DRAFT MEETING SUMMARY

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

SEPTEMBER 16, 2005
SACRAMENTO, CA

Attendees

Sarah Allen, Johnson Controls
Bobby Bailey, Linex Corp.
Scott Brodman, BASF
Paul Brownson, Dow Chemical Company
Juli Broyles, California Chamber of Commerce
Denny Bryant, Carpenter Company
Cheryl Christenson, Edwards Lifescience
Barry Foose, Kaiser Permanente
Don Foret, Montecno-API
Judi Freyman, Organization Resources Counselors
Jonathan Frisch, Pacific Gas and Electric
Greg Gorder, Technology Sciences Group
Cynthia Graham, Huntsman Corp.
Roseanne Harding, California Dental Association
Scott Jewett, Linex Corporation
Jean Kasakevich, Dow Chemical Company
Jim Kegebein
Kimberly Kelley, Kaiser Permanente
Julia Klees, BASF Corp.
Theodore Knudson, Brush Wellman
Lynn Knudtson, Future Foam and the Polyurethane Foam Association
Ashok Kuman, Montecno-API
Arthur Lawyer, Technology Sciences Group
Dan Leacox, Livingston and Mattesich
Will Lorenz, Henry Company
Etta Mason, Southern California Edison
Tom Mitchell, Cal/OSHA Standards Board
Don Molenaar, Bayer
Latoska Price, Akzo Nobel
Julia Quint, HESIS, California Department of Health Services
Bill Robert, BASF Corp.
Susan Ripple, Dow Chemical Company
Jason Schmelzer, California Manufacturers and Technology Association
Jeremy Smith, California Labor Federation
Kevin Thompson, Cal-OSHA Reporter
Elizabeth Treanor, Phylmar Regulatory Roundtable
Willie Washington, California Manufacturers and Technology Association
Vickie Wells, San Francisco Department of Public Health
John Zomer, BASF Corp.

Meeting Staff

Steve Smith, DOSH, meeting chair
Bob Barish, DOSH, meeting co-chair

Steve Smith opened the meeting with a brief review of the January 19 and June 10, 2005 meetings on sensitizing substances. He said these meetings discussed general concepts and laid the groundwork for more specific discussion at this meeting. He said the process had evolved to following two tracks:

1. Development of a notation or footnote to the PEL list in Title 8 California Code of Regulations section 5155, which would be the focus of most the day's meeting.

2. Approaching the process of developing a substance-specific standard for certain sensitizing substances of particular importance. Steve noted that at the end of the June 10 meeting, Cal/OSHA Acting Chief Len Welsh had said that a standard should be developed for additional protection from the health effects of isocyanates.

Steve Smith said that the focus of the day's meeting would primarily be on track 1. He said that an hour would also be allotted in the afternoon for the start of discussion of a standard for isocyanates.

Steve Smith said he had received a number of comments on discussion draft language for amendments to section 5155 that would address sensitizers generally. These draft documents were sent out ahead of the meeting and are posted in the Cal/OSHA PEL advisory web area at: **http://www.dir.ca.gov/dosh/doshreg/5155PELSEN.doc.** The discussion draft documents also included two discussion draft medical questionnaires for sensitizers and a list of possible sensitizing substances. These documents can be found in the web area for this meeting (September 16, 2005) at: **http://www.dir.ca.gov/dosh/doshreg/5155Meetings2005.html**.

Beth Treanor started the discussion by asking what the criteria were for inclusion on the list of sensitizers in the discussion documents. She asked if it was similar to Hazard Communication where one scientific study of a health effect would result in inclusion. Steve Smith said that a list of sources was included with the table. He said the major sources described were from the British Health and Safety Executive (HSE) and substances in the ACGIH TLV list with the SEN notation and others where the critical effect in the TLV Documentation was stated to be sensitization.

Willie Washington asked how a substance would be added to this list. Steve Smith said that if a list such as this were to be adopted to designate sensitizing substances in section 5155 then a member of the public could initiate consideration by means of a petition to the Standards Board to add a substance suspected of causing sensitization. Willie Washington said he thought a new regulatory process was being suggested and so was glad to hear that was not the case.

