

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

**September 6, 2017
Elihu Harris State Building
1515 Clay Street
Oakland, California**

HEAC Members present

Eric N. Brown, DrPH, CIH, CSP, The Aerospace Corporation, El Segundo, CA (Industrial Hygiene)

Michael N. Cooper, MS, MPH, CIH, Principal Scientist, Mcooperconsulting LLC, Eagle, ID (Industrial Hygiene)

Will Forest, MPH, Santa Cruz County Department of Public Health (Epidemiology/Toxicology)

Robert Harrison, MD, MPH, School of Medicine, University of California, San Francisco, CA (Occupational Medicine)

Sarah Janssen, MD, PhD, MPH, Occupational Medicine Department, Kaiser Permanente, San Francisco, CA (Occupational Medicine)

Linda Morse, MD, FACOEM, Kaiser Permanente Medical Center, retired, San Francisco, CA (Occupational Medicine)

Patrick Owens, MSPH, CIH, Shell Oil Martinez Refinery, Martinez, CA (Industrial Hygiene)

Mark Stelljes, PhD, SLR International Corp., Martinez, CA (Toxicology)

James Unmack, CIH, Unmack Corp., San Pedro, CA (Industrial Hygiene)

Public and Interested Parties

Erica Stewart, Kaiser Permanente

Jim Keqebein, Keqebein Consulting

Dan Leacox, Leacox and Associates

Bob Nocco, Chevron

Bill Taylor, PASMA

Saeher Muzaffar, California Department of Public Health, HESIS

Richard Warburton, ChemDAQ, Inc.

Matt Spencer, US Poultry & Egg Association

Matt O'Brien, Agricultural Council

Lindsay Stovall, American Chemistry Council

Kashyap Thakore, Toxicologist, California Department of Public Health, HESIS

Kathleen Vork, Staff Toxicologist, OEHHA, Cal/EPA

Beverlie Franzen, Fetzer Vineyards

David Kernazitskas, Cal/OSHA Standards Board Staff

Russ McCrary, CA Ironworkers Employee Council
Mara Ortenburger, Worksafe
Bob Brown, Bay Area WSPA
Rob Neenan, CA League of Food Producers
Emma Wilson, CDPH
Steve Derman
Harvard RuFong, CDPH
Todd Wealer
Lindsay Adams-Hess, Bowman and Brooke
Stewart Holm, Forestry Council

Division of Occupational Safety & Health

Garrett Keating, Steve Smith, Kevin Graulich and Mike Horowitz

Steve Smith opened the meeting, introducing the Division personnel present, pointed out the sign-in sheets and handouts at the rear of the room. The handouts include the agenda, the summary documents for hydrogen sulfide (H₂S), peracetic acid (PAA), 2-butoxyethyl acetate (2-BEA), aluminum, and manganese. Explained the purpose of the meeting and the structure of the HEAC, and the rulemaking process.

Introduction of attendees. Housekeeping information. Explanation of the HEAC webpage and what documents are available on that website.

Hydrogen Sulfide

Garrett Keating gave second reading on H₂S and described some comments received. 1) American Forestry and Paper Association re: validity of Bhambhani Study. 2) HESIS revised the study used as the basis for its recommendation from CIIT to Brenneman, and 3) Garrett added support for including a STEL.

Garrett Keating discussed that the Bhambhani studies were not designed as toxic response studies, but they did note symptoms and sub-clinical effects. A series of human volunteer studies with short 30-minute exposure to 1, 5 and 10 ppm H₂S Conducted at 50% workload with increasing exposure concentrations. Measured ventilation output, heart rate etc. and blood and muscle biochemical markers (cytochrome oxidase inhibition, lactate,).

Stewart Holm, Forestry Council. Concerned with the idea of meeting the “Material Impairment of health” threshold as stated in Labor Code section 144.6-and feels that Bhambhani study was sporadic and inconsistent with no apparent dose response. With other substances we do not regulate based on biochemical effects, we regulate on impairment. Some issues with the irritation reported with the Fiedler study (nose not clipped). Wants a definition of serious respiratory effects in our document.

Dan Leacox also questioned data from the Bhambhani study. Showed no change? Mode of action? Garrett responded that it showed trends in the enzyme response: Aerobic metabolism inhibition which affects energy production and muscle function. H₂S exposure symptoms tend to be fatigue, and

irritation. Garrett repeated that Bhambhani was intentionally low level exposure for short 30 minute intervals and unfortunately did not look at longer exposures. Stewart Holm raised the question that H2S may not follow Haber's Law (effect = concentration X time) since it is an irritant gas.

Dan Leacox also questioned the economic impact assessment that indicates that costs would be balanced by benefits and would like more information on how we come up with this statement. Steve Smith reminded the group that our goal is to get that information from the stakeholders so that we can use actual data and not generalities.

