DRAFT MEETING SUMMARY

11th Meeting of the Health Expert Advisory Committee (HEAC) for Permissible Exposure Limits for Airborne Contaminants in the Workplace California Code of Regulations, Title 8, Section 5155

March 24, 2010 Elihu Harris State Building 1515 Clay Street Oakland, California

HEAC Members

Michael Cooper, Exponent Corp. Will Forest, Santa Cruz County Public Health Department Linda Morse (retired from Kaiser Permanente Occupational Medicine) Patrick Owens, Shell Oil Refinery, Martinez, CA Susan Ripple, Dow Chemical Company Howard Spielman, Health Science Associates James Unmack, Unmack Everett Environmental

Staff of Assisting Agencies

Jim Collines, OEHHA Dennis Shusterman, HESIS Kashyap Thakore, HESIS

Public and Interested Parties

Gale Bateson, WorkSafe Steve Brink, California Forestry Association Eric Brown, Southern California Edison Paul Burnett, Santa Clara Valley Water District Ken Clark, Willis Risk Consultants Steve Derman, MediShare Judi Freyman, ORC-West Diana Graham, Keller & Heckman Law Firm Ron Hutton, Pacific Health and Safety, Inc. Barbara Kanegsberg, BFK Solutions Dan Leacox, Greenberg Traurig Law Firm Dan Napier, DNA Industrial Hygiene Paul Niemer, Sierra Pacific Industries Catherine Porter, California Healthy Nail Salon Collaborative Roy Rando, Tulane University School of Public Health Olivera Radovanovic, Unmack Everett Environmental Tim Roberts, Lawrence Berkeley National Laboratory Michael Smith, WorkSafe

DOSH

Len Welsh (meeting chair)Bob Barish (co-chair)Steve SmithBob NakamuraMike HorowitzJohn WrottenChris LeeAlan TraenknerOpening Remarks and Discussion – Len WelshChris LeeChris Lee

Len Welsh called the meeting to order at 0935. He welcomed attendees and noted that there was a recent article in the Inside OSHA newsletter about California's PEL activities. He said that since DOSH is one of the few

agencies working on and promulgating PELs in recent years that there has been a good deal of interest in the process. He noted that besides the usual DOSH staff at today's meeting also attending were Chris Lee, Deputy Chief for Enforcement, John Wrotten, Staff Services Manager, and Alan Traenkner on temporary special assignment from Federal OSHA.

Len Welsh briefly reviewed the DOSH process for developing PEL proposals. He noted that DOSH has been working on and promulgating new and updated PELs for several decades, but that the current round of work that started in 2007 differs from the past in that it includes separate advisory committees for assessments of health (the HEAC) and feasibility (the FAC). He noted the process at the last HEAC meeting in September 2009 wherein a number of substances had been moved onto consideration by the FAC (at a meeting December 8) with a range of possible PEL values rather than waiting to reach a single number recommendation from HEAC that had proved difficult for some substances.

Len Welsh said that most of today's agenda was discussion of new chemicals, except for trichloroethylene which has been discussed at several meetings and hopefully can be wrapped up today. He said Bob Barish as lead staff person for the Cal/OSHA PEL Project would lead the discussion and he would interject as he felt needed.

Michael Smith asked Len Welsh about the approach of HEAC generating a range of levels for discussion by the FAC. He said he wanted to clarify if the decision of the FAC is limited just to the two points, upper and lower, of the range of values that come out of the HEAC or if the FAC can consider and recommend any value within the upper and lower end values. Len Welsh said that he had listened to some of the HEAC discussion at previous meetings trying to come up with a single health-based value to recommend for consideration by the FAC. He noted the difficulty of those discussions and said that especially as the health-based values go lower, there is less and less certainty as to health effects. So to address this problem in terms of moving the process forward on establishing new or revised PELs, he thought it most appropriate when the HEAC discussion did not result in a single number recommendation to pass a long a range of values for discussion by the FAC. Michael Smith said he could see a situation where the lower end of the range of a HEAC recommendation might be based on prevention of cancer, and the upper end, for example, based on respiratory irritation. So he said if the FAC recommends the higher level then that PEL might not protect against all health effects. Len Welsh acknowledged this point and said that when there are such different health endpoints in the discussion this should be discussed explicitly to clarify the possible health consequences of different levels of exposure to the same substance.

