

MEETING SUMMARY

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

**JANUARY 19, 2005
OAKLAND, CALIFORNIA**

Attendees

Jim Kegebein, Health and Safety Consultant
Joseph Ascenzi, Advanced Sterilization Products
Jon Frisch, Pacific Gas & Electric Company
Larry Tipton, Southern California Edison
Beth Concoby, Genencor
Deepak Plaha
Barry Foose, Kaiser Healthcare
Bill Chase, McLaughlin Gormley King Co.
Paul Mischalko, State Fund
Barbara Cahrssen, Cahrssen Environmental
Elizabeth Treanor, Phylmar Regulatory Roundtable
Joe Guth, Center for Environmental Health
John Mehring, SEIU
Cheryl Christenson, Edwards Lifesciences
John Vocke, Pacific Gas & Electric Company
Don Molenaar, Bayer Corporation
Julia Quint, California Dept. of Health Services
Robert Harrison, California Dept. of Health Services
Mark Nicas, University of California School of Public Health
Jeremy Smith, California Labor Federation
Ripali Das, California Dept. of Health Services
Mike Wilson, University of California School of Public Health
Patty Quinlan, University of California San Francisco
Scott McAllister, DOSH
Mike Cooper, Vishay Siliconix
Fran Schreiber, WorkSafe
Anita Sarah Jackson, Center for Environmental Health
Quang Bui, Genencor
Judi Freyman, ORC Worldwide
Paul Brownson, Dow Chemical
Mark Pemberton, Lucite International
Greg Gorder, Technology Sciences Group
Arthur Lawyer, Technology Sciences Group
Roseanne Harding, California Dental Association
Susan Ripple, Dow Chemical
Beth Mohr, State Fund
Janice Prudhomme, California Dept. of Health Services
Steve Derman, Medishare

Meeting Staff

Bob Barish, DOSH, meeting chair
Deborah Gold, DOSH
Bob Nakamura, DOSH

Bob Barish opened the meeting with a welcome to participants. He referred to a handout which explained the background and purposes of the meeting and reviewed the agenda and handouts. He noted that this meeting was an offshoot of the process of updating the Permissible Exposure Limits in section 5155 of Title 8 of the California Code of Regulations. The second handout was a diagram of the rulemaking process, from a publication of the California Office of Administrative Law. The agenda was also reviewed. (These handouts are available at the “Handouts” link in the Advisory Committee area of the DOSH website (www.dir.ca.gov/dosh) via the A-Z index.)

The meeting started with a presentation by Dr. John Balmes, Professor of Medicine UCSF and Professor of Environmental Health Science U.C. Berkeley School of Public Health and Director of COEH. Dr. Balmes is a specialist in occupational medicine, pulmonary medicine, and occupational asthma.

Dr. Balmes noted that his presentation was entitled “Lower Respiratory Tract Sensitization” reflecting his expertise in pulmonary medicine. He said he that skin sensitization would be mentioned but not discussed in detail. Slides from the presentation are available electronically at the “Handouts” link in the Advisory Committee area of the DOSH website (www.dir.ca.gov/dosh) via the A-Z index.

Key points made by Dr. Balmes included:

The frequently cited figure of 15% of adult onset asthma being related, though not necessarily directly caused by, substances in the workplace.

Not everyone sensitized goes on to develop asthma – the response is influenced by multiple genes. The key effect is persistency (chronicity) of inflammation

Dr. Balmes noted that the indicator of a substance with immune effects is the occurrence of a delayed response. He noted further that for some of these substances the immunological mechanism of action has been identified and characterized and for others it has not, though they are still presumed to be immunological sensitizers.

Glutaraldehyde, is thought to work by a non-IgE immune mechanism

Atopy is probably not a risk factor for sensitization by low molecular weight sensitizers (eg. isocyanates) other than acid anhydrides

Approximately 20 studies have shown that with removal from exposure there is improvement in symptoms though not full recovery – so the key to prevention is early diagnosis of sensitization and removal of the exposure.

Co-exposure to irritants can aggravate effects of occupational asthma.

A study of isocyanate workers in Ontario since 1983 by Tarlo et al. including airborne exposure measurements and medical monitoring has found an association between earlier diagnosis of

sensitization and improved outcome in terms of decreased workers compensation claims – though part of that effect may be due to decreased isocyanate use.

A question and answer session with Dr. Balmes followed his presentation:

Dr. Janice Prudhomme asked about the relationship of skin sensitization and respiratory sensitization. Dr. Balmes indicated that it is hypothesized that a substance shown to be a skin sensitizer would be expected to have the potential to be a respiratory sensitizer. Dr. Balmes noted that Langerhans cells in the skin may respond similarly to dendritic cells in the lung that are related to immune response.

Dr. Julia Quint asked about the risk of sensitization posed by exposure to total reactive isocyanate groups (TRIG). Dr. Balmes said that this is an active area of study. He noted a case study by Malo which found pneumonitis in a worker exposed to polymeric hexamethylene diisocyanate.

