

Minutes
Cal/OSHA Advisory Meeting: Globally Harmonized System (GHS)
Update to Section 5194, Hazard Communication
Tuesday April 9, Oakland CA

Chairs: Deborah Gold, Steve Smith

Notes: Mike Horowitz, Grace Delizo

Participants

<u>Name</u>	<u>Affiliation</u>
Michael Hall	Pacific Maritime Association
John Messing	OSHA Training Center
Ken Clark	Willis/American Society of Safety Engineers (ASSE)
Kevin Thompson	Cal-OSHA Reporter
Russ McCrary	Ironworkers
Greg McClelland	Western Steel Council
Nancy Bean	GHD, Inc.
Tim J. Podue	International Longshore and Warehouse Union (ILWU)
Carol Barake	Bickmore Risk Services
Laura Stock	LOHP/CAOSHSB
Gina Solomon	Cal/EPA
Michael Musser	California Teachers Association
Carl Borden	CA Farm Bureau Federation
Joan Lichterman	University Professional & Technical Employees (UPTE)-CWA 9119
Mike Smith	United Steel Workers (USW) Local 5
Len Welsh	State Comp Insurance Fund (SCIP)
Mike Welsh	UC Berkeley-Labor Occupational Health Program (LOHP)
Pam Dannenberg	CA State Association Occupational Health Nurses (CSOHN)
Larry Mclouth	Lawrence Berkeley National Lab
Vince Lamaestra	Pacific Maritime Association
Kevin White	California Professional Fire Fighting
Bob Miller	Southwest Carpenters Training Fund
Dan Leacox	Greenberg Traurig
David Shiraishi	Area Director, US Dept. of Labor/OSHA
Dennis Shusterman	CDPH/OHB/HESIS
Chris Kennedy	Kaiser Permanente
Vickie Wells	SF Dept. Public Health
Dave Flores	Grimmway Farms
Steve Johnson	Assoc. Roofing Contractors of the Bay Area, Inc.
Katy Lind Evelyn	CSAOHN
Diane Graham	Keller & Heckman, LLP
Ross Nakasone	BlueGreen Alliance
Ron Espinoza	United Steelworkers
Mitch Seaman	California Labor Federation

Bruce Wick
Scott McAllister
Julia Quint
Jacob Delbridge
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Bob Downey
Dale Goss
Robin Dewey
Ed Klinenberg
Paul Burnett
Michael Herges
Melvin MacKay
Jay Jamali
Wendy Holt
Michael Wilson
Victor Esparza
David Payette
Jay A. Weir
Ronald Kilburg
Patricia Gaydos
Ken Smith,
Robert Wegis
Billy Puk
Dave Harrison
Michael Strunk
Eric Rozance
Kate Smiley
Anne Katten,
Richard A. Negri
Ernest Pacheco
Catherine Porter
Amanda Hawes
Dorothy Wigmore
Mani Berenji
Stephen C. Davis,
June Fisher
Paula Bouyounes
David Kernazitskas
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CALPASC
Cal/OSHA (retired)
Physicians for Social Responsibility

CDPH/OHB/HESIS
Construction Employers Association
Environmental & Occupational Risk Management, Inc (EORM)
UC Berkeley-LOHP
CA Industrial Hygiene Council (CIHC)
Santa Clara Valley Water District
Granite Rock
ILWU Local 10
Enviro-Safetech
CSATF/AMPTP
UC Berkeley-LOHP
International Union Operator Engineers Local 12 (IUOE)
Sacramento Municipal Utility District (SMUD)
A.T. & T.
El Dorado Irrigation District
US Dept. of Labor/OSHA
University of California Office of the President
Grimmway Enterprises, Inc.
Recology, San Francisco
Operating Engineers Local #3 (IUOE)/CAOSHSB
Operating Engineers Local #3 (IUOE)
Phylmar Regulatory Roundtable
Associated General Contractors
CA Rural Legal Assistance Foundation (CRLAF)
Service Employees International Union (SEIU)
Communication Workers of America (CWA)
CA Healthy Nail Salon Collaborative (CAHNSC)
Worksafe
Worksafe
UCSF Occupational Medicine
LaCroix Davis LLC
TDICT Project
PASMA (Public Agency Safety Management Association)
CA Occupational Safety & Health Standards Board (CAOSHSB)
CA Dept. of Industrial Relations, Office of the Director

Also the following, representing units of the Department of Industrial Relations. The Division: Chief Ellen Widess, Deputy Chief Deborah Gold, Suzanne Marria, Steve Smith, Bob Nakamura, Grace Delizo, Mike Horowitz. DIR: Juliann Sum. Standards Board: Marley Hart

Introductory Remarks

Cal/OSHA Deputy Chief Deborah Gold opened the meeting and introduced Juliann Sum, representing the Department of Industrial Relations (DIR); Marley Hart for the Standards Board; and representing Cal/OSHA (the Division) in addition to herself were Suzanne Marria, Steve Smith and Cal/OSHA Chief Ellen Widess. She also acknowledged representatives from federal OSHA, CA Department of Public Health and Cal/EPA.

Chief Widess welcomed and thanked the diverse interests present for the beginning of rulemaking to adopt appropriate changes to California's Hazard Communications Standard and other regulations to address changes made by federal OSHA to incorporate the new Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Widess stressed that the Division wanted to hear from all in this rulemaking process.

She noted that Standards Board had already temporarily adopted most of those provisions of the federal GHS standard that provide improvements to hazard communication. Today, Widess said, begins consideration of those few issues we have determined we cannot simply adopt without a hearing—or “Horcher”—because these federal provisions may actually render parts of California's current Hazard Communication Standard less effective. The Labor Code mandates adoption of rules that are “at least as effective as” new federal rules, but prohibits adoption of new federal standards without a full rulemaking process if the new regulation weakens current protection under existing California standards.

A cornerstone of worker protection, Hazard Communication, or the Right to Know, shaped her life, leading her to lifelong work on occupational safety and health, Widess said. In the late 1970's, Widess was Chief of the Cal/OSHA Pesticide Unit following revelations from the union, OCAW, that male workers at a California production facility for dibromochloropropane (DBCP) had become sterile. These workers were never warned of this hazard of DBCP, nor was Cal/OSHA informed so it could set protective exposure standard.

It turned out that DBCP, first produced as a soil fumigant in 1955 by Dow, Shell, and Occidental Chemical Company, had two major toxic effects: reduced sperm counts in males and damage to kidneys in both sexes of rats. By 1958, Dow and Shell had data showing that DBCP was absorbed through the skin, by inhalation, and affected liver, lung, kidneys and testes in rats. By 1961, the industry had published data confirming the two major toxic effects of DBCP, but the chemical was still registered as an approved pesticide and used widely throughout the world with a label merely stating “Do not breathe vapors, avoid prolonged breathing.” The warning label contained no reference to testicular damage.

Widess explained that the inadequate labeling and lack of any workplace exposure protections continued from the 1950's to 1977 with no attempt made to provide health warnings, PPE or medical surveillance to the workers. Only the worker's own tragic discovery of their sterility and the OCAW union's petition to federal OSHA in 1977 led to a final standard limiting exposure to 1 part per billion becoming effective 1978--27 years after DBCP's introduction and widespread use in CA, the US and the world.

These revelations spurred California to enact the nation's first Hazard Communications law in 1980--*The Hazardous Substances Information and Training Act*—or Right to Know Law and following the law's

adoption, Cal/OSHA adopted the nation's first Hazcom standard. The law and Cal/OSHA regulation received broad bipartisan support because both were based on the fundamental notion of disclosure of harm. The Hazcom statute, and the MSDS and labeling associated with it, is equally vital to workers so they can know the hazards of the chemicals they work with; to employers so they can provide safe working conditions; to doctors so they have the necessary knowledge to diagnose and treat patients properly; to emergency responders for their own protection; and to the Cal/OSHA program so it can do its job evaluating regulations that may be necessary to protect workers from known hazards in workplaces.

Widess noted that it took federal OSHA three more years to adopt a national Hazcom regulation, Since that time California has continued to break new ground with the adoption of Proposition 65 in 1986 to provide notice of chemicals known to cause cancer or reproductive harm.

Today, concluded Widess, as we get comments on how California should address these few sections of the federal standard where California law is stronger, we need to keep in mind the obligation we all have to ensure that every worker can go home healthy after a hard day's work—protected from the invisible hazards as well as the more obvious safety hazards. Our goal is simply **disclosure** of information to protect workers and inform employers so they can provide a safe and healthy workplace.

Current Rulemaking Project and Agenda Review

Deborah Gold summarized the status of the GHS package. Since federal OSHA's announcement of the GHS changes on March 26, 2012, and after Standards Board and Division staff reviewed hundreds of pages of pages of federal rulemaking and the changes made to over 40 related standards, as well as the Hazard Communications Standard, 8 CCR 5194., it was decided that issues that could not be adopted under abbreviated Horcher rulemaking should be divided into two parts for regular rulemaking: 1) Primarily safety issues addressing physical hazards (including issues about definitions of flammable liquids) to be addressed by the Standards Board at a public hearing to be noticed for July, and, 2) health issues to be discussed at today's advisory meeting .

