# Third 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

# June 20, 2017 Elihu Harris State Building 1515 Clay Street Oakland, California

#### **HEAC Members present**

Michael Bates, MS, PhD, Adjunct Professor, Divisions of Epidemiology & Environmental Health Sciences, University of California, Berkeley, CA

Eric N. Brown, DrPH, CIH, CSP, The Aerospace Corporation, El Segundo, CA (Industrial Hygiene) (Called in at 1:00)

Michael N. Cooper, MS, MPH, CIH, Principal Scientist, Mcooperconsulting LLC, Eagle, ID

Will Forest, MPH, Santa Cruz County Department of Public Health

Patrick Owens, MSPH, CIH, Shell Oil Martinez Refinery, Martinez, CA

Kent Pinkerton, PhD, Center for Health and the Environment, University of California Davis, CA

Howard Spielman, CIH, Health Science Associates, Garden Grove, CA

James Unmack, CIH, Unmack Corp., San Pedro, CA

### **Public and Interested Parties**

Erica Stewart, Kaiser Permanente

Jim Kegebein

Dan Leacox, Leacox and Associates

Nicole Marquez, Worksafe

John Martinelli, Forensic Analytical

Saeher Muzaffar, California Department of Public Health, HESIS

Alicia Frazier

Chris Laszcz-Davis, Cal/OSHA Standards Board

Stewart Holm, American Forest and Paper Association

Claudia Alvarado, Chevron

Lindsay Stovall, American Chemistry Council

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

Kathleen Vork, Staff Toxicologist, OEHHA, Cal/EPA

Laura O'Heir, San Francisco Water (SFPUC)

David Kernazitskas, Cal/OSHA Standards Board Staff

Luke Brown, DIR Directors Office

Frank Calisi, DIR Directors Office

## **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 four summary documents for aluminum, hydrogen sulfide, manganese, and 1,2,3-trichloropropane, and an updated priority list. 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.

Garrett Keating asked if the members received the HESIS handouts and discussed the order of the agenda. Keating suggested exchanging the order of manganese and hydrogen sulfide on the agenda so the metals could be discussed in order. Dan Leacox and Stuart Holm requested to move H2S to the beginning of the meeting, the room agreed.

Michael Cooper asked if the priority list reflects the proposed changes, Steve confirmed that it does.

Review of Substance summaries and possible HEAC recommendations for:

## Hydrogen Sulfide

Garrett Keating highlighted the summary document for H2S. The recommendation that the PEL be reduced from the current 10 ppm (TWA), 50 ppm (Ceiling), and 15 ppm (STEL) to 1 ppm (TWA). Based primarily on the Bhambhani studies on the physiological effects in controlled human exposure. He then introduced Kashyap Takore of CDPH to explain the HESIS Draft PEL calculation based on OEHHA cREL derivation.

Kashyap explained their derivation document and summarized the calculations. He explained that they used the 1983c CIIT mouse study to determine the NOAEL and then applied the continuity conversion, occupational inhalation scaling and uncertainty factors to estimate the PEL.

Michael Cooper asked for an explanation of why they used the animal study instead of some human studies.

Garrett Keating asked about the average experimental exposure conversion.

Because the original study was 6 hours 5 days, a discontinuous exposure, to convert to a continuous community exposure to the NOAEL had to be scaled to a 24/7 exposure.

Garrett and Michael Cooper asked about this up conversion and then back down and if the 30.5 is an occupational exposure? Saeher Muzaffar (HESIS) answered that it is not an occupational NOAEL because it was an animal study, so the NOAEL had to be converted to a continuous exposure than converted to a human occupational exposure.

Garrett raised a question about efficiency of rats absorbing H2S as compared to humans. This indicates that these numbers may be very conservative. Saeher indicated there are some difficulties comparing the acute human studies with the chronic animal studies, and that the chronic animal studies may more closely represent the occupational exposures, and there is a lack of long-term human studies. Michael Cooper felt that the human studies would give better data.

Michael Cooper asked if there were two intraspecies factors used in the equation. Human equivalent concentration already took into account the mouse to human factor. Saeher explained that the human equivalent concentration utilizes a standard conversion factor that is further explained in the full report and deals with extra thoracic respiratory effects value of 0.16 X 5.4 to get the 0.85. Will Forest mentioned that the interspecies uncertainty factor defaults at 10 absent additional information, but because the human equivalent concentration was used, the factor was reduced to 3.