Dr. Mark Pemberton asked if all late reactions in adults are occupational asthma. Dr. Balmes replied that they are not, but said that he tells his residents in training to always consider occupational asthma in their workups of new cases of adult onset asthma.

John Mehring asked about the prevalence of employers maintaining medical monitoring programs for sensitizers. Dr. Balmes replied that it would be difficult to know without a detailed poll of employers.

Bob Barish asked about the usefulness of interviews/questionnaires even in the absence of medical tests such as spirometry. Dr. Balmes indicated that while testing is important for obtaining objective medical information, interviews/questionnaires if carefully administered by knowledgeable staff can do quite a bit to identify potential problems.

After the lunch break Bob Barish began the review of handouts of AIHA WEEL and ACGIH TLV lists of substances with sensitizer notations. Susan Ripple discussed the WEEL and TLV processes. She is a member of the AIHA WEEL Committee and has served in a liaison capacity between the WEEL and TLV committees. She noted that the exposure limits and sensitizer notations are not adopted with an expectation that they will become regulations. She noted that the committees work closely using similar methodologies, both using a “weight of evidence” approach in their deliberations. She noted that the ACGIH SEN notation does not distinguish between skin and respiratory sensitizers as the WEELs do. Handouts were provided on substances with SEN notations in the 2004 ACGIH TLV Book, the ACGIH explanation of the SEN notation, and an explanation of the AIHA WEEL committee sensitizer designations containing the 2004 list of WEEL substances including those with the DSEN (dermal sensitization) designation. (These handouts are available at the “Handouts” link in the Advisory Committee area of the DOSH website (www.dir.ca.gov/dosh) via the A-Z index.)

Dr. Robert Harrison noted that the very extensive list of sensitizing substances developed by the AOEC (Association of Occupational and Environmental Clinics) should also be looked at. He noted that list has been adopted by NIOSH for use by SENSOR projects such as his in California for the purpose of tracking cases of occupational asthma. He noted that the AOEC list uses criteria established by Dr. Bill Beckett. Mark Pemberton asked about the criteria for the AOEC list and Dr. Harrison indicated that it was the presence of any case or scientific indication, not weight of evidence.

Fran Schreiber said that she was concerned with respiratory irritants that could cause or promote an asthma episode in workers with sensitive or reactive airways as mentioned in Dr. Balmes presentation. She thought that such episodes should prompt medical surveillance and reporting to the Division.

Mark Pemberton said that in the mid 1990s the question of hyperresponsive airway versus immune response was addressed in Europe. He said that out of those discussions came the term “asthagen” to denote substances which can cause immune respiratory response. He further noted that “risk phrases” (also known as “R phrases”) required by European Union regulations on chemical labeling used R42 for respiratory sensitization

and R43 for skin sensitization. Mark Pemberton noted that “reactive airway disease syndrome” or “RADS” as discussed in Dr. Balmes’ presentation is not seen as a hazardous property of a chemical but rather a health reaction to a chemical irritant.

Dr. Mark Nicas noted that “R phrases” are factors in exposure bands for “control banding,” a developing approach for controlling workplace chemical hazards. He proposed that for substances in Section 5155 that are determined to be asthmagens or asthma inducers that initial air monitoring be required, action levels set, and for workers or operations where the action level is exceeded there be a requirement for medical surveillance.

Julia Quint noted that Mark Nicas’ proposal is structured along the lines of the existing comprehensive standard for formaldehyde.

Joe Guth suggested that coming from his involvement with environmental substances more documentation was needed to support exposure limits chosen. Fran Schreiber reading from section 144.6 of the California Labor Code noted that it does not call for cost-benefit analysis in setting PELs but rather calls for adoption of the level of exposure “*which most adequately assures, to the extent feasible, that no employee will suffer material impairment of health or functional capacity.*”

Steve Derman noted that in determining the action level under the proposal made by Mark Nicas, consideration would need to be given to the lower limits of detection for available air sampling methods. Barry Foose said that the lower limit of detection of the method for glutaraldehyde is 0.016 ppm. Susan Ripple said that four laboratories in the United States can analyze samples for glutaraldehyde down to 0.015 ppm.

Bob Barish asked for attendees’ reaction to the proposal for separate air monitoring and medical surveillance requirements for respiratory sensitizers. In response Dr. Don Molenaar asked if there was evidence that current limits of exposure were not adequately protective? Julia Quint responded that one of the problems is that a number of the PELs for substances generally recognized as confirmed or possible respiratory sensitizers are not set at the level to prevent sensitization. Dr. Molenaar suggested that lowering the PEL would not necessarily address dermal sensitization.

Bob Barish asked again about response to the proposal for a separate requirement for air monitoring and medical surveillance. Judi Freyman said she would like to see details of the formaldehyde standard to fully understand what is being proposed.