Juli Broyles asked if the regulatory process for sensitizers would be different than that for PELs. Steve Smith said that going forward he hoped that consideration of sensitizers could be incorporated into the PEL process. Julia Quint said this could work but that it should not necessarily require a separate advisory meeting every time a new substance was proposed to be added to the list.

Steve Smith gave an explanation of amendments to section 5155 for sensitizers developed for discussion based upon the last meeting on June 10. He said the proposal was different than what had been agreed upon in 2004 for a footnote for the glutaraldehyde PEL. He said what was proposed was an explanation that would be a new subsection in section 5155 to explain a new notation column entry for sensitization. He said industrial hygienists would already be familiar with this approach from its use in the ACGIH TLV book. He said this approach would make it analogous in form to the "S" designation for skin absorbing substances already in section 5155. He said he did not see any difference in terms of enforcement between such a notation, and a footnote as has been proposed for glutaraldehyde.

Arthur Lawyer asked about the origins of dermal symptoms in proposed (d)(2). Susan Ripple said it was from the AIHA Workplace Environmental Exposure Levels (WEEL) definition. Julia Klees said that eye, nose, and throat

irritation should be in the definition for respiratory sensitizers but not for dermal sensitizers. Don Molenaar said he did not recall a discussion distinguishing dermal absorption from dermal sensitization. Steve Smith said that the current 5155 "skin" designation is only for potentially hazardous dermal absorption, and not necessarily limited to sensitization reaction.

Dan Leacox suggested clarifying (d)(1) by retitling it as skin *absorption*. Willie Washington supported the concern about the potential for confusion, noting that most small businesses lack the industrial hygiene expertise to understand the distinction between hazardous absorption and potential for sensitization. Vickie Wells said that the German MAK commission had worked out how to effectively describe the differences between skin irritation, hazardous skin absorption, and dermal sensitization.

Cynthia Graham said that the reference to "dermatitis" from exposure to sensitizers should be distinguished as being "allergic" contact dermatitis. Juli Broyles reiterated Willie Washington's concern about the need to make regulatory language understandable to laypersons including workers. She said also that Cal/OSHA should not get too far ahead of Federal OSHA or other states in regulating hazardous substances.

Steve Smith clarified that the purpose of the language proposed for discussion is to point employers to existing standards that address hazardous substances. He said that any substance proposed to be noted as a sensitizer in section 5155 would have documentation to explain the basis for the associated rulemaking. He said that such additional highlighting was intended in large part to help assure appropriate employee training.

Bob Harrison suggested a need to clearly distinguish the existing designation for "skin" absorption, from whatever might cover "dermal" sensitization. Susan Ripple supported this.

Jason Schmelzer questioned the need for a separate designation for sensitizers in section 5155. He said that if sufficient science existed to support this it would also support inclusion on the Material Safety Data Sheet (MSDS) which would adequately address the problem. Steve Smith reiterated that the purpose was to highlight sensitization risk which can be an obscure hazard. Jason Schmelzer asked if sensitizers were addressed in Cal/OSHA enforcement and consultation activities. Steve responded that they are among the hazards evaluated. Jason responded that if so why is additional regulatory language needed? Steve Smith responded that with minimal additional regulatory burden the discussion proposal language could help highlight for both affected employers and employees standards that are already applicable to sensitizers.

Juli Broyles asked if the Division had information on costs of sensitization-related illness. Steve Smith said that such information was not readily available. He said that because sensitization can result in a worker's being unable to continue at their workplace, and at others with the sensitizing exposure, the costs can be significant.

Jason Schmelzer said that there was not a consensus among employer representatives that what was being discussed was needed. Scott Jewett said that his company which franchises truck bed-lining operations is careful to inform its franchisees of the associated risks. He said he agreed with other points made by employer representatives. Susan Ripple said that a SEN notation was needed to address sensitization-related illness without having to set TLVs and PELs at levels so low that some substances would essentially be banned from use. Vickie Wells said that she did not see major additional burden on employers from what was being discussed. She said it was helpful to clarify what is required for employee training. She said that workers look at regulatory text of section 5155 more than they look at the PEL table. She said in her experience as an industrial hygienist workers are very angry when they find out they have been sensitized from a substance they were not aware had that potential.