HEAC discussion – Bob Barish

Bob Barish reminded attendees to be sure to sign-in for the meeting. He reviewed the agenda, the handouts for the meeting, and the list of substances planned for the day's discussion. He noted that there would be a presentation by Professor Roy Rando of Tulane University on a study on wood dust. Bob Barish asked if there were any comments on the minutes posted at the project website for the previous HEAC meeting of September 10, 2009. No comments on those minutes were raised.

Proposed updating of Priority List of Substances for work by HEAC

Bob Barish noted the one page handout with attachments that listed about 20 possible substances for work by HEAC. He said list of 20 substances included some from the existing priority list posted at the project website, as well as a number of additional substances taken from lists of newly revised or adopted TLVs by ACGIH for the years 2008, 2009, and 2010 that were not included in the original priority list developed in 2008. He said attached to the one –page proposed list of substances for HEAC work were pages from the ACGIH annual reports for 2008, 2009, and 2010 showing the TLV adoptions for those years so that attendees could determine which substances from among the 2008-2010 TLV adoptions were proposed for HEAC work and which, at this point, were not.

The handout noted can be viewed by clicking on the icon below (allow several seconds for the icon to appear):



Bob Barish noted that on the priority list presently posted on the website that is also included in the handout, most of the Priority 1 substances have either been concluded through HEAC and FAC, or are in the process of discussion such as those later in the agenda today. He noted that several phthalates in Priority 1 on the current list were still being worked on by Susan Ripple. She noted that with the recent merger of Dow and Rohm and Haas she now has a conflict of interest with the phthalates and needed to hand the substances off to another HEAC member. Howard Spielman volunteered to take them on and present them at a future HEAC meeting.

Bob Barish then explained the one-page draft updated priority list of substances. In determining which substances to include on this list from among those primarily in Priority 2 on the current list as well as among the recent TLV adoptions he said the following were the major factors considered:

- 1. An air sampling and analysis method adequate to one-half the TLV
- 2. Apparent usage or presence in California workplaces
- 3. Significance of the size of the reduction in the TLV
- 4. Significance of the health effect to be protected against

Bob Barish said the proposed list does not represent a ruling out of other substances in the current priority list, or other recently adopted TLVs, but rather are substances which meet the first criteria above and at least one of the other three listed. So he encouraged attendees to review the draft list (first page of he handout) and the attached list of all recent TLV adoptions, and the current priority list, and let him know if any of the recent TLV adoptions that are not included in the draft priority list are of particular concern to them.

Dan Leacox asked if with the new draft list the priorities in the existing list would be modified. Steve Smith noted there had been some changes made in 2009 and the intention was to look at the whole list along with the draft update and make one new revised priority work list for HEAC. Dan Leacox said he hoped there would be just one list. He asked about how some recent TLV changes were not included in the draft update list. Bob Barish responded that some of the changes are very minor or the substances appear to be unlikely to be used in California. Steve Smith reiterated that attendees should go through both the draft update list and list of recent TLV adoptions and let him or Bob Barish know of any questions or concerns. Steve Smith said he would have for the next HEAC meeting the full priority list updated to include those substances on the draft list handed out at the meeting along with any comments he might receive in the next few weeks.

Trichloroethylene (TCE)

Bob Barish noted a letter dated March 3, 2010 sent to him by the Halogenated Solvents Industry Alliance (HSIA) supporting for the Cal/OSHA PEL the ACGIH TLV of 10 ppm 8-hour TWA for trichloroethylene. Bob Barish said he had distributed this letter to HEAC members.

Will Forest, the HEAC member working on TCE discussed his draft assessment document posted at the PEL Project website. He said he had focused on cancer risk evaluations by major organizations such as IARC, NTP, the European Union, and EPA; he said all of them classify TCE as a probable human carcinogen. He said that OEHHA had set an NSRL (No-Significant Risk Level) for TCE under Proposition 65. He said that in addition to the animal studies providing the basis for quantitative risk assessments, there have been many studies of workers showing evidence of increased cancer risk, especially kidney cancer. Using data in the OEHHA NSRL, he said he calculated a workplace exposure value of 0.38 ppm for the level of 1/1000 increased risk as shown in the draft assessment document. He said further that based on OEHHA's Inhalation Unit Risk Factor he had calculated a PEL of 0.475 ppm for the 1/1,000 increased risk level. Finally he noted that the OEHHA non-cancer Chronic

Reference Exposure Level (C-REL), based on a NIOSH Health Hazard Evaluation, would translate to a PEL of 0.32 ppm. He noted that in his experience it is very rare that the 1/1,000 increased cancer risk level is higher than a level based on non-cancer effects, as it appears to be in this case.

