DRAFT MEETING SUMMARY

Advisory Meeting on Development of Permissible Exposure Limits in California Code of Regulations Title 8 Section 5155

Friday June 9, 2006
Elihu Harris State Building
1515 Clay Street
Oakland, California

Attendees

Heather Borman, State Compensation Insurance Fund
Michael Boyle, Bimbo Bakeries U.S.A.
James Bresnahan, Bricklayers and Allied Craftworkers Local 3
Paul Brownson, Dow Chemical Company
Juli Broyles, California Chamber of Commerce
John Chrysler, Masonry Institute of America
Gary Davis, American Composites Manufacturers Association
Steve Derman, MediShare
Michael End, Aerojet
Judi Freyman, Organization Resources Counselors
Greg Gorder, Technology Science Group
Diana Graham, Keller & Heckman LLP
Roseanne Harding, California Dental Association
Sara Hoover, Office of Environmental Health Hazard Assessment
Jamie Khan, Associated General Contractors
Jim Kegebein, Niomala Kouvali, Scios, Inc.
Dan Leacox, Greenberg Traurig,
Etta Mason, Southern California Edison
Marcie McClean
Chuca Meyer, Pillsbury Winthrop
Richard Morford, EnviroTech International
Julia Quint, HESIS
Susan Ripple, Dow Chemical Company
Jason Schmelzer, California Manufacturing and Technology Association
Fran Schreiberg, WorkSafe
Andrea Setterholm, Latham Watkins LLP
Jeremy Smith, California Labor Federation
Jack Snyder, Styrene Institute and Research Center
Howard Spielman, California Industrial Hygiene Council
Mark Stelljes, SLR International
Elizabeth Treanor, Phylmar Regulatory Roundtable
Vickie Wells, San Francisco Department of Public Health

2001-2004 PEL Advisory Committee Members in Attendance

Patty Quinlan, Industrial hygienist, University of California San Francisco, (Committee member since 1993)
Michael Cooper, Vishay Siliconix (Committee member since 2001)
Craig Steinmaus, Occupational medicine physician, UC Berkeley (Committee member since 2001)

Cal/OSHA Staff

Len Welsh, Acting Chief, DOSH
Steve Smith, Supervising Industrial Hygienist, DOSH
Tom Mitchell, Senior Industrial Hygienist, Cal/OSHA Standards Board

Bob Barish, Senior Industrial Hygienist, DOSH
Deborah Gold, Senior Safety Engineer, DOSH

Summary of Major Discussion Items

Len Welsh said the Division is trying to rethink and resinstitutionalize the PEL development process. The focus is on greater transparency through increased stakeholder involvement and documentation of advisory committee discussions and recommendations.

It was generally agreed that, especially in light of many substances requiring discussion at more than one PEL advisory committee meeting, that by-substance summaries of the meeting discussions, including stakeholder comments, and documentation of the rationale for any recommendations should be prepared, in addition to minutes for each meeting as was done previously. Where appropriate, the documentation would include discussion and rationale for different possible PELs and differing recommendations if there was not consensus.

There was general agreement among attendees, consistent with Labor Code 144.6, that PEL development will be a two-phase process: starting with work on recommended health-based levels using of the PEL advisory committee process and then a separate process for gathering information on possible costs and feasibility issue. There was general agreement that it should be feasible to have a core group of experts for the health committee, as has been the past practice. But that an effective standing committee on feasibility might be more difficult, as the source of most of the information will be interested industry stakeholders. The Division may determine to supplement or replace the 2 step advisory process with a substance-specific advisory processes for some controversial substances. However, the Division will try to use the 2 part process and the accompanying procedures for as many substances as possible.

Concern was expressed by representatives of the California Chamber of Commerce and the California Manufacturers and Technology Association that recommendations of the health committee not be based on a vote of committee members, but rather that the committee meetings serve as a forum for stakeholder comments and discussion. A labor representative felt that without voting the committee could always be overwhelmed by stakeholders. She also said that the idea of "balance" on the PEL advisory committee is unrealistic because labor does not have the technical experts to provide, so most would come from industry and academia. Len Welsh said that the hope was to strive for consensus where possible among the experts, with input from stakeholders, and where it was not, to document the various arguments and positions for the Division and the Board to evaluate.

