# 17th Meeting of the Health Expert Advisory Committee (HEAC) for Permissible Exposure Limits for Airborne Contaminants in the WorkplaceCalifornia Code of Regulations, Title 8, Section 5155

**May 31, 2012**

**Elihu Harris State Building**

**1515 Clay Street**

**Oakland, California**

## HEAC Members

Michael Cooper, Exponent Corp.

Will Forest, Santa Cruz County Public Health Services Agency

Patrick Owens, Shell Oil Martinez Refinery

Susan Ripple, Dow Chemical Company

Howard Spielman, CIHC and Health Science Associates

Jim Unmack, Unmack Corp.

## FAC Members

Steve Derman, MediShare

Virginia St. Jean, San Francisco Department of Public Health

## Assisting Agency Staff

Dennis Shusterman, HESIS

Kashyap Thakore, HESIS

## Cal/OSHA Standards Board

David Kernazitskas

## Public and Interested Parties

Gokul Bose, Flint Hills Resources

Joe Chandler, Flint Hills Resources

Pam Dannenberg, California State Association of Occupational Health Nurses

Mike Easter, Ensight

Judi Freyman, Mercer/ ORC Networks

Diana Graham, Keller & Heckman Law Firm

Barbara Kanegsberg, BFK Solutions

Ed Kanegsberg, BFK Solutions

Dawn Koepke, McHugh, Koepke & Associates, for Flint Hills Resources

Chris Laszcz-Davis, CIHC and The Environmental Quality Organization, LLC

Dan Leacox, Greenberg Traurig Law Firm

Sheila McCarthy, Exponent Corp.

Catherine Porter, California Healthy Nail Salon Collaborative

Julia Quint (retired HESIS)

Fran Schreiberg, Kazan Law Firm

James Simonelli, California Metals Coalition

Kate Smiley, AGC California

Cecilia Stoddard, OCIH

Mario Vasquez, Flint Hills Resources

Dorothy Wigmore, WorkSafe

Cindy Young, California Nurses Association

## Division of Occupational Safety & Health

Ellen Widess (Chief), Deborah Gold (Deputy Chief), Suzanne Marria (Special Counsel), Steve Smith, Bob Barish, Bob Nakamura, Mike Horowitz, Janice Prudhomme, Paul Papanek, Julia Seward

## Opening

Bob Barish called the meeting to order at 9:40 a.m. and thanked those present for their interest and participation. He noted this was the 17th HEAC meeting since the first in August 2007 and that it would be the last meeting of this round of PEL advisory work

DOSH Chief Ellen Widess greeted attendees and thanked them for their participation and commitment to the important work on PELs. She commended the group for perseverance in the long 17 meeting cycle. She noted that as a result of these meetings four revised PELs had been adopted by the Cal/OSHA Standards Board and taken effect as regulations, four more are in process moving to the Board, and four others are having rulemaking packages developed by Division staff. She said this was significant progress, especially compared to other efforts to revise PELs. She said she wanted to continue this kind of work, keeping it effective and transparent as there is an important need to control worker exposures to hazardous chemicals.

Ellen Widess introduced Paul Papanek as a recently hired physician in the Division’s medical unit. She said he is a respected occupational medicine physician and the Division is fortunate to have him newly on board. She also noted the contributions of HESIS to the PEL project, including physician and HESIS Chief Dennis Shusterman and toxicologist Kashyap Thakore.

A few minutes were taken to thank each of the HEAC and FAC members present with a certificate of appreciation for their contribution to the PEL development process since 2007. Bob Barish noted certificates would be mailed to those members not attending the meeting.

Bob Barish then reviewed the agenda for the meeting that had been posted at the PEL project website. He said that with a letter received the day before the meeting from a representative of the California State Association of Occupational Health Nurses regarding work previously requested on the substance bisphenol A that this may be discussed briefly in the afternoon.

All those present then introduced themselves.

Bob Barish asked if there were any comments on the minutes for the previous HEAC meeting December 8, 2011. He noted that Chris Laszcz-Davis had sent him a comment that a NIOSH project related to PELs had been incorrectly attributed to HEAC member Howard Spielman rather than NIOSH Director (and former Cal/OSHA Chief) John Howard. Bob Barish said he would make this correction. There were no other comments or questions on the minutes for the previous meeting.

Bob Barish then reviewed the handouts made available in the back of the room. In addition to items already posted at the PEL project website, there was an updated PEL Project Substance Status List with a new category of status showing Isocyanates as a group of substances planned for consideration in a separate dedicated advisory committee as had been discussed briefly at the start of the HEAC process in 2007. Other handouts that were not posted at the website included five comment letters on the HEAC process as had been requested at the December 2011 meeting, and letters from the Keller & Heckman law firm representing the Vanadium Producers and Reclaimers Association on vanadium pentoxide to be discussed briefly for status in this meeting, and from Flint Hills Resources on trimellitic anhydride to be discussed in detail in the afternoon. The letter on bisphenol A noted above was also provided, as was a copy of the revisions to the four PELs noted by Chief Ellen Widess that took effect March 17, 2012 (for carbon disulfide, hydrogen fluoride, sulfuric acid, and toluene, with the rulemaking documents available at <http://www.dir.ca.gov/oshsb/Airborne_Contaminants_2011.html> ).

