DRAFT MEETING SUMMARY

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

January 29, 2008
Elihu Harris State Building
1515 Clay Street
Oakland, California

HEAC Members in attendance

Will Forest, Santa Cruz County Public Health Department
Bob Ku, SafeBridge Consultants
Linda Morse, Independent
Patrick Owens, Shell Oil Martinez Refinery
Patty Quinlan, UCSF Occupational Health
Julia Quint, Independent
Susan Ripple, Dow Chemical
Howard Spielman, CIHC
Mark Stelljes, SLR International
James Unmack, Unmack Corporation

Public and Interested Party attendees

Heather Borman, State Compensation Insurance Fund
Juli Broyles, California Advocates
Stephen Derman, MediShare
Kyle Dotson, Dotson Group
Mike Easter, Ensight
Willem Faber, Lyondell Chemical and NMP Producers Group
Marti Fisher, California Chamber of Commerce
Clay Freeburg, Chevron
Barbara Kanegsberg, BFK Solutions
Dan Leacox, Greenberg Traurig law firm
Cynthia Leon, California Manufacturers and Technology Association
Barbara Materna, Occupational Health Branch, Calif. Dept of Public Health
Marcie McLean, Independent
Chuca Meyer, Pillsbury Winthrop law firm
Katie Moore, Sonnenschein, Nath, & Rosenthal law firm
Richard Morford, Envirotech International
Jane Murphy, Phylmar Regulatory Roundtable
Suzanne Murphy, WorkSafe
Dan Napier, DNA Industrial Hygiene
Ralph Parod, BASF and NMP Producers Group
Olivera Radovanovic, Unmack Everett Environmental
John Sacco, CalPASC, CCMCA, AGC of CA, MIA, CCNSIG
Fran Schreiberg, WorkSafe
Dennis Shusterman, HESIS
Beth Treanor, Phylmar Regulatory Roundtable

Cal/OSHA Staff

DOSH Research & Standards Unit: Bob Barish (meeting chair), Bob Nakamura, Mike Horowitz
DOSH Legal Unit: Amy Martin

Cal/OSHA Standards Board: Tom Mitchell

Meeting Consensus Items

Substance Selection and Prioritization

A meeting separate from regular HEAC meetings should be held to more extensively discuss substance selection and prioritization for the PEL Project as well as the OEHHA report on PELs released December 2007. *(**Note**: A meeting as described was held on April 4, 2008.)*

A prioritized list of substances for the PEL Project should be developed based on factors described in the PEL Policy & Procedures document, including California usage. *(**Note**: This consensus was re-affirmed at the April 4, 2008 meeting on substance selection and prioritization.)*

The Health Expert Advisory Committee should continue its work while the separate process of substance selection and prioritization for the PEL project is addressed.

HEAC Process Items

***Document distribution lead time*:** There was no objection expressed by meeting attendees to the following proposal by Bob Barish with respect to lead time for distribution of documents generated by HEAC members prior to Committee meetings: *Where a substance is controversial or there are active interested parties, no decision on a substance will be made at an initial or follow-on meeting on the substance unless any new or revised documents are made available not less than approximately 6 weeks before that meeting. Where a substance is not controversial and there are no active interested parties, the 6 week lead time for document distribution will apply only to decision-making at the meeting where the substance is initially presented.*

Submission of comments by interested parties: Although some sentiment was expressed that comments from interested parties for individual substances should only be taken in written form, strong objection was not expressed by HEAC members or meeting attendees present at the time that with the exception of brief statements of position or fact, presentations by interested parties at HEAC meetings would not be accepted on individual substances unless written comments forming the basis of the presentation are provided sufficiently in advance of the meeting for which the presentation is planned (for example at least 2 weeks). It was also generally agreed that even when written comments from an interested party are received ahead of the meeting date, care must be taken to control the time taken from HEAC meetings on such presentations.

Health assessment document formatting: Initial and revised health assessment documents and responses to comments prepared by HEAC members should always include their approximate date of submission to the Division for distribution to HEAC members and website posting. Changes to documents should be shown in strikeout/underline format relative to the previous version.

Meeting Summary

Bob Barish opened the meeting by welcoming HEAC members and interested parties. The agenda for the meeting was reviewed and everyone in the room introduced themselves. Bob Barish asked if there were any comments on the draft minutes for the first HEAC meeting held November 2, 2007. There were no comments on the draft minutes for the November 2, 2007 meeting.