Two points generally agreed on were that the workload previously taken on by committee members to identify, obtain, and evaluate the scientific literature should be carried to a greater extent than in the past by staff (primarily DOSH with assistance of HESIS, DHS, OEHHA, other government sources), and that the primary task of the expert advisory committee should be to weigh the evidence and stakeholder comments and try to develop a consensus recommendation where possible, or make a recommendation and note and respond to stakeholder disagreements where consensus is not possible.

Meeting Summary

Len Welsh welcomed meeting attendees and offered his view that this meeting was a good example how an agency working with the public can be good for both the quality and the transparency of government decision-making. He said that the Division's PEL development process had operated for many years without controversy until 2004 when a Governor's Executive Order required all agencies to review their regulations and rulemaking processes to assure compliance with the Administrative Procedures Act. The result of that assessment, and stakeholder comments, was that while many PELs being developed by the Division were non-controversial, some were. He said that glutaraldehyde was the first example of the Division addressing a controversial substance with additional stakeholder meetings.

Len Welsh concluded his introductory remarks by saying that the Division is trying to rethink and reinstitutionalize the PEL development process as something that can be more easily understood and supported by all stakeholders.

He said a major issue discussed at the last meeting on December 12, 2005 was how to maximize development of groups of PELs simultaneously where possible in the interest of efficiency, and how to recognize early-on when a substance would need to be separated out for its own advisory process. Len Welsh said that since the December 12 meeting he had come to recognize more clearly the value of continuing to make use of an outside advisory committee of experts to assist the Division with the technical issues related to the health risk assessment of airborne contaminants. He said the key to this advisory process being successful going forward would be to have greater stakeholder involvement and a clearer record for the Standards Board of the committee's deliberations and stakeholder comments to accompany its PEL proposals.

Meeting attendees introduced themselves.

Len Welsh asked if there were any comments on the draft minutes for the December 12, 2005 meeting posted at the Division's PEL advisory process webpage. There were none.

Len Welsh continued that it was important to come to closure at this meeting, or very soon, on the process the Division should use going forward for PEL development, in order to avoid the potential for the legislature to impose its own process. He said that any process the Division develops should be driven by stakeholder involvement, but that the Division would be the final decision-maker with respect to what proposals are sent to the Standards Board for possible adoption as regulation. He said he hoped the day's discussion could produce agreements among the various parties present that could be reflected in minutes of the meeting with only minimal follow-on discussions being required.

He said that the outline of the process for PEL development with stakeholder involvement contained in the draft document had been circulated for comment as a start to institutionalizing the Division's PEL development process of using a core group of experts for advice as has been done since the early 1980s. He said that with the language of Labor Code section 144.6, the PEL development process essentially consists of two phases, identification of exposure levels appropriate for worker protection and then consideration of feasibility. He emphasized that these are two essential but different issues that need to be addressed by the Division's process, and that he believed they should be kept as separate processes. He said that while the health risk assessment primarily uses published scientific information, the feasibility assessment inevitably makes use of industry information on costs and technical issues. He noted that both considerations involve uncertainty and at times substantial differences of opinion and controversy.

Len Welsh said that he envisioned the PEL advisory committee consisting of at-large generalist experts pertinent to chemical health hazard assessment, experts who are close to the relevant science though not necessarily any particular substance. He said the key was that the committee be balanced in order to avoid actual bias or appearance of bias in the process of developing recommendations for proposed PELs. Stakeholder involvement, comments, questioning etc. will also contribute greatly to assuring that issues that could develop are addressed informally at the level of the advisory committee rather than arising only in the Standards Board's formal rulemaking process.

Len Welsh said that after developing a health-based recommendation, the process is intended to address an assessment of economic impact and feasibility. He said that this process by its nature is more likely to involve primarily stakeholders, as it will be difficult to identify a group of experts to sit as a core ongoing committee on feasibility. This is because the cost information and feasibility assessment for each substance is more likely to be industry-specific than is the assessment of health risk.