Jim Unmack asked what is the justification for changes in volume and is it significant as applied to H2S.

Howard Spielman asked about the differences in metabolic rates making a difference.

Garrett indicated that the PBPK model may explain those differences in more detail.

Patrick Owens brought up post mortem examination of nasal lesions in the CIIT study

Stewart Holm brought up the 2002 study that discussed nasal effects in a 10-week rat study at higher doses.

Michael Cooper indicated that he believes that there are sufficient human studies and do not need to use animal data.

Michael Bates indicated that his H2S studies were based on environmental exposures and they may not be the best studies to use for this calculation.

Michael Cooper brought up other human studies, i.e. Japan studies.

Garrett agreed to review the studies and report at the next meeting.

Michael Bates requested a copy of the full study to support the HESIS one page document.

Patrick Owens indicated that the draft summary does not address a STEL, do we intend to change that too?

Garrett indicated that he would look at that for the next meeting.

Howard Spielman brought up sensory levels as a target for STEL. Several members discussed olfactory fatigue, irritation, etc.

Garrett Keating brought up reproductive studies discussed in the H2S summary.

Howard Spielman asked about exposure data in petroleum industry, what 8-hour TWA doses were being seen?

Jim Unmack mentioned that exposure is more of a problem for drilling than refining.

Stewart Holm indicated that in their POTW's etc., low ppm levels detected. Pulp and paper mill, you will smell it, but low concentrations.

Stewart indicated he would prepare formal written statement of his comments that would claim that the current research data does not meet the "material impairment of health" bar to justify the proposed PEL.

Garrett Keating stated that he would re-review the data and report back. We will also discuss the proposed PEL, STEL, and ceiling.

Steward Holm asked that Division look at other studies. He recommended that the NAS 2009 AEGL report on H2S be reviewed by staff. He was critical of the Bhambhani studies. As for PBPK, he indicated that he would supply the Schroeter 2006 paper to us.

## <u>Aluminum</u>

Garrett Keating introduced and summarized the aluminum summary. Mentioned that this summary does not address any of the soluble forms of aluminum and that we should address that one way or the other.

Michael Bates asked if this form only addresses aluminum metal? Garrett indicated that this is for aluminum metal. Steve Smith explained that the PEL would be for aluminum metal and its insoluble compounds. He mentioned that the ACGIH TLV combined all insoluble compounds into one TLV where Cal/OSHA current PEL's have different levels for different compounds, and that is a topic for discussion here. Michael Bates asked if this combining was justified by ACGIH. Garrett indicated that the ACGIH documentation did not clearly address their justification for this combining, nor did they address soluble forms.

Jim Unmack described how each form of metal and even how it is worked changes the size and shape of the particles, and changes the effect that it has on the body.

Garrett Keating described the studies used for the summary. Most of the studies on the effects of aluminum on workers were based on blood levels and not really on air levels. He mentioned two studies that found marginal neurological effects on aluminum welders to show how he established the 1 mg/m3 proposed PEL.

Garrett asked for input on other forms of aluminum, i.e. Aluminum alkyls and soluble compounds.

Patrick Owens asked if Jim had found any studies on Alkyls? Jim indicated that when he saw the variability of the different forms of aluminum, he focused on welding fume. Patrick asked if we should focus this on welding fume. Steve pointed out that we currently have a PEL for welding fume at 5 mg/m3. Do we want to leave the rest at 5 and only bring welding fume down to 1 mg/m3?

Howard Spielman equated this issue to the challenges with asbestos years ago where we knew that different forms of asbestos had different health risks, but that rulemaking would be difficult and confusing, so they decided to focus on one level that was protective for all forms. We may want to look at something like that here. If we believe 1 respirable for welding fume is protective of all forms of aluminum, we may want to group them here.

Jim Unmack indicated that if we look at the larger particle sized, he saw little information to justify reducing those levels. That is why he was looking at the sub-micron particle size for welding fume.