Bob Barish announced that three HEAC members had decided not to serve on the Committee: Richard Cohen, John Froines, and Mark Nicas.

Bob Barish reviewed the meeting agenda, noting that the first part of the meeting would focus on the OEHHA report on PELs released December 2007 as well as a discussion of substance selection and prioritization for the Committee's work. Substances planned for follow-on discussion at this meeting were dichloroacetic acid and n-methyl pyrrolidone with initial presentations planned for hydrogen chloride and sulfuric acid. Bob Barish noted that HEAC member Mike Cooper is on a temporary work assignment overseas and so follow-on discussion of the substance he had presented at the November 2 meeting, hydrogen fluoride, would wait until he returned.

Discussion of OEHHA Report on PELs

Julia Quint opened the discussion by explaining that HESIS commissioned the OEHHA report in 2004 in support of its legislatively mandated role of making recommendations to the Division with regard to occupational exposure limits for toxic substances. Bob Barish acknowledged the OEHHA report as an impressive and potentially very helpful contribution to the Division's PEL project. He noted that the report covers approximately 130 chemicals and that it can best be approached, as suggested to him by Sara Hoover of OEHHA, by looking at its Tables 19 and 20 for substances presenting risk of cancer or reproductive effects respectively. Bob Barish said that having the information presented in the report in hand, especially as summarized in Tables 19 and 20, then raises the question of how the Division should go about selecting which substances to work on, in what priority order, and how to then efficiently complete the process of developing PELs for those substances chosen for work.

Substance Selection and Prioritization

Fran Schreiberg said she thought the PELs Policy & Procedures document addressed development of the list of substances for work in the project including assessment of the California risk of exposure, or at least usage if detailed exposure risk information isn't available. She said that the OEHHA report should assist this process, and speed the process of PEL development for the chemicals included in the report by showing which already had risk assessments completed by OEHHA or EPA.

Dan Leacox said substances in the OEHHA report should be screened for selection for addition to the existing Division list of substances for the PEL Project. Beth Treanor agreed with Fran Schreiberg that selection and prioritization for inclusion in the PEL Project list should include an assessment of likelihood of worker exposure in California. She said she thought such information might be available from some Certified Unified Program Agencies (CUPAs) through the hazardous materials business plan inventories. She supported holding a special meeting on substance selection and prioritization to address this point. Juli Broyles agreed that the prioritization process discussed in the PEL Policy & Procedures document should not be abandoned.

Julia Quint noted that HESIS in 2002 commissioned a report by UC Berkeley on availability of sources for information that could be used by HESIS to assess likelihood and risk of employee exposures. She said the report concluded that such information is not reliably available at either the state or national level. In light of the report's findings she said that the information to be used for prioritization based on California usage needed to be clarified.

(**Note**: The UC Berkeley report on potential information sources is available in the publications area of the website for the HESIS project on tracking workplace chemical hazards: http://www.dhs.ca.gov/ohb/HESIS/chemtrackpubs.htm)

Bob Barish asked Julia Quint what information sources she would recommend if the UC Berkeley report indicates reliable information is not available to assess California usage and potential worker exposure. She replied that information from industry partners would be the best approach. She said that local hazardous materials business plan information is not generally aggregated in a way that would be useful for selection and prioritization of substances for the PEL Project and that AB 816 sponsored by Assembly member Sally Lieber in 2006 would have facilitated collection of information from employers on chemical use but was vetoed by the Governor. Julia Quint suggested that the best information that might be available would be the information on chemical applications in the TLV Documentation for individual substances. She said such information was also available in reports for individual substances prepared by the National Toxicology Program and available at their website.

Will Forest said that one factor in prioritization should be the degree to which information is readily available for the HEAC to conduct its evaluation. Patty Quinlan agreed with Will Forest that the availability of useful information for the health assessment should be a factor in prioritization. She said that all of the various lists being discussed should be considered in development of a single prioritized list. Linda Morse proposed a table displaying the major factors discussed for prioritization and urged that HEAC use health assessments that have already been developed where they are available.

Bob Barish suggested having a separate meeting on prioritization that would include a more extensive presentation and discussion of the OEHHA report. Dennis Shusterman said that Sarah Hoover could probably give such a report. Fran

Schreiberg suggested that HESIS develop a list of substances recommended for the PEL Project based on the OEHHA report. Bob Barish said that he would work to put together for the special meeting on prioritization a table listing possible usage indicators for substances in the OEHHA report and the existing Division list based primarily on TLVs.

