DRAFT MEETING SUMMARY

First Meeting of the Health Expert Advisory Committee (HEAC) for a New Round of Development of Permissible Exposure Limits for Airborne Contaminants in the Workplace California Code of Regulations Title 8 Section 5155

August 21, 2007
Elihu Harris State Building
1515 Clay Street
Oakland, California

HEAC Members in attendance

Richard	Cohen	UCSF
Mike	Cooper	Exponent
Will	Forest	Santa Cruz County Public Health Dept.
Bob	Ku	SafeBridge Consultants
Michael	Kleinman	UC Irvine
Linda	Morse	Kaiser Permanente Occupational Health
Patty	Quinlan	UCSF Occupational Health Clinic
Julia	Quint	Independent
Susan	Ripple	Dow Chemical Company
Howard	Spielman	Health Science Associates
James	Unmack	Unmack Corporation

Public and Interested Party attendees

Craig	Bernard	Rio Tinto Minerals
Michael	Boyle	Bimbo Bakeries USA
Juli	Broyles	California Advocates
Jim	Collins	OEHHA
Lee	Coogan	Sorptive Minerals Institute
Angust	Crane	North American Insulation Manufacturers Assoc.
Steve	Derman	MediShare
Marcia	Dunham	Pacific Gas & Electric Company
Diana	Graham	Keller and Heckman law firm
Wendy	Holt	Alliance of Motion Picture and Television Producers
Lynn	Knudtson	Polyurethane Foam Association
Artie	Lawyer	Technology Sciences Group
Dan	Leacox	Greenberg Traurig law firm
Tina	Ling	Asian Law Caucus
Danielle	Lucido	WorkSafe
Barbara	Materna	Occupational Health Branch Calif DPH
Marcie	McLean	Retired

Chuca	Meyer	Pillsbury Winthrop law firm
Richard	Morford	EnviroTech International
Olivera	Radovanovic	Unmack Everett Environmental
John	Sacco	CalPASC, CCMCA, AGC of CA, MIA, CCNSIG
Peter	Scholz	Cal/OSHA Consultation Service
Jeremy	Smith	California Labor Federation
Fran	Schreiberg	WorkSafe
Dov	Shellef	Poly Systems USA
Elizabeth	Treanor	Phylmar Regulatory Roundtable
Craig	Wolfson	Clorox Company

Cal/OSHA Staff

Steve Smith (meeting chair), Tom Mitchell, Bob Barish, Bob Nakamura, Mike Horowitz

Steve Smith opened the meeting. He explained that the Division had made modifications to the list of substances proposed for work by the HEAC since it was presented at the initial public meeting June 19, 2007. He also noted that there are changes to the list of HEAC members posted on the PEL website: John Froines of UCLA has withdrawn from the Committee. Steve Smith said that this first meeting is to review the process for the Committee's work and to make the first assignments of substances for review at the next meeting. He noted that a draft template is posted on the website which is intended to be used to present and share the Committee's findings on the individual substances as they are under review and discussed in meetings. Steve Smith said that the Division will post other supporting documents on the website when it does not present copyright problems.

One Committee or Two?

Richard Cohen noted that the HEAC group has almost twice the number of members as prior PEL Committees run by the Division. He asked if consideration was being given to breaking into two separate committees with separate meetings. Steve Smith said this had been considered but that at the moment the Division would proceed with one committee and one set of meetings. Julia Quint said she thought it was important that all members, or as many as could attend, hear presentation of the review of every substance under consideration for a new or revised PEL. Dov Shellef said that a bigger meeting would promote greater participation. Susan Ripple said that if two committees are formed, they should meet together for final consideration of substances. Juli Broyles suggested staying with one committee, and asked how interested parties can submit materials for consideration at Committee meetings. Steve Smith said that submissions by interested parties for the HEAC health review of substances can be mailed or e-mailed to him, or to Bob Barish, and they would pass them along to the HEAC team members working on the substance concerned for evaluation and possible inclusion in their review. Even if not considered in the HEAC review, the Division would review all comments received in the process. Steve Smith said that when cost and feasibility are considered in the second phase of the process after the HEAC deliberations on a substance, a broader range of comments beyond just health studies can be considered**.**

Responding to Juli Broyles, Howard Spielman also suggested that the Committee post their initial draft completed templates on the PEL website before the meeting at which it is to be discussed and ask for comments.