Chris Laszcz-Davis asked if we have received any input from the two aluminum industry associations. Jim Unmack indicated that he had contacted them both, and had received approximately 3000 pages to review. Chris stated that she could put us in touch with aluminum industry experts so we could get their input.

Patrick Owens asked Garrett if the draft is not particle sized based. Garrett indicated that he followed Jim's lead that most fume would be respirable, so just collect total. Jim stated that if we are talking sub micron sized particles, there would be 100% pass-through with a cyclone so the results should be about the same if a cyclone is used or not.

Kent Pinkerton asked if welding and grinding is something that is frequently done together. The consensus was yes. If they are done together then it changes the deposition of particle size. Jim Unmack stated that most of the studies were based on work on light rail where there were long beads of weld with minimal grinding.

Michael Cooper asked what are the alternatives to working just on welding fume?

Steve Smith stated that ACGIH lumped them all together as 1 mg/m3 respirable for aluminum and insoluble compounds.

Michael Cooper stated that there is no BEI level in ACGIH because it was not feasible as of 2007. Given that there is no BEI, are there any studies that relate exposure to clinical data?

Will Forest indicated that our recommendation is a simple one, and in all honesty, aluminum is so complicated that it is very difficult to do otherwise. He believes that it would get too convoluted to try to split it out, so he supports this simpler approach. Michael Cooper agrees, but thinks we should add some explanatory language to show that we are simplifying.

Howard Spielman asked about the differences between the effects of soluble verses insoluble, and wondered if we should address it separately.

Jim Unmack said that the information is here, but it is a matter of teasing it out of the data.

# LUNCH

#### Manganese

Garrett Keating, summarized the recommendation of 0.02 mg/m3 respirable 0.1 mg/m3 inhalable for manganese. Review of the studies was similar to aluminum in that there is not good animal data for neurological effects. We relied on smelting and welding studies. Concern with 0.02 is that it is derived from older smelter studies that generates larger particle size, where welding generates much smaller particle sizes from which Mn would be more bioavailable. So is this 0.02 protective enough?

HESIS summarized their report. Explained their derivation that was based on 92 workers in a battery plant (Roels). Garrett asked if the developmental studies supporting the uncertainty factor were based on

human exposure, and HESIS confirmed. A December 2008 study. One study is looking at in-utero exposure in pregnant women and correlated manganese in cord blood with exposure levels.

Will Forest asked about what their benchmark concentration definition was. Saeher indicated that OEHHA had used the lower 95% confidence level of the 5% effect for eye hand coordination outcome. Michael Cooper asked about the range, Saeher said they did not publish the full range, but they would try to find it.

Patrick Owens asked about the 5.3 year factor. Saeher explained this was the average number of years worked by the 92 workers. That made the study sub-chronic so an uncertainty factor of 3 was used.

Howard Spielman asked if there is any biological index to compare with these critical effects. Garrett answered that there is a PBPK model that evaluates blood levels and rate of increase based on concentrations. Will Forest added to Howard's question is there data on the correlation between exposure and blood levels? Garrett said there are some models to do that but we will have to look into it further. Will Forest indicated that we will probably have to look at air level to effect and air level to blood level, then extrapolate blood level to effect.

Michael Cooper inquired about basal (homeostatic) level accumulation at about 0.01? Garrett said the study was well parameterized with extensive animal studies and human tracer studies. Michael asked if any of the 92 workers from the study were tracked as female pregnant workers. Saeher was not sure but would check into it.

Michael Cooper asked if we know the blood levels in ROELS Roels study and levels from non-workplace exposures. This would be good to know. Garrett Keating said the core blood levels in the developmental studies did not control for exposure factors.

Patrick Owens asked about the welding fact sheet. Garrett Keating answered that it shows at what air concentrations we start seeing accumulations in the brain.

Howard Spielman said the curve would suggest a floor of 0.4 in the brain as a background so then based on this data, where is the line of criticality in terms of accumulation. Garrett said some levels of manganese can be handled by the body. This model shows what some air concentrations can do to manganese levels in blood.

Howard Spielman stated based on the curve at the 20 microgram/L level, there is barely a rise.