Role of the HEAC in Conducting and Reviewing Risk Assessments

There was discussion of the role of the HEAC, especially in relation to using existing OEHHA risk assessments for substances that might be under consideration. Julia Quint said that HEAC should not develop risk assessments for substances from scratch if they have already been done by OEHHA. Howard Spielman agreed that he did not see the HEAC, for the most part, doing its own risk assessments from scratch, but rather reviewing ones that have already been done. He said that where risk assessments in addition to those conducted by OEHHA have been done for a substance being worked on they should be considered in the HEAC review. Bob Ku expressed agreement with the points made by Howard Spielman. Patty Quinlan said that prior to 1995, the PELs advisory committee pretty much focused on just evaluating the ACGIH TLV but that the process had evolved to doing more evaluations with other available data.

HEAC Process and Health Assessment Document Distribution Lead Time

Bob Barish said that there is a problem with having chemical health assessments from HEAC members sufficiently far ahead of the meeting date to facilitate participation and comment by interested parties. Julia Quint agreed that where there are interested parties, lack of distribution of assessments well ahead of the meeting where they are presented or discussed could inhibit outside review. Bob Barish asked if there should be a requirement for a lead time of about 6 weeks for posting of assessments before the meeting if there is to be a decision made on the substance at that meeting. Patty Quinlan expressed concern that such an approach could result in extensive delays in coming to PEL recommendations. Howard Spielman suggested it would be rare for a substance to be completed at the meeting where it is first presented.

n-Methyl Pyrrolidone (NMP)

(Note: The NMP Producers Group plans to submit written comments prior to the HEAC meeting on April 29, 2008 that will more thoroughly capture the material from their presentation detailed briefly in the notes below)

Julia Quint and Linda Morse expressed concern with an anticipated PowerPoint presentation by toxicologists from the NMP Producers Group. She said that it didn't allow any time for review, that anything to be presented by interested parties should be submitted ahead of the meeting in writing to allow time for members to review so that there can be an informed discussion.

Julia Quint said she thought it had been agreed that the HEAC process would start with an evaluation of government sources of information, particularly risk assessments, because they are processes open to public observation and comment. She acknowledged however the need for the Committee to conduct a literature search to evaluate if new information needed to be incorporated into the assessment.

Julia Quint clarified that her assessment of NMP reviewed the Solomon publication which presented publicly the data from the study of Staples (1990). Regarding comments of the NMP Producers Group on their letter of December 17, 2007 responding to her initial assessment document, Julia Quint said that her assessment gave primary weight to the study of Solomon rather than that of Lee which the Producers Group thought was more appropriate since OEHHA chose Solomon as primary study in its risk assessment. She acknowledged that the Solomon paper can be hard to understand as it presents data from a developmental study in animals conducted within a reproductive study.

Responding to a concern expressed in the written comments of the NMP Producers Group letter of December 17, 2007, Julia Quint said her recommended PEL of 1 ppm is based on developmental effects identified in the Solomon study, not reproductive effects. She explained that derivation of the 1 ppm recommendation was generated by the standard practice of adjusting the animal NOAEL based on the exposure times from the study to what would be the NOAEL based on continuous community exposure times, and then adjusting that value for the more limited time of occupational exposure.

Julia Quint said she was still waiting for a response from Jim McDonald of OEHHA regarding the status of the OEHHA assessment of NMP for reproductive toxicity (it is currently on the Proposition 65 list only for developmental effects). She said however that her recommended PEL is based on developmental effects only, not reproductive effects.

Mark Stelljes asked why Julia Quint's recommended PEL of 1 ppm differed from the HESIS 2006 recommendation of 5 ppm. Julia Quint responded that this difference resulted from application of an intraspecies uncertainty factor of 10 consistent with Federal OSHA's deliberations on glycol ethers as detailed in the original health assessment document distributed for the November 2, 2007 HEAC meeting and explained further in the revised health assessment document distributed for today's meeting. Julia Quint also said that the question raised by Mike Cooper in the meeting November 2, 2007 regarding potential for absorption of NMP by the test animals from aerosol contact was addressed by the fact that in the Solomon study exposures were all below the 140 ppm at which aerosols form. Bob Ku asked about the potential for absorption of vapor through the skin. Will Forest said that the potential for absorption of vapor through skin was probably similar for both the test animals and humans and so therefore should not be a factor.

