DRAFT MEETING SUMMARY

CAL/OSHA PERMISSIBLE EXPOSURE LIMITS
PUBLIC ADVISORY SUB-MEETING
ON SENSITIZING SUBSTANCES IN 8 CCR 5155

JUNE 10, 2005
OAKLAND, CALIFORNIA

Attendees

Jim Kegebein, Health and Safety Consultant
Jon Frisch, Pacific Gas & Electric Company
Etta Mason, Southern California Edison
Beth Concoby, Genencor
Barry Foose, Kaiser Healthcare
Elizabeth Treanor, Phylmar Regulatory Roundtable
John Mehring, SEIU
Cheryl Christenson, Edwards Lifesciences
Don Molenaar, Bayer Corporation
Julia Quint, California Dept. of Health Services
Robert Harrison, California Dept. of Health Services
Jeremy Smith, California Labor Federation
Patty Quinlan, University of California San Francisco
Julianne Broyles, California Chamber of Commmerce
Paul Brownson, Dow Chemical
Greg Gorder, Technology Sciences Group
Susan Ripple, Dow Chemical
Steve Derman, Medishare
Marcie McLean, United Food and Commercial Workers Local 870
John McCoy, Lakeview Professional Services
Vickie Wells, San Francisco Department of Public Health
Edward Calderon, Shea Homes
Julie Klehs, BASF Corp.
Ken Carrigan, Occupational Medicine Resident, UCSF
Jason Schmelzer, California Manufacturers and Technology Association
Kevin Thompson, Cal/OSHA Reporter
Teresa Pichay, California Dental Association
Ted Brucker, CalTrans
Dan Leacox, Livingston & Mattesich
Roger Richter, California Hospital Association
Mike Horowitz, DOSH District Manager, Oakland
Tom Mitchell, Cal/OSHA Standards Board

Meeting Staff

Steve Smith, DOSH, meeting chair
Bob Barish, DOSH, meeting co-chair
Bob Nakamura, DOSH
Deborah Gold, DOSH
Len Welsh, DOSH

The meeting was opened by Steve Smith, DOSH Supervising Industrial Hygienist. He noted that this was the second public advisory meeting on the topic of sensitizing substances, the first having been on January 19, 2005. He

explained that advisory meetings are pre-rulemaking processes intended to help the Division determine the potential value and feasibility of rulemaking and to inform the process of developing a formal proposal for consideration by the Standards Board. It was noted that the sensitizer process is an outgrowth of the meetings held in 2004 to discuss a revised Permissible Exposure Limit (PEL) for glutaraldehyde, a substance generally believed to be a respiratory sensitizer. Finally he noted that the Division's Advisory Committee webpage is in the process of being updated to include documents such as handouts and agendas for meetings such as this one.

Bob Barish chaired the first meeting on sensitizing substances on January 19, 2005 and provided a brief overview of that meeting. He noted that it included a presentation by UCSF and UCB School of Public Health Professor John Balmes on lower respiratory tract sensitization. Bob noted that a copy of Professor Balmes' presentation in PowerPoint can be accessed via the "2005 meetings" link in the sensitizers area of the Advisory Committee website. Bob noted that European activity with respect to sensitizing substances was also discussed on January 19. He noted also that a proposal was made to apply to sensitizing substances the air monitoring and medical surveillance requirements of the Cal/OSHA standard for formaldehyde (Title 8 section 5217). Bob asked if there were any comments on the draft minutes distributed for the January 19 meeting and there were none raised.

Steve Smith then reviewed the planned scope of the day's meeting. He noted the importance of deciding on a process and criteria for identifying substances as sensitizers and noted the handout provided listing substances in the ACGIH TLV book as designated sensitizers or with indications of "sensitization" (S) or "asthma" (A) as the basis/critical effect for the TLV. Bob Harrison asked about the terminology "sensitization" and "asthma" from the TLV book and the distinction between the two. Susan Ripple suggested that the "asthma" term is older. Vickie Wells suggested that clarification could be obtained by writing to ACGIH.