D. Gold noted that hazard communications is a complicated area of regulation in California because it is rooted in the Hazardous Substances Information and Training Act, Sections 6360 – 6399 in the Labor Code, which was passed in 1980. Three years later, federal OSHA adopted their first standard, which led to amendments to California's standard. In 1992, the Standards Board updated the Hazcom regulation to reflect the 1986 Proposition 65 law, requiring notice of chemicals known to the state of California to cause cancer or reproductive harm. In 1997, federal OSHA amended its approval of California's state plan to include wording around Proposition 65. The tools of Hazcom – labels and MSDS, [now SDS], have come to be the underpinning of programs, legislation, and regulations of other California agencies involving Community Right to Know, emergency response, safer cosmetics, and safer chemicals.

Also in the 1990s, Gold said, the Legislature established an abbreviated process by which the Standards Board could adopt a federal standard. At the November meeting of the Standards Board, a hearing was held regarding the Division's proposal to use that process [Horcher] to adopt *portions* of the federal changes, *but not all*, because some of the changes, that we will be discussing today, might either conflict with the Labor Code, or make the standard less effective. Many comments were received.

At its March, 2013 meeting, the Standards Board approved the *temporary* limited adoption of most of the federal language. These changes will have to be readopted as permanent changes later, but may need to be readopted as a temporary measure within 6 months. The old California standard remains in effect today, but we anticipate the Office of Administrative Law (OAL) to approve the adopted changes within the next few weeks, at which point the temporary language will be in effect. You have a handout of that language, Gold said.

The GHS contains many improvements to Hazcom, and the vast majority of the federal language is proposed to be adopted, for example, how labels are structured, SDS contents, and training and education. There are certain other changes that federal OSHA made that the Division believes require discussion, and may require specific California language to address. Those are the subjects noted on the agenda, and draft language for discussion today is available as a handout, Gold said.

She then identified each of the other handouts for the meeting. Pointing at a chart illustrating the California rulemaking process, Gold explained that today was the first step in preliminary activities prior to formal rulemaking under California's Administrative Procedures Act. Soon, the Division will prepare a package to go to the Standards Board with proposed changes to subsection (d) of 8CCR 5194. Subsection (d) applies to manufacturers and importers, but not to employers who rely on an SDS provided by a manufacturer or importer. SDS are used by employers to make decisions about which products to purchase, how they will be used, which airborne contaminants to monitor for, choice of personal protective equipment, and for training. If an employee becomes ill, the SDS provides information about ingredients to medical personnel so that they can know what the employee was exposed to. Employers have increasingly come to rely on the SDS to choose which chemicals to use, so as to restrict the effects of chemical use on employees and on the public. But employers are not required to prepare SDS. Gold noted that the blue handout, the "discussion draft" is the Division's first shot at addressing the regulatory changes. The draft is a tool to focus discussion at today's meeting, not a rulemaking proposal. This is a first step, and, she stressed, we will review all comments, verbal and written.

Gold introduced the meeting agenda, noting that the requirement for the Director's List of Hazardous Substances and the biennial updating of the list was created by the Hazardous Substances Information and Training Act (HSITA), and that some of the GHS features will require the Division to renew work regarding the Director's List. Gold said the advisory meeting needed to address the relationship of the federal GHS rule to the HSITA as well as the needs of workers and employers.

Gold identified the five main points of the agenda and asked for a show of hands of those who were planning to speak on each. Gold also mentioned that in addition to the main agenda items, other issues needed to be addressed via brief discussion, such as: 1) making GHS changes to standards that are not federal standards—this is mainly changing references from MSDS to SDS; 2) making parallel changes to substance-specific standards that the Feds don't have (diacetyl, EDB, and MBOCA) so required labels reflect GHS use of terms like danger and warning; and 3) proposals to require annual haz com training.

Catherine Porter, Healthy Nail Salon Collaborative, asked for clarification about the rulemaking process. Gold said she expected July 1st to be the effective date for the temporarily adopted GHS rules. These rules adopted at the Board's last meeting were good for six months; this action was taken so that employers know what they need to do to train employees to comply with the first federal GHS implementation deadline of December 1, 2013. Either the advisory process would result in permanent rulemaking being completed within 6 months, or it will be necessary to re-adopt the language again on

temporary 6 month basis. People who sign the attendance list today will become part of the list used to notify the public of steps in this process.

Porter asked if Title 8 language on one positive study and the source list had been part of the Horcher adoption by the Board. Gold clarified that this language was still in the standard and still in effect; the California Hazcom standard presently still requires source lists and one positive study to be used for SDS preparation. We are trying to figure out how to keep that and satisfy federal OSHA.

Agenda Topic 1: Source lists

Gold then introduced the first agenda topic, "Source Lists". In the federal GHS system, in a change from the previous requirement for chemical "evaluation", chemicals are to be "classified" by weight of evidence for hazardous effect. It is left to the SDS preparer to review all the studies, positive and negative, on a chemical and decide on the proper classification. If the SDS preparer decides a chemical is not classified, there is no requirement to list the chemical on the SDS. This is a departure from the former federal standard which required that chemicals for which the American Conference of Governmental Industrial Hygienists (ACGIH) had adopted a Threshold Limit Value (TLV) be listed on the MSDS, as well as the associated hazards. Chemicals listed by the National Toxicology Program (NTP) or the International Agency for Research on Cancer (IARC), as carcinogens, or by 29 CFR 1910.1000(federal PEL list) are also required to be listed on the MSDS with associated hazards. In California, Gold indicated, the Director's list includes substances listed by the International Agency for Research on Cancer (IARC) as human or animal carcinogens, listing by federal EPA as water and air pollutants, substances listed by the FDA and substances for which there is a California permissible exposure limit. It also requires the List to include those substances for which the repository of health information in CDPH, which is under Dr. Dennis Shusterman, has issued a hazard alert.

The existing California standard also includes as chemicals with health effects those that had been referenced in the pre-GHS federal Hazcom standard: the IARC, NTP and OSHA lists of carcinogens, and other hazardous chemicals on the OSHA PEL list, and the ACGIH TLV list. Gold added that all of these various lists of chemicals were compiled and published by national and international bodies after extensive research and public comment.

Under the GHS classification system, classification typically means a chemical's hazardous effects are placed on the label and SDS, Gold said. The discussion draft would require that where one of the authoritative bodies have already made a weight of evidence determination, a manufacturer or other SDS preparer would need to consider that it met the GHS criteria for classification. Gold said that Cal/OSHA believes this will lead to greater consistency. She added that federal OSHA does retain a requirement for IARC or NTP listed carcinogens to be noted on the SDS.

Dennis Shusterman, MD: I have two comments, both derived from occupational clinical experience rather than my position as HESIS Chief. I was as an attending physician at an occupational health clinic at UCSF, and I practiced for a decade before that. I appreciate Ms. Widess' recount of DBCP history. In preparation for today I compared the 1994 and 2000 hazard communications proposals. One thing that has been deleted is the word "floor." "Floor" translates to the Director's List. "Floor" sounds to me like a safety net; it means a floor for the worker Right to Know. I was a practicing physician before the California Right to Know legislation. Patients used to come in with symptoms they attributed to chemical exposure but they wouldn't know what the chemical was. They would ask if they should sneak from work a jar filled with the chemical so it could be analyzed. I remember one patient who had been

cleaning with a chemical that they mixed with bleach which had caused the patient to wheeze. The manufacturer claimed the ingredients were a trade secret. Having some idea of chemistry, I asked, "Can you tell me if the product has ammonia in it?" The technical consultant said he couldn't say because it was a trade secret. Only when I persisted did the manufacturer's consultant say that while he wouldn't confirm if ammonia was in the product, he could say that the reaction that occurred when the product was mixed with bleach was not an ammonia-chlorine reaction. The average primary care doctor would have been stonewalled. This is the historic place from which we came before the Right to Know Act, and it is not a place I want to go back to.

June Fisher, MD, Physician and Senior Scientist at TDICT Foundation: I have worked in occupational health and safety for many years; some of my students have grey hair. I'll be 80 in two months and I'm very selective on which events like this I attend. But I had to come today to provide historical perspective. I will come to the next hearing. I had to come today because, as Ellen said, the Right to Know is the cornerstone of occupational safety and health because it is essential to preventing disease from chemical exposures. If we lose anything, it will go backwards when we need to go forwards. It was, and still is a nightmare. MSDS are still not clear or easy to understand. I was a lab tech before I became a physician and worked in lab with lots of chemicals. I didn't know about the risks of chemicals and didn't know what chemicals I was exposed to. I worked with a lot of chemicals, using them with impunity. Then for 15 years I worked as a bench scientist and treating physician at Stanford, again exposed to a lot of chemicals. As result of those exposures now I am sensitive to various things. Formaldehyde, for example. When I walk into a room where it is present, I begin wheezing, and I have to leave, even if I am scheduled to speak. I was a consultant to the San Francisco Fire Department, but I couldn't find out what they were exposed to.