## PLANNING FOR NEXT ROUND OF PEL ADVISORY WORK

### Specific Substances

DOSH Deputy Chief for Health Gold then started discussion of the current status of substances in progress or planned shortly for work by the HEAC. She noted that at the start of each round of PEL advisory work there is discussion of the substances to be worked on. She noted that for the current round of work that started in 2007, an effort was made to assess California usage and exposure potential of substances being considered although the information resources for that remain limited. She said that of the substances shown on the PEL Project Substance Status List posted at the PEL project website and passed out in the meeting, revised as noted above for Isocyanates, about half had completed the HEAC and FAC processes. So a question to discuss is which of these substances should be carried over into the next round of work by the HEAC.

Deborah Gold first asked about hydrogen sulfide. Mike Cooper the HEAC member working on this substance passed out a draft health assessment document he said he is still working on (currently 5 pages). He said he still needed to obtain and review several additional studies, but he anticipated from what he had seen thus far that there may a scientific basis for a PEL lower than the current value of 10 ppm (8-hour TWA), and so he thought this substance should be carried into the next round of PEL advisory work. There were no comments on this from others in the meeting and so Deborah Gold said it would continue into the next round of work.

Will Forest then gave a brief review of the status of vanadium pentoxide. He noted that EPA held a meeting on this substance on the day of the last HEAC meeting December 8, 2011. He said that EPA was in the process of taking comments on this discussion. Bob Barish noted that the letter sent on behalf of the Vanadium Producers had also referred to the EPA process and requested that HEAC work on this substance wait until EPA had concluded its review of comments received and finalized its assessment document.

The letter sent on behalf of the Vanadium Producers and Reclaimers Association can be viewed by clicking on the icon: 

Will Forest said EPA should have a risk assessment number out of this process and so he recommended carrying consideration of vanadium pentoxide over into the next round of work. Howard Spielman said that the technical issues raised by comments to EPA, including those from the Vanadium Producers, addressed fundamental questions in toxicology assessment and so he thought it might be a protracted period before the EPA completes its assessment. Mike Cooper wondered if there is sufficient worker exposure potential in California to warrant further work on this substance. Bob Barish said he had looked into usage and exposure potential in California and that he had not been able to find much information directly relevant to usage and exposure potential in California workplaces, although from his review it could not be ruled out either. He noted that most commonly discussed is potential for exposure with oil-fired equipment related to vanadium pentoxide being a contaminant in some petroleum products, though he did not know if this could be relevant to California or not. He said that more work could be done on this assessment. It was agreed that HEAC would wait for completion of the EPA assessment before continuing work on vanadium pentoxide in the next round and that more assessment of exposure potential could be done before venturing into extended discussion of the health risk.

Fran Schreiberg said that as a member of the public she wanted there to be a discussion of usage of substances being considered by HEAC. She said she hoped Cal/OSHA can make a list of possible substances for discussion available early in the process so that she and others can research California usage and exposure potential. Deborah Gold said the plan would be to have such a list. Julia Quint said she had addressed usage and exposure potential in her rationale for substances in a priority list she had developed for HEAC work in 2008 and she encouraged including such information in the list being developed by the Division in the interest of transparency and usefulness of the process.

Fran Schreiberg asked if there is a timeline for when the next round of the process would start, when would the first HEAC meeting be held. Deborah Gold said she hoped to be able to have a HEAC meeting in September or October of this year. And so she said items such as additional comments on the process or on specific substances, as well as interest in, and nominations for, participating as a member of the HEAC or FAC, should be sent in to Bob Barish preferably by the end of July, latest end of August, to receive full consideration for planning of the next round of work.

Bob Barish asked for comments on the formatting and the information to include in the limited space of the [Priority list of substances to add or update in Section 5155 (as of 10/2010)](http://www.dir.ca.gov/dosh/DoshReg/PEL%20Priority%20List.xls) viewable at this Internet link at the project website. He encouraged suggestions for making this list a useful tool for transparency and prioritization of substances for work by the HEAC.

Deborah Gold then asked if there were any opinions as to substances that should be deleted from the current Substance Status List. She asked specifically about ethyl alcohol, listed in the category of substances that have had some level of discussion in the HEAC but are not yet completed with a health based recommendation. Susan Ripple said that for this substance which she had volunteered to review she was trying to get through about 800 studies of its health effects in order to come up with an appropriate initial recommendation to the committee. She suggested that it should be carried over into the next round of meetings and she would work to have it ready with a draft assessment document for a September meeting of the HEAC. There was general agreement with the proposal to continue working on ethyl alcohol into the next round of HEAC meetings.

Mike Cooper asked about beryllium. Deborah Gold said it was not on the current Substance Status List. She said the Division would be looking at which among the Priority 2’s in the Priority List of Substances posted at the project website would be the most important to include in the next round of PEL advisory work. Beryllium is among the Priority 2 substances in that list. (**NOTE**: Beryllium is listed in Priority 2 of the Priority List of Substances based on reduction of the TLV in 2009 from 0.0002 mg/M3 – “total” particulate, to 0.00005 mg/M3 – inhalable particulate. Effective 2006, the Cal/OSHA PEL was reduced 10-fold to 0.0002 mg/M3 – “total” particulate in response to a 1999 proposed change of the TLV to this value. The rulemaking documents for this change can be viewed at <http://www.dir.ca.gov/oshsb/airbornecontaminants2005.html> )

Howard Spielman asked about hydroquinone shown on the Substance Status List. He questioned whether there was much use or employee exposure in California. Bob Barish said when he had looked at this he saw the main use had been in x-ray film processing, although that process may today be mostly or completely digital. Steve Derman said there is very little processing of x-ray film anymore. No decision was made to remove it from the work list so the Division will look again at its usage and workplace exposure potential in California.