Julia Quint said that for some pesticides the SEN (sensitizer) notation in the TLV book is based upon anti-cholinesterase activity which is probably not directly relevant to the discussion of this meeting. Beth Concoby said that identification of sensitizers required a clear process. Vickie Wells suggested looking at the description of the SEN notation in the TLV book, and noted that the German MAK commission has it's own methodology. Steve Smith suggested interest in a process that included recognition of substances by other organizations such as ACGIH, thus the possible value of the ACGIH SEN notation. Beth Concoby asked if what was being considered was a list of sensitizing substances in Section 5155 (PELs) which would refer to a single footnote such as that developed for glutaraldehyde, or possibly there might be several footnotes for substances with similar effects. Julianne Broyles wanted to know what group or groups would be looked to for assistance in identifying substances as being sensitizers. Steve suggested ACGIH for one.

Julianne Broyles asked if there is data showing the existing situation in California with respect to sensitizing substances is not adequately protective. Steve Smith said that sensitizers raised a unique health concern. Julianne Broyles asked if Federal OSHA or any other states are addressing the subject. Steve Smith said that a number of existing regulations such as Hazard Communication address sensitizing substances and are in effect nationwide. Julianne asked if California is getting out ahead of Federal OSHA on this subject. Steve Smith said that California has taken initiatives beyond Federal OSHA on a number of topics, such as with the Injury and Illness Prevention Program. Deborah Gold mentioned that the Bloodborne Pathogens standard promulgated by Federal OSHA addresses the sensitization potential of latex gloves.

Don Molenaar noted that industry is sponsoring a study on the adequacy and utility of PELs and medical surveillance for isocyanates with the goal of better management of employee health protection. Julie Klehs noted that NIOSH was a co-sponsor on this project. Bob Harrison asked if a protocol was available for that study. Don Molenaar responded that he was not sure if a protocol had been finalized for distribution but that he would provide it when it became available. He said that the study was being carried out by the Respiratory Disease Division at NIOSH in Morgantown, West Virginia.

John Mehring said that employees often feel they need more information relevant to their particular situation. He said that many members of his union working with glutaraldehyde do not know or understand that it is a sensitizer and that an informative footnote from Cal/OSHA could help with that. He noted that the footnote is informational and not an additional regulatory burden. Steve Smith agreed that getting information to employees is consistent with the

preventive mission of Cal/OSHA. Don Molenaar and Susan Ripple also felt the footnote could be of value in providing more information on sensitizers to both employers and employees.

With regard to the industry study mentioned by Don Molenaar, Julia Quint noted that Professor Balmes' presentation at the January 19, 2005 meeting indicated that past studies have shown the value of medical surveillance in decreasing the severity of asthma cases. She asked what additional information was being sought in the industry study. Don Molenaar indicated that it was a 5-year prospective study intended to detect the effects of exposures to lower levels of isocyanates. He also indicated that it was hoped that the study might be able to distinguish between cases of asthma or airway reactivity resulting from irritation and those resulting from true sensitization as well as better correlate effects with exposure levels.

Beth Treanor asked if the Division can enforce a footnote. Steve Smith said that what is being considered for glutaraldehyde provides information on symptoms from exposure and directs employers to some other Title 8 sections that are relevant to control of the hazard. Bob Harrison suggested that it appeared that the footnote would not add an additional employer obligation but would merely clarify existing requirements that apply to sensitizing (and other) chemical hazards. Beth Treanor and Julianne Broyles expressed agreement with this assessment. Jon Frisch suggested that a sensitization designation and footnote would help to highlight the hazard for employers and hopefully get them to go back and re-evaluate their chemical control programs and possibly look for less hazardous substitutes.