Once, during my prior life as a treating physician, I was lecturing on the dangers of ethylene oxide (ETO) at the Central Processing Unit of a hospital. The man who delivered the ETO bottles to the hospital didn't believe what I was saying about the dangers. The delivery man said, "Oh, that's crazy. My employer would have told me if that were true." But then the delivery man came secretly to my office to ask whether the multiple problems of a child recently born to him and his wife were related to his exposure to ETO.

I believe it is important that we use every source list that is available on health effects of chemical hazards. We have, in California, scientific criteria for accepting appropriate source lists. In California, it is important to keep those standards requiring use of source lists to identify hazards of chemicals.

I also believe that retaining the single positive study requirement is imperative. The single positive study, if well done, is important to use. We have history, with various chemicals, of waiting 20 or 30 years before widely identifying a chemical's harmful effects. One positive study will allow to us to apply the precautionary principle while spurring more research on the chemical. In my own research, I never want to publish because I never think I have enough data. But in the case of chemical exposures, we need to move. So don't use me as an example; retain the single positive study requirement. I promise to come back to the next meeting, when we may discuss expanding and improving the hazard communication rule.

Billy Puk, Recology, San Francisco: When a customer brings a material that is declared a hazardous waste, how does that affect us? It is brought to our facility as recyclable material, as we consolidate these wastes as a product, for example as paint. The customer doesn't provide an SDS. At our facility this hazardous waste is turned into a hazardous material that people are able to re-use. We allow

general public to take these consolidated wastes, or we send them overseas for recycling. How should we categorize this material? I think you should put in a definition. Once a chemical is returned to use, do we need to create an SDS?

D. Gold: If you become a manufacturer of a product you take on responsibility as manufacturer. We can talk later about the specifics of a recycling operation. The fact is, it is fairly common for companies to have reclaim chemicals from their hazardous waste streams and sell or reuse the material. Cal/OSHA is very aware of such treatment, storage and disposal (TSD) operations. In many cases these companies do have to produce an SDS. When I was a compliance officer I inspected a company that took the waste stream from plating shops and turned them into a composite they sold as “smelter cake”. This company had the responsibility to figure out what hazardous chemicals were in the smelter cake (hazardous metals such as lead, toxics, etc.) You may need a hazard determination procedure.

B. Puk: Both Cal/OSHA and federal OSHA help lines told us that under the old standard our product was not covered but it would be under the new GHS standard. D. Gold responded that they should discuss this further separately, because of the specific circumstances he is describing.

Julia Quint, PhD, San Francisco Physicians for Social Responsibility: I am retired from the California Department of Public Health (CDPH). I was HESIS Chief. My comments are as a toxicologist performing classifications of hazardous materials to identify hazards. I’m very concerned about federal OSHA striking source lists. This will lead to great disharmony. Toxicologists don’t see eye to eye looking at the same data or study. To have manufacturers and individuals classifying chemicals without guidance will lead to confusion. The agencies that create the source lists have guidance. But looking at Appendix A, I don’t see guidelines here. It is horrifying to me, although it is well meaning, looking at Appendix A and the prospect of having individuals do weight of evidence determination following Appendix A. The result will be that some people will use NTP and IARC and classify a chemical as a carcinogen, while others will decide that they will not classify the same chemical as a carcinogen. If you tell me you based your classification of a chemical on IARC, I can readily see how you arrived at your conclusion. Under the federal GHS, some SDS preparers will list chemicals based on those source lists, while others will do de novo weight of evidence determinations. This leads to inconsistency. It is very hard from the outside to figure out how an SDS preparer arrived at independent weight of evidence conclusions. I couldn’t tell, and DOSH won’t be able to tell. I guess they are supposed to keep a record, but this is not clearly stated. The European Union has a clear requirement for such a record, but Appendix A does not.

The standard is poorly enforced and it is getting worse. In the European Union GHS system, manufacturers are not required to use authoritative source lists. The EU system requires manufacturers to submit notifications on their chemicals’ classifications. I searched more than 2000 EU notifications on the classification of sulfuric acid, but found only 80 that classified sulfuric acid as a human carcinogen even though IARC listed sulfuric acid as a human carcinogen in 1992. Since the EU serves as the bellwether of GHS implementation, I am concerned about the lack of transparency, lack of consistency, and lack of disclosure in the federal GHS proposal. Appendix A says to look at the full range of information when classifying a chemical, which would include IARC, NTP and the other source lists. If you are a manufacturer, you are subject to liability for the accuracy of your SDS. The failure to require source lists will lead to inconsistencies and incongruities, which is bad for manufacturers. I think it is just wrong, Quint said.

Lastly, speaking as former HESIS director, I think the Director’s List is essential. After the DBCP situation, the legislature wanted to establish a California system that would issue a California alert about

chemicals like DBCP found to hazardous in the future. This system was HESIS. Since its formation, HESIS has issued four or five hazard alerts for chemicals that were not on other source lists. [HESIS alerts are a source for the Director's list-ed.] For example, 1-Bromopropane. HESIS issued an alert on 1BP ten years ago. California has the only standard in the country for 1-BP. We don't want to roll back all of the gains we have had in California on the communication of chemical hazards. If we start now a new process of letting everyone decide what is a hazard, workers and employers are going to suffer.

C. Porter, CA Healthy Nail Collaborative: My organization focuses on reducing hazardous chemical exposures to women who work in nail salons and hair salons, where the workers are women of child bearing age, and mostly Vietnamese and other non-English speakers. We applaud any change that leads to more consistency in SDS and labeling. We support Julia Quint's comments. On source lists, we should remove the discretion of manufacturers about including chemicals that are on a source list on the SDS as much as possible. Without a source list requirement, this will lead to competitive disadvantage for some manufacturers who are trying to be more responsible by including a chemical on their SDS while other manufacturers are trying to hide the ball by not disclosing this information. We should make sure the economy supports the manufacturer trying to do the right thing.

Eric Pacheco, Communications Workers of America: CWA District 9 and the AFL-CIO fully support retention of the source lists. We are fighting legislation that attacks some of the lists. Our members work with over 5500 chemicals. We've been reviewing these chemicals and trying to get employers to shift to safer and greener products. Source lists are key to this effort, so delisting would be a real blow.

D. Gold: Are there any comments regarding the specific lists mentioned -- the Director's List, PEL list from federal OSHA, ACGIH list of threshold limit values, IARC, NTP, other lists?

Dorothy Wigmore, Worksafe: The Right to Know is what got me involved in health and safety; it is a fundamental and ethical issue. Bob Sass wrote the Right To Know law used in Canada, and he's the person who first trained me as an industrial hygienist. We've been active in the CHANGE coalition pushing for lists to be used in OSHA and other regulations. We recommend CAL/OSHA expand the lists required to include the list of lists to be used in Green Chemistry regulations. There are many more reputable lists out there for Cal/OSHA to consider. I'd be happy to supply you with them.

MSDS's are a constant thorn to me. They are hard for me to read. I've come to learn they lie by omission and misinformation. One example is a product called "BabbitRight," widely used for welding pipe joints, in air conditioning piping and other applications. The United Steelworkers issued a hazard alert about this product. Most MSDS it claimed the ingredients were a "trade secret." In 2006, I found an MSDS from one manufacturer, Rotometals, of San Leandro. Their MSDS said that none of the ingredients were classified as hazardous. Testing of the product done by the USW revealed this product contained 40 to 50% asbestos. "BabbitRight" is used all over the US and Canada. If manufacturers can't be trusted to tell us that asbestos causes cancer, what else will they hide from us? Without a list to tell companies like Rotometals that they must look at a list like IARC when preparing the SDS, and must disclose carcinogens, no one will have the right to know. I urge Cal/OSHA to stick to the lists and improve them and figure out how to deal with the Rotometals of the world.

J. Quint: I've submitted written comments in which I urge that the Prop 65 list be included as a source list for the Director's List. While carcinogen lists are good, they don't include reproductive hazards. The Director's List does not have a reproductive toxicants list as a source. I also urge that the ACGIH TLV list be included as a source list for its listing of respiratory (rsen) and skin (dsen) sensitizers. None of the PEL lists disclose the basis for the PEL. One of the good things about the TLV list is you know the basis for the listing. When classifying the health hazard of a chemical it is a real help to know the basis for the listing, whether it is a neurotoxin, a skin sensitizer, or if it is an acute or chronic toxin.

Ken Smith, University of California Office of the President: My comments today are my own professional opinion. I'm a certified health physicist and certified industrial hygienist. Currently the GHS standard in federal OSHA's Appendix A contains 35 hazard categories with criteria for each. Certainly, it is left to the manufacturer, importer or distributor to categorize properly. Whether or not Cal/OSHA maintains a list of list, it will cause problems. The problem is circular references among the lists. Labor Code 6382 contains five sub-lists that make a chemical eligible for inclusion on the Director's List. Many of these subsidiary lists overlap with the criteria for classification in Appendix A. For example, the carcinogen category includes NTP and IARC. A second example: The Labor Code requires listing if a chemical is on the federal OSHA PEL lists. I recommend you parse the lists.