Looking Back at Previous Rounds of PEL Development in Cal/OSHA

Bob Barish then introduced Richard Cohen an occupational medicine consultant and member of the PEL Advisory Committee in the last two rounds of its work. Richard Cohen said that prior to the round of PEL development

initiated in 1996 when he first participated on the PEL Advisory Committee, the process consisted mostly of industrial hygienists looking at and, in most cases, recommending adoption of ACGIH Threshold Limit Values (TLVs). But he noted that while the TLVs do not always address all hazardous endpoints, Richard Cohen said that in his experience occupational safety and health professionals look at Cal/OSHA PELs as no-effect or "safe" levels of exposure. In response to this situation, the PEL Advisory Committee starting in 1996 worked to assess all potentially hazardous endpoints of chemical exposure, including cancer, and that this approach changed the entire PEL development process. He said that in the Committee's work since 1996, stakeholders for some substances did participate in the process, but often they did not or could not provide dose/response data that the Committee could use in its health evaluations. On the other hand he noted that Bruce Wallace, the Division staff industrial hygienist for the Committee's last two rounds had also at times been able to arrange for presentations to the Committee by national and international experts on the health effects of a number of the substances under review.

Richard Cohen also noted the challenge of often having only animal toxicology studies for many substances. He said that trying to determine how to extrapolate from animal data and apply appropriate safety factors was a frequent source of discussion at Committee meetings since 1996. He said that individual substances were generally assigned for review to teams of two members, although one usually took the lead. He said that for some substances the result of the Committee's review led to recommendations close to or identical with the TLV, while for other substances the recommendations were significantly different.

Julia Quint noted that there were often participants from other agencies at previous Committee meetings. She asked to what extent the Committee used existing approaches for determining the assessments, such as those of the California Office of Environmental Health Hazard Assessment (OEHHA) or U.S. EPA, for developing PEL recommendations. Bob Ku, a member in the last round of the Committee's work, said that OEHHA risk assessments emphasized public health protection while the committee was concerned with worker protection and the Division had left it to the Committee's judgment to decide if and how such assessments would be used when available. Richard Cohen noted that Craig Steinmaus who participated in the last round of the Committee's work had experience with health risk assessment and that he (Richard Cohen) worked on development of occupational exposure limits (OELs) for the pharmaceutical industry.

Julia Quint added that in her experience, there has been discussion in the federal OSHA documentation especially on carcinogens that is helpful. She agreed with Bob Ku that the Division had not provided specific guidance on use of risk assessments by OEHHA and other agencies.

Susan Ripple asked what guidance there will be to the present Committee especially about the use of unpublished research. Richard Cohen said that Bruce Wallace did make an effort to incorporate such data when available into the Committee's deliberations. Bob Ku said that he felt that the Committee should limit itself to peer reviewed studies.

Will Forest commented that in the last two rounds of PEL development the Committee tried to make the process more science based. He said he thought the Committee should use existing risk assessments that have been done by other agencies as a preliminary basis for review, but that many of the substances for possible consideration do not have risk assessments, and he thought these are the ones that should get the focus of the effort from the group.

Howard Spielman asked about the term "health-based." He said he sees it in documentation and even legislation. Does the committee actually agree on what that means? Beth Treanor said that public health standards are generally intended to protect the most sensitive populations such as children and the elderly and assume lifetime exposure durations. The discussion turned to clarifying that there are different critical endpoints for different substances, and that the approach of the Committee in the last two rounds has been to recommend PELs based on substances' most sensitive endpoint for which credible data is available.

Susan Ripple asked again about use of unpublished data. She said in her experience working on development of occupational exposure levels relying only on published studies can result in omission of the most recent studies and studies not pursued with an intent of publication.

Mike Cooper, a member of the Committee for the previous round of PEL development discussed the approach used to review the literature and develop recommendations. He said that in the Committee's last round of work the two-person teams assigned, or one person lead, would do a search of the scientific literature, and other sources including OEHHA, EPA, IARC, etc. The Committee would then discuss the team's findings. Information was provided to Committee members to review prior to the meeting whenever possible. In general, though with some exceptions, the Committee worked to the 1 in 1,000 increased risk level suggested as being obviously of concern in the decision of the U.S. Supreme Court on federal OSHA's benzene standard. Mike Cooper said that as discussed by Richard Cohen, the approach taken in the previous round of the Committee's work was to identify all potential endpoints of concern and then decide on the endpoint on which to base its recommendation. He said that sometimes a potential endpoint of concern could be identified but there was not always adequate credible data available upon which to base a PEL recommendation.

