Second 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

March 7, 2017
Elihu Harris State Building
1515 Clay Street
Oakland, California

HEAC Members present

Michael Bates, MS, PhD, Adjunct Professor, University of California, Berkeley, CA
Eric N. Brown, PhD, CIH, Tri Alpha Energy, Irvine, CA
Michael N. Cooper, MS, MPH, CIH, Principal Scientist, Mcooperconsulting LLC, Eagle, ID
Will Forest, MPH, Santa Cruz County Department of Public Health, Santa Cruz, CA
Bob Harrison, MD, MPH, University of California San Francisco, CA
Linda Morse, MD, FACOEM, Kaiser Permanente Medical Center, retired, San Francisco, CA
Patrick Owens, MSPH, CIH, Shell Oil Martinez Refinery, Martinez, CA (arrived at 10:30)
Kent Pinkerton, PhD, Professor, University of California Davis, CA (called in, left at 12:00)
Howard Spielman, CIH, Health Science Associates, Garden Grove, CA
Mark Stelljes, PhD, SLR International Corp., Martinez, CA
James Unmack, CIH, Unmack Corp., San Pedro, CA

Public and Interested Parties

Diana Graham, Keller & Heckman Law Firm
Lilly Kaneshige, Kaiser Permanente
Dan Leacox, Leacox and Associates
Nicole Marquez, Worksafe
John Martinelli, Forensic Analytical
Saeher Musaffar, MD, Chief, CDPH, HESIS
Bob Nocco, Chevron
Renee Pinel, Western Plant Health Association
James Seward, MD, DOSH
Tim Shester, American Chemistry Council
Lindsay Stovall, American Chemistry Council
Kashyap Takore, Toxicologist, CDPH, HESIS
Kathleen Vork, Staff Toxicologist, OEHHA, Cal/EPA

Division of Occupational Safety & Health

Garrett Keating, Steve Smith, Bob Nakamura 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 were the feasibility addendums for the three substances previously considered by the HEAC, an updated priority list for future meetings, and a an updated procedures document for discussion at the meeting today.

Discussion of previous meeting minutes

Michael Bates said the minutes read more like a transcript. Transcripts are good, but prefer more summarized minutes. Steve Smith agreed and indicated that we would try to shorten. Idea echoed by Will Forrest and Michael Cooper. Steve indicated that we would also try to indicate transition through agenda items to make minutes more useful.

Steve Smith said these pre-rulemaking meetings are more informal than during the formal rulemaking process, but these minutes are relied on as the basis of what is discussed, and the recommendations of the committee members and public commenters, and helps us develop a rulemaking proposal that should meet less resistance during the formal rulemaking.

Review of three Substance summaries and discussion of Feasibility Addendums

Steve Smith said these three substances were discussed during the last sessions of the HEAC, and the recommendations have been posted for the last 5 years or so. What we did now is draft a supplement to discuss feasibility concerns since we no longer have a specific feasibility committee. We do not intend to go back over what was already agreed on, but to use this discussion as an opportunity to get advice on these three substances as far as feasibility is concerned, from both the committee if they wish and from the stakeholders.

Garrett Keating summarized how the HEAC came to their recommendation for each substance prior to addressing the addendum.

CYCLOHEXANE: Critical study of neuro effects and extrapolated down to the level recommended of 50 ppm.

Michael Bates questioned which study was used to support the conclusion for the summary. Garrett indicated that he would have to defer to Patrick Owens who prepared the cyclohexane summary. Michael Cooper indicated that he did not see it under Mali and was not able from the math to get the 50 ppm. Garrett indicated that he did not think there was an explicit calculation presented.

Steve Smith said he was trying to avoid a re-evaluation of the recommendation of the past committee and wanted to focus on the addendum/feasibility. However, the Division will look at the previous minutes and will need that information to complete the rule-making document. These questions are indicative of why we are trying to go to one style of summary document.

Michael Bates agrees with Michael Cooper's comments that the reasoning and calculations on how the proposed level was reached needs to be clearly spelled out to make the upcoming rule-making "bullet-proof". Most in the room were in agreement.

Bob Harrison supports building on previous work, but recommends updating the literature that is 5 or 6 years old. Primarily focusing on any new studies that may change the prior recommendation.

Kent Pinkerton: seconded Bob's recommendation to update literature.

Steve Smith said the Division did do reviews on the literature in 2015, and Garrett did an additional review in preparing for this meeting. We agree that updates should be done for substances that have been

around for a while. The Division did that and in fact of the six that were left from the previous committee, only Trichloroethylene had literature that supported a change and the Division did make a change to the proposed PEL.