D. Gold: A question for you; I don't think Appendix A requires classification as a carcinogen if the chemical is on IARC or NTP lists. The Appendix just says you can or may use these lists. Are you saying that we should not use these lists?

K. Smith: Also, Appendix F requires the use of IARC and NTP.

D. Gold; Appendix F is non-mandatory. Our concern is without mandating the lists, a MSDS preparer can disregard the IARC determination. As Julia Quint said, two toxicologists with opposite opinions can disagree with the conclusions of a study. Do we want to allow that kind of inconsistency for chemicals that have already been scientifically categorized by an authoritative agency like IARC? We're saying that if a chemical is listed by IARC, the SDS must indicate that the chemical is on the IARC list.

K. Smith: Certainly that's one of the challenges. But for instance consider aluminum, which is on the Director's List for its airborne PEL. By its inclusion on the list, a manufacturer making an aluminum can or ingot would have to provide an MSDS to any individual.

D. Gold: In regards to the aluminum can, there is an exception in Hazcom for "articles" which are anticipated to remain intact, as compared to something like welding rod. She asked if there were any comments regarding other exceptions that should be included, in relationship to the lists. Dan Leacox, Greenberg Traurig: The key factors to keep in mind: consistent criteria and multiple lists. The aim of GHS is to have chemical evaluations done with same criteria; lists don't necessarily use the same criteria or agree. Where lists do agree, there is a weight of evidence factor where we are getting consistent determinations that should lead to the same

classification. One way to look at SDS determination is to see if it is compliant with the federal rule. A lot of the examples we've heard are for items not compliant with the federal rule. The problem is not about disclosing IARC or NTP, but whether the chemical has been listed on the basis of consistent criteria. The lists need to be viewed in the context of the problem of omitting data. There is a problem that lists do not agree on the criteria.

D. Gold asked Dan Leacox whether it is desirable, in terms of listing chemicals, that a toxicologist dispute whether a substance listed by IARC or NTP should be listed on the SDS. She asked whether it would create more consistency if everyone had to list substances for which authoritative bodies had already determined there was sufficient weight of evidence to disclose the hazard. Shouldn't everyone classify a chemical on the basis of its NTP or IARC listing? If not, who has the final say?

D. Leacox: The final judgment rests with the enforcement authority. You are setting it up as a conflict of a list versus an SDS preparer. Ultimately, when you look at an SDS and see somebody trying to hide data, that person has a problem under the federal rule.

Mike Wilson, PhD, Director Labor Occupational Health Program (LOHP), UC Berkeley: As part of the Center for Occupational and Environmental Health (COEH), LOHP was set up 30 years ago to provide assistance to the state on occupational health problems, he said. We need to move in the direction of providing more information to workers, users and downstream businesses.

On the Cal/EPA side, downstream businesses are seeking information on carcinogens. It is important to those businesses to have the information on the SDS. To get rid of the lists, or to open up the listings to interpretation looks like dispensing with the global direction of recognizing the use of those lists to provide the accurate scientific information to the public despite the years of work and research that went into including these chemicals on the lists in the first place. The MSDS is only a piece of paper but it is the only required piece of information, the only requirement upon the chemical manufacturer to disclose information about the 74 billion pounds of chemicals in commerce every day.

Over the last five years a number of California businesses in the Business NGO Working Group have signed on to a declaration calling for more information and standardized information about materials they are receiving. Lists are the best we have but they are also antiquated. Information from the lists should be included on SDS. It will be a problem if California moves to dispense with the obligation to use floor lists, Wilson concluded.

Richard Negri, Pasadena Service Employees International Union (SEIU): It is mindboggling that this is a conversation about withholding information vital for our members and patients to be healthy. Withholding information from the floor lists that could affect all of that, that's nuts. In the letter we are submitting, we ask if any of our nurses work with chemicals and are not fully aware of the hazards, how can we be protected and carry out patient care? This could lead to a situation that is awkward or life threatening.

D. Leacox: I have a couple of more points. First, it is unfair to characterize the GHS and federal rule and process and criteria that federal OSHA signed on and agreed to as an effort to reduce information or hide the ball on employees. That was not the purpose of the GHS, which was a UN process. Where a producer is trying to comply, and if presented with differences in criteria because lists have different criteria, then you have a potential for a difference about what is compliant in California and what is compliant in another jurisdiction elsewhere under federal rule.

Second, the proposition that more information is always better is not true. In the GHS we have a determination that there must be some judgment about where to draw the line on information overload to make sure that what's there is valuable and you don't lose what's important due to the volume.

J. Quint: Maybe I'm misunderstanding Dan's reference to inconsistent criteria. There's a lot of consistency. IARC, NTP, and EPA all have guidance documents and their criteria are remarkably similar. I don't know if we are talking about the same thing. When I looked at Appendix A as a toxicologist, I needed more guidance; I didn't find Appendix A as being so crisp. I just saw this played out on a committee I was on that looked at the weight of evidence different groups used. These are the conversations that happen among toxicologists and why it takes 20 years to get a risk assessment done on a chemical. As a toxicologist doing this work, I needed more guidance under the federal rule, for example, looking at pharmacological data and modes of action. What literature search do you do? And then there is grey literature—unpublished data. There are no guidelines or tracks to follow in Appendix A. It made me dizzy to look at the amount of work necessary to properly classify a chemical, and to realize how we will never be on the same page.

D. Wigmore: I have two points. In response to Dan on the difficulty of California possibly having differences from other jurisdictions, GHS is an international agreement that took 10 years to create; I want everyone to understand that its first principle was to not reduce protection in any jurisdiction. Around the world different criteria are being looked at to define what is hazard and what information to include. In Canada, for example, the revision will retain some of the criteria Canada has had since 1988 that are different and better than the US. Australia and the European Union are doing different things. Those manufacturers who are involved in international trade have to worry about Indonesia, the EU and elsewhere.

In December, 2011 I wrote a letter to the California HEAC Advisory Committee in which I pointed out that the weight of evidence means different things to the chemical industry than to worker advocates. I suspect that Dan Leacox and I have different views. Therefore, without the floor lists it's harder to agree on what weight of evidence means.

D. Gold: As it says on the top of the blue sheet, some people were not able to attend today and are sending comments in. I encourage people to send in comments on this topic. We will continue to accept comments and will be posting them on line.

Agenda Topic 2: One Positive Study

D. Gold: Compared to source lists, there has been less discussion about whether you disclose a substance for which there is one positive study. A single positive study is a short way of referencing regulatory language which refers to a study which provides “statistically significant evidence... conducted in accordance with established scientific research and principles.” Let’s agree that when we are referring to one positive study this includes that assumption. In the past, if you had one positive study, say on 1-bromopropane, you would disclose its presence on the MSDS so you knew 1) that it was there and 2) the health effect that was studied. That’s taken out of the federal standard under GHS and we’re suggesting continuing to include it in California’s Hazcom regulation. . If you have one positive study and the chemical is not on one of the lists then you do a weight of evidence determination. To be clear, federal OSHA requires disclosure of one positive study for carcinogens, but it is unclear in the federal regulation how this is to be actualized. In the case of one positive study, should the name of the chemical and the health effect be listed on the SDS? Should you also have to list the positive study on the SDS? Should you have to list all ingredients if there is a positive study on a mixture? Gold asked if there were comments on language in the discussion draft regarding one positive study?

J. Quint: Are we talking about defining a health hazard with one positive study or are we just talking about listing one positive study on the SDS?

D. Gold: We have thought about three possible ways to deal with one positive study:

- 1) list the information somewhere on the SDS (Section 3, 15, or 11, or somewhere else);
- 2) put a similar statement into Appendix A which is how you’re going to classify chemicals;
- 3) keep the existing California definition of health hazard which says if there is one positive study, then the chemical is a health hazard.

J. Quint: I support listing one positive study as one of the definitions of a health hazard, given that the EPA guidelines for neurotoxicity, developmental toxicity and reproductive toxicity, they clearly outline that, with evidence from a single study, you can classify something as a neurotoxicant, developmental toxicant or reproductive toxicant. Look also at the California PELs; some of them are based upon one positive study. One study in glycol ethers has led to a HESIS Alert. It’s not like the government is testing all of these chemicals before they come into the market. We are waiting for some investigator to publish something so we can have a published study. Except for the NTP, we don’t have any government agency testing chemicals to see if they cause health problems. When an investigator looks at a developmental effect and

publishes a study, it's important. Ethylene oxide carcinogenicity listing is based on a single industry-sponsored study that was never published. But it was submitted to the EPA, so ethylene oxide got listed under TSCA (Toxic Substance Control Act). Many studies are not published; they just get submitted to the EPA.

D. Gold asked if J. Quint was satisfied with the statement about one positive study as placed in the federal Appendix A, which states that it may be the basis of classification?