Bob Barish asked if there were different underlying studies for the cancer risk values based on the OEHHA NSRL and the OEHHA Inhalation Unit Risk Factor. Will Forest said there were, and he said he believed the NSRL based value represented the more standard assessment. Howard Spielman asked about the choice of an uncertainty factor of 10 for intraspecies variation used by OEHHA in the calculation of the C-REL. Will Forest said that 10 had presumably been used by OEHHA as a default value in the absence of data suggesting departure from this value. At this Len Welsh asked Will Forest to explain the paradigm of default uncertainty factors.

Will Forest said that uncertainty factors have longstanding use in non-cancer risk assessments. He said that the default uncertainty factor values that have been discussed and used by the HEAC in previous meetings are not just a matter of convenience but rather have been shown to have one or more underlying scientific basis. As has been discussed at previous HEAC meetings, these can include, for example, metabolic differences between species and between individuals of the same species.

Howard Spielman said he asked the question about uncertainty factors because in the committee's decision on toluene (at the December 2008 HEAC meeting) an intraspecies uncertainty factor of 3 rather than 10 had been used even though for TCE there appeared to be more data available from human epidemiology studies than for toluene. Dennis Shusterman pointed out that the C-REL is based on an uncertainty factor of 10, and that the cancer values which do not employ an uncertainty factor in their calculation are similar in value. Howard Spielman said he thinks it still matters in terms of consistency with other HEAC assessments, for example for toluene as he'd mentioned. Will Forest said that if information was available to show that there was less intra-species variation, it might be reasonable to reduce the intra-species uncertainty factor to 3 as Howard Spielman suggested, but that such data was not available for TCE.

Eric Brown asked Will Forest why he had used both interspecies and intraspecies uncertainty factors in the noncancer assessment. Will Forest said this is the standard method in non-cancer risk assessments; it simply reflects that there is variation both between species and within species. Dennis Shusterman said that especially with the human studies indicating cancer risk with TCE, in addition to the animal cancer assessments, the focus for the PEL for TCE should be on the cancer endpoint. Will Forest said his recommendation was for a health-based PEL value of 0.4 ppm based on the 0.38 ppm value calculated from the Proposition 65 NSRL. Howard Spielman said that in the TLV Documentation there were 22 studies of the health effects of TCE. Will Forest did not argue with this but said that those studies were not on cancer.

Bob Barish asked if there were any other comments on the 0.4 ppm suggested by Will Forest for the PEL based on cancer risk. Susan Ripple noted that she had a conflict of interest with TCE, and noted that her company Dow Chemical has an internal occupational exposure limit significantly lower than the current Cal/OSHA PEL of 25 ppm. There was a question as to whether TCE could reliably be measured in air at 0.4 ppm. Bob Barish said the OSHA and NIOSH air methods for TCE can be used to measure well below this level.

Bob Barish asked HEAC members again about the value of 0.4 ppm and no disagreement with it was raised.

Steve Smith asked about the STEL of 25 ppm that is part of the TLV. Will Forest initially suggested possibly a STEL of 20 ppm to provide some basic measure of short-term exposure control. Susan Ripple said that a STEL should be based on documented health effects rather than exposure control strategy. It was noted that an 8-hour TWA PEL of 0.4 translates mathematically into a 15-minute STEL of about 12 (0.4 x 32 15-minute periods in an 8-hour shift). Will Forest said his view on the STEL would depend on the PEL TWA adopted. If it is close to the 0.4 ppm recommendation, there would be no need for a STEL; if it is significantly more than the 0.4 ppm agreed to, then he might want to have a separate STEL.

With the recommendation for the 8-hour TWA PEL of 0.4 ppm, there was no agreement or recommendation for a STEL for trichloroethylene, and the discussion was concluded.

Wood dust

Bob Barish said that after the presentation by HEAC member Linda Morse of her draft health assessment document there would be a brief presentation by Professor Roy Rando of Tulane University on a study conducted in the wood processing industry sponsored by the Inter-Industry Wood Dust Coordinating Committee.

Linda Morse distributed a handout indicating a few additions and corrections to her document posted on the project website. She noted that in her draft document she proposed a PEL for wood dust consistent with the ACGIH, ie. 1 mg/M3 inhalable particulate and for western red cedar 0.5 mg/M3 inhalable particulate.