Mike Cooper said he thought that isopropyl alcohol should be deleted from the Substance Status List and not carried forward into the next round of PEL work. Bob Barish said the lowering of the TLV from 400 ppm TWA/500 ppm STEL to 200 ppm TWA/400 STEL was not dramatic, but that it is a widely used substance. Barbara Kanegsberg said it should be retained for work in the next round as it is widely used in controlled industrial environments. Howard Spielman echoed this view. Deborah Gold said it is commonly found in paints and other products. Dorothy Wigmore said it is widely used as a disinfectant. Bob Barish said it sounded like there was mostly agreement that it should be looked into further. Mike Cooper said he thought it might be more of a community exposure concern and that his point wasn’t that it shouldn’t be considered but rather that there were probably more important substances to work on first. Will Forest expressed agreement with this.

Summarizing the discussion, Deborah Gold said it sounded like there was general agreement to continue to keep vanadium pentoxide on the active work list, and for the Division to look further and decide on the priority of continuing work on hydroquinone and isopropyl alcohol.

Catherine Porter said she strongly recommended keeping phthalates on the list for active work. Bob Barish asked if her concern was with all four of the phthalates that had been noted in the OEHHA (2007) report on PELs, or primarily on the two that appeared to be most prevalent in industry, dibutyl phthalate, and di-(2-ethylhexyl) phthalate? Virginia St. Jean said that in her hazardous materials inspections in San Francisco she was seeing more phthalates present in paints in auto body shops. Julia Quint noted there are other phthalates on the Proposition 65 list besides those noted in the OEHHA (2007) report. She said that usage of particular phthalates is changing over time. Bob Barish asked her to send him information on what she thought were the most important phthalates to take up for PELs in the next round of work.

 [**NOTE**: The OEHHA (2007) report referred to can be viewed at <http://www.cdph.ca.gov/programs/hesis/Documents/riskreport.pdf> ]

Howard Spielman noted for substances with low vapor pressure such as phthalates there needs to be an evaluation of how it is used to determine if it is even possible for it to be inhaled. For example, is it used in a heated operation, is dust generated, etc. He said if the chemical is not in its natural state and you don’t know how it is being used then it’s possible it may not be an occupational hazard.

Deborah Gold acknowledged the importance of considering how hazardous substances are used. She noted that, for example, spraying of isocyanates with low vapor pressures can generate hazardous exposures.

Also with regard to the active Substance Status List, Virginia St. Jean asked about polyvinyl chloride (PVC) dust. Bob Barish said HEAC member Linda Morse had been working on this substance and he thought that she was close to being finished with her data review and assessment write-up. He said he thought this substance should continue in the next round of work.

Concluding the discussion of which substances from the Status List should be carried over for more work, Deborah Gold encouraged those present to send information to Bob Barish by the end of July. She said the Division was especially interested in information that might be provided on use and workplace exposure potential of any of the substances being discussed. She also noted that although the Division has not be able to hire a toxicologist or other technical personnel to augment the PEL project, some help is being arranged and more may be possible from among other existing staff and new hires.

Susan Ripple said new hazards have developed or been more fully characterized since the Priority list was developed for HEAC in 2007. As an example she cited use of n-propyl bromide (1-bromopropane) in dry cleaning and in parts cleaning operations. She said that NIOSH had a project on this substance and she noted that it is not on the current Priority List of substances for PEL work. [**NOTE:** A new Cal/OSHA PEL for 1-bromopropane of 5 ppm took effect August 3, 2010. The rulemaking documents for this change can be viewed at <http://www.dir.ca.gov/oshsb/airborne_contaminants09.html> . Since 2010 ACGIH has had pending a proposed reduction in its TLV for this substance to 0.1 ppm.]

Susan Ripple said she also wanted to suggest consideration of *ortho*-phthalaldehyde (OPA), which is marketed and sold as an alternative to glutaraldehyde. She said there have been reports of anaphylactic shock from exposure to this substance.

Deborah Gold noted the problem highlighted in Green Chemistry discussions of substances intended as substitutes for chemicals of concern presenting new hazards. She encouraged everyone to send information on substances they may be concerned with to Bob Barish by the end of July if possible.

Julia Quint noted the HESIS work she had been involved with on the Cal/OSHA PEL for 1-bromopropane. She said it was important that this chemical, and n-methyl pyrrolidone (NMP) that she had worked in on the HEAC were both examples of developing hazards with increasing usage and frequency of worker exposure. Deborah Gold noted that the rulemaking package for NMP is close to being sent to the Cal/OSHA Standards Board. She reiterated the importance of providing information to the Cal/OSHA PEL project on substance usage and worker exposure potential in California.