Juli Broyles expressed concern that the science of the health assessment component not get ahead of what is practical for employers to accomplish, as can happen in corporations as well as government. She also expressed concern with PEL proposals being developed without stakeholder involvement. Len Welsh reiterated that a major part of the reason for updating the PEL development process was to ensure the opportunity for greater stakeholder involvement in the process.

Juli Broyles suggested that establishing the PEL advisory committee of outside experts as a voting body on proposals could be viewed as exceeding the Division's authority. Len Welsh responded that in the past some committee's convened by the Division have voted, but more and more what is strived for is consensus. He emphasized that it will be the Division which makes the decision on going forward with a PEL proposal and at what level. He said that the Division cannot abdicate to the PEL advisory committee the responsibility for deciding what proposals go to the Standards Board.

With regard to the functioning of the PEL expert advisory committee Len Welsh made the following points:

1. Staff (eg. primarily DOSH along with assistance from HESIS, DHS, and possibly OEHHA) would be performing the essential staff work of gathering information, and possibly generating initial proposals for the committee to consider. He said that unlike in the past, he did not want committee members to be the primary source for gathering the information needed on substances under consideration. He said their time should be spent refining the database to be used for determining the PEL proposal, and weighing the scientific evidence and stakeholder comments, as well as refining the assessment process itself as appropriate.

2. The Division would continue to use ACGIH, AIHA, NIOSH, OEHHA and similar sources as tools to gather information, but that the focus would be on using them as resources rather than as direct sources for recommended proposals for PELs.

3. With a core group of experts on the PEL advisory committee, even though the process might be modified from what it has been in the past, he thought that members would develop proficiency in the process as they gained experience with it.

Jason Schmelzer was concerned that PEL committee members might be viewed as "super stakeholders" which he thought could be detrimental to the process. Len Welsh said this might be true in the sense that PEL advisory committee members would be general technical experts who would also be perhaps be the most familiar with the committee's process. But he said what was most important was that all stakeholders had confidence in the fairness and competence of the committee members, and the process as a whole.

Jason Schmelzer asked if different meetings would be held for different substances. Len Welsh said that management of the agenda would be key to efficiency and effectiveness of the committee. He said that while it would probably not be possible to have effective discussion of 10 substances in one meeting of the committee, he hoped it would generally be possible to have discussion of more than just one or two.

Juli Broyles said that sufficient notice to potential stakeholders of committee meetings would be important. Len Welsh said that with stakeholder involvement being so important to the process working effectively, notice to potential stakeholders likely to generate participation would of course be given attention.

Dan Leacox said that it was important that future processes be inclusive of stakeholders, rather than as he had witnessed previously that the committee graciously received stakeholders' presentation of their concerns but then excluded them for the discussion of the issues.

Len Welsh said he agreed that the committee process needed to include stakeholders in the discussion. He asked those present if there was any disagreement with this. Patty Quinlan said it was not accurate that stakeholders were shut out of the discussion in previous meetings of the PEL advisory committee. She said that the committee members would listen to what stakeholders had to offer but often simply did not agree with their point of view.

Len Welsh and Dan Leacox both agreed that suggesting that stakeholders had been excluded or "shut out" of prior committee discussions was an unfair characterization of events. Len Welsh noted that even with the supplementary follow-on meetings in 2004 to take additional comments from stakeholders on below-TLV proposals and on glutaraldehyde, some stakeholders told him they still felt "shut out."

Jack Snyder suggested the problem might be characterized as stakeholders not feeling they were "at the table" in the committee's discussions. Len Welsh said that it was always his intention that stakeholders be included in the committee's discussions. He said that looking at the situation literally, it is possible that the relatively small rooms in which previous committee meetings were often held might have contributed to some feeling of exclusion among stakeholders, where there was only enough physical room around the table to accommodate committee members while stakeholders had to sit on the periphery of the room. Several attendees agreed that rooms of sufficient size were important to promoting a full sense of participation among stakeholders.

Julia Quint responded to comments of Dan Leacox regarding his perception of exclusion of stakeholders from PEL committee deliberations. She said that in her many years of involvement with the process the committee did accept presentations from interested parties and would then discuss them.