J. Quint: I like what is in the existing regulation. Rather than putting the information from one positive study in Section 11 of the SDS or whatever, I think it is stronger as part of the existing definition for health hazard. This is consistent with the EPA and 29 CFR 1990.143, which clearly list one positive study as basis for listing. NTP is a bioassay in which one study is often used to list a chemical as a carcinogen.

M. Wilson: The floor list issue is a way to bring to light legacy chemicals that authoritative bodies have recognized as chemicals of concern. The one positive study is a way to see what's coming. The SDS is the only way risk from toxic chemicals is communicated from chemical producers to downstream users and purchasers; there is no other requirement for the manufacturer to communicate this information.

A single positive study is a scientific achievement. Statistics tend toward the null. A statistically significant demonstration of a health effect is an extraordinary scientific finding—often the result of the personal dedication of a life's work to this study. The bottom line is it would be less protective for California to step away from the requirement for producers to disclose the information.

I've heard the word "precautionary" used. I'd frame it as "the early indicator of harm." Businesses purchasing substances don't want to wait until there is clear evidence of a cause and effect. Knowing the results of a single positive study means you will make better informed decisions as a downstream business. This information is important, and I guarantee that the information will be put to use by businesses and others who use chemicals. Downstream users rely on this information for purchases because they have downstream liability. Knowing that a single study says a substance causes reproductive harm is important. It is appropriate for government to guarantee that the market has appropriate information on which to function. It is important for the most problematic chemicals to be so designated. I encourage Cal/OSHA to hang on to the one positive study requirement and to strengthen it to the degree possible so as to list the positive study and list the ingredient on the SDS.

Gina Solomon, MD, Cal/EPA: Speaking as an occupational physician, when I was a resident in the mid-1990's in Boston I saw a pregnant woman referred from an OB/GYN. She worked in company producing chemicals in batches for photography and the computer industry. She wanted to know if she should be concerned about any of the chemicals she worked with, and asked her OB/GYN who didn't know and referred her to me. I looked at the MSDS which were very helpful. One chemical that she handled every day was a solvent, N-Methylpyrrolidone

(NMP). One positive study showed NMP caused fetal toxicity in rats. So we were able to advise the woman to not continue handling NMP. The inclusion of the one positive study on the MSDS allowed us as physicians to give informed and useful information to that company and patient at that time. Since then there have been many studies that have confirmed that NMP is a reproductive hazard.

J. Fisher: Are drugs covered and required to have an SDS?

D. Gold: Labeling for drugs is covered by the FDA, but Hazcom does apply to drug manufacturers with exposure to employees. Assembly Bill 1202 might affect workplace requirements for certain antineoplastic and other hazardous drugs defined by NIOSH.

J. Fisher: Drugs are an area of rapid introduction of new products, in which the precautionary principle is ignored. Pentamidine was introduced in the 1990's at San Francisco General Hospital. We raised concerns about exposure of workers and we were told by colleagues that we'd kill patients if we didn't use it. Often colleagues don't know. There was one positive study indicating the potential harm, but this concern was overridden in the enthusiasm to treat patients. Meanwhile, in Sweden, patients were administered pentamidine in isolation booths because Sweden applied the precautionary principle to protect the health care workers. It is a fantasy to think that the FDA would require informing the exposed worker based upon a single study. The introduction of drugs into the health care environment is much more rapid and complex than the general chemical area.

Steve Davis, LaCroix Davis: Talking about hazard communication. I don't agree that providing more information to workers is better. There are health professionals that need this information but somehow these differing needs need to be separated. Maybe include additional information in the toxicological section of the SDS. Using the old MSDS, it seems the thought was the more information the better. But in communicating hazards to workers, you had to sift through a lot of information to find what was necessary for clarity.

Ron Espinoza, USWA. I worked for 27 years at Shell Refinery, in Martinez. Now I'm working for International Local 5. I've listened to all that has been said and am humbled by the toxicological expertise that has been assembled. I am a worker. The issue I am concerned about is that we don't take our eyes off the State of California and what we stand for. I've traveled around the country doing union trainings and meetings and I always get, "Oh, you're from the 'left coast.'" I'm proud to be from the 'left coast' because we do the 'right thinking.' Harmonizing doesn't say we have to diminish what we have in California; it leaves open the possibility to have what we have in CA or to add. I don't want MSDS to be novels, but I don't want them to be Reader's Digest version either. If you're a worker, you are told do your job, do it well and you won't have any problems. If I don't have the information to guide me, I rely on the boss to tell me. Workers wonder about a smell or a rash, but often managers overlook the hazard. When it comes to safety, there is a history of people being harmed on the job. I agree with Ellen we want workers to come home safely. But when does the other shoe drop because I was dealing with gasoline emissions and shipment of material off the ship and later get leukemia? Our Health and Safety director sent a letter to Cal/OSHA. I have two documents to add: the Eula Bingham study and a report on DBCP. Thank God that DBCP is now banned. But back then there was a single

positive study and wives talking at a ballgame realizing they all had problems reproducing. If it is happening to me, it is significant.

D. Wigmore: Ellen has talked about the DBCP example. In 1961 a study was submitted for publication and was also submitted to the EPA, although companies asked the EPA to keep it secret. It included effects on female rats, but also documented effects on male rates, which no one talked about. The filmmakers of the documentary “Song of the Canary” tell the DBCP story. I have a clip where a plant manager talks about how the company interpreted the one study’s description of testicular atrophy in male rats as not relevant to the plant’s male workforce. *[Wigmore attempted to play the excerpt from a recorder into the microphone, but few in the audience could hear clearly. The excerpt is included as an advisory committee document. At this point there was a break in the meeting for lunch-ed.]*

After lunch, D. Gold asked speakers to try to identify which of four potential regulatory actions on the single positive study the speaker could support. The four options were written on the white board at the front of the room, as follows, if one positive study existed for a chemical:

- A) Classify  Label, SDS
- B) List Ingredient/Studies SDS
- C) List Ingredient/health “effect” SDS
- D) Define as health hazard

D. Leacox: On the one positive study, it is important to distinguish between the definition of health hazard, which runs counter to the classification system, and the concept of disclosure. Once one makes a decision about one positive study, one shouldn’t enshrine that study forever. The reasons one can’t do that include human relevance of the study and the degree of exposure experienced by workers. Studies are the inputs of evidence into evaluation, they are not the result.

The other thing on the assignment of a classification to a particular hazard is that it is also true about one positive study is that it may shut down further study, and it may not turn out to have been an accurate study. There are valid considerations such as the study may not be relevant to humans, and that may mean the study is not necessarily dispositive. Also, the nature of a study can be a problem – even if the study meets criteria as a credible single positive study, there might have been fraud in the study. Recently, 2000 peer reviewed studies were withdrawn by the journals that published them; 65% of the withdrawals were for fraud or suspected fraud.

D. Gold: Are you opposing option C?

D. Leacox: It makes a huge difference in what you have to do. There are a lot of large data sets, and you risk overburdening the SDS preparer.

D. Gold asked whether he was opposed to all the options listed, or to option C. She asked D. Leacox if, for example, there were one positive study providing evidence that toluene was a

neurotoxin, and the MSDS preparer determined that this was insufficient to justify classification. She asked D. Leacox if he would say that the information on toluene neurotoxicity should still be listed in Section 15 of the SDS? D. Leacox: The position I'm bringing at this meeting is to match the federal rule, and even if there is one, to acknowledge the limitations with a single positive study. If you do use the study for disclosure, there is a risk that depends on the nature of the disclosure policy. If disclosed it is necessary to say that it is not dispositive that there is a single study. It is important to take this into account.

Len Welsh, State Compensation Insurance Fund: I think Dan Leacox is saying that first position is, he supports the federal language only. But if that's not going to happen, then on the disclosure thing, it matters how much actual information has to go into the disclosure box. Is it as simple as stating that 'may be a liver toxin according to at least one study' or 'may be a liver toxin according to XYZ study?'

D. Leacox: Yes. There is a difference between listing every study and a general statement of the existence of hazard as indicated by one study. If you cross the line to using that as a definition of hazard, you cross another line that is a whole other problem.

D. Gold: So am I correct that you are saying that you are against Option A. You are against B, listing every study. Option C is okay, if the requirement is for a general statement. You oppose Option D.

D. Leacox: Right.

D. Gold: You could more live with C even though it's not what you came to advocate for?

D. Leacox: Right.

L. Welsh: I cannot see a logical rationale to doing away with the source lists as de facto weight of evidence compliance. The less we standardize the weight of evidence application, the more we are going to see different companies coming out with different assessments of whether their particular chemical is hazardous or not or what level of hazard it constitutes. There are hundreds of manufacturers who will all be coming up with a MSDS and different pronouncements about the hazardousness of the substance. I don't understand the logic of why federal OSHA came up with what it did, or why. I think federal OSHA will support a protocol to utilize the source list.

Currently the health hazard definition looks like it is in conflict with Appendix A because it says a single positive study is a health hazard, while the Appendix does not. Whatever final version of the definition is passed, it will have to solve that conflict.