Linda Morse noted that wood dust is a complicated problem because there are many different wood species, and other potentially hazardous substances including fungi, endotoxin and other biologic substances as well as naturally occurring and manmade residual chemicals can be associated with wood dust. She said also that there is no longer what could be regarded as a "healthy workforce" in the U.S., based on the population prevalence of respiratory problems and obesity and this needed to be taken into account in considering a PEL for wood dust based on effects on the respiratory system. She noted that the current Cal/OSHA PEL for wood dust is 5 mg/M3 ("total" dust), while the Federal OSHA PEL treats wood dust as nuisance particulate with a PEL of 10 mg/M3. She said NIOSH has proposed an OEL of 1 mg/M3. She suggested that the major exposure problems are with indoor work and not with outdoor operations.

Linda Morse noted the presentation to be given by Professor Rando of a study published in 2008 that assessed of wood dust exposures on pulmonary function. She said that asthma which is a partial basis for the TLV is primarily from woods not found in the U.S., other than western red cedar which has its TLV that she proposes be considered for a revised PEL. She noted with respect to cancer risk that oak and beech which are classified as confirmed human carcinogens in the ACGIH TLV they tend to be more inflammatory than other woods which may contribute to, or help explain, the apparent increased cancer risk they have been found to present.

Tulane study of respiratory health in the wood processing industry

Professor Roy Rando of Tulane University School of Public Health said he that while his travel to today's meeting was paid for by wood industry organizations, he does not speak for the industry. Rather, he said, his role at the meeting is to share the data and conclusions from the study done by his institution that was sponsored by the Inter-Industry Committee and published in 2008 (Longitudinal respiratory health study of the wood processing industry, Glindmeyer HW et al., <u>Am J Ind Med.</u> 2008 Aug;51(8):595-609). Professor Rando passed out a short handout of slides, which can be viewed by clicking on the icon immediately below (**allow several seconds for the icon to appear**):



Professor Rando noted his tenure of about 30 years at Tulane has been focused primarily on research into the etiology and epidemiology of respiratory diseases. He said that in the mid-1990s they were approached by industry representatives to do a major study on respiratory health in wood processing operations in the U.S. After an initial scoping study the larger study started in 1998. He said that in designing the study the Tulane group looked at previous research on health effects of wood dust and chose to conduct a 5-year longitudinal health study. As noted in the slides, 10 study locations were selected from out of a total of 480 possible sites to provide a variety of different operations and conditions. Locations processing western red cedar, because of its documented

allergenic effects, were excluded from study. As indicated in the second slide the 10 sites studied consisted of 4 furniture plants, 3 cabinet plants, 1 plywood mill, 1 saw/planer/ plywood mill, and 1 secondary millworks. Wood dust exposure and health assessments were done at the 10 locations. Over 2,300 air samples were collected with the Respicon sampler which enabled simultaneous assessment of the inhalable, thoracic, and respirable particulate fractions of airborne wood dust. Additionally a selection of these samples were analyzed to separate out "wood solids" from "residual particulate matter" consisting of some materials derived from wood (water and wood volatiles), contaminants originating in processing and storage, and background particulate material originating with the industrial environment.

Professor Rando said that early on in the data analysis it became clear that significantly different health responses were being measured in different operations. As a result, the analyses of the different locations were separated into four subgroups: furniture-cabinetry, plywood, milling, and sawmill-planing-plywood. The furniture-cabinetry segment consisted of seven study locations, while the other three were comprised of one location each. He noted that the highest levels of exposure were seen at the furniture-cabinetry locations, and that there were significant differences in exposure levels even within the same facility.

As noted in the abstract of the Tulane study, exposure to wood solids was not associated with significant adverse effects, although residual particulate matter was found to be associated with an obstructive effect in the milling facility, and with a restrictive effect in the sawmill-planing-plywood facility. Professor Rando noted also that formaldehyde was suspected to be a possible confounding factor for some of the effects detected, and was included as a possible confounder in the statistical analysis. Also, given studied workers' movements between operations in the locations there may have been unmeasured exposures to other substances.

Linda Morse said she felt the Tulane study was well done, maybe the best among those she reviewed in her assessment. She noted that those administering the pulmonary function tests had been properly certified and other elements of the study were high quality. She did take issue with separately analyzing the effects of "wood solids" and "residual particulate matter." She said she understood why this was done, but questioned the validity of the approach given that all wood will have some potentially hazardous residual material associated with it, especially with more and more wood products being made from composite wood materials such as particle board. Len Welsh asked if the data from the Tulane study could be reworked to account for the entirety of the particulate exposures.