Juli Broyles said that she had attended several PEL committee meetings, and possibly as a result of not being able to participate on a technical level had felt shut out by the process.

Vickie Wells suggested that a standardized process was needed for the search of the scientific literature to be used to develop the proposed health based level. Len Welsh agreed, saying this raised the question of how to make use of the work of ancillary and other government agencies and voluntary organizations such as ACGIH. Vickie Wells said that other sources besides ACGIH such as the German MAK commission and the European Union SCOEL process should also be looked to as sources for information. Fran Schreiberg suggested the PEL development procedures should state what sources are to be looked at for initial information besides ACGIH. Len Welsh acknowledged that more was needed in the draft document on sources to be used for starting the literature review.

Len Welsh said that since he did not see the PEL committee as being a voting body he wanted to be sure that minutes of meetings reflected opinions of committee members and stakeholders/interested parties, so that the Standards Board, and others, could see the full dimensions of the discussion. Juli Broyles said that this would be important. Fran Schreiberg said that typically when stakeholders have disagreed with the committee's recommendation for a PEL that the Standards Board generally overruled the committee.

Len Welsh said that going forward it would be important to assure greater attendance and involvement at PEL committee meetings of stakeholders when there are any. He said it was important to have all sides participate to avoid surprise comments to the Standards Board at the time of the public hearing and written comment period on the proposal.

Dan Leacox said that it needs to be clear in the process who makes the call on what proposal to recommend to the Standards Board, based on the health risk and feasibility assessments. Len Welsh acknowledged the comment and said that it was not impossible that the Division might consider several recommended PELs based on the feasibility assessment, and it would itself choose which one to recommend to the Board for consideration as a proposal to be sent out for public comment**.**

Vickie Wells asked what would be the expected work product of the PEL committee. Would it be minutes as in the past detailing discussion and conclusions on recommendations? Or just a recommended PEL number with documentation? Len Welsh responded that minutes reflect discussion, but that needs to be organized into a form that can be understood by someone not familiar with the process, and reflect the positions of participating interested parties. Dan Leacox agreed that it would be important to have an established structure for documentation of any recommended proposal. Len Welsh agreed, saying that there needed to be more than just minutes of the committee's discussions.

Juli Broyles asked if the process would start with a proposal from the Division. Len Welsh said that it probably would, based on initial staff work.

Mike Cooper said that the last committee had developed a methodology for use in deciding on PEL recommendations. Len Welsh said that it would probably be one of the first tasks of the next committee to work together to draft a methodology and what the last committee had developed would certainly be looked at. Mike Cooper said that having an established methodology would help provide greater transparency for stakeholders.

Beth Treanor agreed that a stated methodology was needed. She said that a documentation "framework" was needed. Mike Cooper and Patty Quinlan said the committee's draft methodology and discussion had been accepted for publication by the International Journal of Occupational and Environmental Health.

Jim Bresnahan brought up the issue of silicosis related to exposure from dry sawing of concrete blocks and urged the Division to do more to enforce the existing regulations limiting silica exposure, including prevention of "take-home" exposures that can affect family members. He said it was important to keep in mind that PELs and their enforcement serve an important public health purpose. Len Welsh acknowledged Mr. Bresnahan's concern and thanked him for participating in the meeting.

Len Welsh then returned the discussion to the question of the PEL development methodology. He reiterated that methodology should be one of the first items of discussion when the committee meets again. However he said it might not be desirable to restrict the committee's work ahead of time through an inflexible methodology. Beth Treanor said that whatever methodology is adopted should be subject to modification as long as that is documented.

Dan Leacox said that the process should have some minimum standard criteria in the interest of transparency. Len Welsh said that what would be essential for transparency would be to organize the minutes including an explanation of how decisions are made on individual recommendations for PELs.