Steve Smith noted that section 5155(d) directs for substances with the "Skin" to provide appropriate protective measures such as the additional washing facility requirements of section 3366 to prevent skin absorption. He felt that an analogy could be drawn to a footnote for sensitizing substances directing employers to look at other potentially applicable Title 8 sections.

Julia Quint asked if the footnote created a presumption, or at least suggestion, that the PEL was completely effective in preventing development of sensitization. Steve Smith replied that just as the "Skin" notation in section 5155 did not provide complete protection from the skin absorption potential of individual substances, the contemplated footnote and the Skin notation, are not related to the PEL number itself but rather are intended to be a supplement to the PEL by highlighting the additional potential hazard. For sensitizing substances the footnote serves to highlight that the PEL alone is not sufficient by itself, that employers need to be concerned as well with other aspects and regulations related to exposure control. Deborah Gold gave as an example, that section 3203 requires employee training if employees are exposed to a chemical hazard in the workplace, even if the PEL is not exceeded. Bob Harrison felt this was a good point and provided support for the concept of the footnote.

Bob Harrison went on to point out that the NOTE in section 5155(a) states explicitly that the PELs cannot be expected to protect all workers from adverse effects of chemical exposures. He felt there should at some point be discussion of the question of the level of protection the PELs are intended to provide. Susan Ripple expressed agreement with Bob Harrison and noted that particularly with sensitizing substances the protective exposure level is often not clear from the scientific data available. She felt that with the data often being so unclear, setting occupational exposure limits for many sensitizing substances presented special challenges. She said that the reasoning of the AIHA WEEL committee in establishing DSEN and RSEN notations for substances was that for sensitizers more is needed than just the exposure limit to effectively protect employees adverse effects.

Etta Mason said that she was unsure of the value of the footnote for sensitizers in the form currently suggested because it was not clear what it directed employers to do. Steve Smith said that its main purpose as currently contemplated is to raise awareness of the hazard and other potentially applicable Title 8 sections related to control. Etta Mason asked what value the footnote provided beyond the information in the Material Safety Data Sheet and suggested that if an employer did not read the MSDS they were unlikely to read the footnote. She further suggested that without providing a solution for protection in the footnote that those reading it might just become frustrated. Steve Smith responded that the solutions for employee protection in terms of Title 8 requirements and generally recognized safe practices are already available. He reiterated that the purpose of the footnote was primarily to highlight the sensitization potential of certain substances and raise employer awareness of the need to consider other protections and Title 8 requirements.

Vickie Wells agreed with Susan Ripple that it is difficult to establish occupational exposure limits where data is unclear and it is difficult for employers to deal with mixtures such as isocyanates. She said that employers need to evaluate their particular situations and that an awareness footnote could help prompt them to do that.

Etta Mason said again that she felt that MSDS information should be sufficient. Beth Concoby said that even if a sensitization warning is on an MSDS or label that the footnote could provide additional helpful information or prompting to action.

John Mehring said that information on a substance, such as in the form of a footnote, coming from Cal/OSHA is generally more easily accepted by workers. He said that some workers don't fully trust MSDSs.

Bob Harrison said that the footnote as currently contemplated does not address medical monitoring. He said that studies have shown that medical monitoring can reduce the occurrence and severity of asthmatic reactions. Steve Smith noted that medical monitoring is an element of the footnote by its reference to symptoms and detailing that the 3203 communication system shall inform employees where to report possible health symptoms. Bob Harrison said though that it did not include a requirement for medical monitoring and he felt the science supporting medical monitoring for occupational asthma was strong enough to warrant its inclusion as a requirement. Beth Concoby suggested that the evidence for medical monitoring might be strong for some sensitizing substances but not necessarily for all.

Steve Smith said that with the footnote in its current form medical surveillance is noted. He said that in section 5191 for laboratory situations there is a medical monitoring requirement in response to symptoms and exposures from spills. Mike Horowitz noted that section 5155(f) provides that for individual employers the Division can write an order to take special action for medical surveillance but that this requirement provides only "after the fact" protection for employees at an individual company rather than comprehensive protection.