Ken Pinkerton asked if there is evidence of bioaccumulation of manganese or is it gradually eliminated? Garrett responded that the body can eliminate it a certain rate but at certain levels it overwhelms the excretion mechanisms. If you take in more it will accumulate in the body in tissues such as brain. Garrett indicated that he would work on this more. Additionally particle size is a huge factor in welding accumulation and many of the NOELs were based on smelters with larger particle size.

Ken Pinkerton indicated that they have done recent work with silver that shows rate of transfer from one organ system to another and dependent on particle size.

Michael Cooper asked if we know the particle size associated with the benchmark dose. Garrett answered that he doesn't think so. Roels used both total and respirable. Saeher said they used the data for respirable dust for the benchmark dose.

Garrett Keating described the data on the welding hand out.

Patrick Owens said his concern is the studies on women with unknown exposure.

Martha asked if the developmental effects endpoint is a relevant endpoint used for development of a PEL for occupational settings. Garrett replied yes if it is a significant figure.

Howard Spielman said we are using blood lead levels that consider developmental issues.

Garrett Keating said it sounds like we have many questions to answer. Raised a question about the table that listed a mean of means at about 0.02 and we may still have some risk. Something to consider further.

Steve Smith pointed out that just like aluminum, the TLV has lumped together manganese and inorganic compounds and removed the fume TLV.

Howard Spielman talked about some different available sampling methods and sampling equipment to be used.

Jim Kegebein mentioned that there is a degree of difficulty in sampling welders with and without cyclones. Both in and out of the hood.

Michael Cooper said if it doesn't have the respirable note, sampling is typically outside the hood and would not accurately represent the exposure.

John Martinelli echoed that it is difficult to get good data from a welder, getting a cyclone under the welding hood etc.

The room discussed sampling issues but the consensus is that it is solvable. The bigger issues are epidemiology and toxicology, then we will look more into feasibility.

# 1,2,3 trichloropropane

Garrett Keating introduced TCP, the current standard is 10 ppm and that we are not proposing anything at this time since we have been unable to identify California usage with the exception of a few universities. Does the committee want to move forward on this, or should we move it back to priority 2 until usage information can be obtained.

Will Forest, if ACGIH states 0.005, it discourages its use and warrants adopting a lower standard to guard against its use in the future. Additionally, if we have little identified use in California, there should be little to no opposition to setting a lower standard.

Michael Cooper agrees, however indicated that we have a lot of other substances to consider and doesn't know that we want to spend the time on this with the limited resources we have.

Steve Smith stated that we will look more into use and waste sites and at aerospace. We are proposing that we move down to P2 now and can bring it back up if we find usage information that justifies it. We will use HESIS to help with usage data.

The room showed general agreement.

### **Priority List Discussion**

Garrett Keating presented the revised priority list and proposed to lock this list in until next year. The room showed general agreement.

The next substances up for work will be Peracetic Acid and 2-butoxyethylacetate.

Erica Stewart, Kaiser Permanente, indicated that they have a concern with peracetic acid use in the health care industry.

Howard Spielman and Michael Cooper volunteered to work on peracetic acid.

Will Forest and Kent Pinkerton will assist on 2-butoxyethylacetate.

Lindsay Stovall, American Chemistry Council wanted to state that isocyanates are very different and should not be grouped together. They should be reviewed separately. Steve Smith asked if they wanted to keep these in special committee or bring them back to this group. Lindsay stated that she would get back to us on that after she confers with her group.

Erica Stewart, Kaiser Permanente, asked if there was a time frame on revisions to Formaldehyde. Steve Smith replied that it will be a separate committee since it is a stand-alone standard and there is not currently a time line for it.

Michael Cooper wanted a four or five point list explaining the priority 2 selections and how it gets to group 1. He indicated that it was missing from the minutes of the last meeting and would provide his list to us so it can be included. Steve explained that we tried to incorporate the justification in priority 2 list notations.

Garrett Keating gave a recap of the meeting. We will be going back over the four summaries and do more on them. He opened the floor for additional comments, and none were offered.

Set a date for the next meeting, the first Tuesday of September is the 5<sup>th</sup>, the day after Labor Day. A little challenge since it is the day after a three-day weekend. So far the consensus is the 5<sup>th</sup>, Garrett will follow up with the committee for confirmation of the date.