Beth Treanor said the documentation should not be limited to just the minutes of the committee's meetings. Len Welsh agreed, saying the documentation should be more than a chronology of the committee's discussion but also a summary and explanation. Paul Brownson said the documentation for the recommended PEL for each substance should include an executive summary. Len Welsh agreed with this idea. Howard Spielman said that elements to be included in the documentation should be established. Referring to the comments of Jim Bresnahan, he also asked if the PEL committee's recommendations would be limited only to PELs. Len Welsh said in response that the committee recommending work practice controls was not beyond the realm of possibility especially where a PEL recommendation could not be agreed upon.

Patty Quinlan suggested the Division's documentation of PEL recommendations might look like an abbreviated version of documentations of TLVs as published by ACGIH. She noted with regard to past practices, that committee members working on a substance had submitted summary sheets of their findings and possible recommendations, and that these were discussed in meetings but not always fully captured in the minutes. She thought it should not be that hard to develop a process for documenting recommendations that would be acceptable to stakeholders.

Vickie Wells said that particularly with sometimes multiple meetings including discussion of the same substance, it was really necessary to develop a work product document. She also said it would be important to manage that process so that stakeholders could be included but without the process bogging down as a result. Mike Cooper said that such bogging down was most likely to occur if the health and cost/feasibility phases of the process were not kept separate. Len Welsh said this was precisely why they needed to be kept separate.

Recapping, Len Welsh said he understood what attendees wanted was both by-meeting minutes of committee discussions along with documentation by-substance. There was general agreement with this.

Jack Snyder asked if the health and cost/feasibility committees would have different core members. Len Welsh said that the health committee would have core members but that it might be more difficult to find core members for the cost/feasibility committee. He said he thought the latter committee's discussion would be likely more dominated by stakeholder interest that the Division would then process.

Dan Leacox wanted to discuss how to prevent decisions being biased as a result of health committee core members being "super stakeholders" as Jason Schmelzer had suggested earlier. Dan Leacox gave as examples "bias" of experts for certain test methods and "bias" resulting from variability of attendance and participation at committee meetings. Len Welsh said that bias can arise from other sources such as vendors participating to promote their own products. He said that since no one can be excluded from participation the process would simply have to explicitly recognize and accommodate the impact of the bias in order to be effective.

Juli Broyles said that in spite of the possible difficulties, the process being discussed sounded more agreeable to her than what it had been. She said that her group's concerns would be addressed by the greater transparency, stakeholder involvement, and documentation that had been discussed so far. She said that bias is always present but that it could be addressed in part through the Standards Board comment process.

Jason Schmelzer suggested there should be follow-up meetings on committee recommendations before they are made to the Board. Len Welsh said he did not want to lock the Division into this additional step for all substances. He said that if concerns remained after recommendations were made he could see having follow-up review meetings for substances on a case-by-case basis. Juli Broyles said that this possibility should be added to the draft flow chart for the PEL process.

Related to follow-up meetings, Juli Broyles asked if e-mails would be sent out to interested parties detailing potential recommendations to the Board before they were made in order to obtain final comments. Len Welsh said that this is routinely done with advisory processes, and that even though the PEL committee process was of a more ongoing nature he said that potential recommendations could be sent out for additional comments before becoming recommendations to the Board. He reiterated that where a substance or recommendation was particularly controversial a follow-on meeting could be considered.

Etta Mason asked how the PEL advisory committee members would be chosen. Len Welsh said that the Division would choose from among those expressing interest or recommended by stakeholders. He said the committee would probably would have about 8 members. Juli Broyles asked who would chair the committee's meetings. Len Welsh said that the Division would chair in its staff role.

Beth Treanor said that given the work and the number meetings that can be involved it is not that easy to get people to volunteer for the committee.

Vickie Wells said that one committee with 8 members would not be enough. She said that more than one core group would be needed. She said it was important for the process document to make clear that committee members are chosen and contribute based on their own expertise, not as representatives of particular employers or interests. She said a conflict of interest policy should be developed as the ACGIH TLV committee had done. Len Welsh agreed that the next committee should consider developing such a policy.

OEHHA Presentation

Len Welsh proposed moving on to a presentation on health risk assessment by Jim Collins, Staff Toxicologist in the Office of Environmental Health Hazard Assessment in Oakland.