Finally, I saw a comment at the March Standards Board meeting that suggested manufacturers would have to produce two sets of SDS or even labels, one for California and one for the rest of the country. This could be a problem if we don't get the language right and get federal OSHA

clarification that they will accept the approach to SDS and labels before the Standards Board votes.

J. Quint: I wanted to clarify Dan's comment about the difference between exposure and health in terms of criteria or assessing a study. They are very different. We're talking about health or toxicology here, not exposure. Exposure is site specific and should be covered in training.

I am a strong proponent of maintaining one positive study in the definition of health hazard. I am now in the process of reviewing chemicals on lists. Many chemicals are already on a list. What chemicals come off lists if you don't use one positive study? The federal standard says the SDS preparer must use expert judgment. Experts don't take one study in isolation but consider how to evaluate a single study to see if it, can be used to support a non-carcinogen health hazard classification. Note that the EPA uses single positive studies in their reproductive and neurotoxin analyses. If we eliminate the use of single positive studies as a basis for classification, this will mean taking the hazard classification recommendations of authoritative bodies off the list.

Carl Borden, CA Farm Bureau Federation: If there are many studies that are negative and one positive study, I would have to question the value of that positive study. It may be an outlier, fraud or just bad science. If you have a positive study in the absence of other studies, then I would have to give weight to that. But if other studies come along that cannot replicate the results of the one positive study, then you have to take the whole of the studies into account to determine whether a hazard exists.

I echo comments of Mr. Leacox and Davis on the danger of an overload of information. I represent agricultural employers so they are end users. They need to understand the real hazards and need to be able to communicate those to their employees. If we are talking about adding additional hazards, and other comments and information on the SDS, we need to consider the risk of overloading the employees with unneeded information. We have to take into account the actual risk and severity of the risk that employees are facing. If everything is a priority then nothing is a priority.

I hope that whatever is done will facilitate the production of better, clearer, and succinct labeling and SDS.

D. Gold: Do you oppose all options on the board?

C. Borden: You have to take into account the context. If one positive study is sound, it could be a harbinger; if other studies show negative results, then maybe the hazard should no longer be listed on the SDS. If there are a multitude of negative studies but then one positive study comes along, you have to take that into consideration.

D. Gold: People talked this morning about the null hypothesis. This does not mean finding no effect but it means that the results of a study were not statistically significant. We are using the

term “negative study” to mean that there was less than a 95% probability that the health effect seen was real. So a study, in which there was a 94% chance that the effect was not due to chance, or was real, would still be counted as a negative study. “Negative study” also often means we didn’t find an effect, which can be for a variety of reasons.

C. Borden: I’m a non-scientist but I admire the scientific process. If I have one positive study followed by many other studies with other results, it seems to me that this should make a difference.

Ann Katten, California Rural Legal Assistance Foundation: We support option A because the consequence of overlooking a potential adverse outcome is greater than the consequence of over-protecting people. In terms of falsified or fraudulent results, studies may be falsified in both directions. Many of the retracted studies that were referred to were pesticide studies, and many were erroneous in the negative direction. So falsified results can occur in studies with negative results as well.

B. Puk: Are you going to be the oversight agency to verify all the positive studies to be listed on the SDS in order to protect human well-being? Or is this just an option for those classifying chemicals to be monitored? And how are the penalties going to come out. For the toxicologist, it is really important for them, but for the manufacturer, or even the hazardous waste recycler, we need that information. But by the same token, will that one positive study steer us, who actually utilize that information on the SDS, to the wrong direction, and what is the penalty behind that?

D. Gold: One purpose of listing an ingredient because there is one positive study is so that people know that an ingredient is present. As Mike Wilson alluded to, there is no requirement otherwise to list all ingredients. One effect is that one positive study could result in listing or disclosing the presence of the chemical on the SDS. If you are going to try to process a hazardous waste stream and you don’t know what’s in that hazardous waste stream, you are at a big disadvantage because a hazardous waste stream of known constituents is much cheaper to process than if you have to test it and figure out how to classify that hazardous waste stream. The advantage of listing something based on one positive study, independent of the toxicological information conveyed, is that you’d know whether it’s on one of the lists that requires you to dispose of it in certain ways in California, which is somewhat different from federal disposal.

Status quo right now is option C. We don’t classify right now; classification is something new that came with GHS. With the status quo right now, if there is a positive study you list it on the MSDS along with the health effect. If Cal/OSHA enforcement comes in and finds an MSDS that that didn’t list toluene or didn’t list it as a neurotoxic health hazard, Cal/OSHA would say it should be so listed. That’s how it gets enforced now. We are able to say you didn’t list toluene or you didn’t disclose its toxic health effect. That goes away if the only reason something has to be listed on the MSDS is because it has to be classified by weight of evidence. If it is not disclosed on the MSDS, Cal/OSHA would have to determine, first that the material is there; we

would then have to say it should have been disclosed because you should have classified this weight of evidence differently. .But under GHS we would have to have a battle of toxicologists about weight of evidence. This is one reason we are concerned about getting rid of the one positive study requirement. Even if we don't go to where Julia Quint wants to go, which is the single positive study defines a health hazard, you at least have to disclose the chemical is present and what might be its health effect so that employees know, doctors know, Cal/OSHA knows, you know, so you can classify your hazardous waste stream.

B. Puk: Ultimately that's what I want to see but if there is no penalty for not complying, then manufacturers could decline to disclose more often.

D. Gold: So are you saying that you support that we mandate putting the one positive study in.

B. Puk: Exactly.

J. Quint: There are guidelines, EPA, and OSHA for carcinogen policy, about negative data and what constitutes something really being non-positive or negative. What establishes non-positive? The way this standard is written allows individuals to decide that I've got five negatives even though those studies may not have been conducted appropriately. And they count up the negatives and they count up the one really robust positive and they can come up with a non-health hazard. There is so much that is not in here that is part of practice for people who do this on a regular basis. This standard jumps in with all of these things-- no guidelines-- that people who have done this work for a number of years. Agencies—not our agencies—have really sort of dealt with.

When you talk about one positive study, you are not eliminating or overlooking weight of evidence. Every scientist uses weight of evidence because you don't want to cherry pick the data and choose what you want to choose. That's not science. You have to look at everything that is on the board. These things have different qualities. There's also such a thing as de-listing. Things on the Prop 65 list get delisted.

We can't wait 5 years and be wrong with a diacetyl or something like that. The SDS is the primary means of communicating information. You can't wait and say you need five more studies when somebody is ill. This is particularly true with sensitizers. A person who keeps getting exposed could have a really serious episode. There are all sorts of reasons why a second positive study might be delayed. You might have one case of something positive, respiratory sensitization, and later on you get more cases. It needs to be documented somewhere, because then when somebody works with it and they see it on there and says, "I had wheezing when I went home." So that's case number two. If it's not on the SDS, you just affect more people.

Ross Nakasone, BlueGreen Alliance: Our organization has a health Initiative program that is really designed to protect workers. We maintain the ChemHAT database which is designed by and for workers. We are working to educate workers by creating curricula and other web based

teaching tools on the federal GHS standard. How we get information about chemicals to talk about is really important. We get information from the SDS, the only way that happens. The list of lists is fine but other than that the single study rule is only other way to get this information on the SDS. We think hazard classification should be based on one positive study. At a minimum, list the ingredients and the health effects, but you should give serious consideration to hazard classification based on one positive study.

M. Wilson: On how much exposure information should be disclosed on the SDS, I did my doctoral work on exposure assessment. How a chemical may be used in the workplace, in commerce, that information is not knowable by the producer because an exposure assessment would have to be performed for all likely exposure scenarios. The producer of trichloroethylene wouldn't try to understand all the possible uses for trichloroethylene. That is not practical. So I came to the conclusion that what is important for a downstream user is to understand the potential health effects.

In Europe, under REACH, producers must communicate with end users and gather information about how the chemical is being used and address it on the SDS. The producers are finding many uncontrolled, inappropriate uses they had not anticipated. Prior to the REACH regulation, this kind of downstream information was unknown. Here we are not talking about this massive increase in communication up and down the supply chains. We are just talking about disclosure and transmission of basic hazard information from the producer out to the end user using the SDS as the vehicle to do that. We aren't talking about exposure, or vulnerability or risk. This is just the question of hazard information and the way that information is transmitted.

Second, on the issue of fraud in scientific peer-reviewed literature, I am not familiar with the NAS study about retracted papers that Dan Leacox raised, but I am familiar with Von Saul's work finding that problems arose in industry sponsored studies, particularly with bisphenol A where he found zero problems with the academic (positive) literature. The great majority of negative studies that were problematic—I don't know if you would say fraudulent—from a scientific viewpoint--were sponsored and paid for by the manufacturers of that substance. It's important for California to at least retain this basic requirement of disclosure of ingredients and health effects because the tendency 'lean back' from the weight of evidence if you are the manufacturer, to "lean back" from making a clear declaration that your product causes a clear health effect and to be reluctant to communicate this to the public. Which perhaps is rational economic behavior, but this is where it is incumbent on California to make it clear that this is simply a requirement of conducting business if there has been a positive study that is a statistically significant finding that has been through the peer review process, this is a substantive finding that should be communicated.