### Discussion of the PEL Advisory Process

Deborah Gold moved onto discussion of the process of the HEAC. She said that at the December 2011 meeting she had talked about a change in the practice of HEAC members developing the draft health assessment documents for substances under discussion. She said that what is indicated as the process on page 5 of the Policy & Procedure for the PEL Advisory Committee Process is that it would be the Division, rather than HEAC members, developing the health assessment documents for comment and discussion in the meetings. She acknowledged that since the HEAC started its work members had decided they wanted to develop these assessment document themselves and went ahead and did that. She said she wanted to go back to the approach envisioned in the Policy & Procedure document with the Division developing the assessment documents, with an emphasis on the major reviews and recommendations of governmental and other organizational bodies such as ACGIH. She said the Division would post the assessment documents on the website before the meetings and that the discussion would focus on comments on the choice of studies focused on by the Division and their interpretation in developing an initial PEL recommendation. She said this approach would be consistent with the Policy & Procedure document.

Susan Ripple asked if this approach would have the Division doing the search of the scientific literature rather than HEAC members themselves. Deborah Gold said yes, the Division would prepare a document summarizing key information, especially credible assessments by other agencies and organizations and their underlying scientific studies. She said in her experience there are usually a handful of the same studies that are cited by most of the organizational assessments and these would generally be the focus of the Division’s assessment document which HEAC members would then be asked to review and comment on.

Steve Derman expressed concern with respect to the Division’s capacity to conduct a sufficiently comprehensive search of the scientific literature for each substance. He noted that Susan Ripple had said she had 800 studies to review for her assessment of ethyl alcohol which she is still working on.

Deborah Gold responded to Steve Derman that for some substances a large number of studies would have to be reviewed, but that often they are repetitive or similar in nature. She said that reviewing every study that could be found on a substance would not be the threshold for making a recommendation for a new or revised PEL. She said the Division would survey the literature and bring to the HEAC an initial recommendation based on what appeared to be the most important study or studies. And the purpose of the advisory process would be for the Division to receive comments on the studies it suggests as the basis for the recommendation and how the data in those studies was interpreted to reach that recommendation.

Susan Ripple said that it would be important for the Division to at least review the abstracts of the latest studies since more information is always coming out. She also asked that the Division stop short of making the health-based recommendation for a new or revised PEL. She suggested as an alternative that the Division bring multiple possible recommendations to the discussion and have the committee discuss them and come up with their recommendation from among those or another value. She was concerned that a single recommended value could prejudice the committee’s eventual recommendation.

Deborah Gold said the Division will ultimately have to be the one to decide on the health-based recommendation. She said she wanted the Division to bring to the meetings the calculated values based on exposure adjustments for each study and not to have that type of calculation being done in the meeting.

Julia Quint said that it would be important for transparency for the process to operate consistently, for example with consistent application of uncertainty factors as was a point of discussion in the current and last round of PEL advisory meetings. Deborah Gold acknowledged the comment but noted that application of uncertainty factors can always be a point of disagreement. She noted the example of thalidomide which appeared safe in animal studies but when used by humans caused birth defects.

Mike Cooper asked if the Division will make available to the committee the full text of studies it relies on for its recommendations. He noted that he and some others on the HEAC had paid fees to obtain some articles. Deborah Gold said that copyright restrictions had to be respected and so studies not otherwise freely available on the Internet could not be posted on the project website. She said abstracts could always be made available and that full text would be provided to the extent reasonably possible.

Dan Leacox said the approach of the Division making the initial PEL recommendation would be a deviation from the Policy & Procedure. He noted the following language on the first page of the Policy & Procedure document:

A health expert advisory committee (HEAC) will be used to review the scientific literature and, where it deems there is sufficient scientific evidence, recommend a new or revised PEL to protect the health of employees.

Ellen Widess said that procedure would be followed, with the Division laying the scientific foundation that the HEAC can then comment on and suggest additions to.

Dan Leacox said that approach would never provide the same level of transparency as the process of HEAC members themselves developing the draft assessment documents and initial PEL recommendation.

Deborah Gold said that the HEAC will have full opportunity to comment on the Division’s assessment and initial recommendation. However she said that consensus of the committee while desirable if it could be achieved was not a requirement for a health-based recommendation. She reiterated her view that it was generous of HEAC members since 2007 to take up the slack of developing the draft assessment documents and initial PEL recommendations that the Division may not have been in a position to do then, but that approach is not consistent with the Policy & Procedure document which envisioned the Division doing that work.

Will Forest said he didn’t see much real difference in the process of individual HEAC members developing the assessment documents and initial recommendations as has been done since 2007, or the Division doing that work and the HEAC commenting on it. Julia Quint said it is the job of the Division to develop the PEL proposal for the Cal/OSHA Standards Board, and the process being discussed will have the HEAC commenting on the development of that proposal.

Deborah Gold asked Dan Leacox if he was recommending to stay with the process of the assessment documents being drafted by individual HEAC members rather than the Division. Dan Leacox said he was concerned that what Deborah Gold was proposing was use of other agencies’ risk assessments, rather than the Division doing its own quantitative risk assessments.