Bill Chase noted that his company produces pyrethrum which was shown on a handout passed out at the meeting as a substance with an ACGIH TLV having sensitization listed as a Basis or Critical Effect. The handout (included with this summary in a revised format) noted that the pyrethrum TLV does not currently include the SEN notation. Bill Chase noted that while technical grade pyrethrum is recognized as a sensitizing substance, in its more diluted form applied as a pesticide it is not believed to have this effect. He noted that there are strict federal requirements for application, re-entry etc. Bob Barish noted that Division’s jurisdiction over pesticides is generally limited to non-application exposures such as during manufacturing.

Beth Concoby said that air monitoring is not appropriate for skin sensitizers. She noted that her company manufactures subtilisins and has found it difficult to monitor for them. She noted that as with pyrethrum, sensitization is indicated as a Basis-Critical Effect for the ACGIH TLV though it does not currently carry the SEN notation. She also said that for laboratories, resources were better spent on control measures such as laboratory fume hoods than on air monitoring. She also said that if a separate requirement was to be promulgated for monitoring airborne exposures to sensitizing substances care should be taken to ensure that monitoring methods are available that are can measure down to the PELs or action levels adopted. Susan Ripple noted that ACGIH TLVs and AIHA WEELs are set without respect to the availability of monitoring methods.

Artie Lawyer said that the approach of the formaldehyde regulation might be good for low molecular weight aldehydes and similar substances but that additional consideration might be needed for other types of substances

such as those with high molecular weights. He also noted that the approach from the formaldehyde standard being suggested would not address the risk communication component as did the footnote for glutaraldehyde from the meeting on October 14, 2004.

Bob Barish referred to the handout with text of a proposal for a footnote for glutaraldehyde that was developed by an advisory meeting on October 14, 2004 and is contained on page 3 of the minutes for that meeting that are available at the “Handouts” link in the Advisory Committee area of the DOSH website (www.dir.ca.gov/dosh) via the A-Z index.)

John Mehring said that if the approach of the formaldehyde standard for exposure and medical monitoring was taken for respiratory sensitizers then the footnote for glutaraldehyde discussed at the meeting on that substance on October 14, 2004 might not be needed. Patty Quinlan said she saw no point to the restatements and references to other existing regulations for glutaraldehyde suggested by the footnote shown in the minutes from the October 14 meeting.

Fran Schreiber noted the importance of the Division moving quickly to revise the PEL for glutaraldehyde. Joe Guth said his reading of the minutes for the meeting of October 14, 2004 on glutaraldehyde suggested that the footnote was to make up for not accepting the recommendation of the Air Contaminants Advisory Committee for a PEL of 0.015 ppm Ceiling for glutaraldehyde. Beth Concoby noted that if the footnote is pursued the word “allergic” should be added before “contact dermatitis.” Dr. Mike Wilson objected to the glutaraldehyde footnote as being a poor precedent of a specific footnote for a specific substance. He preferred the approach suggested from the standard for formaldehyde. Dan Leacox said that the spirit of the meeting on October 14 was that the footnote was an interim measure just for glutaraldehyde, with the understanding among those in attendance that the present meeting would be held to try to establish a footnote or other approach that would address sensitizing substances more generally.

Fran Schreiber reiterated her concern with irritant induced respiratory reactions. Julia Quint said that if irritation occurs from a substance which has a PEL based on preventing irritation then it suggests that the PEL was exceeded. Fran Schreiber said that she had a construction project in which a number of employees suffered respiratory irritation from chlorine gas – an episode for which she thought there should be a reporting requirement.

Roseanne Harding said she felt that the dialogue around irritants tended to confound the discussion of sensitizing substances. Mark Pemberton said a number of researchers have theorized that some chemicals may cause sensitization only after long term exposures. Roseanne Harding suggested that any regulation on sensitizers be “scaled,” ie. recognize sensitizer strength in the magnitude of what would be required.

Susan Ripple suggested that it would be best to start with a proposal for immunological sensitizers and only later try to address substances that might induce asthmatic reactions by irritant effects.

Beth Concoby said it would be important in designating sensitizing substances to differentiate between respiratory and skin sensitizers.

Robert Harrison suggested not relying on just the TLV and WEEL tables for designating sensitizing substances. He said that the AOEC list mentioned earlier should also be considered. He noted that Dr. Balmes in his presentation did not discuss the other sources used to designate lists of sensitizing substances.

Susan Ripple said that terminology was important, for example allergen vs. asthagen, as in European Risk Phrase 42.

Artie Lawyer said that representatives of manufacturers and users of high molecular weight sensitizers such as enzymes were not in attendance at the meeting and they might feel that different approaches are needed for such

substances. He said he would try to get individuals with interests in these substances involved in the next meeting.

Mike Wilson said that the goal of the discussion of the meeting was safer workplaces using inherently safer substances. While the Cal/OSHA PEL process does not directly promote substitution, requirements related to use are important because they not only help to control exposures but can also encourage the use of safer materials.

There was brief discussion of a follow-up meeting. Bob Barish indicated that he would provide notice of the next meeting to attendees of this meeting and to interested parties contacting him.

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