On single positive studies, California needs to make clear that this is the policy of disclosure of substantive findings of should be communicated even if there is just one study. Single positive studies have been through a peer-reviewed process and represent a substantial finding that is scientifically valid.

I heard about the concerns that an inundation of information would make SDS harder to understand or unusable, but from my experience it is just the opposite. There is a deficiency of information spawned by government policy and inaction. This is but a small step to require simple disclosure when we have a positive finding. I urge the Division to retain the existing language at the least and, if possible, to expand the information required to be included on the SDS.

D. Gold: We need to move on to the next topic. I encourage everyone to send further comments to the email address at the top of the discussion draft handout, and to propose any additional language. This is the best time to do it before we get into formal rulemaking. Encourage you to do that. We are going to move to topic number 3, regarding testing.

D. Leacox: One last comment on one positive study: I want to restate my earlier comment about where there is lack of evidence of potential harmful exposure to workers because of the products use. In the criteria for listing a substance on the Director's List, there is a provision that a substance not be listed if it is found to be not hazardous in its physical state or that it is in a volume or concentration not relevant for workplace exposure. For example, what are the hazards of a chemical contained in an IV product being used during clinical trials. The chemical is contained in the product, in the IV lines, and since the health care worker is not being treated, there is then no exposure. Is that a relevant exposure? This doesn't mean there are not unknown uses.

Ken Smith: If California does adopt a different health hazard definition through any mechanism on the board there will be inconsistency in classification of hazardous materials with others. Using toluene neurotoxicity as an end point—there may have to be different hazard codes in CA than for other jurisdictions. You may want to append a separate code identifier for California, so that California and federal OSHA would have separate codes. RCRA (Resource Conservation and Recovery Act) laws provide an example of this with unique codes for California-only categorized waste. California could see how many SDS would have to be modified because of a stricter basis for including a chemical on an SDS.

D. Gold: The discretion you speak of is being exercised under the federal system by every single manufacturer to conclude if a chemical is or is not health hazard. That inconsistency isn't state versus federal. California would be saying "make this presumption" in constructing your federally compliant SDS; this is how we want you to apply the appendix.

Topic 3: Testing

D. Gold: Moving on to discussion of testing: Federal OSHA said "this is a communication standard not testing standard." We do not disagree with that. Neither Cal/OSHA nor federal OSHA is requiring a chemical manufacturer to dose rats to determine toxicity. But federal OSHA has also maintained that where toxicological study results are known, they must be disclosed. With the GHS modifications, federal OSHA inserted a statement that 'no testing is required' in order to determine the hazard into subsection (d)(2), even though in Appendix B

there are a number of physical tests required to determine flammability. There is an apparent contradiction between these two statements. Also, we have found situations where a substance's content is not known, and we would issue citations to the manufacturer for not having determined content through chemical analysis—but not for not doing toxicological tests. We feel that the statement that no testing is required is too broad. The GHS says it is test method neutral and that re-testing is not required where authoritative testing exists. The discussion draft proposed to insert a slight modification of the GHS language that is more in line with the actual intent. We are not suggesting that toxicological or epidemiologic testing be required of chemical manufacturers.

S. Davis: You could achieve that result by stating in appendix A that no testing is required except as specified.

D. Gold: It doesn't deal with the other issue which is the constituents of a mixture, which is of interest to people. It doesn't deal with the issue of what's in smelter cake, for example.

J. Quint: I totally agree that the federal statement is confused. Xylene, technical grade, is contaminated with the carcinogen ethyl benzene. It seems that the manufacturer in this case should be required to chemically test to determine the percentage of ethyl benzene, because that percentage will affect the nature of the hazard. I think the suggested wording in the draft fixes the problem.

M. Wilson: Your sense of the consequences of the confusion goes toward an outcome where there would be less information on ingredients that we have now?

D. Gold: Yes, because even the manufacturer won't know what is in it.

M. Wilson: In my work with the Business NGO Working Group, whose members seek safer chemicals, Staples CEO Roger McFadden has expressed frustration with the inability to characterize the chemical hazards of Staples product lines because they can't determine the ingredients. Without that information, Staples can't select the products they want to have on their shelves and in their supply chain. We should resist any GHS change that takes away the substantiveness and transparency of ingredient disclosure.

D. Wigmore: I just wanted to be sure that I understood what the testing was about (testing to find out what the hazards of a chemical are versus testing for the ingredients). If it's testing for ingredients, Cal/OSHA needs to be specific about that and make it clear that it's ingredients, not toxicological properties. There is a problem with the chemical policy in this country. If we can get testing addressed and Cal/OSHA can enforce it, we'd be a tiny step ahead and there is still a lot to do.

D. Gold asked that if people have suggestions for rewording this item, they send them via email.

D. Leacox: Your statement is you see the federal rule reference as a step backwards?

D. Gold: We are just saying it's imprecise.

D. Leacox: It's the ingredient discovery process that I question. I thought from your statement that you are losing the right to enforce.

D. Gold: That's right, the old standard required hazard determination. You can't cite for incomplete hazard determination with the new language; if don't know ingredients, you can't classify.

D. Leacox: Have you cited for this?

D. Gold: Yes. The citation would be for inadequate hazard determination, (d)(6).

C. Borden: Mr. Puk does mixing of spent paint, then shipping. Does that make him an employer classifying for commerce.

DG: Mr. Puk is special case; they are not making a product for commerce. If he was making the paint available for commerce he might be the manufacturer required to do classifying for commerce. Because his situation is so specific, we are going to discuss it off-line.

C. Borden: So the employer classifying a chemical is one mixing chemicals together?

D. Gold: No. Generally employers do not classify chemicals, even if they mix them. The classification is done by the manufacturer or importer, unless the employer decides that they do not accept the hazard classification done by the manufacturer. If the employer decides to classify the chemicals, they must follow the standard, but non-manufacturing employers typically do not do that.

Topic 4: Criteria for listing of chemicals in mixtures

D. Gold: Handout of a couple pages from Appendix A. In the past, any IARC or NTP carcinogen in a mixture was required to be listed at 0.1% and for a non-carcinogen at 1.0%. In the GHS appendix A there are two types of percentages referenced regarding evaluation of chemicals. Bridging principles (about mixtures) are not what we are talking about here. One departure from the current standard that we are concerned about is that Category 2 carcinogens, if present at level from .1% to 1%, have to be listed on SDS but the categorization does not have to be on the label. That is a departure (breaking of .1% for carcinogens) from existing regulations on disclosure of carcinogens. Similarly, for Class 8, Targeted Organs, Category 3 for "transient effects" like narcosis, there is no specific percentage that would require placement of the information on the label. Appendix A allows a concentration of up to 20% of Category 3 chemicals in this class, but also says, it could be more, or it could be less. By adopting Appendix A, we would be changing the current requirement for classification and disclosure. This is arguably less than current system. The change was adopted in Horcher but maybe should not have been. We wanted to raise this issue for you to think about and to solicit

comments now, or by email. We need to decide overall whether the classification system in Appendix A is good enough or if need to make changes for the reasons just discussed.

K. Smith: I'm absolutely fine with the federal GHS, especially Category 2 carcinogens. There is inconsistency. Under category 2, 0.1% means put the information on the label. On the Director's List, the requirement for listing varies from 0.1 to 1 to 2%. So there is inconsistency in the Director's List that could be addressed.

D. Gold: Other comments?

D. Wigmore: In other parts of the world percentages disclosed for carcinogens, mutagens, respiratory and skin sensitizers, and reproductive toxins is often 0.1%. In Canada, the plan is to retain WHMIS rules where a chemical must be declared if the chemical is any of these four nasties and is at a concentration of 0.1%. This has been the rule since 1988. Note that on page 36 of the international GHS agreement, the concept of "harmonize up, not down" is stated. Table 1.5.1 on page 36 of international GHS agreement uses lower numbers than federal OSHA. Harmonize up not down

We argue that we should avoid percentage cutoffs, especially for endocrine disruptors, such as flame retardants, which have been shown to have effects well below 0.1%. There is a severe dose-response curve. Californians for a Green & Healthy Economy argued strenuously to avoid cutoffs for endocrine disruptors, which are both reproductive toxins and affect other body functions, and affect in very minute concentrations. We urge Cal/OSHA to catch up to the science on endocrine disruptors so disclose on labels and SDS.

Paul Burnett, Santa Clara Valley Water District: Speaking for myself, I've been worried for years about 0.1% and 1%. These guidelines are decades old. Instrumentation technology has improved to the extent that we are measuring in not just parts per billion, but parts per trillion and we are detecting effects at these levels as well. Are we still stuck with 0.1% which is 1000 parts per million and 1% which is 10,000 ppm? Should we not pay attention to threshold limit values below 10,000 ppm or 1,000 ppm? I don't think so. No one would accept this anymore. We have a standard that anything below 1/10 ppm, we don't have to list on the SDS. Is everyone happy with that?