Fran Schreiberg asked that before the presentation there be at least a brief discussion of OEHHA's role in the PEL development process. She noted that WorkSafe! comments on the draft process document had asked that OEHHA and HESIS be formally recognized and incorporated into the process but that she did not see this mentioned in the revisions to the draft. Len Welsh said that he welcomed the participation of OEHHA and HESIS in the process and this could be reflected in revisions to the document. Fran Schreiberg suggested the Division consider contracting with OEHHA for assistance. Len Welsh said the Division has a contract with HESIS. He said he would explore how best to involve OEHHA in the process.

Juli Broyles said that while she supported involvement of other agencies with appropriate expertise, she had seen situations where outside agencies initially providing assistance can come to "take over" a project. In response to this Len Welsh said the key point is that the Division will be the one making the decision as to the PEL recommendation to the Standards Board.

Jim Collins presented the OEHHA risk assessment process for establishing chronic reference exposure levels (RELs). He noted that interest in having OEHHA participate in the PEL process reflects the desire not to "reinvent the wheel" of risk assessment that has been developed by the U.S. Environmental Protection Agency and other regulatory agencies and scientific bodies' approaches used by OEHHA.

Jim Collins' presentation included discussion of the Air Toxics Hot Spots Act of 1987 which was California's response to the industrial disaster in Bhopal, India in 1984. Among other mandates the legislation directs OEHHA to develop guidelines for health risk assessment of chemicals known to be routinely emitted from industrial facilities in California. As indicated in the presentation slides, the chronic Reference Exposure Level (cREL) is the concentration in air at or below which no adverse health impacts are anticipated following long-term exposure. The cREL is meant to protect most of the general public, including sensitive individuals, although they may not account for idiosyncratic responses. Exceedance of the cREL does not necessarily result in adverse health consequences. It was noted that PELs are more narrowly focused on the working population and not necessarily at the most sensitive groups among workers (for example individuals previously sensitized to a substance), and may not protect against all health effects because they take feasibility into account.

Depending on the data available OEHHA uses a NOAEL (No Observed Adverse Effect Level), a LOAEL (Lowest Observed Adverse Effect Level), or a Benchmark Dose (usually an incidence of 5%) as a point of departure in non-cancer risk assessment. Uncertainty factors (subchronic, interspecies, intraspecies, etc.) are used to extrapolate the experimental data to Reference Exposure Levels (RELs) for the general public. OEHHA has developed a specific methodology for chronic RELs which has been peer-reviewed and has developed chronic RELs for 80 chemicals. As examples, Jim Collins went over OEHHA's derivation of the chronic RELs for ammonia and carbon disulfide.

Jim Collins noted in response to a question from Howard Spielman that the U.S. EPA sets a maximum acceptable uncertainty factor of 3,000, and above that a substance would probably be regarded as not having sufficient basis to establish a REL. In response to a question from Vickie Wells, Jim Collins said that picking of the "best study" upon which to base the risk assessment was a matter of judgment. He said there is also sometimes judgment involved in deciding whether an effect is "adverse."

Jason Schmelzer asked if study size or dose chosen for animal studies could affect results. Dr. Collins said that yes study size and animal dosing levels can affect conclusions.

Vickie Wells asked Jim Collins if OEHHA has a standardized process for their literature search. He responded that there is no written formalized process, just that a thorough job is done on the search.

Fran Schreiberg asked, looking at Jim Collins' slides, for example for the REL assessment for ammonia if the uncertainty factors and time adjustments for public exposure were removed if the resulting NOAEL could be used as the PEL for ammonia. He said that it might be looked at that way. It was noted that the NOAEL for ammonia indicated in the presentation of 9.2 ppm based on occupational exposures was in the same general range as the current PELs for ammonia in section 5155 of 25 ppm 8-hour time-weighted average and 35 ppm Short Term Exposure Level.

After Lunch

Steve Smith took over to chair the meeting for the afternoon. He started by asking attendees what sources in addition to ACGIH TLVs should be added to the process document for starting points. Fran Schreiberg said there was too much emphasis in the process on TLVs. She said that the top focus of priority for consideration for new or revised PELs should be substances identified by California state government as cancer or reproductive hazards, particularly where occupational use can be documented. She said second priority for consideration should be those recognized as cancer or reproductive hazards by other governmental organizations such as the National Toxicology Program or USEPA. She said third priority should be substances with an OEHHA chronic REL.