Kathy Vork suggested looking at other agencies regulatory updates not just new studies for example, N-Propanol had studies that used a different end-point than what we used based on a 1942 study and a review of recent literature would not have picked that up.

Bob Nocco was concerned that old studies do not meet the modern "weight of evidence" or scientific rigor of modern studies.

Michael Bates was concerned with the use of Significant and Statistically Significant. Be careful with the use of these words and use relative risk, confidence intervals, and p values instead.

Bob Harrison asked for clarification if the Division is asking the current committee to make a recommendation on cyclohexane, TMA, and n-Propanol? Steve answered No, only trying to supplement the recommendations from the previous committee in regards to feasibility concerns. Bob requests to move on to feasibility issues, and wanted to clarify that the committee actions on these three substances is different than what the committee will be asked to make recommendations on for upcoming substances. All agreed.

Steve asked for feasibility concerns from the room and discussion of the feasibility addendums that are on the table at the back of the room. Then Steve summarized the addendum for cyclohexane.

Mark asked about any actual air monitoring data, do we know if anyone is actually over the proposed level of 50ppm. If not, cost could be zero. In addition, if the cost estimates were based on a higher PEL, cost could be higher. Steve agreed that this method of estimation is just to get a ballpark number, and the purpose of putting this out there now is to see if any of the stakeholders and users would be willing to provide data that would help us generate a better estimate. Members seem to believe that the estimated cost is high and not consistent with the proposed control methods listed in the document. Howard Spielman related to past FAC meetings as being silent because users typically have not done monitoring to determine what their current levels are, much less have an idea of what it would cost to meet a new PEL. The committee is not, in most cases, in a position to determine costs. Steve Smith clarified that we are not asking the committee to decide if our numbers are accurate, or that they concur, it is more the Division's attempt to reach out to stakeholders to try to get better numbers through their comments. Mark asked if it might be better just to say that cost to comply is unknown. Michael Horowitz indicated that the Board is required to submit an economic impact statement and even though "unknown" might be more accurate, he does not think the board would accept that without a number.

Bob Harrison suggests looking at Fed OSHA exposure database for additional feasibility/monitoring data evidence for our rulemaking package. Also look at household products database by the department of health and human services on the web that gives some insight into the product use. For example for cyclohexane, it identifies arts and crafts, automobile products, and home maintenance as consumer uses. Third comment, used as an adhesive and solvent agents used intermittently. I.e. brake cleaning products. These uses are typically relatively short-term peak exposures and wondered if 8 hour PEL is best estimate of actual use as opposed to a short-term exposure limit.

Eric Brown shared that he has done some of his own research on trying to find stakeholders by contacting some of the companies that provide SDS services for end users such as 3E, MSDS online, Cintas, Cytak, etc. He asked them to assist while providing a service to their clients in that we would provide them a substance that we are working on, they would query their database and obtain a list of users of the substance and let their clients know what we are working on and when our stakeholder meetings would be. Should be more effective than cold calling.

Steve Smith indicated that we have an email list of some 300 interested parties that we send these notices to, and we try to supplement when we can for specific substances. This connection may be very helpful to expand our outreach.

Will Forrest indicated it is good to invite, but if you want information from them, we need to ask in advance, perhaps send out a questionnaire in advance. Michael Cooper liked the idea along with a disclaimer that we were not going to use the information to come after the employers. Eric Brown indicated that he would put together a draft for board review.

Nicole Marquez wanted to make sure that unions that represent potentially exposed workers are also included in the information gathering stage. Steve Smith confirmed that stakeholders from all sides are needed.

Garret Keating asked if any additional comments regarding cyclohexane? None provided.

N Propanol:

Steve Smith summarized the addendum.

Michael Cooper asked if numbers of users were based on CERS data, and if so then there is a reporting limit of 55 gallons. In that case, employers using smaller cans would likely not be included in the count. Steve Smith agreed that the SDS service companies list would be more inclusive because the user of just a few spray cans of adhesive should have the SDS so there could be many more employers, however these smaller users would likely not have the significant exposure that would require significant cost expenditures to comply with the new PEL.

Jim Unmack looked into the list of users and was not able to find anyone that actually use it.

Howard Spielman asked if the database covers only cans of pure products, or mixed products. Garrett and Mike Horowitz replied that it did include mixed products as well.