Michael Cooper indicated that we were not seeing clinical changes in the enzyme that we claim is the mode of action and relying on sub-clinical measurements may be problematic. Will Forest responded that it is hard to demonstrate a trend when the study group was only 16 to 18 people, but that we should not rule out that the trend is meaningful just because the statistics are weak.

Garrett indicated that he will explain the Bhambhani studies in more detail in the next draft.

Robert Harrison indicated that he supports our recommendation, and is ok with leaving it up to the Division as to whether it reaches the level of "material impairment of health".

Garrett reminded that the Bhambhani studies were conducted with healthy men and women, average age of 25.

Jim Unmack indicated that the sensitive population might be a population with allergies or other sinus conditions.

Bob Harrison asked about an update on the HESIS recommendations on Nasal lesions. Which is the most critical endpoint? HESIS (Kashyap Thakore) updated their recommendation to use the 10 week, sub chronic rat study – Brenneman, 2000. This is the same study that EPA used for their IRIS reference concentration. It evaluated various lesions in the olfactory regions. Garrett felt that the human data was easier to extrapolate to humans, where there were some concerns with the animal studies. For example, rats have much more sensitive/complex olfactory systems and may be more sensitive to the exposures.

Bob Harrison asked for clarification on the studies used by HESIS. Saeher Muzaffar, responded that OEHHA used the CIIT, 1983c study and EPA used the Brenneman 2000 study. Both studied olfactory lesions.

Eric Brown indicated that the odor threshold is so low that it is not feasible in the occupational setting for there to be the long-term exposures that these studies indicate. Short - high level exposure maybe, and could show olfactory lesions, but not sure about the long duration exposures.

Garrett also indicated that most occupational epidemiology studies tend to show exposures to other substances as well.

Jim Unmack asked if any studies show long-term exposure and olfactory response. Has not seen any documentation of long-term loss of smell.

Michael Cooper is concerned with sub-clinical result that we don't see in humans being used to set a PEL. Eric Brown echoed that he is concerned with using 2 people in one study to base an entire recommendation on. Patrick Owens brought up the Fiedler study that showed 5 ppm for 3 hours with no reported effects. Garrett reminded that it was no clinical measures, only self-reported irritation assessment.

Garrett stated that he would better clarify the justification before the next meeting.

Jim Unmack questioned nasal lesions and how similar is a rat nose to a human nose. Rats have more surface area, higher sensitivity, and are only nose breathers.

Bob Harrison asked about the STEL. Concerned with the acute exposure deaths from H₂S. IDLH is 100 ppm, is 10 ppm low enough? Will lowering the STEL help prevent deaths? Eric Brown indicated that the Ceiling is more relevant than the STEL. Michael Cooper agrees that ceiling is critical. Eric Brown asked at what level are the paralytic effects? Jim Unmack indicated that at about 400 ppm or higher there is a single breath knockdown.

Will Forest asked for relevant economic data to be submitted by stakeholders now and not to wait.

Brian Wolf California Farm Bureau Federation- Dairy industry exposure and other agriculture exposure will attempt to acquire data from the people he represents and get that to us. Both exposure and economic data.

Bob Brown with Western States Petroleum is concerned with the 1-ppm proposal for H₂S due to operational issues. Steve asked if he was aware of what their current levels are. He indicated that he would have to check for specifics on that.

Peracetic Acid

Garrett Keating gave summary of the data. Very little exposure data to work with and no chronic studies yet. Current recommendation is for 0.4 STEL and 0.15 TWA. Would like to jump to the analytical issues. Currently no validated analytical methods available.

Mark Stelljes asked what the value of a PEL is if there is no analytical method. Will Forest asked if it is possible/reasonable to set a standard based on the mixture? Mike Horowitz talked to OSHA about estimating based on the hydrogen peroxide level, but that was not feasible because it is in constant flux. Very difficult analytical system since it is primarily a four-component system. Michael Cooper asked if it is an azeotrope solution, or does the concentration change in air and with time? Mike Horowitz replied that it is in constant change with a half-life for PAA in air of about 22 minutes. Michael Cooper said that for this four component system, we have a very difficult analytical situation.

Linda Morse noted that accident record is usually equipment error or PPE error. Recommends a Hazard Alert as opposed to a PEL.

Richard Warburton, ChemDAQ- presented information on their equipment for continuous monitors. Range of sensor from 0.04 to 3 ppm. Not affected by hydrogen peroxide or acetic acid or sulfuric acid. Indicated that it is in a slow equilibrium, takes time to shift. Hard to assess the mixture because different manufacturers use a different ratio of components in the solution.

Patrick Owens asked if 8 hour or STEL is based on human or animal studies. Garrett answered that the PEL is based on human studies; the animal studies are primarily 90-minute studies.