Deborah Gold said for each of the key studies the Division will show the calculation of the PEL the results suggest, for example based on the NOAEL and/or LOAEL found in the study, and the committee will have an opportunity to comment on that entire process.She said this approach would be more transparent than that used by ACGIH where the basis for using a particular study or set of studies to support a particular TLV is not always clear in the Documentation.

### Conflict of interest

Fran Schreiberg said in her comment letter on the HEAC process that she had requested additions to the conflict of interest statement for HEAC and FAC members contained in the current Policy & Procedure document. She noted also that the Labor Code does not require a consensus for the Division to make a recommendation to the Standards Board. She said that lack of consensus was often put up as a roadblock to rulemaking, including on PELs. She said she supported the Division developing a health-based PEL proposal separate from consideration of feasibility. But she said especially with the difficulty of getting labor representatives to the meetings she suggested that the discussion of health and feasibility be combined into one meeting. Howard Spielman said he thought they should be separate meetings and discussions.

Deborah Gold said she agreed with the comment that the Policy & Procedure document isn’t sufficiently detailed on the matter of conflict of interest of HEAC and FAC members. She said it had been discussed in the HEAC meetings, along with questions of lead time for distribution of items for discussion at meetings, comment submissions by interested parties and their presentations in meetings.

Ellen Widess said it is the Division’s responsibility to make recommendations to the Standards Board for PEL proposals, with consideration of the advisory meeting discussion and other comments submitted in that process. She said with the Division developing the health assessment documents the process should move more quickly and efficiently and by reducing the work expected of HEAC members could help attract and retain new participants.

Fran Schreiberg said dealing with potential conflicts of interest of committee members should be more clearly addressed in the Policy & Procedure document. Howard Spielman noted page 4 of the Policy & Procedure states that HEAC members are expected to disclose organizational affliations that might be a source of bias. Fran Schreiberg said she felt the existing statement was watered down from what she had suggested when the Policy & Procedure was being developed and asked that her approach be considered for the next round of HEAC work.

Dorothy Wigmore said the process for addressing possible conflicts of interest of advisory committee members proposed by Fran Schreiberg is consistent with that used by other agencies. She said that to prevent conflict of interest committee members should recuse themselves from discussions where it could be an issue.

Deborah Gold noted that advisory committees are not decision-making bodies like the Standards Board and so its members are not subject to the disclosure requirements of Board members and some Cal/OSHA personnel.

Ellen Widess said she would have DOSH Special Counsel Suzanne Marria review the matter, including the language previously suggested by Fran Schreiberg. Susan Ripple said care should be taken in addressing conflict of interest to avoid unwarranted exclusion of qualified participants from being HEAC or FAC members. She said that she pays her own way to the meetings, and believes everyone has some level of potential bias.

Chris Laszcz-Davis said we’re all advocates for workers with the same goal of protecting their health. She said the issue of conflict of interest is really a matter of trust. She suggested the only way to judge the process is to try it and see how it works. Howard Spielman said he was concerned with too much focus on conflict of interest preventing participation by some with important expertise. He said he had seen the concern go too far at times, for example, prohibiting or discounting consideration of industry sponsored studies.

Deborah Gold said it’s important to distinguish between advice-giving and decision-making. The Division is going to bring information to the committee of experts and ask for input on that, its value as scientific evidence for a new or changed PEL. The Division always needs the advice of experts close to the actual problem in the workplace, from both labor and industry. She said the opportunity to comment to the Standards Board in the formal rulemaking process would always provide an opportunity for input into any PEL changes. And conflict of interest policies for advisory committee members do not restrict anyone from commenting to the Division during the advisory phase of the process. She noted that advisory meeting minutes are part of the rulemaking package and reflect the discussion, including disagreements with the Division.

### Other aspects of the Policy & Procedure for the HEAC and FAC

Catherine Porter expressed concern with a consensus approach given the time it can take. Judi Freyman thanked Deborah Gold for the discussion going through the Policy & Procedure document and clarifying some of the issues. She echoed the comment of Chris Laszcz-Davis that she and her constituents wanted to give a chance to what was being discussed and see how it works with the Division developing the assessment documents, to see if it can make the process more efficient than it has been.

Steve Derman took exception to the suggestion that only certain groups represented in the meeting should be viewed as being advocates for workers. He said that the codes of ethics of the major safety and industrial hygiene professional organizations provide that their members must be advocates for worker protection.

Barbara Kanegsberg said she hoped the HEAC and FAC processes would remain with separate meetings. She suggested the FAC process might be expedited by working more actively to include its members in the HEAC process, so that they could start thinking early on about feasibility and cost issues given the levels being discussed in the HEAC. Howard Spielman said that FAC members’ review of the meeting minutes and draft assessment documents as they develop already provides for such “early warning” to FAC members.

Deborah Gold said these comments on the FAC did not address the concern of Fran Schreiberg regarding the resources of labor representatives to participate fully in both processes. She said she thought the HEAC and FAC processes should remain separate so that each gets full consideration, and also so FAC members and anyone else wanting to comment on feasibility doesn’t have to sit through an entire HEAC meeting unrelated to their particular interest. She was also concerned that possible issues with an air sampling method being sensitive enough to detect below the recommended PEL not inhibit the HEAC discussion because, for example, if the air limit of detection is above the PEL but less than 10 times the PEL it can still inform the choice of respiratory protection which is important for worker protection.