Linda Morse said that given the exposure levels measured in the Tulane study were all below the current Cal/OSHA PEL, and the authors report no significant adverse health effects associated with these levels of exposure, that lowering the PEL would appear to offer benefit in terms of reducing risk to exposed employees respiratory health.

Dennis Shusterman asked Professor Rando if health effects were seen from exposure to particulate not differentiated into "wood solids" and "residual particulate matter." Professor Rando said yes there were health effects seen before separating the dust into these components, but only related statistically to the respirable fraction. Dennis Shusterman noted that the pie chart in Professor Rando's presentation showed that residual materials are inherently present in wood dusts. Professor Rando acknowledged this and said he agreed that these residual materials are probably an important factor in the health effects. Linda Morse asked him about the study's assessment of fungi. Professor Rando said they wanted to look at this but that the archived samples from the location where it was the biggest issue were destroyed in Hurricane Katrina.

Steve Derman asked about the particulate size fraction if the ACGIH TLV. It was noted that the TLV of 1 mg/M3 is based on the inhalable particulate fraction.

Professor Rando noted some of the issues with inhalable versus total dust sampling. He said he has worked with NIOSH on evaluation of several inhalable sampling devices. He said the main problem with use of an inhalable standard for wood dust is that a few large particles can greatly bias the sample results. He noted that in most of

the epidemiologic studies that have been done on wood dust the measurement method is "total" dust collected on a 37 mm closed face filter cassette rather than inhalable. He said the "total" dust fraction has generally been found to be intermediate between the thoracic and inhalable fractions and can vary greatly with sampler orientation and other factors. He noted that the respirable particulate fraction would be the most relevant if looking at effects in the lower lungs.

Bob Barish asked if there was anyone present from the American Forest and Paper Association who wished to make a statement on wood dust but they apparently did not have a representative at this meeting. He noted the AFPA had sent a letter questioning the 1 mg/M3 TLV being recommended for consideration as the PEL but had not suggested a clear alternative level.

Will Forest asked Linda Morse if her assessment supported the value of the TLV for the PEL and if so is there an explicit basis for that. Linda Morse replied that there is not explicit basis in one or a set of studies for the TLV value of 1 mg/M3 inhalable dust, partly because the interrelated issues of fungus and other wood contaminants is always present.

Bob Barish asked Linda Morse about western red cedar. She said that the health effect, and the basis for the TLV for western red cedar are more straight forward than for wood dust generally.

Eric Brown asked about separating out the cancer effect attributed to some wood dust and also the site of the cancers that have been found. Linda Morse said that the respiratory cancer found in some studies to be associated with wood dust is nasal cancer, as well as laryngeal and lung cancer.

Will Forest asked Professor Rando if the wood processing industry recommends an alternative value to the TLV of 1 mg/M3 inhalable. Professor Rando responded that he was not aware of a particular alternative value being recommended, that there are limitations to the Tulane study in determining an appropriate occupational exposure limit, and there was concern that in the study different levels of effect were associated with different operations.

Ron Hutton noted that the bar graph in the 5th slide of Professor Rando's handout showed a number of operational situations with exposures over the inhalable TLV of 1 mg/M3. He noted that the same graph showed that the geometric mean respirable dust concentrations measured for the four situations noted in the Tulane study were below 0.2 mg/M3, suggesting this as a PEL that might thus be feasible to achieve.

Howard Spielman asked Professor Rando about effects of respirable versus inhalable particulate fractions measured. Professor Rando responded that the main effect actually seen was with respirable particulate. Susan Ripple asked if in the Tulane study they assessed the exposures to glues and other chemicals especially in the plywood processes. Professor Rando acknowledged the significance of the question but said the Tulane study did not include quantitative assessment of other chemical exposures. Mike Cooper asked if there was only significant effect associated with the residual particulate as defined in the study then is that the real problem. Professor Rando responded that the fundamental problem was defining what "wood dust" actually is and whether it is the wood or other substances that can be associated with it that presents the health hazard.

Eric Brown suggested that if residual material is the problem the PEL for wood dust should be specified differently for different industries.

Bob Barish said he had asked Dennis Shusterman and HESIS if they could review studies on possible mechanisms for the effects of wood dust on the respiratory system, and the significance of studies showing impairment of muco-ciliary clearance associated with wood dust exposures.