Mike Cooper noted that 'the AIHA WEEL Committee has a conflict of interest form. Dov Shellef asked who will decide and act on potential conflicts of interest among HEAC members and also who will look at potential conflicts of interest among the researchers whose studies are relied upon by the Committee in their deliberations.

Fran Schreiberg said that the 1 in 1,000 increased risk level noted by Mike Cooper is not sufficiently protective and is not consistent with the Supreme Court's decision on OSHA's benzene standard. She said the Supreme Court's decision on the benzene standard is clear that working to a risk level of 1 in 1 billion would be overly conservative, and that 1 in 1,000 is clearly of concern, but it did not say 1 in 1,000 is necessarily the appropriate risk level to work to. Addressing concerns expressed on conflicts of interest among researchers, she said she would be concerned by the conflict presented by relying on industry studies of chemical hazards. She also questioned why the Committee needed to do its own risk assessments for substances for which they had already been done by OEHHA, EPA, or other agencies

Mike Cooper responded that for some substances the Committee worked to different risk levels depending upon what could be supported by the available scientific data. Bob Ku echoed this, saying that the risk level of PEL recommendations for different substances can differ based upon the data available. Richard Cohen said that risk assessments by other agencies can certainly contribute to the work of the Committee. He also said that the 1 in 1,000 increased risk level was looked at by the Committee in previous rounds primarily or exclusively where cancer was the endpoint of concern. He said the increased risk level to be worked to is a political decision that the Division should provide to the Committee.

Will Forest said that EPA includes the increased risk levels protected against in its risk assessment documents but you have to look for it. He said that workers should have access to information on the risk levels associated with PELs. Patty Quinlan agreed that an important factor to include in the whole process is that the public should be provided with the risk factor information.

OEHHA Presentation on Proposition 65, Risk Assessments, Information Sources

Bob Barish said that a discussion of uncertainty factors in risk assessment would follow a presentation by Sara Hoover, a Research Scientist with OEHHA, in order to accommodate her schedule.

Sara Hoover said that Bob Barish had asked for a presentation to orient Committee members and interested parties to OEHHA, the resources available from its website or upon request, background on the Proposition 65 list, and the availability of OEHHA risk assessments on Proposition 65 listed chemicals and other chemicals.

Sara Hoover began by saying that substances are added to the Proposition 65 list in a variety of ways including court orders, labeling requirements such as those of the U.S. Food and Drug Administration labeling some pharmaceuticals as carcinogens, and determinations by authoritative bodies such as IARC, NIOSH, NTP (National Toxicology Program), EPA, and FDA. She said that the fact that a substance is on the Proposition 65 list does not mean necessarily that OEHHA or another agency has performed a risk assessment on the substance. She further indicated that if an OEHHA risk assessment is available for a Proposition 65 listed substance, it may be available on the OEHHA website, or otherwise would be available by inquiring to OEHHA.

She continued that a useful tool at the OEHHA website for accessing information on individual substances is the Toxicity Criteria Database. She noted that this database is updated periodically, not continuously, so absence of a substance there is not a definitive indication that it has not been evaluated by OEHHA. Also, the information available in the database on a substance may not be the most up-to-date that OEHHA has, but it is a place to start a search, and provides an indication of whether a risk assessment(s) has been conducted by OEHHA.

As an illustration of how to find information for a chemical of interest online, Sara Hoover went through the example of hexachlorobenzene. Beginning with the Toxicity Criteria Database, she noted that for hexachlorobenzene the database lists an OEHHA cancer potency value and cancer unit risk value, an OEHHA Public Health goal, derived based on the carcinogenic effects of hexachlorobenzene, and a No Significant Risk Level (NSRL) established under Proposition 65, which is the daily intake level associated with an excess lifetime cancer risk of 1 in 100,000. She further explained that hexachlorobenzene is listed as a developmental toxicant under Proposition 65, but a Maximum Allowable Daily Level (MADL), which is the daily intake level at which the chemical would have no observable adverse reproductive effect assuming exposure at 1,000 times that level, is not yet available for hexachlorobenzene. She went on to show that the OEHHA cancer risk assessment for hexachlorobenzene can be found in the Hot Spots document online. She also explained that a noncancer risk assessment for hexachlorobenzene based on its effects on the rat liver could be found in the U.S EPA Integrated Risk Assessment (IRIS) database, which is a useful online source of cancer and noncancer risk assessments conducted by US EPA.

