004 showed that mice and rats metabolize 1-BP very differently from dibromopropane. (Dibromopropane is a recognized reproductive hazard and possible human carcinogen similar in structure to 1-BP and regulated by Cal/OSHA with its own comprehensive standard and a PEL of 1 ppm). Mark Stelljes finished by reiterating the need for the PEL to be based on a complete review of all of the scientific literature relevant to the hazard posed by 1-BP rather than just the subset of scientific work that appeared to have constituted the review of the PEL Advisory Committee.

Bob Barish asked about Mr. Morford's suggestion that little or no adhesives work is done in California using 1-BP. Julia Quint responded that the HESIS assessment of uses in California was based on what individuals in interviews told them about how it was used. Julia Quint said that use in aerospace degreasing as described by Mr. Morford probably was one of the largest uses because of limits on VOC emissions. Mr. Morford reiterated that it is one of the only uses in California. Julia Quint said that not all Air Pollution Control Districts are as strict on VOC emissions as Southcoast (LA) area and so may see aerosol use in other areas of the state. She said HESIS had seen aerosol products in use containing 1-BP. Mr. Morford acknowledged that there is aerosol as from spray cans in electronics but said that there is a significant difference in exposure potential between that and adhesive use where large quantities can be used (eg. 55 gal/employee/day).

Bob Barish asked Mr. Morford for clarification if it was accurate to say that adhesives applications involving 1-BP were very limited or non-existent in California. Mr. Morford acknowledged Julia Quint's point that while due to VOC emissions limitations 1-BP may not be used in adhesives operations in the Southcoast Air Quality Management District, it is possible that it may be done elsewhere in the state but that adhesives use was mainly on the east coast. He said that there are only about 25 manufacturing operations in the United States using 1-BP in adhesives, primarily in furniture manufacturing as a solvent for the glue because it evaporates quickly. Bob Barish asked Mr. Morford how this information on 1-BP use had been obtained. Mr. Morford responded the information was provided to him by members of IBSA and the polyurethane industry which supplies foam materials to the furniture manufacturers.

Julia Quint responded to comments of Mark Stelljes with regard to what studies and methods were used by the PEL Advisory Committee to reach its recommended PEL of 1 ppm. Julia Quint said that the recommendation of HESIS to the PEL Advisory Committee is reflected in the minutes of the meeting of January 9, 2004 as being for a PEL between 1 and 3.3. She said that 1 ppm was based on the OEHHA risk assessment which used the Ichihara study showing male reproductive effects and a safety factor of 300. She said that 3.3 ppm was based on the NTP-CERHR study consistent with the No Observed Adverse Effect Levels (NOAEL) as suggested there. She said there was not, as Mark Stelljes suggested, disregard of other studies. She said those were looked at in the OEHHA and NTP reviews but they were not the basis of the committee's recommendation. Mark Stelljes objected that it was inappropriate to use just 2 of 90 studies as the basis of recommendations when many of those other studies contradicted the 2 used. Julia Quint said that the NTP-CERHR review's conclusion incorporated looking at the other studies referred to by Mark Stelljes and was the primary basis for the HESIS recommendation of 3.3 ppm reflected in the minutes of the committee.

Nancy O'Malley said that in 1990 when EPA was mandated to develop the Significant New Alternatives Program (SNAP) for chemicals with less potential for atmospheric ozone depletion, Albemarle looked into brominated solvents as a replacement for more potent ozone depleters and began toxicology tests on a number of these. This led eventually to a 2-generation reproductive study of 1-BP. She said that Albemarle has never supported emissive uses of 1-BP such as in adhesives but rather only more controlled use in degreasing as mentioned by Rich Morford. She said that risk assessment of 1-BP is an ongoing process – as information becomes available it is incorporated into the risk assessment. Albemarle initially adopted a 100 ppm recommended workplace limit based on a 90-day animal study finding of mild liver effects at 400 ppm. Later the recommendation went down to 25 ppm based on feasibility in customer facilities.

She said that NTP is not only interested in reproductive endpoints, but also cancer on OSHA's recommendation to NTP. She said that NTP is conducting a 2-year cancer study. With only relatively recent introduction of 1-BP there are not extensive years of exposure that would allow for epidemiologic assessment of chronic effects. She said that differences in recommended

exposure limits lie in assumptions and application of risk assessment approaches rather than in looking at different studies. She said that Albemarle does not agree with the ACGIH TLV of 10 ppm adopted in February 2005. She also said that the TLV should include a "Skin" notation to highlight risk from skin absorption.

Nancy O'Malley further noted that some of the studies conducted in Japan had shortcomings, that they did not comply with "Good Laboratory Procedures" and in some cases only small numbers of test animals were used. She said that exposures may not have been appropriately quantified as they may have included not only the intended exposures but also exposures from food and bedding as the animals were exposed in their cages. She said these shortcomings should be considered when looking at the results of these studies.

She said that the advantage of the benchmark dose approach used by Mark Stelljes is that it takes into account data all along the dose response curve. She said that benchmark dose modeling can reduce uncertainty and the need for uncertainty factors for adjustment. She recommended looking at the review conducted for Albemarle by TERA (Toxicology Excellence for Risk Assessment) which discussed benchmark dose approaches, and how and why uncertainty factors should be used. She said that Albemarle could provide extensive air sampling data showing that with Albemarle products used in cold batch degreasing and precision degreasing, all exposures can be kept below 25 ppm and most can be kept below 10 ppm.

Julia Quint acknowledged and congratulated the industry on the 2-generation reproductive study. She also said she was glad to hear that industry representatives supported a "Skin" notation for 1-BP. She said she was also surprised that the ACGIH TLV did not include the "Skin" notation.

Rich Morford said that there are more toxicology studies on 1-BP than on most other substances. He said that once the 2-year NTP cancer study is completed there will not be a lot of additional animal testing to do. He said he had found only one other TLV that referred to a 2-generation study of reproductive effects.

Mike Cooper asked if IBSA has a recommended airborne exposure limit for 1-BP in the workplace. Rich Morford responded that IBSA does not have a recommended limit but that his company, Envirotech, recommends 100 ppm which is the average of the scientific evaluations they had commissioned.

Bob Barish asked if there were any more comments on 1-bromopropane. Hearing none he closed the discussion of that substance.

Cyclonite, 1,4-dioxane, vinyl bromide, vinyl fluoride

Bob Barish asked if there was anyone present who wished to comment on the PEL recommended for any of these substances. No one came forward to comment.

Meeting Conclusion

Bob Barish thanked everyone for their participation. He said that silica was likely to need another meeting. On the other substances discussed he said he did not want to commit to additional meetings. With the comments on those made in the meeting he said that additional information could be gathered and there might be some phone calls or correspondence. Rich Morford asked if comments and other information gathered will be taken back to the PEL committee for additional deliberations. Bob Barish said that might happen but the committee did a lot of work previously and is not actively meeting. He said that if the Division felt that could be constructive it might be done and commenters at today's meeting so informed so that they could participate.

Mike Cooper noted that a number of participants in the meeting had traveled some distance to attend. He said he appreciated their involvement and the perspectives they offered on approaches to evaluating data for risk assessments.

Bob Barish again expressed his appreciation to participants, especially those who traveled from a distance for just their portion of the meeting. He suggested that if any of the remaining attendees planned to send more comments they should try to do that by the end of June. Julia Quint asked if there is a deadline for the process. Bob Barish responded that he hoped to be well along by the end of calendar year 2005 in reviewing written comments and the comments provided verbally in the meeting.

END