Steve Smith asked the group if pursuing the footnote made sense as a first step in increasing employee protection for sensitizing substances. Beth Treanor suggested that early detection is critical. She felt that the footnote could be helpful in promoting immediate reporting of possibly symptoms and additional awareness of what symptoms would be of concern. Susan Ripple agreed that the footnote could help with awareness. She also asked if substances that would be designated with the footnote would be separated into dermal and respiratory sensitizers. Beth Concoby and Jon Frisch felt it would be a good idea to have separate notations for dermal and respiratory sensitizers.

Julia Quint asked if a choice was being proposed between a footnote for sensitizers and the suggestion from the last meeting that the air monitoring and medical surveillance requirements of the formaldehyde standard be applied to substances designated as sensitizers. Steve Smith replied that his first goal was to reach agreement on a footnote and then discuss the formaldehyde approach.

LUNCH BREAK

After the lunch break Steve Smith reviewed the group's apparent general agreement with the footnote concept. He then moved on to discussing separate designations and footnotes for dermal and respiratory sensitizers. He asked for comments on the language of the footnote generally agreed upon at the advisory meeting on glutaraldehyde held October 14, 2004.

Deborah Gold suggested that the footnote should emphasize that the PEL cannot be completely effective in preventing induction of sensitization. There was discussion of specific language to make this point in the footnote. Beth Concoby said that such language might be appropriate for some substances designated in the future as sensitizers but not necessarily all. Susan Ripple agreed that the airborne concentration threshold for induction of sensitization is clear for some substances and unclear for others.

Steve Smith suggested separate designations and footnotes for dermal and respiratory sensitizers. Deborah Gold suggested that for carcinogens with comprehensive OSHA and Cal/OSHA standards (eg. asbestos, inorganic arsenic, etc.) OSHA acknowledges that there is residual risk and so has requirements beyond the PEL to try to address that.

Discussion of distinguishing the often similar effects of irritation and sensitization ensued. Also the distinction between "signs" and "symptoms" of disease.

Steve Smith brought the discussion back to language for two footnotes. He asked the group if the footnote for dermal sensitizers should make reference to requirements for personal protective equipment and hygiene facilities, especially regarding suitable washing agents and cleansers. Beth Treanor said that it should. Paul Brownson said with regard to language of the proposed footnote from the glutaraldehyde meeting that use of the term "contact dermatitis" was inappropriate because it encompassed both irritant and sensitization induced dermatitis.

Bob Harrison suggested that reference also be made to substitution of less hazardous substances as a means of hazard control. Steve Derman suggested at least a general reference to the standard hierarchy of controls, ie. engineering, administrative, and PPE.

Steve Smith asked if the goal with respiratory sensitizers was primarily prevention of occupational asthma. Beth Concoby said that the goal should also be to have attention paid early to symptoms of allergy and thereby possibly prevent or delay development of occupational asthma.

Discussion ensued about specific terminology to identify the sensitizing effect of concern. Julie Klehs said most people know what work-related asthma is. Steve Smith said he felt there was general agreement and enough language suggestions for DOSH to work on a draft of the footnote that he would then bring back to the group for further comment.

Steve then asked if the footnote should have additional language with regard to medical surveillance such as that found in section 5191 for laboratory use of chemicals. Steve suggested that this might also be addressed through changes to section 5155(f) which currently authorizes DOSH to write for individual employers an "order to take special action" for medical surveillance.

Beth Treanor asked if what is being contemplated was a medical surveillance requirement triggered by the mere presence of a substance or would, for example, the PEL need to be exceeded for it to take effect. Steve Smith replied that the medical requirements of section 5191 for laboratory use of chemicals are triggered by exposure above the PEL/action level for selected substances, by exposure during a spill, or by signs/symptoms of exposure.