Steve Derman support services with health care industries concerned with analytical methods. Not able to find correlation with exposure and effect. Still accumulating data but no good results. Working with NIOSH.

Erika Stewart- primary health outcome is sensory irritation and not sure that an IDLH should be so close to the PEL. Thinks that California going forward with this work could get industry attention and focus to bring data forward. Steve Smith asked about their experience with analytical methods, and she indicated that they are using the Hecht Method utilizing the SKC silica gel tube and seems that the variation issues are getting better.

Matt Spencer- Questions the information from NIOSH. The poultry industry is currently conducting research in the use of PAA. Steve Smith asked about experience with analytical methods. He answered that they are using the ChemDAQ primarily and the SKC method.

Mike Horowitz - the Hecht 2004 Method, OSHA was only able to achieve about 80% recovery, and their protocol requires at least 90% recovery for validation. Some of the concern is with a very high back pressure on the sampling train.

Bob Harrison- defers on analytical methods, so if we don't have a good method his recommendation would be that we not go forward, however from a health effects standpoint, some indication that work related asthma may be caused by PAA. Not sure we are quite at a point where with reasonable probability we can say it causes asthma, but of concern to place it under high scrutiny and do studies to determine cause. Some good anecdotal evidence so far for asthma so very concerned. Wanting data to be submitted so we can watch it and act accordingly.

Rob Neenan said that he has no data to share at this time, but will pass on any data they do obtain. And wanted to go on record to say that if there is no reliable analytical method, we should not go forward.

Mike Horowitz added there are concerns with analytical because PAA is present as both an aerosol and vapor depending on how it is used so the sampling method has to be capable of capturing both.

Todd Weaver is a distributor of PAA and encourages everyone to follow the labels.

Steve Smith asked if the committee wants to consider a PEL with analytical method that is not validated. No gold standard but maybe a silver standard? Asks for data and concerns to be submitted by the stakeholders. There are concerns about exposure and risk so do we move forward with less than perfect analytical standard?

2-BEA

Garrett Keating summarized that we have a lot of data on 2-butoxyethanol (2-BE) but virtually none on 2-BEA. However, 2-BEA is rapidly and thoroughly converted to 2-BE when it enters the blood stream or tissues so health effects data for 2-BE were used as a surrogate for 2-BEA. Garrett noted that before compiling the summary for 2-BEA he wanted to discuss with HEAC the two possible critical effects that other agencies have assessed for 2-BE. Both EPA and OEHHA relied on the same rat study but EPA used blood toxicity and OEHHA used nasal hyaline/eosinophilic droplets as the points of departure. Mark Stelljes supports a blood endpoint based on the relevance of the droplets. Garrett continued that EPA used a PBPK model in its calculations while OEHHA used uncertainty factors.

Robert Harrison asked if this is related to the mechanisms from the Glycol ethers from the past. If so he can send the case reports from those. Will Forest raised a concern that the metabolic process may not be the same.

Garrett Keating brought up that 2-BE has the biologic exposure index because of its dermal absorption. Possibly do a skin notation for this substance as well. The Division will proceed with including 2BE into the summary document, and will use the EPA basis for evaluation.

Lunch

Manganese

Garrett Keating introduced the changes to the summary document from the last meeting. Addressed particle size in the revised summary. Recommendation based on 0.01 mg/m³ respirable fraction. Welding fume is typically <1 µm aerodynamic diameter and smelting particulate is typically > 1 µm . Concern is that in welding fume manganese may be more bioavailable due to its smaller particle size. Linda Morse indicated that the smaller particles will get down into the alveoli and are only one cell away from the bloodstream.

Jim Kegebein offered support to the 0.02 mg/m³ proposal from the previous draft. Has concern with the reproductive hazard in males from a New Jersey study. Supports keeping up with the ACGIH recommendations that include a BEI. Also mentioned that about 10 years ago they collected samples that were analyzed for a panel of 21 metals in approximately 200 different environments related to the ironworker industry. Based on the current data, if we go to 0.02 we will have to utilize PAPR's in our fabrication shops and cartridge respirators and ventilation systems that would have to work. Noted that our summary mentioned that most employers currently have ventilation systems which they do not, and that they are relatively inexpensive, which they are not. Is there a potential of doing a BEI on welders for a panel of metals as opposed to just one? Right now, there are many BEI's for other metals. The air

sampling is a very difficult task in this industry. Especially if we say respirable where they would have to put a cyclone under the welding hood.

Garrett wanted to turn back to toxicology at this time, but acknowledges that the feasibility issues still need more work. Stated that HESIS recommended a 0.002 using classic uncertainty factors. They have revised their basis using the PBPK model but ultimately came to the same recommendation.