### Planning for the next round of PELs advisory work

Moving onto planning for the next round of meetings, Deborah Gold asked if current HEAC and FAC members present are interested in continuing on in that role. She noted from the HEAC originally assembled in 2007 the expertise of current members is predominantly industrial hygiene. So she hoped in addition to current members letting the Division know if they wanted to participate in the next round of meetings, that nominations would be made particularly for individuals from the other disciplines mentioned in the Policy & Procedure document, ie. toxicology, epidemiology, and occupational medicine, as well as industrial hygiene. She anticipated having three or four meetings of the HEAC per year.

Deborah Gold said that the job of the HEAC would be to review the materials and recommendations assembled by the Division as has been discussed, and then provide suggestions. She asked all present to send to Bob Barish their own interest to be a committee member or to nominate someone else, preferably by the end of June.

Mike Cooper said one area of expertise that has been missing from the FAC is for economic analysis. Dan Leacox noted that the FAC had started out with an economist and he didn’t know why that individual decided not to participate after the first meeting. Deborah Gold said that the economic analysis of the effect of a new or revised PEL can be daunting. She noted that Federal OSHA has economists of staff, or otherwise available to them, and their analyses can be very extensive. Jim Unmack suggested that with the amount of work it can involve the Division should have an economist on staff. Deborah Gold said unfortunately in the current environment there was little chance of hiring an economist. She asked anyone present who might know an individual with expertise in relevant economic analysis and possible interest in being a member of the FAC, for example a public health economist, to please forward their name to Bob Barish.

Deborah Gold concluded the morning meeting noting that she hoped the HEAC and FAC could be well-balanced both in terms of having a good mix of expertise as well as active involvement of the various stakeholder groups that are interested in PELs.

## LUNCH BREAK

The meeting resumed after lunch at 1:15 p.m. There were questions about the timeframe for announcing the new committee memberships. Bob Barish said he thought it should be around the end of August.

### Trimellitic anhydride

Bob Barish started the discussion of trimellitic anhydride (TMA) noting a correction in the latest draft health assessment document posted to the project website. He said the OSHA air sampling method’s reliable limit of quantitation shown on page 4 of the document should be changed to 0.299 ug/M3 as listed in OSHA Method 98, from the 0.229 value shown. He said that the posted draft document is a revision of what Patrick Owens had passed out and discussed at the December 2011 HEAC meeting. Bob Barish said he recognized that the ACGIH STEL value recommended in the draft document was lower than might be capable of being detected by the OSHA air sampling method, but he said that question would be put to the side for now to focus today on discussion of the health assessment.

Patrick Owens said he had added some additional discussion of the Grammer (1999) paper to the draft assessment document since the December 2011 meeting. Bob Barish said the Grammer study was one of a series conducted by researchers from the Northwestern University medical center in Chicago, near a Joliet, Illinois plant that manufactures trimellitic anhydride. The researchers at Northwestern had worked with the previous owner of the plant, Amoco, until the early 2000’s when the plant was purchased by Flint Hills Resources. Bob Barish noted that three health and safety personnel from Flint Hills Resources were present to discuss their industrial hygiene and medical surveillance programs for trimellitic anhydride: Mario Vasquez, Corporate Industrial Hygiene Manager, and from the Joliet plant Joe Chandler, Health and Safety Manager, and Gokol Bose, Senior Environmental Engineer and Industrial Hygienist. Bob Barish noted that in the week before the meeting Flint Hills Resources had sent him a set of comments on TMA that was included as a handout for the meeting.

The comments from Flint Hills Resources comment can be viewed by clicking on the icon: 

 Mario Vasquez said his company’s Joliet plant was the only site of TMA manufacturing in the United States. He said, as noted in the handout, that TMA is widely used as a specialized plasticizer, for example, in the manufacture of residential and commercial wiring insulation. He said that in addition to the production of the Joliet plant, substantial quantities of TMA are also imported into the United States. He said the interest of his company is to share the approach they use at the Joliet plant to control the hazard presented by exposure to TMA. He said that the key factor in protection of workers exposed to TMA is not the occupational exposure limit such as a PEL or TLV but rather a comprehensive medical program as they operate, along with a comprehensive industrial hygiene program to minimize exposures. He said that the company’s view is that TMA is an acutely toxic material, a respiratory sensitizer, and so their internal guidance value for exposure control is a ceiling limit of 0.02 mg/M3 measured as inhalable particulate. Reiterating what is stated in the handout, he said that just a lowered PEL value without a complete program including medical surveillance, and specifics on such items as exposure control and personal protective equipment, would not fully address the risk presented. He said the focus of the medical surveillance program is surveillance for development of an immune system response to exposure. He said he felt there were questions about the full-shift sampling data of the Grammer (1999) paper cited as one of the central studies for the TLV, and also suggested as the most key paper in the draft health assessment document for a revised Cal/OSHA PEL.

Dennis Shusterman acknowledged the importance of medical surveillance to control risk from exposure to a sensitizing substance such as TMA. He passed out an abstract of a 1983 study of eighteen workers exposed to TMA and said its results suggest that a PEL Ceiling value of 0.02 mg/M3 may not be fully protective. [The 1983 study referred to is by Bernstein, D.I., et al. and the abstract can be viewed at <http://www.ncbi.nlm.nih.gov/pubmed/6643875> ] . He noted the study found that with exposures in the range of and somewhat below 0.02 mg/M3 (shift-long average) one of the 18 workers continued to experience TMA rhinitis and a rise in specific IgE antibody. He said that this finding supported the need for an 8-hour TWA PEL as well as a STEL.