Dennis Shusterman said he had reviewed studies on mucociliary clearance, and found reports of prolonged clearance (saccharin transit time) with increasing dust exposure among wood workers. He said that impaired mucociliary clearance can be important as an indicator of physiological effect, and is important in its own right

possibly as a contributor to increased risk of cancer or other respiratory effect by increasing the residence time of airborne contaminants in the respiratory tract. Reporting specifically on one of the studies cited in the TLV Documentation for wood dust (Andersen et al., 1977) he said that with regard to reversibility of mucociliary impairment, at the end of the weekend, two-thirds of workers exposed to wood dust showed substantial recovery, indicating some degree of reversibility in most cases. Significantly, exposure of workers in the Andersen et al. study to plastic microspherules, did not cause altered clearance, so the authors concluded there were specific soluble chemicals in the wood dust that caused the effect. Dennis Shusterman concluded that he didn't see any reason to think nose and chest are different in this regard.

Kashyap Thakore of HESIS confirmed that Linda Morse's draft review included those studies that he was able to determine, by literature search, were relevant to the possible mechanism of action of wood dust. These included studies documenting both oxidative stress and cytokine induction in vitro (i.e., cell culture systems).

Dan Leacox suggested getting a table of the air sampling results from the Tulane study. Professor Rando responded that these results are broken out in a separate paper (A survey of size-fractionated dust levels in the U.S. wood processing industry, <u>Kalliny MI</u> et al. <u>Occup Environ Hyg.</u> 2008 Aug;5(8):501-10.)

Related to the question about the mechanism of action of wood dust discussed by Dennis Shusterman, Bob Barish asked if the wood that had been used in the laboratory studies had been separated from residual material as suggested by the methods of the Tulane study. Linda Morse and Dennis Shusterman said that the wood particulate used in the mechanism studies was highly purified.

Steve Derman echoing Will Forest's earlier question asked Professor Rando if he felt there was adequate basis in the TLV Document for the TLV of 1 mg/M3 inhalable. Professor Rando responded that if the basis for the TLV is effect on pulmonary function then respirable dust would appear to be the most appropriate measure. He said he thought the TLV Committee in adopting an inhalable standard had wanted to also protect against the cancer risk presented by the larger particles that are deposited predominantly in the nasal cavity. He said he thought that if the purpose was to protect against both effects there should be different TLVs for each effect, one based on the respirable fraction and the other on the inhalable.

Len Welsh thanked Professor Rando for his presentation and contribution to the day's discussion and complimented Linda Morse on her analysis and presentation of the issues associated with the consideration of a PEL for wood dust.

LUNCH BREAK

After the lunch break BobBarish asked HEAC members to think about the substances in the draft updated priority list they would pick to work on next.

Benzyl chloride

Bob Barish noted that he had found two California locations listed with benzyl chloride on-site in significant quantities in the EPA Tri- Explorer (EPA EPCRA 313) database on the Internet. One of these may have been a distributor rather than a user of the substance in an industrial process, and the other, which appeared to be a chemical formulator, did not return his telephone call inquiry.

Susan Ripple presented her health assessment. She said that the TLV was based on acute effects, most notably respiratory irritation which she said is the basis for the current TLV of 1 ppm. She said that ACGIH gave benzyl chloride the "A3" carcinogen designation: *Confirmed animal carcinogen with unknown relevance to humans*. She said benzyl chloride was a widely present intermediate in chemical manufacturing but is generally not found in commerce. She said there is an OEHHA acute REL based on respiratory and eye irritation.

Susan Ripple said the PEL value of 0.03 ppm recommended for the PEL and derived as shown in her assessment document was based on reducing additional cancer risk to 1/1000, from the 32/1,000 for the current PEL based on the method used by OEHHA and indicated in their document of December 2007 on PELs.

Bob Barish asked Susan Ripple if her employer Dow Chemical had any interest in benzyl chloride which needed to be disclosed for potential conflict. She replied that she did not think so as the company sold their facility that made benzyl chloride in 2001.

Mike Cooper asked about information in the assessment document on the air sampling method. He said it seemed to suggest that a sample size greater than the 10 liter maximum recommended by OSHA's Salt Lake City Laboratory might be needed to get sufficiently below the PEL being recommended. Susan Ripple noted that yes the Limit of Quantitation (LOQ) of the OSHA method is only slightly less than the PEL she is recommending.

Susan Ripple noted that a couple of typographical errors in the cancer risk calculation section of the document would be corrected for the next version that is submitted to be posted on the project website.