Bob Harrison suggested first determining what is good occupational health practice and then require medical monitoring at some level of the PEL along the lines of the traditional action level concept reflected in existing regulations for certain substances such as asbestos and lead.. He suggested that medical monitoring should be a periodic requirement in order to facilitate the determination of work-relatedness.

Julie Klehs responding to this agreed that there should be some trigger exposure level. She said that an important issue with medical monitoring, and especially with determining the medical questionnaire to be used was the endpoint trying to be determined. She said that an overly long questionnaire could be avoided by focusing on a few key questions related to occupational asthma. She said that medical monitoring could function to tie exposure documentation to actual existence of asthma thus facilitating the determination of work-relatedness. Bob Harrison agreed, noting that this process can take years.

With regard to frequency of medical monitoring Julie Klehs said that it could be annual for isocyanates but that annual was not necessarily needed for all substances. Julia Quint noted the latency of asthma. Julie Klehs acknowledged that as another aspect to consider. Steve Smith noted that the section 5191 requirements did not provide for annual surveillance but did call for the physician's opinion on the need for medical follow-up. Bob Harrison said that it was important that employees exposed to a well-documented asthmagen such as flour dust be placed with a qualified medical provider and not just a local industrial medicine clinic that would be focused more on the workers compensation aspect of the problem and less on prevention.

Beth Concoby said that her company performs skin testing on employees exposed to enzymes and wondered if this was applicable to other sensitizing substances. Julie Klehs said that skin testing would not be applicable to most

potential sensitizers but rather the focus would be on use of an effective medical questionnaire. Paul Brownson noted that, where it is appropriate, skin testing is not primary prevention for sensitization as it identifies antibodies only after it has occurred, albeit though possibly before development of symptoms. Beth Concoby acknowledged this but said that it could identify employees early in the process before development of symptoms. Bob Harrison noted that it was difficult to get employers to administer an effective questionnaire, let alone conduct skin testing, but he supported at least a voluntary questionnaire.

Steve Smith asked if there is currently an effective questionnaire. Bob Harrison said yes. He suggested that BASF might have contributions to this. Steve Smith asked about the medical questionnaire for formaldehyde in section 5217 non-mandatory Appendix D. Beth Concoby said that this questionnaire was too long, with questions non directly relevant to sensitization such as about "nervousness." Bob Harrison agreed that a better questionnaire than that in section 5217 could be developed.

Steve Smith said it appeared there was agreement on the value of a medical questionnaire - to which the group generally expressed agreement. Steve said that it appeared there was general agreement on having separate footnotes for dermal and respiratory sensitizers along the lines of what had been discussed. He said that language with regard to medical surveillance remained to be developed further. A number of participants offered to help with that.

Steve Smith then asked what the group wanted to do with respect to looking at broader air monitoring and medical requirements for isocyanates.

Julia Quint said that section 5217 for formaldehyde provided a good model for this and it had the advantage of having already gone through a promulgation process. She noted that to this point in the meeting medical surveillance had been discussed fairly extensively but without addressing medical removal protection provisions.

Steve Smith asked if the group wanted to consider application of the air monitoring and medical requirements of section 5217 to isocyanates. John Mehring said yes. Beth Treanor said that it was too early to be looking at it for polyisocyanates. Steve suggested for the moment looking at the monomeric forms of isocyanates.

Julia Quint said that a review of the scientific literature showed that asthma can be caused by the polyisocyanates and points to the value of controlling exposures based on a standard for "total reactive isocyanate groups" (TRIG). She said that other countries in Europe and elsewhere had adopted standards for TRIG equivalent to the current PEL for toluene diisocyanate of 0.005 ppm (8-hour TWA). Deborah Gold noted that Oregon OSHA has a standard specifically for the HDI trimer. She noted a recently published review of metrics for TRIG. She noted that a mg/M^3 standard for TRIG self-adjusted for total molecule size and thus provided a consistent standard for the hazardous isocyanate (NCO) group regardless of the molecular weights of the monomer or the pre-polymers in the mixture.