Bob Harrison suggested that it is in the printing industry but may be in small concentrations and is likely an intermittent exposure and not likely going to hit the 8 hour PEL.

Michael Cooper had same comment regarding the cost as for cyclohexane

Trimellitic anhydride:

Michael Horowitz summarized the addendum; explained that we are adjusting the proposed PEL up based on analytical feasibility. HEAC was proposing .002 for STEL, but due to analytical feasibility, the proposed limit was raised to 0.04. (some discussion about units and analytical methods).

Bob Harrison is requesting that we have the current HEAC go back into the recommendation and re-visit and update the summary before it moves forward. Raised concerns about respiratory sensitizers, and possibly adding a footnote.

Michael Horowitz continued with the addendum discussion. Talked about the medical monitoring issue and respiratory sensitization and proposed a footnote similar to glutaraldehyde. Group supported that idea.

Very few users were identified in California and Division talked to the highest users. It appears that most users use it in very small quantities.

Michael Cooper indicated that he does not know of any labs that analyze for TMA. May be a feasibility issue if you cannot find a lab, but we know of three labs that do. Bottom line is that analytical method limitations will cause us to raise the proposed STEL, and the current document needs some more work before it goes forward. Steve asked if there were any more comments on TMA before we move on with the agenda.

Revisions to the Priority List of Substances for consideration under Section 5155

Garrett Keating summarized the updated table that lists prioritization and explained the notations on the table. The table lists health effects and usage. Listed which substances were lowered from P1 to P2. Added a few new P1's (butyl acetates, manganese, and trichloropropane). Would like to keep 10-15 as a working list for a given year to work on. Intends to update this list annually. We also are considering removing some of the pesticides from this list.

Kent Pinkerton thinks this list looks reasonable but no further comments.

Steve Smith further explained intent to remove or lower some pesticides from the list due to discussions with the Department of Pesticide Regulation (DPR) who indicated that at least 5 of the pesticides listed are no longer in use.

Bob Harrison has some recommendations for moves from P2 to P1 list. Now or after lunch.

Steve Smith explained that we tried to get a balance on this list and not cater to any one particular group because everyone and every group will have their list of favorites that they want addressed first and that is why we intend to revisit the list annually to try to maintain balance.

Mark Stelljes asked why some of the P2 substances had notations for going to Special Committees and what the criteria used for that was. Steve answered that those were his notations for a variety of reasons. 1BP has some political and policy reasons as to why it would need its own committee so as not to bog down this committee. Beryllium, Formaldehyde, arsenic have stand-alone regulations and would require special handling that would not only look at adjusting the PEL, but also other elements of those regulations. Some other substances that may be grouped (phthalates etc.). Mark asked if there could be some brief explanation as to why the asterisk and Steve agreed.

Linda Morse asked about these other committees and Steve explained that they are only in the concept stage and will do our best based on staffing limitations etc. Bob Harrison suggested a "HEAC +" committee to help keep things moving. That may add topic experts for each subject where we already

have a lot of expertise in this group that could be utilized and avoid significant delays in trying to field another equally qualified committee.

Katherine Vork said some of the substances are captured based on other agencies input and suggests getting updated information from these agencies to see if new information may be available. Steve agreed that that would be good.

Mark Stelljes asked if number of users could be added as a criterion to assist in prioritization.

Howard Spielman suggested going around the room to state some priority substances that each individual may an interest.

Michael Cooper suggested housekeeping idea of grouping the * items for clarity. And adding anything done by OARS TERA (replaced WEEL).

Dan Leacox asked about the pesticides and other things on the 3 & 4 list. Did the list disappear? Steve and Garrett indicated that the list still exists; we only printed P1 & P2 so as not to overwhelm the group.

Howard Spielman said Cobalt, Nickel & Chrome 3 are substantial components of metals that are ground & welded.

Eric Brown said acetonitrile (P1 to P2), MEK, Naled pesticide widely used, Titanium dioxide (nano).

Mark Stelljes said P1 to P2-acetonitrile for same reasons, pyridine due to use, P2 to P1 -diesel exhaust, Hexahydrophthalicanhydride, monochloroacetic acid has high usage, styrene and tert-amyl methyl ether.

Michael Bates agrees with Diesel exhaust.

Bob Harrison recommended BPA, 1 bromopropane to this committee, carbon nanotubes, diacetyl only dealt with in food manufacturing. Formaldehyde, second MEK and Styrene.

Linda Morse seconds Bob's, remove polyvinylchloride, acetone in wide use should move up.

Michael Cooper agrees with acetonitrile, formaldehyde. Review procedure for updating list.