Bob Barish said it appeared that the only potentially significant issue being raised with the PEL recommended by Susan Ripple for benzyl chloride is the air sampling method and that this is an issue that can be discussed in the FAC meeting. Susan Ripple said that if it is decided that the PEL proposed should be higher than the value she recommended based on measurement limitations then that should be clearly indicated as the reason for the change from the recommendation in the draft assessment document, rather than suggesting it was a change resulting from disagreement on the risk assessment.

Patrick Owens asked about the EPA IRIS cancer assessment and the source of the data it referred to in mice. He said it was not clear in the assessment document what the experimental animals and dosing were, so he had checked this in the Lajinsky paper and said he hoped that Susan Ripple could clarify this in the final draft for the next meeting. Susan Ripple said she would go back and recheck on the substantive and editing questions raised in the discussion and revise the document accordingly.

1,1,2,2- tetrabromoethane

HEAC member Jim Unmack who drafted the health assessment on this chemical said the information on it was rather limited. He said its principle use is in gauges due to its high specific gravity and in ore processing operations especially to separate out gold and other precious metals. He said the basis for the TLV of 0.1 ppm which he recommends for the PEL is based on the study of Hollingsworth (1963) which found a NOAEL of 1 ppm in subchronic inhalation studies of five animal species (rabbits, guinea pigs, rats, mice and a monkey), with findings of pulmonary edema and fatty liver degeneration at higher levels of exposure. The TLV of 0.1 ppm was derived by applying a total uncertainty factor of 10 to the Hollingsworth finding. Jim Unmack said he thought this was a reasonable basis for the PEL.

Jim Unmack's assessment indicated that the NIOSH air sampling method is sensitive to about 0.06 ppm in a 100 minute air sample. Howard Spielman asked about the basis of the TLV being inhalable fraction and vapor, how much could be particulate. Jim Unmack said that in mining and ore processing it was possible to generate a mist, and that alternatively condensation particles might form from vapor. Patrick Owens noted that the NIOSH air sampling method for this substance uses a silica gel tube. Howard Spielman suggested that the plugs in the tube may be able to collect and be analyzed for the particulate fraction.

Susan Ripple noted that one of the studies cited in the TLV Document is from DOW, but that they no longer make or market any brominated compounds.

Patrick Owens asked about skin absorption. Jim Unmack said that as noted in his assessment the Van Duren (1979) study had found transcutaneous absorption and a statistically significant increase in forestomach papillomas in mice. This finding generated discussion and questioning as whether the papillomas found resulted from skin absorption or ingestion from grooming. He said the TLV did not include a Skin notation. Dennis Shusterman asked if there is an RD-50 or a cancer risk assessment. Jim Unmack replied that there was neither and that the closest assessment on this substance for cancer was the positive Ames test noted in the assessment document.

Will Forest asked why no default intraspecies uncertainty factor of 3 or 10 was applied to the NOAEL in deriving the recommended PEL. He said this factor should be ten if there is no data supporting a lower factor. Mike Cooper suggested that the Hollingsworth study in five animal species yielding a NOAEL of 1 could a support an inter-species uncertainty factor lower than 10. Jim Unmack said he would look at the studies again and send Bob Barish a document either with revised uncertainty factor and PEL recommendation, or an explanation of why not.

<u>Arsine</u>

HEAC member Patrick Owens briefed the meeting on his assessment of arsine gas. He said his PEL recommendation was to go from 0.05 ppm to 0.005 ppm 8-hour TWA based on non-cancer effects. He said human urinary arsenic levels associated with peripheral neuropathy have been linked to arsine concentrations. Establishing a PEL at 0.005 ppm for arsine should prevent a urinary arsenic level associated with peripheral neuropathy in humans and hemolysis seen in rodents. The recommended limit is for an 8-hour TWA and not a STEL because the effects seen in referenced studies are full-shift exposures and no acute effects were observed at a level 32 times the proposed limit.