Beth Treanor said that the costs of medical surveillance need to be considered. Arthur Lawyer reminded attendees that during discussions on glutaraldehyde in 2004 it had been agreed that there would be a follow-on process to address sensitizers more generally. Jason Schmelzer questioned if what was being discussed was the most effective way to address the problem. He, Willie Washingon, Juli Broyles, and Lynn Knudtson, said that if Hazard Communication requirements were not effectively addressing the problem why would anything else? Jonathan Frisch asked why sensitization was being singled out for special reiteration as opposed to other effects associated with hazardous chemicals.

Steve Smith reiterated that the purpose of what was being discussed was to provide additional highlighting of sensitizer risk, recognizing that it is something that can develop slowly over many years with devastating health and economic consequences for affected workers.

Cynthia Graham said that as a toxicologist she could not imagine employers and employees being able to effectively read an MSDS for sensitization effects. She supported highlighting the problem as Steve Smith had proposed.

Jeremy Smith said that if employers are opposed to development of a generic approach to sensitizers that supporters such as labor unions could simply petition the Standards Board for much lower PELs to protect against development of sensitization in all cases.

Willie Washington said he would be more open to what was being discussed for sensitizers if he heard why it was so critical. Steve Smith reiterated that the discussion was a consensus follow-on from the three meetings on glutaraldehyde held in 2004 and summarized the results of that meeting for Mr. Washington since he did not participate in those meetings.

Discussion of Proposed Language

Vickie Wells said that in the discussion draft for 5155(d)(2), discussion of exposure monitoring and ventilation systems was not relevant to dermal exposures. Arthur Lawyer said that the 4th line of (d)(2) should refer to Hazard Communication specifically for sensitizers.

Ted Knudson of Brush Wellman asked with regard to the discussion draft for 5155(d)(2) what other occupational dermal sensitizer responses are there beyond allergic contact dermatitis? He suggested striking the second line's reference to "responses such as contact dermatitis."

With regard to the first sentence of the discussion draft for 5155(d)(3) on respiratory sensitizers Ted Knudson asked how "occupational allergy" was proposed to be defined. Cynthia Graham suggested deleting reference to "occupational allergy." Bob Harrison said it was intended primarily to refer to work-related asthma. He suggested a possible language change to "work-related asthma due to specific sensitizing agents." Dan Leacox supported this suggestion as being clear to a layperson. Julia Klees and Paul Brownson suggested "can cause work-related asthma as a result of sensitization."

Cynthia Graham suggested striking "irritation" from the draft 5155(d)(3) language. Julia Quint responded that formaldehyde can cause irritation. Paul Brownson said that formaldehyde is a substance that causes both irritation and sensitization, but there are some substances that only cause sensitization.

Jon Frisch pointed out an apparent typographical error in the spelling of "necessary" at the end of the draft for (d)(3).

Medical Consultations and Examinations

Steve Smith moved the discussion to the proposal for adding a consultation and examination requirement to subsection (f) regarding medicals. Employer representatives objected, seeking explanation for rationale before discussion of details. Steve Smith said that the discussion proposal for medical response triggered by certain events was based on discussions at the June 10, 2005 meeting and summarized the results of that meeting.

California employer representatives said that such a proposed requirement ventured into the realm of workers compensation insurance for which they said they believed the Division did not have authority. Steve Smith acknowledged the comment and said that the language was based on that found in the standard for laboratory health and safety (8 CCR 5191). He said that many existing Title 8 standards for hazardous substances have medical components. He said the requirement of the lab standard was a minimalist approach to medical response, triggered only by occurrence of symptoms, PEL exceedance, or a spill, as compared to the more comprehensive medical surveillance approach in the standard for formaldehyde.

Jason Schmelzer said that if an employee has symptoms of sensitization that would be a workers compensation insurance claim. Steve Smith acknowledged the comment and said that what was in the discussion proposal was more prevention oriented, requiring that workplace exposure information be provided to the examining physician, record keeping, etc.

Juli Broyles asked if what was being proposed was a baseline examination. Steve Smith said it was not because it was only triggered by certain events (overexposure, spill, or symptoms of sensitization).