M. Wilson: I'd like to underscore that point. I served on the Science Panel for Cal/EPA to address exposure levels from products with endocrine disruptors and verified human health effects in the parts per trillion level. We won't resolve this issue now, but is a really important issue that shouldn't be lost.

D. Gold: In Appendix A, the label does not have to show carcinogen on the label if it is Class 2, present at 0.1 - 1% but it would have to be disclosed on the SDS. California has not taken position yet. We are raising this question here. If we took the position that this information must be on the label, we would have to amend the language in Appendix A. We've given you the current Appendix A language in a handout.

M. Wilson: You would have the backing of most of science on carcinogenicity, reproductive effects and endocrine disrupters that 0.1% is too high and should be reduced by 3 orders of magnitude.

B. Puk: For percentages is it by weight or by liquid volume?

D. Gold: Percentage is defined in Appendix A.

B. Puk: Nano-products are now being seeing in waste facilities, e.g. sunscreen which includes Nano-titanium dioxide. Nano-products are exempt now but how would this be handled in the future?

Amanda Hawes, Worksafe: This is compelling case for harmonizing upwards. More information can't hurt you; less may lead to consequences that can't be fixed.

I've watched the process evolve for over 30 years. In the 1980's in our law practice a woman came in who was pregnant and was exposed to inorganic glass called Frit. The 1986 MSDS lists lead oxide as "greater than 1%." The 2007 MSDS for the same product listed the lead oxide content as "less than 75%." The woman who used the product while pregnant has a developmentally disabled son. He'd be here today but you wouldn't be able to understand him. (Submits the two MSDS's for the record.)

Victor Esparza, International Union Operator Engineers Local 12: I hope California doesn't go backwards. Go forward for the kids. The federal government has not protected us as Cal/OSHA has. I worked in the rock yards for 31 years. I have asbestos and silica in my lungs. MSHA did air monitoring but never got the information from the company to the workers. Mexico has more stringent standards than we do, but they are never enforced. I hope we go forward for our kids.

Topic 5: Period for revising labels

D. Gold: On labels, the past requirement was the time permitted to revise labels after learning new significant information was three months. Cal/OSHA was surprised to recently learn that in 1994 federal OSHA had put an administrative stay on enforcing this label requirement. In the recent GHS adoption, federal OSHA expanded the time allowed to revise labels to 6 months, judging this to be more feasible. This appears to be a change in practice, as Cal/OSHA never adopted the administrative stay on enforcement of the three month rule. The question before you is in section (f)(11). Are there any comments on extending the period for updating labels to six months?

D. Leacox: As a practical matter, the new knowledge triggers a re-evaluation of the label. I support six months.

Steve Johnson, Associated Roofing Contractors: Products can sit on warehouse shelves for 6 months, nine months, so six months makes more sense.

J. Quint: I'm opposed to the change. I tried to go back to the preamble of the rule in the Federal Register to understand the basis for the change. It seems flimsy. I haven't heard that it was a hardship before, just that it was an administrative stay. I think manufacturers should get correct information to downstream user as soon as possible. If you don't have a rational basis except for the federal OSHA stay, why change? If we roll back on the standard, it means whittling away at what is important.

D. Gold: asked D. Leacox whether the language which refers to a manufacturer newly aware of any significant hazard, must change the label for materials "shipped after that time," so she asked whether that addresses his concern regarding time for compliance throughout the supply chain?

D. Leacox: I don't have the full answer. You would need to go to a person more expert in distribution issues. This all begins after significant new information. Even process of doing evaluation takes time. How that affects the ability to supply corrected shipping labels, I'm not sure.

D. Gold: Labels required for interstate shipping, like EPA mandated labels, are outside the scope of Cal/OSHA. Updating the SDS with the new information still has the three month revising period.

D. Leacox: Labels that go on a product is a much more involved and crowded area. Due to the complexities, it must be the subject of written comments.

B. Puk: DOT regulation for hazardous materials manifests and labeling also was changed by GHS. So proper shipping labels changed; the Department of Transportation (DOT) gave the industry seven years. With generating shipping labels being so easily done on computer what is the point of further delay?

M. Wilson: I worry that moving to six months from three months is less protective. We have 36 million people and 17 million workers in California; this is expected to be 50% higher by 2050. Currently 4 ½ pounds per person per day of chemically formulated products are being handled by workers. Thinking about the millions of workers potentially exposed makes allowing an additional three months to provide information seem less protective. My own experience when working with the auto repair industry and a HESIS alert listing 35 products containing n-hexane, the industry re-formulated and relabeled nearly immediately. We had identified 14 workers with n-hexane induced peripheral neuropathy. I think industry is more nimble than is being characterized here. Six months seems excessive and less protective.

J. Fisher: I want to re-iterate what Mike is saying. If given six months, this encourages de-prioritizing until right before the deadline.

On the point that other states have less stringent requirements, let them learn from us. We should produce the best. Look at the bloodborne pathogen standard first adopted in CA and then became the model for other states and the nation. If manufacturers want to produce two labels and SDS, let them. I don't think they will; I think they will use the California standard.

Paula Bouyounes, PASMA: My concern is too much information on the label. I've been in safety for over 20 years. Having too much information on the label results in it not being read. Like prescriptions, people don't read the fine font. Labels should be simple and accurate. I believe in accuracy and training on the SDS.

I am also concerned that the NFPA and GHS numbering systems are opposite systems.

D. Gold: In GHS the higher number is less hazardous; the higher number in NFPA/HMIS is more hazardous.

M. Horowitz: This issue is discussed in the final rule. OSHA said NFPA needs to conform to GHS.

D. Gold: We recognize that until NFPA and OSHA come into agreement, there will be a problem which will have to be addressed by training.

P. Bouyounes: The issue is the safety of our employees. We have to train by December 2013; how are we going to train them? Is it possible to leave out the numbering on labels?

D. Gold: Classification is involved. The labeling requirement uses pictograms.

P. Bouyounes: When a chemical is transferred to a secondary container, are there specific requirements?

S. Smith: You can still use your own system for labeling as long as your employees understand that system.

Training and Other Standards

D. Gold: The last item on the agenda is other standards that are affected by the GHS adoption, and any other issues people want to raise. .

Jay Jamali, Enviro-Safetech The deadline for training is 12/1/2013. The standard doesn't go into effect until July 1. Five months later we have to have trained every employee at every site. Give us an additional six months. Federal OSHA adopted the requirement in March 2012 with training by Dec. 1, 2013.

The written Hazcom program book revision is due in June 2016. This requires two-step training. Cal/OSHA should develop the written Hazcom program first, then do the training.

Cal/OSHA Consultation should develop a template of the revised written Hazcom program to help employers. For the written program, use the same as the IIPP models with a template that employers can use with all GHS compliance elements for small to large employers.

On training. There is no definition for what “effective” means. I recommend that you make this clearer and require a written exam at the end of training to ensure effectiveness.

Regarding electronic forms of the SDS. If you only hold an electronic form, after an earthquake, it will be very difficult to or power outage for employer to give an SDS to first responders or treating physicians retrieve an SDS when you might most need it. I recommend you require at least one hard copy on site for the employer to use to give as needed. California can improve on the federal standard.

C. Porter: As mentioned before, there are many non-English speakers. Language access is a big concern. Both how understandable the language is to an English speaker and also to a person whose first language is not English, much less a non-English speaker. I understand that federal standard makes using pictograms discretionary and you can substitute words instead, for example, “skull and crossbones.” I encourage Cal/OSHA consider how changes like that impact non-English speakers. Also consider thinking about requiring SDS in languages other than English. California is a state of many languages. We need to move the issue of language access to the front burner.

D. Gold: The problem of language access is currently being addressed with renewed emphasis by the Department of Industrial Relations . I can raise the issue with the department. On the issue of training, the requirements for the SDS and labels are known now, along with the December first deadline. You can begin training now; there is no reason to wait until July 1st. There is no disagreement with federal OSHA on this. What we have been discussing is how a manufacturer arrives at the content of the label for any given product. Labels will be standardized. I encourage everyone to get the training rolling on items due by December 1. Don’t wait. Look at the section on labels; the sixteen categories on the SDS are all there. Please don’t wait. There is a phase-in of the GHS requirements on the federal level. People are already receiving SDS and labels using the GHS standard. Even if OAL rejects the limited Horcher, the labels and SDS’s will be arriving in California and employees need training on how to read them.

D. Gold: : We’d like to get written comments from you, and others who did not attend on any of the items we have discussed, or other related issues. The draft proposed language on the blue sheet will be posted on the website within the next week. You can email Mike with comments.

We do not expect another in-person advisory committee meeting before sending a recommendation to the Standards Board because we have limited time to get a formal rulemaking done and we’ve had a good discussion here. Once there is proposed language, there will be a public hearing scheduled at the Standards Board and you will have the

opportunity to make comments on that final proposal. In the interim, we are having discussions on possible text. You can email us your suggestions. Please send us comments by May 1, or at least let us know that your comments are coming.