Patrick Owens said some government agencies have historically combined arsine gas with other arsenic compounds thus categorically labeling arsine as a possible carcinogen. However, he said HEAC's assessment of arsine as a carcinogen should consider that it is a highly water soluble gas, that is absorbed differently than when arsenic is inhaled as a particulate or is ingested. Patrick Owens said that with respect to cancer risk, several references state that arsine passes rapidly through the lungs and into the blood with the result that there is less risk of lung cancer than with inhalation of inorganic arsenic particulate which can remain in the lungs for a period of time. Linda Morse said that the lung cancer risk may be reduced if the residence time of the arsenic is so short that no significant damage occurs to the lung tissue. Dennis Shusterman suggested that Craig Steinmaus be consulted on this. He said that Craig is an expert on arsenic in drinking water and was a member of the PEL Committee in the last round of work from 2001 to 2004. A question arose regarding the basis for the 1975 NIOSH Criteria Document's recommended limit of 0.0006 ppm as a STEL. Patrick Owens said this reflected the position of NIOSH that all inorganic arsenic compounds (including arsine) are carcinogens.

Bob Barish said that in addition to its use in the semiconductor industry there may also be some exposure in battery manufacture during charging and possibly from charging of large banks of batteries. He said he has contacted a representative of the battery manufacturing industry about this. Howard Spielman suggested this was probably due to arsenic being an impurity in the lead used in lead-acid batteries. Jim Unmack suggested the arsenic is added to the lead in the battery as a hardener. Howard Spielman and Dennis Shusterman both noted the risk in semi-conductor manufacture, where arsine used in toxic gas systems, is primarily from accidental release rather than from ongoing exposure as appears might be the case with battery charging.

Dennis Shusterman asked Patrick Owens to estimate an exposure limit based upon the EPA IRIS RfC and send it to him for review. Patrick Owens said he was going to double-check the 1975 NIOSH Criteria Document for arsine-specific data and obtain several more references prior to the next HEAC meeting.

<u>Gallium arsenide</u>

Patrick Owens also drafted the health assessment for gallium arsenide He said that as with arsine gas, there might be health effects from arsenic with gallium arsenide. However, he there can also be effects from gallium which

need to be considered. He said several references indicate that gallium arsenide can dissociate into arsenic and gallium *in vivo* and cause systemic arsenic toxicity. Dennis Shusterman said that for each element to exert its effect the molecule would have to dissociate. Patrick Owens said he did not find any epidemiologic studies in his work on this substance. He said that for effects observed in animal studies, it is not entirely clear to him if the most sensitive endpoint is caused by gallium arsenide, elemental arsenic, elemental gallium, or metabolites of one or more of these. He said he would try to better resolve this question for the next meeting.

Howard Spielman said that in his experience a major problem with gallium arsenide is that it can easily migrate and contaminate a workspace, especially ingots are being sliced into wafers. He said that a key factor in employee protection was control of contamination. Susan Ripple said that because gallium arsenide is an expensive material most locations do try to contain it with recovery systems.

Mike Cooper said there is a lot of use of gallium arsenide in California in the manufacture of diodes and solar cells.

Bob Barish asked if there were any comments on Patrick Owen's recommendation for the PEL of the TLV of 0.0003 mg/M3 to protect against lung hyperplasia seen in rats [based on a NOAEL of 0.01 mg/M3 in NTP (2000) as noted in the draft HEAC document]. Patrick Owen's draft assessment document said that this level should also protect against cancer based upon the rat NOAEL of 0.1 mg/M3 reported in NTP (2000) noted in the draft HEAC document. He said also that the TLV is well below the developmental NOAEL for mice of 10 mg/M3 reported in Mast (1990) noted in the draft HEAC document.

There were no comments from HEAC members or other meeting attendees on the presentation on gallium arsenide.

Concluding Remarks

Bob Barish said the plan for the next meeting would be to conclude the discussion of the substances started today and to present a more final updated priority list of substances for HEAC work that would be posted before the meeting.

There was discussion of substances from the draft updated priority list already being worked on or volunteered for by HEAC members. Patrick Owens said he had taken on hydrogen sulfide but noted that he had a potential conflict since there can be exposure in petroleum refining. Mike Cooper had already volunteered for sulfur dioxide on the draft updated list. Susan Ripple volunteered for monochloroacetic acid. Susan Ripple also said that with her potential conflict due to Dow's purchase of Rohm and Hass she would give the three phthalates she had been working on to Howard Spielman to present as the assessments were close to being finished

The meeting adjourned at 3:20 p.m.

END



MEETING NAME Health Expert Advisory Committee for PELs

DATE Wednesday March 24, 2010

CHAIRPERSONS Len Welsh/Bob Barish

LOCATION Room 1304 1515 Clay Street, Oakland

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NEW ATTENDEES: PLEASE BE SURE TO WRITE YOUR NAME, AFFILIATION, AND E-MAIL ADDRESS CLEARLY

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