Roseanne Harding asked if the proposed medical response requirement would apply to offices of physicians and dentists. She said it would confuse them. She asked what the purpose was. Juli Broyles said that workers compensation insurance statutes require physicians to provide claims form to employees reporting potential symptoms of occupational disease.

Steve Smith said that the requirement as suggested is already at 8 CCR 5191 for laboratories. Roseanne Harding said that most employers were probably not aware of this existing requirement or were confused by it. Vickie Wells said it might be more feasible for laboratories than some other workplaces due to their being relatively controlled worksites.

Don Molenaar said that if the purpose of the medical response requirement is to protect worker health it does not go far enough because it does not include criteria for when an employee might need to be removed from exposure to prevent sensitization reaction. He said that what was being suggested could work but that it required examination by a physician knowledgeable in sensitization. He said also that medical examinations might be more appropriate for some sensitizing substances than for others. Vickie Wells supported the need for any examination to be performed by a knowledgeable physician in order for it to be useful. She suggested it might be necessary to limit the medical response requirement to only certain substances for which it could be most meaningful.

Julia Quint said a presentation by Dr. Susan Tarlo at the first glutaraldehyde meeting in 2004 suggested that medical response could help reduce severity of sensitization. Don Molenaar said that removal from exposure was required to achieve that. Julia Quint said that formaldehyde has an action level triggering medical assessment but that a threshold had not been identified for isocyanate sensitization. She said that TLVs and PELs are generally based on lowest levels of occurrence of effects rather than no occurrence levels and so the extra precaution of availability of a medical exam in the event of symptoms, spill, or overexposure was appropriate.

Bobby Bailey asked if there would be a threshold number of employees for requiring the medical response in the event of symptoms, overexposure, or spill. He said that for the hundreds of small locations his company deals with it would not be reasonable.

Steve Smith said it was clear that there was no consensus on the discussion language for the medical examination. He thought it might be addressed again this afternoon after the isocyanate discussion.

LUNCH BREAK

Isocyanates

Steve Smith opened discussion of a substance specific standard for isocyanates. Cynthia Graham asked if this was being pursued because of discovery of increasing problems? Steve Smith responded that they are being looked at as a well-recognized sensitizer of particular concern.

Jean Kasakevich asked what data is available on isocyanate cases in California. Bob Barish said that his informal discussion with personnel of the NIOSH-funded Sensor project in the California Department of Health Services indicated they had identified about 20 cases of confirmed isocyanate-related respiratory effects in California workplaces from the mid to late 1990s. Bob Barish said that this was the number identified through the Sensor process and that given limitations in reporting and confirmation should not be viewed as necessarily being the actual number of cases developing in California during that time.

Lynn Knudtson and Julia Klees said that in their facilities they had seen cases of respiratory illness from exposure to isocyanates declining. Bob Barish asked participants to send him data on their illness rates, as well as information on product stewardship programs and how illness may be tracked at customer locations. Steve Smith said it sounded like a good next step would be a sharing of data by HESIS, manufacturers, and isocynate users with the Division.

Cynthia Graham said that even though isocyanates are a group of substances each one would require a different standard. Julia Quint said that recognizing this potential difficulty European Union authorities had proposed an occupational exposure standard based on total reactive isocyanate groups (TRIG). She said that was something that should eventually be looked at.

Bobby Bailey said his company has 300 franchisees applying MDI polymer truck bed liners and so if there was a health problem to address his company would know about it. He said his company would be happy to assist the process of information sharing by providing its safety manuals and information on its processes for product application.

Steve Smith noted that OSHA Region V was looking specifically at potential issues with truck bed liner applications and exposure to isocyanates. Lynn Knudtson said that the Region V emphasis was prompted by reports of illness from truck bed liner applications but was not limited to that. He said the Wisconsin office of Federal OSHA had chosen to look at isocyanate exposures in a range of industries.

Bill Robert said the Alliance for the Polyurethanes Industry asked OSHA for an alliance to study truck bed liners.

Susan Ripple asked what the impetus was behind looking at isocyanates for a possible standard. Steve Smith said the Division had been looking at the issue for the last several years, including the appropriateness of a TRIG standard.