Sara Hoover went on to explain that a noncancer risk assessment is typically based on the most sensitive noncancer endpoint. She noted however that risk assessments for noncancer effects may not cover all possible endpoints, or even necessarily the most sensitive endpoint, particularly if new studies have come out since the risk assessment was conducted. She also pointed out that for chemicals that have both noncancer and cancer effects, cancer will usually be the critical endpoint, providing the most sensitive basis for establishing exposure limits.

Sara Hoover discussed an example of how to adjust an OEHHA cancer unit risk value for application in an occupational setting. She noted that the cancer risk assessments conducted by OEHHA for the general population typically assume continuous 70 year exposures with inhalation of 20 cubic meters of air per day. She explained that to adjust a community cancer risk assessment for the occupational setting, the shorter duration of a worker's exposure would have to be taken into account. She stated that under Proposition 65 regulations, a worker is assumed to have exposures limited to 40 years, 8 hours per day, 5 days per week for 50 weeks per year. She further explained that under Proposition 65 regulations a worker is assumed to breathe 10 cubic meters of air over an 8 hour workday. She noted that in order to generate an occupational exposure limit using a cancer unit risk value, it is also necessary to choose an acceptable cancer risk level. She explained that under Proposition 65, the acceptable cancer risk is 1 in 100,000, but indicated that the Committee could select an alternative risk level, such as 1 in 10,000 or 1 in 1,000, for example.

Sara Hoover went on to describe factors that would need to be considered in adjusting a noncancer risk assessment conducted for the general population to apply to a worker population. She noted that some of the noncancer risk assessments that might be particularly useful to the Committee would be those that have derived reference exposure levels or reference concentrations. She explained that the first step in adjusting a community risk assessment to the occupational setting would again be consideration of the appropriate worker exposure scenario.

She also explained that the details of the noncancer risk assessment would have to be looked at carefully, to determine whether the uncertainty factors need to be adjusted. For example, she said that the intraspecies uncertainty factor in a community risk assessment might address the sensitivities of children and the elderly, who wouldn't be expected to be present in the workplace. She noted that for this example, the intraspecies factor might need to be reduced. She also explained, however, that in some cases the intraspecies factor might still be applicable for workers, depending on the health endpoint and the relevant target population. She emphasized that such issues would have to be carefully considered for each noncancer risk assessment.

Mike Cooper asked about requesting information from OEHHA for the chemicals being looked at by the Committee. Sara Hoover suggested sending the Division's finalized list of substances for this round of PEL reviews to OEHHA. She indicated that she could at least see what is available from OEHHA for each substance and then could work to provide needed information to Bob Barish for the Committee. She also said that the Committee could request that OEHHA conduct risk assessments on chemicals considered to be of high priority.

Julia Quint asked whether OEHHA risk assessments account for skin exposures. Jim Collins, a Staff Toxicologist of OEHHA, responded that risk of effects from skin exposure is not generally addressed in OEHHA assessments but that in some instances it has been. Jim cited the example of nickel which is a recognized skin allergen.

Fran Schreiberg asked if after lunch there would be discussion of the list of substances for PEL consideration. Mike Cooper said the Committee should get started working on substances.

LUNCH BREAK

Discussion of application of uncertainty or safety factors

Bob Barish introduced Bob Ku to discuss uncertainty factors. A spreadsheet handout (posted at the website along with these minutes) was provided by Bob Ku. It summarized uncertainty factors used in risk assessment by various agencies and authors. Bob Ku said he wanted to show how the previous Committee worked with published safety factors from various sources. He said looking at the handout, the safety factor of 10 is especially prominent.

Bob Ku said safety factors are typically used in risk assessments for non-cancer endpoints. They were first applied in 1954 by the U.S. FDA which published factors of 10 for inter and intra species variabilities, for the evaluation of food safety. From then to now not much has changed, the individual factors usually ranging from one to ten. One added since 1954 is for LOAEL to NOEAL conversion. He noted that the Dourson et al. (1996) reference on the handout tabulated other safety factors being used: Canada had 1-100 for incomplete database, and 1-10 for modifying as another level of judgment. With refinement of understanding such as detailing of toxicokinetic and toxicodynamic responses, uncertainty is decreased and so safety factors can be reduced. But this requires knowing if the animal model works the same in humans. Bob Ku explained that the handout is a glimpse of commonly used safety factors, but if they were used all at once, it would be overly conservative because many of the factors rely on the same or similar bases. Picking a factor can be contentious, there is no rule for it. However, in general he said the more credible data that is available, the lower the factor for uncertainty, and vice versa.