Mario Vasquez acknowledged that by itself the 0.02 mg/M3 value they use for internal control may not be fully protective for the effects of TMA. But he said that in conjunction with the medical surveillance program and a comprehensive industrial hygiene program they have not seen adverse health effects among employees exposed to TMA**.** Joe Chandler said the 0.02 mg/M3 value is at the limit of what they can reliably measure in air on a short-term basis.

Mario Vasquez said the purpose of his group’s participating in the meeting was not to advocate for a particular PEL value for TMA but rather to emphasize the importance of a comprehensive risk control program including medical surveillance.

Bob Barish asked how the Flint Hills Resources medical surveillance program for TMA works. For example, what is the basis for removing an employee from exposure to TMA? Joe Chandler said the program starts with pre-screening of employees to be assigned to certain tasks involving TMA exposure and then on-going medical screening, primarily immune system surveillance with an annualblood test.

Gokul Bose said their medical surveillance program is carried out under the supervision of Jonathan Bernstein, a physician faculty member of allergy and immunology at the University of Cincinnati medical center. He said that blood tests are done annually, or more frequently for employees in certain processes. Bob Barish asked if there are specified criteria with respect to actions taken in response to the blood test results. Gokul Bose said that medical decisions such as removal from TMA exposure are made by Dr. Bernstein based on the totality of his medical judgment with respect to each employee. Bob Barish asked if there are any written criteria for removal or other actions under the medical surveillance program. Gokul Bose reiterated that it is strictly up to the judgment of Dr. Bernstein.

Steve Smith summarized the discussion, saying it sounded like the main message being brought to the meeting by the attendees from Flint Hills Resources is that for TMA a PEL should not stand by itself but rather there also needs to be a full industrial hygiene and risk control program. He noted that in the latter part of the 2000s there had been several advisory meetings discussing a standard specifically for sensitizing substances, including medical surveillance. He said that that there are already examples of Cal/OSHA regulations that address medical surveillance for sensitizing substances.

For example, he noted that the medical surveillance component of the Federal OSHA formaldehyde standard also adopted by Cal/OSHA (Title 8 section 5217) addresses sensitization. He said also that a footnote to the table of PELs in section 5155 addresses risk of sensitization from exposure to glutaraldehyde, and notes that hazard communication training for this substance must address the measures taken by the employer to evaluate and control the risk of exposure including medical evaluations. He concluded that while work on the PEL for TMA would go forward as a needed component of risk control, consideration would also be given to development of an approach possibly like that taken for glutaraldehyde, or maybe along the lines of the medical program that had been discussed in the advisory meetings on sensitizing substances.

Bob Barish asked if Dr. Bernstein at Cincinnati would be the source to contact for more information on the Flint Hills Resources medical surveillance program for TMA. Joe Chandler said he could try to address questions to Dr. Bernstein at least as a starting point for discussion.

Howard Spielman noting that Flint Hills Resources is a manufacturer of TMA suggested it sounds like they are taking a
“best available control technology” or “as low as reasonably achievable” approach to controlling exposures, with the 0.02 mg/M3 internal limit as a guideline. Joe Chandler responded there are some areas where they mandate use of powered air-purifying respirators. Bob Barish asked if they have customers in California buying TMA. Joe Chandler said he did not know if they ship TMA to customer locations in California.

There was discussion of the internal limit of 0.02 mg/M3 ceiling inhalable used by Flint Hills Resources, respirator assignment related to this exposure level, and whether exceedances of this limit had been found to be associated with health effects. Dawn Koepke accompanying the Flint Hills Resources attendees said they hadn’t seen any health effects at this level of exposure. But Mario Vasquez noted they were not attending to promote the 0.02 value as the lowest PEL or any other number, reiterating that they were there to describe their program and experience and emphasize the importance of the total program beyond just a particular Devalue. Dawn Koepke said part of their concern with advocating on any particular PEL value separate from a comprehensive program including medical surveillance is that they not contribute to a false sense of security a PEL by itself might convey.

Will Forest said it sounded like the 0.02 mg/M3 (ceiling) internal exposure guideline used by Flint Hills Resources could be viewed as something close to a Lowest Observed Adverse Effect Level (LOAEL). He said he could support the TLV STEL of 0.002 mg/M3 based on a factor of 10 for extrapolating from a LOAEL value.

Bob Barish asked committee members and attendees if based on this and the health effects studies discussed if there was support for the health-based recommendation of the committee to be at the level of the ACGIH TLV (0.00005 mg/M3 TWA, 0.002 mg/M3 STEL, both as inhalable particulate). There was no objection to this. Dorothy Wigmore asked if there would be consideration of a Skin notation. Bob Barish said the TLV includes a Skin notation and he anticipated the PEL would as well. There were no objections to this. At the suggestion of Susan Ripple HEAC support was also expressed for inclusion of at least a footnote to the PEL, as was done for glutaraldehyde, which would include its identification as a respiratory sensitizer. NOTE: The TLV Documentation for TMA cites an animal study indicating that it may also be a skin sensitizer.