Steve Smith asked again if there was a willingness to discuss application of the formaldehyde standard elements of monitoring and medical surveillance to isocyanates, at least for the monomeric forms with PELs in section 5155 as a first step. He said that considering a PEL or PELs for polyisocyanates as well as application of the formaldehyde standard to these substances should be taken up after discussion and resolution on the monomers. Susan Ripple asked if what was being proposed for discussion was application of the formaldehyde medical requirements for all substances designated by DOSH as sensitizers at some future time. Steve said the discussion for the moment would be limited to application to the isocyanate monomers.

Susan Ripple asked what additional burden this would constitute for employers. Steve said that what was suggested by some participants at the previous meeting on January 19, 2005 was application of the requirements of section 5217 for air monitoring and medical surveillance, which does include medical removal protections. Steve said that a first estimate of the cost burden of such an action on employers might be obtainable through the Federal Register notice for the final rule announcement for the OSHA formaldehyde standard.

Dan Leacox suggested that the current meeting did not include key stakeholders related to isocyanates. Julie Klehs said that other key stakeholders included users and secondary manufacturers. Beth Treanor suggested that if a medical surveillance requirement is considered for isocyanates a medical panel or equivalent should be convened to determine the appropriate elements.

Steve Smith summed up the meeting to that point by saying that the Division would, based on the meeting's discussion, draft language for separate footnotes (for section 5155) for dermal and respiratory sensitizers to be designated by criteria still to be determined process. He said that the footnotes would include medical elements based on the model of Title 8 section 5191(g) for medical surveillance related to laboratory use of chemicals.

Beth Treanor asked Steve if he anticipated a need for definitions of terms in the footnotes. Steve said that with the footnotes being only informational he did not feel definitions would be needed.

Len Welsh, Acting Chief of the Division (who had joined the meeting a few minutes earlier) said that he had asked Steve Smith to bring up the question of isocyanates. He said he felt that all in the meeting could agree that isocyanates are a real employee health problem and that a regulation to address the hazard they present would be a real service to California workers.

Julie Klehs asked if the discussion of the standard for isocyanates would be separate from the discussion of the more general footnote for dermal and respiratory sensitizers. Len acknowledged that he did not want the discussion of isocyanates to interfere with the consideration of the footnote for sensitizers more generally. There was general agreement that consideration of the footnotes, and the consideration of a standard for isocyanates, should be separate processes. Bob Harrison said that it would be good to address isocyanates because they are the most common cause of workplace asthma, but he agreed that he did not want that process to interfere with consideration of the footnotes discussed. Julie Klehs agreed that isocyanates warranted a separate process. Len Welsh concurred with these sentiments.

Susan Ripple said that it would be important to also look at the whole question of polyisocyanates and control of exposures to total reactive isocyanate groups. Len Welsh said that care should be taken with moving too quickly and exceeding the resources available for proper vetting of a regulation or regulation for isocyanates. He said that the process should go one step at a time, with careful assembly of a group that could effectively consider the various issues.

Susan Ripple and Julie Klehs suggested a number of sources for safety guidance materials on isocyanates. Len Welsh acknowledged that significant new regulations should also include guidance materials from Cal/OSHA.

Bob Harrison suggested that attendees could work on the process and criteria for designating substances as sensitizers which would then have the dermal, and/or respiratory sensitizer footnote. Steve Smith welcomed this assistance particularly from Department of Health Service staff in such an effort.

Steve Smith asked that by July those present and other stakeholders send suggested language for footnotes and medicals along with suggestions for substances that might appropriately be designated as sensitizers in section 5155. Steve said that for the next meeting the Division would look at the draft language and develop a proposed list of 5155 substances for designation of one or both SEN notations.

END