Bob Barish asked about the origin of the value of 10 as common for safety factors. Bob Ku said this was originally proposed by Lehman and Fitzhugh (1954) when they found it to be protective in all of the situations they were looking at. He said that without a basis to change, 10 is widely used, though as noted above the availability of additional data can reduce the individual uncertainty factors or the number of them applied in a risk assessment.

Julia Quint said that a consistent approach to the Committee's evaluations is important for transparency of the process. She added that the TLVs won't necessarily be a good basis for everything so there should be a uniform approach developed for the evaluation. Mike Cooper agreed that the Committee should attempt to be consistent in how it looks at each substance. He reviewed a set of information points he had developed that were used by the last in the last round of the committee's work in which he participated.

Susan Ripple asked if safety factors can be applied to reflect the quality of the data available. Richard Cohen said in his two rounds of work with the Committee those were the key judgments that were made, assessing the strengths and weaknesses of the different studies. Will Forest said that the approach of the prior Committees was using what they judged to be the best of the studies to make the PEL recommendation.

Julia Quint asked about the pharmaceutical industry approach to setting OELs. Bob Ku said that they typically assume worst case exposures. He said the process involves judgments about the value of different data and so can be hard to explain at times. Julia Quint said this difficulty, which is true of all risk assessment processes, is why she and Fran Schreiberg encourage use of existing risk assessments undertaken with established processes such as by OEHHA and EPA, in order to avoid use of inconsistent approaches in applying the same data between environmental and workplace exposures.

Discussion of substances for consideration

Fran Schreiberg asked about the list of substances that the Committee would be considering. Steve Smith said that he and Bob Barish had reviewed the list discussed at the general meeting on June 19 and made changes based on the discussion at that meeting. Steve Smith said that the list is always open to modification based on new information coming in. However, he said he wanted the Committee at this meeting to start picking substances to work on for the next meeting, so that work could start on the summary templates and getting ready for the discussion.

Fran Schreiberg noted that some substances discussed in June were still not on the list for the Committee's work. She said that while toluene was moved up to the priority 1 group based on the June meeting discussion, dibutyl phthalate which was also discussed is still not on the list. Steve said that in the case of dibutyl phthalate, there has not been a recommendation to change the TLV.

Fran Schreiberg said that the list does not include many carcinogens for which OEHHA has done quantitative risk assessments. She said that with such resources already available the TLVs should not be the only source for consideration. Will Forest agreed and noted that 1-bromopropane is still not on the list for this Committee. Steve Smith said 1-bromopropane is still being worked on by the Division based on the last round of the Committee's work.

Howard Spielman said that priority for consideration by the Committee should be based in part on usage levels and exposure potential in California. Juli Broyles said she had looked but had not found a database that could be used to reliably assess this. Julia Quint agreed that in the absence of a comprehensive database it is difficult to reliably determine California usage or exposure levels. Jim Collins said that there is a list of the top 100 pesticides by usage level, and that there is Hot Spots emissions data. Lynn Knudtson suggested EPCRA Toxics Release Inventory (TRI) and Tier I and Tier II inventory reporting could be another useful source.

Fran Schreiberg suggested starting the Committee's work with solvents that are carcinogens or suspect carcinogens. Steve Smith said he thought it would be better to start with the least controversial items to work out the mechanics of the process. Will Forest agreed that it would good to start with some lower profile substances and said that he would take on one of the initial assignments.

John Sacco said that on the list of substances developed by the Division, hydrogen chloride, carbon disulfide, hydrogen fluoride, and toluene are all widely used. Julia Quint said western red cedar and natural rubber latex were two high use items for which the TLV might be appropriate and so might not require as much initial work.

After discussion the substances agreed on for the planned November meeting and the HEAC member assignments were:

dichloroacetic acid (Susan Ripple, Will Forest)
n-methyl pyrrolidone (Julia Quint, Susan Ripple)
hydrogen fluoride (Richard Cohen, Mike Cooper)
hyrdrogen chloride - provisional if time (Jim Unmack, Michael Kleinman)

For the planned January meeting the following substances were chosen:

toluene (Julia Quint, Mark Nicas)
carbon disulfide (Patrick Owens, Howard Spielman)
sulfuric acid (Bob Ku, Patty Quinlan)
trichloroethylene (Julia Quint, Will Forest)

An attempt was made to choose the date for November meeting but it was agreed that the Division would send out selected possible dates and set the meeting based on responses received.

END

Attachment: Bob Ku handout on uncertainty factors