### Aluminum welding fume

Bob Barish moved the discussion on to aluminum welding fume. James Simonelli askedif the discussion of aluminum in the HEAC was now limited just to consideration of a PEL for welding fume. Bob Barish said it was decided at the last meeting in December 2011 to focus for the moment on welding fume and that other forms of aluminum may be taken up later. He said the current PEL for aluminum welding fume in section 5155 is an 8-hour TWA of 5 mg/M3 total particulate.

Bob Barish said that Jim Unmack has revised his write-up to focus on aluminum welding and that it was posted at the website for this meeting.

Jim Unmack started by saying he thought the PEL, whatever it was revised to, could continue to be based on total particulate which is easier to sample than respirable particulate, because welding fume consists of only small particles. Patrick Owens suggested though that during welding workers may also be exposed to larger particles, for example from grinding and other operations. Jim Unmack said that his research had suggested that larger particles could be respiratory irritants, but probably would not present a risk of neurotoxicity as has been one of the concerns with welding fume. Jim Unmack suggested that when sources other than welding are also present, then it would be prudent to sample for welding fume using a respirable particulate sampler.

Jim Unmack reviewed some of the research in his assessment document. He said that one study of welders, Ellinder et al. (1991), had found that aluminum can accumulate in the body, including in the bone with longterm exposure and that subtle neurological effects were detected with the long term longitudinal study. He said such effects were not seen in cross sectional studies nor in short term (4 year) longitudinal studies. Jim Unmack reported that the study of Buchta et al. (2003) with a median respirable dust exposure near 0.5 mg/M3 had looked at a number of neurological parameters over a 4-year period and found no significant differences between welders and non-welders. That study did report a relationship between reaction time and urinary aluminum level, but noted the presence of confounding factors. Mike Cooper questioned the significance of the reaction time finding if it was the only adverse effect indicated in a battery of neurological tests. Paul Papenek supported looking into this further. Jim Unmack noted that Russian

toxicologists used increased reaction time as the most sensitive indicator of a toxic effect. So it was not clear from this study if the 0.5 mg/M3 respirable particulate should be regarded as a NOAEL or a LOAEL from which a PEL might be derived. Jim Unmack noted that the follow-on study to Buchta et al. (2003) by the same research group had not found any neurological effects [Kiesswetter et al. (2009)]. [NOTE: In the 2009 study exposure had been measured in terms of total particulate with the air sampling media positioned outside of the welding helmets which in this study were reportedly ventilated with forced air.]

Although uncertainty remained there was some agreement that the median exposures in the range of 0.5 mg/M3 in the Buchta et al. (2003) study could be viewed as representing a NOAEL or a LOAEL from which a PEL might be derived. Will Forest said that if this is a LOAEL value then the PEL should be set below the 0.5 mg/M3 respirable level reported. Susan Ripple said that based on what had been presented a PEL for aluminum welding fume in the range of 0.5 mg/M3 could be appropriate.

There was general agreement that there should be more research to clarify the points of uncertainty brought out in the discussion.

### Bisphenol A

Bob Barish noted that Pam Dannenberg from the California State Association of Occupational Health Nurses had joined the meeting. She signed the letter on bisphenol A (BPA) included as one of the handouts for the meeting.

Bob Barish said it was his understanding that the current status of BPA under Proposition 65 is that in July 2009 it had been voted down for listing under the Qualified Experts mechanism by the Proposition 65 Developmental and Reproductive Toxicant Identification Committee. But on the same day of the Committee vote a petition was received from the Natural Resources Defense Council (NRDC) for BPA to be listed as a reproductive toxicant under the “authoritative bodies” listing mechanism in light of a 2008 report from NTP-CERHR (National Toxicology Program – Center for Evaluation of Risks to Human Reproduction). The NRDC petition and additional information can be viewed at this OEHHA website: <http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/requests_info/callinBPA021210.html> .

Bob Barish said that given the extent of the controversies and disagreements around the level of reproductive risk presented by BPA, and the limited toxicology resources available to the Division, he was not sure how this would be approached as far as developing a PEL. He suggested that because BPA is a relatively non-volatile substance it might be reasonable to adopt a requirement for skin protection initially without an airborne PEL. Susan Ripple opposed this, saying it could be viewed by some as suggesting that BPA was not hazardous with inhalation. She said it was her understanding that the ACGIH TLV Committee had recently discussed BPA but decided there was not enough data even to include it on its Under Study list.

Dennis Shusterman said that HESIS had included BPA on its March 2011 Chemical Watch List for emerging chemical hazards in the workplace. The HESIS Chemical Watch List can be viewed at:

<http://www.cdph.ca.gov/programs/hesis/Documents/ChemWatchList2011.pdf>

### Wrap up

Dennis Shusterman asked who was going to be working on hydrogen sulfide going forward. He said he would be happy to help with the write-up. Mike Cooper said he would be happy to have Dr. Shusterman’s help with it.

Bob Barish said that as indicated by Deborah Gold the plan was to reconvene for the start of a new round of PEL advisory work in the fall. He thanked everyone for attending the meeting and for their participation in the HEAC since 2007.

**END**