Lynn Knudtson said that a study of the effect of an isocyanate standard in the province of Ontario in Canada suggested that there had been no decline in cases of sensitization with the required program. Bob Barish asked if this had been documented. Lynn Knudtson and Bill Robert said they believed that it had. Julia Quint said that there is inevitably much underreporting of isocyanate-related illness and that as Dr. John Balmes noted in the January 19 meeting the threshold for sensitization is not known.

Susan Ripple said it was difficult to assess how great a problem isocyanates present. She said it could be a problem of communication, for example if spills occur but are not reported. So she said it was unclear what to address in a standard to be effective. Julia Quint acknowledged this difficulty, saying a major purpose of the meeting was to try to better define the problem with the assistance of interested parties.

Steve Smith asked participants to submit to him **or Bob** any information they might wish to provide, or which they had mentioned in the meeting, by the end of October 2005.

Return to Sensitizers Discussion Proposal for Medicals

Steve Smith suggested that work on development of the medical requirement be undertaken by a subgroup. Interested participants include Julia Klees, Julia Quint, Paul Brownson, Beth Treanor, Lynn Knudtson.

Lynn Knudston asked if the proposed sensitizer medical response requirement would be in addition to the requirement of section 5144 for a respirator medical assessment. He suggested that if other regulations such as for respirators and hazard materials emergency response had medical components then additional as was being suggested was not needed.

John Zomer asked if the existing section 5155(f) and the Order to Take Special Action process might be used to address the problem of medical assessment. Steve Smith said that it has been used to require employers to provide medical assessment of employees exposed to isocyanates but only after the fact, it was not a preventative approach to the problem.

Will Lorenz asked why the medical questionnaire distributed for discussion asked about smoking history. Julia Klees said that was just a routine part of a baseline respiratory health assessment.

Julia Klees said that the question of having a medical response requirement, and the details of the medical questionnaire, if any, were two separate discussions. She said that it was necessary to first decide if there would be a medical response requirement before discussing details of a questionnaire.

Bob Barish asked representatives of companies present which make or use isocyanates if they had medical programs for their employees. Don Molenaar said that his company and most other isocyanate manufacturers generally do have programs for periodic medical assessment of respiratory health. Bob Barish asked if these are more preventative in nature than what was being proposed for discussion. Don Molenaar said yes. Bob Barish asked isocyanate manufacturers if users of their products had similar programs in place. Manufacturing representatives responded that some do. Don Molenaar said that medical programs are a good idea but that they can be difficult to operationalize effectively, and that without medical removal provisions they are not effective.

Discussion of Sensitizers List

Steve Smith asked if it was necessary to separate whatever list was developed into respiratory and dermal sensitizers, and if so how that should be done. Arthur Lawyer suggested looking at ACGIH TLV Documentation for substances with the SEN notation. Susan Ripple said that the TLV Documenation indicates whether a substance is a respiratory sensitizer, a dermal sensitizer, or both.

Julia Quint noted that for some substances the TLV is based on analogy to a different substance with similar structure. She also said that the TLV for glutaraldehyde is based on respiratory irritation and only recognizes skin, not respiratory, sensitization.

Vickie Wells suggested that information from the German MAK Commission could be helpful in separating respiratory and dermal sensitizers.

Julia Klees asked what criteria the Division or the general PEL Advisory Committee would use in the future to designate substances as respiratory or dermal sensitizers. Steve asked attendees for assistance with that question. Manufacturer representatives suggested looking at each company's website for their isocyanate product stewardship program to see how they address the issue**.**

Arthur Lawyer said that he is in contact with trade groups for nickel and wood products which have tried to address the sensitization risk from some forms of those substances.

Will Lorenz asked if the Division was relying on industry or others to determine the list of sensitizing substances. Steve Smith responded that assistance is being requested with development of the process and criteria for developing the list. Will Lorenz asked how the Division addresses conflicting study results. Steve Smith said that when there is convincing evidence of a need to decrease a PEL based on the best studies, sensitization may then be taken into account if it is the critical effect upon which the PEL is based. Susan Ripple said that in the ACGIH TLV process a "weight of evidence" approach is normally used where studies conflict. .

Steve Smith wrapped up the meeting by asking participants to send him **or** Bob the information requested previously for medicals and isocyantes along with suggestions for criteria for identifying substances in section 5155 as respiratory or dermal sensitizers by the end of October 2005.

END