Jack Snyder said that IARC (International Agency for Research on Cancer) should not be one of the priority sources since their process for developing recommendations is not transparent. Fran Schreiberg responded that since the PEL process will be transparent there should not be any objection to using IARC or similar bodies' findings as source material that will be openly evaluated. There was agreement from a number of other attendees that such other sources could appropriately be used as references. Jack Snyder said this was acceptable as long as what was used from these sources were their identification of the substance as potentially

hazardous, and the references for their recommendations, but not the conclusions drawn and acceptable levels recommended (if any).

There was brief discussion of availability of data on chemical-related injury and illness but it was generally agreed that such information is currently so limited that it was unlikely to be of substantial widespread value, other than possibly for a few specific substances or classes of substances or effects. Susan Ripple said that when such information is available and looked at for prioritization it is important to assess if cases are occurring due to noncompliance with the existing PEL or if the PEL is too high.

Vickie Wells said that in the interest of efficiency and focusing limited resources on substances of importance to California workers, to the extent possible work on substances not used in California workplaces should be avoided. This was generally agreed to, though difficulties in determining the extent of use, or verifying absence of use, were generally acknowledged.

Returning to the list for prioritizing in section I.A. of the draft document, Steve Smith said it was not intended to cover the entire universe of potential sources. Fran Schreiberg acknowledged the difficulty but said that the current list was too limited. Howard Spielman suggested in the interest of flexibility that the priority list refer to looking at "organizations such as…" Several attendees voiced agreement with this.

Patty Quinlan said she felt the last few lines of section I.B.6. in the draft process document suggest the goal of the PEL process is to maintain section 5155 roughly consistent with the ACGIH TLVs. She thought that reference should be removed for a number of reasons, including the fact that many TLVs are for substances that may not used in California. Vickie Wells noted for example that there are TLVs for a number of organophosphate pesticides which are no longer used in California. Deletion of the last few lines of I.B.6. was generally agreed to by attendees.

Fran Schreiberg said she was still confused about the role of the PEL advisory committee in the process. She was concerned that the committee's expertise could be overwhelmed by interested stakeholders if the committee itself is simply another meeting participant. She said the committee needed to have the role of coming up with something concrete, not just be another voice in the room. Steve Smith reminded attendees that Len Welsh had said in the morning that the goal of the committee's meeting was to strive for consensus where possible.

Various attendees suggested that when consensus was not possible that the work product document of the committee record the various points of view, disagreements, etc. Jason Schmelzer suggested that these be included in a summary of the discussion. Juli Broyles suggested it could be like a legislative bill analysis in which pros and cons are discussed.

Juli Broyles said further that section II.A. of the draft process document on the role of the PEL committee, differed from the role suggested by Len Welsh in the morning discussion. She said this section needed to be re-worked to capture what Len Welsh had said about the committee's role including holding discussion with stakeholders and documenting that discussion. Juli Broyles said that the committee process should not involve voting as that would amount to a quasi-regulatory process without legislative authority. She said that Len Welsh's morning statements that the Division would be the decision-maker on recommendations to the Board should preclude the committee from voting on recommendations.

Dan Leacox said that in the second sentence of the first paragraph of part II.B. of the draft document, the word "represent" should be deleted, consistent with earlier comments that PEL committee members are intended to serve as independent experts, not as representatives of particular interests.

Fran Schreiberg said that the idea of "balance" on the PEL committee is not possible since labor does not have independent technical staff, and so should not be suggested in the draft process document. She said the committee would always be dominated by experts from industry or academia and that this would simply have to be recognized and dealt with by the Division and the Standards Board when looking at the recommendations developed. She suggested in the interest of having a technical expert that an OEHHA toxicologist be a member of the PEL committee.