Robert Harrison asked if Garrett was saying that Manganese is more of an acute effect than chronic. Garrett said that ultimately a tissue dose over time but has a rapid uptake. Not acute per se, but rapid.

Eric Brown asked if the neurologic effects tend to reverse over time. Linda Morse and Garrett responded that some do recover but others do not. Once brain atrophy, it tends to not recover, but other effects such as tremors, eye to hand coordination, may recover. But in the Roels study, none of the mid to higher dose cases returned to baseline.

Garrett Keating mentioned blood & cord levels spiked during pregnancy, which raises developmental questions. Additionally, ACGIH and NIOSH may be addressing welding fume soon so we may get some help from there.

Robert Harrison stated that there is an “order of magnitude” difference between what the Department of Public Health recommends based on the pharmacokinetic model and what we are proposing based on the neurobehavioral outcome. Mark Stelljes responded that the model used is well documented and validated, so is confident in the proposal. But if you don’t believe in the model, than you may not accept the recommendation.

Patrick Owens asked about OEHHA risk assessment. They are using multiple studies and applying several uncertainty factors. There is variability built into the model, so do we need to add the uncertainty factors on top of that? Saeher Muzaffar explained the intention of the use of the uncertainty factors, and indicated that they may be able to remove one of the uncertainty factors.

Garrett Keating moved the discussion on to feasibility. Bob Harrison raised a concern regarding respirator use. What does it take to get welders in PAPR or supplied air not only for Manganese but other hazardous metals? Eric Brown said we need to look at what is appropriate, what is necessary, and what if feasible? A concern about Parkinson-like symptoms from Manganese exposure.

Steve Smith reminded that up to now the PEL’s are based on Total particulate knowing that in reality the number is the respirable level. Current PEL’s are 10 total, 5 respirable, and 5 welding fume. Eric Brown said the sampling for respirable under a welding hood is not very feasible. In a study of 1900 sampling events they showed a 0% difference between inside and outside the hood. There are other studies that show a plus or minus 15% difference, so no significant difference. Will Forest clarified that roughly 85% of the mass of welding fume is respirable, so it is roughly the same. Steve summarized that we keep with the model of 0.1 total, 0.01 respirable, and 0.01 welding fume.

Steve Smith trying to get a recommendation from a health effects point of view, then we can deal with the feasibility aspect. We would like some submittals from stakeholders on feasibility concerns. What respirators would be required, etc.

Linda Morse stated that we still need to look at fetal and reproductive effects. Sarah Janssen said she has not looked at male reproduction. Not sure what ratio of male to female welders (roughly 2-5% female). And what is the ½ life of manganese? For a female welder that may want to try to get pregnant, how long to they need to be away from exposure? Also some concern about manganese as an endocrine disrupter.

Russ McCrary said that it is not just welders in the Iron Industry. Fitters, checkers, etc. in the shop may have tangential exposure.

Eric Brown asked if there was any data on the epidemiological effects in long term wearing of a respirator due to the increased cardiovascular burden. Linda Morse indicated that there were no long-term effects.

Aluminum

Garrett Keating summarized the Aluminum package. He indicated that there were no revisions to the health effects section. We updated the table regarding proposed limits. We are proposing this as the final recommendation unless the committee has significant questions or comments.

Michael Cooper asked where the 1 respirable level came from? Eric Brown said if we can avoid using a cyclone we should. Will Forest proposes that all set at either 2 or 1 non-respirable. Jim Unmack said that it was based mostly on Finland studies on welders, and was pushing for a 0.1 or 0.5 level, but would be willing to live with 1. Much discussion about what level is best 1 or 2. Many studies get to the point that 1 mg is too high.

Consensus in the room is that it is defensible at 1 mg/m³ total for all forms of AL. We will revise the summary accordingly to indicate that we are proposing one listing for Aluminum and its compounds as Al at 1 mg/m³ Total with no respirable fraction. We can move forward with rulemaking at 1 total and can accept submittals for feasibility as we move forward for incorporation into the final rulemaking package.

Past Items

Garrett Keating asked for feedback on TCP. Steve Smith stated that we were going to move TCP to priority 2 until usage information warrants moving it back up to 1. The room was in agreement.

Garrett Keating recapped the meeting. Manganese uncertainty factors and feasibility will be reviewed. PAA – we will revisit the sampling methods and get feedback. 2BEA – we will incorporate 2BE into the

document as a joint summary to move forward with. H2S – we will revisit studies. Look at STEL or Ceiling recommendations. The committee proposes a ceiling. Are there sampling concerns for a ceiling?

Next Meeting

The CIHC is on December 4-6th and would interfere with our meeting date. Proposal is for either Thursday December 7, or Tuesday December 12. No consensus at this time, Garrett will follow up.

MIBK will be considered for the next meeting. Will Forest and Eric Brown volunteered for the sub-committee.

Meeting adjourned.