Will Forest setting standards where there is currently none should be priority. Also 1BP should be done here, not other committee.

Jim Unmack agrees with acetone, aluminum is a challenge due to many factors he uncovered while evaluating during previous HEAC. Extremely complicated.

LUNCH

Linda Morse suggested putting substances on the board and taking a vote, with top 12 staying priority 1. Garrett Keating said his intent was to take comments today and then revise the list accordingly. Steve indicated that there are sometimes other factors that go into this list and may need further discussion.

Eric Brown wanted reasoning behind the list change or new OEL and the degree to its widespread use in California. It seems that the usage is the main area that we are lacking data. Garrett indicated that the

usage data is difficult to get and limited, but we continue to try to find better sources of data. Howard indicated that we could rely at least partially on the Board's experience. Steve mentioned that we don't want to waste resources if we know the substance is not used, but difficult to quantify or be more analytical in gathering this data. Eric said we spend so much time evaluating the priority 1 list substances, but if we knew usage information, we could try to focus our attention better.

Bob Harrison in favor of priority based on 2007 OEHHA list done by Sara Hoover: Table 2 Prop 65 cancer chemicals without PEL's, Table 3 is reproductive hazard chemicals without PELs. This is a short list. Probably significant workplace exposures would be styrene Oxide, ceramic fibers, and diesel exhaust from list 2 and list 3 had 1BP and oxyphthallates. I would put those up high on the list.

Howard Spielman said NIOSH has just published its chemical carcinogen policy that may be a useful resource. He talked to John Howard last week and got the name of someone at NIOSH as a contact (Paul Schulte) for assistance. Will Forrest supported using Prop. 65 list as well as other peer reviewed risk assessments that are scientifically supported. Howard agreed that that is what the NIOSH policy includes.

Steve Smith, back to the priority 1 list, heard that there were three substances that were suggested to move down to priority 2; PVC dust, Acetonitrile, and pyridine. Bob Harrison indicated that thallium is not widely used, so possibly move it down as well. Steve said they would consider that as well, but will check CERS data first.

Steve Smith any suggestions to move up? One was acetone. Based on volume of use. Howard Spielman indicated that there is no indication that it is other than an upper respiratory irritant. Maybe not worth moving up, Michael Cooper would prefer focusing on a substance with no PEL. Steve indicated that we would table that one for now.

Steve Smith mentioned pesticides, and Howard Spielman mentioned that pesticides in schools is a big issue and teacher exposures are a concern, but Steve indicated that we are working with the pesticide program and that we would bring them up again if they became an issue for this group to consider.

Michael Cooper mentioned benzaldehyde and acetamide, would be nice to see CERS data. Diesel exhaust was mentioned, but concerns regarding sampling. ARB looked at sampling with truck drivers, railroad, and docks. May be able to get data to look at there.

Steve Smith mentioned MEK, any interest in moving up? Still heavily used and a high ratio of OEL to PEL. TLV of 10 and PEL of 200. Room was quiet, but sounded like the overall response was affirmative.

Question about Latex allergies. Sensitization issues with no real discussion.

Steve will keep the subject open for follow-up emails and will revise before the next meeting.

Will Forrest asked if we could acknowledge that this prioritization list is not strictly scientifically derived and that we are ok with that? He wants to put this out there because people always ask and we want to acknowledge that this was the intent and we are ok with that. The room was in consensus, but we strive to get better and we base it on the best available data for California. Difficult where exposure data is limited. Steve Smith reminded that that is part of what makes our rulemaking process great, in that we are

one of the few agencies that have this advisory process and request stakeholder input up front and open to the public to get the best available data.

Dan Leacox stated that it is ok to use the best guess and experience in the room approach to move things around on the list, but when on priority one, then we dive down into the data and get more scientific evidence prior to moving it forward. Steve agreed and reminded that it is our hope that stakeholders come forward with additional data and use information.

Eric Brown wanted to bring up Butyl acetate and MIBK as primarily irritant effects and possibly drop them down. Someone asked about the HESIS notation on some, and Saeher Muzaffar mentioned that Butyl Acetate was there for the cancer risk in excess of 200 per 1000 workers. Room agreement to leave it where it is. As for MIBK probably there because of common usage and the room was leaning toward lowering that one, but we will look more at it.

Tim Shestek mentioned that he has members with interest in substances on both priority 1 and 2, and they ask what is the process and timeline, and how can they best participate. Steve Smith said that the biggest help would be on use in California and exposure data if available. They can email Garrett Keating at any time with their data for us to consider and use as we move forward.