Julia Quint said she found the comments of the NMP Producers Group in their letter of December 17, 2007 to be very thought provoking. Responding to the Producers Group question as to why the study of Solomon was chosen as the critical study she said it had also been used in the OEHHA assessment. She also said that OEHHA had looked at the studies of Lee and Saillenfait but chose to rely on Solomon. She acknowledged that the NOAEL in the Saillenfait was higher than in Solomon but said that the exposure regime was different, that it did not occur in the place where test animal mating took place. She said she had responded to comments about viewing pregnant workers as a sensitive population as the basis for the intraspecies uncertainty factor of 10 and focused instead on the OSHA approach for glycol ethers. She also acknowledged that PBPK (physiologically based pharmacokinetic) studies of metabolism and uptake are currently underway for NMP, and that these results could be incorporated into her assessment when they become available.

Ralph Parod a toxicologist with BASF who attended for the NMP Producers Group said he thought that Julia Quint had done a good job of laying out the technical issues on NMP and responding to the Group's initial comments on her assessment of NMP, but that his group had only had her revised assessment for a week before the meeting and so had not had time to prepare and distribute written comments in response. He said that Willem Faber from Lyondell Chemical had prepared a presentation to give to the Committee for the Producers Group. Julia Quint expressed concern with the Committee's process in terms of new information being presented to members at one of its meeting but without being in a written form that members could review and evaluate in advance of the meeting in order to be able to have a meaningful discussion with the interested parties and other HEAC members. Mark Stelljes said that he did not oppose getting new information on a substance whenever it is provided. Linda Morse said she agreed with Julia Quint that information provided to the Committee should be in writing. Will Forest and Patty Quinlan said they thought that the PEL Policy & Procedures document had already stated certain limited criteria for presentations Julia Quint said it is a fundamental issue since the Committee doesn't have the capability to review every risk assessment that may be brought in by an interested party.

LUNCH BREAK

Ralph Parod of BASF said that he and Willem Faber of Lyondell Chemical wanted to present information to the meeting on the Exxon study (1991) that formed the basis for the evaluation of NMP by the US EPA. He said that a BASF study in 1999 showed that there were genetic issues with the test animals in the Exxon (1991) study. He also said that the Solomon study should not be the critical study for the Committee's assessment in that it is difficult to understand and that EPA has based their assessment on a different study. There was discussion of whether these comments had been made to OEHHA in its deliberations on NMP. Julia Quint asked if they would be presenting this information in writing. Ralph Parod said they would work on that. Howard Spielman asked the Producers Group representatives if the studies they were referring to were publicly available. They responded that they were not but that they would work to get their findings to the Committee.

Willem Faber said a major issue with the Solomon study was the use of "SD" rats which as a result of excessive in-breeding had a high rate of testicular atrohpy unrelated to chemical exposure. He also said that the key factor in the Solomon study was supposed to be fetal body weight. He said however that what they actually assessed was postnatal

body weight.

Given the problems noted above, Willem Faber said the NMP Producers Group believes that Saillenfait should be the key study for setting the PEL, not Solomon.

Ralph Parod said that he would provide the Committee with the OECD SIDS (Screening Information Data Set) SIAM (Initial Assessment Meeting) report on n-methyl pyrrolidone.

Julia Quint asked HEAC members how they wanted to deal with the comments of the NMP Producers Group. She said she objected to HEAC reopening the OEHHA assessment which had already gone through a public process and comment period. She said the Producers Group comments on the OEHHA assessment should be responded to by OEHHA.

Linda Morse suggested that presentations by interested parties at HEAC meetings were not the best use of the Committee's limited meeting time and should not be accepted. She proposed that interested party comments to HEAC should only be accepted in writing**.** Susan Ripple said that the US EPA's committee process for work on Acute Exposure Guideline Levels (AEGLs) limits presentations by interested parties to 10 minutes. Juli Broyles said she did not agree with the idea of preventing interested parties from speaking at HEAC meetings altogether. She suggested the concept of an "open mike" period where interested parties would be allowed to air their concerns for a limited period of time. There did not appear to be strong objection to this concept. Dennis Shusterman reiterated others' concerns that written comments should be the primary means by which comments from interested parties are accepted in the HEAC process and that they should be submitted sufficiently in advance of the meeting to facilitate review and preparation by HEAC members on the substance they address.