Vickie Wells said it would be problematic to have a government staff person as a member of the PEL committee unless they were clearly there not as a representative of their agency, but as an independent expert. Juli Broyles said it was important to avoid putting committee members in the position of possibly having private agendas as could be the case with a government agency staff member. Jason Schmelzer said that while industry representatives had agendas, it was clear to everyone they were acting as advocates not as independent experts.

Vicky Wells reiterated her earlier suggestion to have a conflict of interest policy for PEL committee members.

Feasibility Assessment

Steve Smith moved the discussion to the assessment of feasibility. Howard Spielman said that assessment of feasibility of PEL recommendations should be a process separate from the health assessment. He also suggested that the health committee might be able to assist with the feasibility assessment as well.

Steve Smith asked attendees if they thought there should be a separate standing committee on feasibility. Fran Schreiberg responded that could be difficult because each substance will have its own interest group to represent it.

Attendees generally agreed that the assessment of cost and feasibility should not be part of the health risk assessment process, though members of the health committee were welcome to participate in the separate cost/feasibility assessment process.

Patty Quinlan said she was skeptical of the likelihood of the Division being able to assemble a group of experts such as process engineers for ongoing assessment of cost and feasibility issues.

Juli Broyles suggested the process of the federal Small Business Regulatory Enforcement Fairness Act (SBREFA) as a possible model for cost/impact assessment of PEL recommendations. She said it would be unlikely to get plant managers or process engineers to sit on an ongoing committee for cost/feasibility assessment. She suggested using the Office of Small Business Advocate to locate interested parties for the cost/feasibility assessment and comments.

Fran Schreiberg said that it was important to have both the original health-based recommendation and the level adjusted for feasibility in the recommendation given to the Standards Board so that the public record would be complete and the Board could do its own assessment. She said that consistent with rulings of the U.S. Supreme Court the burden of demonstrating infeasibility of a proposed rule was on industry.

Juli Broyles said that the California Administrative Procedures Act requires cost impact assessment. Fran Schreiberg acknowledged this requirement but said that costs cannot be the deciding factor in what PEL is adopted or proposed for adoption.

Juli Broyles said that she agreed with the PEL committee selection process as suggested in the draft process document and discussed further in the meeting. She suggested the Division look at how cost and feasibility are assessed in the SBREFA process and through the Office of Small Business Advocate.

Fran Schreiberg said that she sees the cost/feasibility process as more of a standard regulatory advisory meeting, that is primarily stakeholders providing informal comment to the Division. Steve Smith said that an attempt would be made in both the health and feasibility processes to reach consensus. But Fran Schreiberg said that striving for consensus did not satisfy the requirement of Labor Code section 144.6 for a protective standard. She said it would be important for the process documentation to make some statement about acceptable risk level or levels, i.e. how many affected workers was the goal for the level chosen, as the U.S. Supreme Court had suggested the 1 in 1,000 increased risk level possibly being an appropriate allowable maximum in its 1980 decision on the OSHA benzene standard.

Vickie Wells responded that it was not always possible to set the PEL at the 1 in 1,000 increased risk level. Fran Schreiberg acknowledged this and suggested there might be a range that is worked toward. She suggested the importance of there being transparency in the risk levels for the PELs for different substances to the extent

possible to determine. She said for example that PELs for a number of substances in section 5155 presented increased cancer risk levels above 1 in 1,000. She said that the PELs in section 5155 generally did not address the cancer risk.

Richard Morford said that deciding on the acceptable risk level was a policy decision beyond the scope of the role of the PEL advisory committee. Fran Schreiberg acknowledged the comment and said in any event she wants the PEL process document to state what risk levels should be strived for, or what range might be acceptable. Dan Leacox agreed with the idea of stating in the PEL process document a range of acceptable risk levels as a goal for the PELs recommended by the committee to achieve. Sara Hoover said that stating such a range could help with the feasibility assessment.

Steve Smith asked for any additional comments on the draft procedure document to be sent to Bob or himself by the end of the month. Fran Schreiberg said that she would try to work with Beth Treanor on further comments on the draft process document.

The next step would be for the minutes of this meeting and a revised draft to be sent out to all participants later this summer for a final review and to determine if any further meetings are needed.

END