Revisions to the HEAC Procedures Document

Steve mentioned that we have posted the revised HEAC procedures document and asked if there were any comments on that document.

Diana Graham mentioned that she does not see any feasibility part to the new document. Found one sentence in section 3, but wants to make sure that stakeholders have time to respond to feasibility data.

Dan Leacox is concerned that the previous 10-page document had more information about what the Division would do. Primarily about the Division's ability to document some information before going to the Standards Board. Information such as meeting minutes and decision tables and other information for the formal rulemaking process. Steve Smith mentioned that there is a memo posted that describes the 19 steps in the rulemaking process on our units website.

Bob Harrison pointed out that we use the term consensus, which by definition means "agreement by all". There may be times that the HEAC is not in full agreement, so we need a mechanism to advise the Division when there is not unanimous agreement. Suggests a vote. Room tended to agree with the idea of a vote if there is no consensus. Steve Smith mentioned that in the past, we have had times where there was disagreement and the board had a majority opinion and a minority recommendation that the Division had to move forward with and determine through the rulemaking process which approach was best. Mike Horowitz brought up that typically, the minutes will show the "sense of the body", and we may not actually need to take a "vote" and by having that in the procedures document, we may get criticism for "failing" to take a vote.

Bob Harrison additionally asked what mechanism the public has to make recommendations to the Division. Steve Smith brought up the formal process of filing a petition, informal process of sending an email to our staff requesting that we look at something. Bob said he would like to see it reflected in the procedure document somewhere so that it is clear how that happens.

Linda Morse encouraged the co-chairs to stick to the agenda and keep the meetings moving, and thinks that this team has done that well with that today.

Michael Cooper concerned with the word "occupational" in the document, or make it clear by giving a definition for example (3)(a) that lists OEL and not sure if it should be OEL or PEL. So add definitions for OEL, OSHSB, and DIR should be added here. Room agreement.

Saeher Muzaffar wanted to clarify where feasibility data comes into the picture here outline that a health-based recommendation would be put out first, then seek feasibility data, and secondly to standardize the methods for PEL derivations. It seems that different authors took different methods, and it is not clear. Looking for more consistency.

Planning for the next meeting

Garrett Keating will update the list with annotations. There may be a degree of difficulty, so some might take two or three meetings, where others may take more than a year. Question for the committee: some members did full summaries of the literature, or just focus on key health issues that have driven the OEL revision or not? The other column feasibility to seek information as well as some other relevant issues like particle size, etc. Now would like to identify three or four substances to begin work on the new summaries.

Mark Stelljes asked if he could answer the questions that Garrett asked: in terms of focusing on a key study or summarize the literature, our committees approach has been using weight of evidence, and not sure how that could be accomplished if the literature is not summarized. He acknowledges that there may be some studies that could be ignored (ie. LD50 etc.) but key human studies sub chronic or chronic studies that evaluate endpoints whether or not they are the key endpoints, that informs the committee in making their decisions. Agreement from Michael Cooper based on the integrity of the committee. The committee agreed that that is an issue that they could help with so as not to slow down the process any more than necessary.

Steve Smith asked members to state their interest as we go down the list of Priority 1 substances.

Aluminum: Jim Unmack worked on it before. Was near completion of the recommendation, but had raised a question that was not answered by the previous committee. Long term exposure to develop a measurable cognitive deficit; is that an endpoint that we want to use? That will make a difference in the proposed level. Steve indicated that we do not need to solve this issue today, but we are simply looking for a list of names to assist Garrett with each substance. Jim Unmack agreed to assist on aluminum, but wants the committee to think about that question. Patrick Owens also agreed to assist.

Hydrogen sulfide: Michael Cooper and Michael Bates volunteered.

Manganese: Mark Stelljes, Eric Brown and Linda Morse volunteered.

MEK: Eric Brown thought this one was important and the OEL looked like a big change so should be moved forward. Will Forrest also volunteered. Garrett will confirm the OEL need to move forward on MEK and get in touch with Eric and Will after the meeting.

Steve Smith asked the group to work toward getting a preliminary draft on these four substances ready for the next meeting.

Set a date for the next meeting, the first Tuesday of June is the IH conference. Either Thursday June 1, or June 20th. Tuesday, June 20th was the agreed upon date with only Bob Harrison reporting unavailability.

Steve Smith opened the floor for additional comments. None offered, so he did a brief meeting recap and adjourned the meeting.