Bob Barish concluded the discussion with the NMP Producers Group representatives by saying that to be of use in the record for HEAC the information they had presented in the meeting would need to be provided in writing as it could not be adequately captured in meeting minutes based upon their verbal presentation and summary slides alone. He said that if they are to possibly be considered by HEAC any unpublished studies would also need to be provided.

Dichloroacetic Acid – follow-on discussion from initial presentation on November 2, 2007

Susan Ripple presented the most significant of the changes she had made to her assessment document for dichloroacetic acid which she had presented at the last HEAC meeting November 2, 2007. There was discussion of the approach used to calculate the cancer risk. Susan Ripple noted that the changes in the document had not affected the recommendation for the PEL of 0.1 ppm. She said one change had been to add the reference to the paper of Moser regarding neurotoxic effects.

Bob Barish said it appeared that the draft document and recommended PEL for dichloroacetic acid could be at least tentatively ratified at this meeting, subject to a minor change to the document clarifying how the ACGIH TLV was reached, ie. removing reference to back-calculation of an uncertainty factor of 34 for the TLV. Bob Barish also suggested, in light of the situation with dichloroacetic (ie. no interested parties and no apparent controversy), that the idea discussed earlier in the meeting of requiring a 6-week lead time for posting of documents for a HEAC meeting in order to allow a decision to be made at that meeting, be refined to apply only to the initial meeting on such substances, and to any follow-on meetings on a substance where interested parties had come forward or where controversy was apparent or reasonably anticipated. There was no disagreement with this suggestion, and the document and recommendation for dichloroacetic acid was tentatively adopted by the Committee subject to the minor change noted above.

Hydrogen Chloride - initial presentation

HEAC member Jim Unmack made the presentation of his assessment. He said consideration of this substance was prompted by ACGIH lowering the TLV from a Ceiling limit of 5 ppm to a Ceiling limit of 2 ppm in 2003. He noted the Cal/OSHA PEL is a Ceiling limit of 5 ppm. He said the health endpoint of concern is respiratory irritation and that the study on which the TLV is based used young adult asthmatics. But he said this was not necessarily the most sensititive population for the effect of concern. He suggested a revised PEL be based on prevention of upper

respiratory tract irritation, eye irritation, pulmonary edema, and dental erosion. He said he thought the PEL should be a STEL of 2 ppm rather than a Ceiling limit since measurement of the ceiling level would require special instrumentation not normally available to industrial hygienists in the field. He did suggest keeping the existing Ceiling PEL of 5 ppm to guard against high instantaneous exposures that might still occur.

Dennis Shusterman asked if the respiratory irritation generated by hydrogen chloride was pulmonary or nasal. Jim Unmack said that most of the data was from exposure chamber studies with volunteers which simply queried how they felt with different levels of exposure.

Dennis Shusterman asked if an RD-50 value had been determined for hydrogen chloride. He explained that the RD-50 is the chemical exposure level at which the rate of respiration in a test group is reduced by 50%. Susan Ripple said she thought that an RD-50 had been determined for hydrogen chloride and she would try to obtain it. She noted further that her employer Dow Chemical makes hydrogen chloride and so she would recuse herself from the decision on the committee's recommendation on this substance.

Dennis Shusterman noted that OEHHA recently published a paper on RD-50 values. He said that data from exposure chamber studies is probably not the ideal source of information for setting a PEL. Jim Unmack said he agreed.

Julia Quint asked about long term exposure data. Jim Unmack said he did not think those could be used as the levels reported were below sensory limits. Julia Quint said her concern was for situations where sensory fatigue could allow exposures that might cause other toxic effects. Dennis Shusterman said he did not think long term effects were the critical endpoint for hydrogen chloride.

Mark Stelljes asked about older scientific literature on hydrogen chloride. Jim Unmack said this was where data on dental erosion was found.

Dennis Shusterman said there is likely to be a hypersensitive population for hydrogen chloride. He said references were needed to address the threshold for sensory irritation. Jim Unmack said he would work to get those, and Susan Ripple said again that she would work to get the RD-50.

Susan Ripple said that it might be fruitful to look at studies of effects from exposure to chlorosilanes and other substances which convert quickly in air to hydrogen chloride.

The meeting adjourned at 3:45 p.m.